ASEPTIC TECHNIQUE AND PACKAGING: A STUDY OF POTENTIAL CONTAMINATION PATHWAYS DURING THE USAGE OF STERILE PACKAGING IN AN OPERATING ROOM CONTEXT

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ABSTRACT

ASEPTIC TECHNIQUE AND PACKAGING: A STUDY OF POTENTIAL CONTAMINATION PATHWAYS DURING THE USAGE OF STERILE PACKAGING IN AN OPERATING ROOM CONTEXT

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Healthcare associated infections (HAI) are a significant burden to society in terms of harm to patients as well as being a financial burden. Most recent estimates place the burden to society in tens of billions of dollars, and it is estimated that 1 in 25 patients has an HAI at any given time. In order to address this issue, airborne contaminants, hand sanitation, and reservoirs of bacteria on operating room equipment have been explored in attempt to address contamination of sterile items in the operating room (OR). Packaging has been studied on a very limited basis.

In the medical device packaging industry, ISO guidelines are followed in attempt to decrease the risk of sterile items becoming contaminated, not only in transit but in use. Although testing procedures have been developed by ASTM and ISTA for evaluating the ability of packages to maintain sterility during distribution and handling, the usage of packages is less standardized. Aseptic presentation to the sterile field, though referenced in the standard ISO11607-1, does not have evidence-based procedures to evaluate it or a consistent, evidenced-based medical guideline to direct it. To fill these gaps in understanding about aseptic technique and packaging, three studies were conducted.

The first objective was to add to a limited body of evidence which suggests that pouch size is a contributing factor to contact between a sterile device and non-sterile surfaces during aseptic transfer, specifically to investigate the *source* of contact (i.e, the hand or the package). A total of 159 participants opened four packages of two different sizes, with simulated contaminant coatings applied to gloves and packages in a counterbalanced fashion. Products were dispensed

into a simulated sterile field and evaluated for contamination in a binary (yes/no) fashion. Although there was insufficient evidence to detect a difference between sources of contamination (P=0.87), large pouches were still found to have a higher rate of contamination than small pouches (P=0.0017). This is consistent with previous findings.

The second objective explored what the term aseptic presentation means to healthcare providers involved in peri-Operative environments. To accomplish this, a semi-structured interview was conducted with 13 surgical technologists and 2 nurses. Participants were presented with three styles of packages that, based on previous work, were received positively or negatively by healthcare professionals. Questions involved their experience using the packaging, their experiences learning aseptic technique, and their perceptions of what constitutes "aseptic presentation" and what does not. Interviews were transcribed and analyzed in light of several theories, in particular affordance theory (packaging use) and situated learning (workplace learning) theory. The work herein presents packaging affordances within aseptic presentation, and specifically ties the individualistic nature of affordances to the necessity of field study, and describes packages' role as a communicator of risk and utility.

The final objective was to understand why users interacted with the packages in unintended manners and, using a simulated contaminant and a customized peeling apparatus, to provide pilot data regarding contamination as a result of strength of the seal and position of the pull. Although significant relationships between positions and seal strengths were found (which lead to higher opening forces), the exact reason for the contamination was not identified. However, the work has provided some evidence in support of claims made in other work, and has provided a methodological basis for work that can target specific contaminants (i.e., dust, blood, or hair).

This dissertation is dedicated to my father, who always pushes me to realize my dreams. You told me to never graduate when I entered college and I took your advice entirely too seriously. I also want to dedicate this to Shupei Yuan, my team mate, co-adventurer, and part-time inspirational speaker. Thank you for your support and love.

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1 Chapter 1: Introduction

Healthcare-associated infections (HAIs) are a significant burden to hospitals in the United States. In 2007, it was estimated that 1.7 million HAIs occurred annually in the United States. Although the numbers have improved recently (a little over 720,000 by 2014 estimates), there remains much work to be done. The burden of HAIs became apparent when Medicare began moving towards a results-based model in 2008, pushing the financial consequences on to the affected hospitals. Since then, efforts have been made in the form of training programs to promote hand hygiene at the hospitals, some of which funded by government grants targeting these infections.

Up until recently, the predominate producer of research has been from the healthcare provider side. Doctors have studied topics such as contaminated equipment, ventilation, door openings into the operating room, and hand hygiene. Many of these studies have served to ground "best practices" in some evidence-based thinking. Professional guidelines, such as those from the Association of peri-Operative Registered Nurses and the Association of Surgical Technologists, have also traditionally sought to mitigate the risk of these infections procedurally. However, many of these procedures have been lacking in foundational data, particularly those specific to packaging usage in the operating room.

Studies which investigate packaging usage have until very recently been focused on the ability of the package to maintain integrity. Studies of packaging *usage* are far fewer in number but the body of work is growing. Understanding the role of the package in aseptic presentation of products to the sterile field is critical within the field of packaging. The medical device industry standard ISO11607 mandates that manufacturers of terminally sterilized medical devices ensure

that their packages allow for aseptic presentation. Unfortunately, a rigid definition of that procedure is not present, and there is little evidence which supports any one method.

This work fills, in part, that critical gap. The first study in this dissertation investigates non-sterile contact pathways during the dispensing of sterile contents in simulated presentations. Two package sizes were chosen and two contact pathways (hand or pouch) were identified and analyzed. Additionally, participants were surveyed about their experiences disposing product they considered contaminated. The second portion of the work uses situated learning theory and affordance theory as a lens for studying the experiences of the participants. This qualitative study illuminates opening behaviors and the work environment of the end-user of packages. Finally, a quantitative bench-top study seeks to quantify possible contaminations as a result of behavioral choices, particularly where to start peeling the pouch on chevron pouch designs. All three studies add data to a nebulous problem.

2 Chapter 2: An overview of the operating room environment and packaging use

2.1 User profile: registered nurse

Registered nurses (RN) are often in charge of managing and documenting patient care, administering treatments, and advising patients on home care after release from the hospital (BLS, 2014). RNs often specialize in fields such as addiction, rehabilitation, cardiovascular care, and critical care (BLS, 2014). Additionally, nurses can specialize in peri-Operative nursing, which encompasses pre-operative, intra-operative, and post-operative patient care ("Perioperative Nursing," 2016). Intra-operative nursing includes two key roles in operating room (OR) care: the scrub nurse, and the circulating/scout nurse ("Perioperative Nursing," 2016). The scrub nurse is responsible for the selection of supplies for the operation as well as passing instruments to the surgeon during the operation (Mayo, 2015). Circulating nurses are responsible for managing the operating room environment (Mayo, 2015) and are responsible for opening non-sterile packages and distributing the contents to the sterile field. Nurses, with additional training and education, can also function as an RN First Assistant or as a Nurse Anesthetist ("Perioperative Nursing," 2016). Nurses often are the group which participate in in packaging-related studies (Cai, 2012; Crick, Chua, Canty, & McCullough, 2008; Minckley, 1969; G. Smith, Vindenes, Keijzers, & Rando, 2009; Trier, Bello, Bush, & Bix, 2014) and consumer panels (Allen, 2010, 2011, 2012, 2013, 2015; Butschli, 2008).

2.2 User: surgical technologist

Surgical technologists are in charge of preparing both the patient and the operating room for surgery (BLS, 2014). Additionally, they may serve in a role similar to the scrub nurse in that

they pass items to the surgeon during surgery (BLS, 2014). Surgical technologists may receive training to become surgical first assistants and assist in the surgery itself, using suction tools on incision sites and/or suturing wounds (BLS, 2014). Surgical technologists, by virtue of being responsible for so many packaging-related tasks (gowning and gloving, setting up sterile fields, operation tasks, and dressing wounds), are heavy packaging users but seldom serve in packaging related studies (Cai, 2012; Seo, 2014; Trier et al., 2014) and, as such, many of their insights are missing from the literature.

2.3 **Aseptic technique**

Packaging usage by healthcare providers is guided by professional guidelines from organizations such as the Association of Surgical Technologists (AST) and the Association of peri-Operative Registered Nurses (AORN). There is no universal standard which is followed by every healthcare professional in every hospital—the implementation of these "standards" is highly localized. The two sets of guidelines utilized in this discussion were selected because they come from two large, recognized professional organizations in the United States. Additionally, they were readily available and accessible to the authors.

Throughout the dissertation, "aseptic technique" and "aseptic presentation" will be used interchangeably to refer to packaging-specific processes in introducing items to the sterile field. Aseptic presentation, though itself non-standardized, receives attention from the medical packaging industry in ISO 11607. The ISO defines aseptic presentation as "introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination" ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems ", 2006). The

standard discusses packaging in terms of a *sterile barrier system* which is defined as the "minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use" ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems ", 2006). ISO acknowledges that "procedures" exist for aseptic presentation but stops short of calling them out explicitly. The standard's framing of aseptic technique is further discussed in Chapter 3.

2.4 Sterile drapes and sterile fields

The work environment of the registered nurse and the surgical technologist is an important component within "the sterile field." AORN defines the sterile field as:

> "The area surrounding the site of the incision or perforation into tissue, or the site of introduction of an instrument into a body orifice that has been prepared for an invasive procedure. The area includes all working areas, furniture, and equipment covered with sterile drapes and drape accessories, and all personnel in sterile attire." (*AORN Guidelines for Perioperative Practice*, 2016)

Figure 1- Sterile Drape

Sterile drapes (Figure 1) serve to "create a barrier between a surgical field and possible sources of microbes" as well as isolate incision sites ("Standards of Practice for Surgical Drapes," 2008). Drapes are placed over table surfaces such as mayo stands (small tables for instruments), basins, and back tables. Drape placement and use is specified in Recommendation IV in AORN's *Peri-operative Standards and Recommended Practices – Recommended Practices for Sterile Technique*. Recommendation IV states that drapes should not be moved after initial placement due to movements creating "air currents on which dust, lint, and other particles can migrate" (*AORN Guidelines for Perioperative Practice*, 2016). The potential risk for air currents carrying contaminants is echoed in Recommendation VII which lists this as a risk of removing a drape covering a sterile field (*AORN Guidelines for Perioperative Practice*, 2016). Recommendations IV and VII caution that only the top of the drape (i.e., the top surface of the sterile drape bound by the table edges) is considered sterile, and that any portion of the drape (and any item going over the edge of the table) must be considered non-sterile (*AORN Guidelines for Perioperative Practice*, 2016). Recommendation IV also indicates that drapes not be placed such that non-sterile personnel lean over the sterile field or allow their non-sterile apparel to contact the sterile field (*AORN Guidelines for Perioperative Practice*, 2016). Additionally, the recommendation cautions against puncturing the sterile field due to perforations opening "portals of entry" for microbes on to the sterile field (*AORN Guidelines for Perioperative Practice*, 2016).

With respect to traffic about the sterile field, AST's *Standards of Practice for Creating the Sterile Field* is much in agreement with AORN's recommendations. The Standards of Practice (SOP) II, III, and IV similarly describe the potential risk of contaminating due to air currents in the OR. SOP II cautions against the placement of the field near the doors to the OR

due to door movement resulting in particles being “stirred up” in the air and any sterile field should be “12-18 inches away from the wall and other non-sterile furniture and equipment” ("Standards of Practice for Creating the Sterile Field," 2011). Movement is again emphasized in SOP III which calls for instruments to be arranged in a manner such that movement is minimized ("Standards of Practice for Creating the Sterile Field," 2011). See Table 1 for an organized presentation of the usage of drapes between both guidelines.

Topic	AORN		AST	
Areas of drape considered sterile	SRP Recommendation IV.a.8	"Only the top surface of a sterile, draped area should be considered sterile. Items that fall below the sterile area should be considered contaminated."	"Once a drape has been positioned, it should not be repositioned. The top of furniture, such as the OR table, back table and prep table are considered sterile, and the portion of the drape hanging below the edge is considered nonsterile."	SOP for Surgical Drapes I-5
Airborne contamination due to air currents	SRP Recommendation IV-a.2	"Sterile drapes should be handled as little as possible. Rapid movement of draping materials creates air currents on which dust, lint, and other particles can migrate"	(IV) "The number of surgical personnel entering and leaving the OR should be monitored and controlled. Preferably only those surgical team members assigned to the surgical procedure should be entering and leaving the OR on a limited basis. A. Controlling the traffic aids in keeping air movement to a minimum, thus reducing the particles that enter the atmosphere and the amount of airborne contamination."	SOP for Creating the Sterile Field II, III, and IV
Covering the field with a drape when not in use	SRP Recommendation VII.b	VII.b. "When there is an unanticipated delay, or during periods of increased activity, a sterile field that has been prepared and will not immediately be used may be covered with a sterile drape. [2: Moderate Evidence]"	"Once a drape has been positioned, it should not be repositioned …Repositioning can bring the nonsterile portion of the drape into the sterile field, causing contamination, as well as possibly transferring microbes onto the field, placing the patient at risk for acquiring an SSI."	SOP for Surgical Drapes I-5

Table 1- Usage of Drapes, Standard comparison between AORN and AST

Monitoring the field is advocated by both sets of guidelines. AORN's Recommendation VIII states that "keeping the hands and arms above waist level allows the perioperative team member to see them constantly", which reflects Recommendation VII's claim that observation decreases the risk of contamination (AORN Guidelines for Perioperative Practice, 2016). This particular claim regarding the attentiveness comes with a disclosure of "No evidence". In AST's *Standards of Practice for Gowning and Gloving,* SOP I similarly states that regions that cannot be observed are considered non-sterile ("Standards of Practice for Creating the Sterile Field," 2011). AORN's recommendation VII.c and AST's SOP *Creating the Sterile Field* call for the healthcare provider to monitor for breaches in sterility, and for the healthcare provider to be cognizant of how their method relates to their actions over sterile fields (AORN IV,VI and AST III-c). See Table 2 for a comparison of the guidelines.

Topic	AORN		AST	
Monitor the field	SRP Recommendation VII.a	"Once created, a sterile field should not be left unattended until the operative or other invasive procedure is completed. [5: No Evidence] Observation increases the likelihood of detecting a breach in sterility."	"As with sterile packages, the concept of event-related sterility applies to the sterile field.... policy should include that the sterile field is kept under constant observation in order to identify contamination that may occur and to control traffic in and out of the OR A sterile field that is not kept under constant observation should be considered non-sterile and broken down."	SOP for Creating the Sterile Field V-2
Leaning over the sterile field	SRP Recommendation IV, VI.b	"Items should be delivered to the sterile field in a manner that prevents unsterile objects or unscrubbed team members from leaning or reaching over the sterile field. [1: Strong Evidence]"	"Items should be opened in such manner that the nonsterile person is not extending over the sterile field."	SOP for Creating the Sterile Field, III-3c
Monitor for breaks in sterile technique	SRP Recommendation VII.c	VII.c. "Perioperative personnel should observe for, recognize, and immediately correct breaks in sterile technique when preparing, performing, or assisting with operative or other invasive procedures and should implement measures to prevent future occurrences. [1: Strong Evidence]"	"During all phases of surgical case management, the surgical team members must exhibit a high level of surgical conscience that demands when creating the sterile field, if an individual breaks aseptic technique, he/she will immediately communicate this to the other team members, or if another team member points out a break in aseptic technique, the individual who broke technique will take corrective action."	SOP for Creating the Sterile Field. Rationale section

Table 2- Monitoring the field, Standard comparison between AORN and AST

2.5 Aseptic presentation

Before opening, both sets of guidelines recommend an inspection of the package for sterility, integrity, and expiration dates (See Table 3):

Topic	AORN		AST	
Inspecting packages prior to use	SRP Recommendation VI.a	"Perioperative team members should inspect sterile items for proper processing, packaging, and package integrity immediately before presentation to the sterile field. [1: Strong Evidence]"	"Prior to opening a sterile item, the following should be verified: A. The external chemical indicator or integrator has changed color indicating the item has been exposed to a sterilization process. B. The integrity of the packaging material is intact, eg no perforations, tears or evidence of strike-through. C. Confirm expiration date, if present."	SOP for Creating the Sterile field III-2.b.

Table 3 - Inspection of packages, Standard comparison between AORN and AST

Some guidelines are specific to packaged products. AST's SOP III in *AST Standards of Practice for Creating the Sterile Field* specifies that one must check expiry dates, sterilization indicators, and seal integrity of packaged products ("Standards of Practice for Creating the Sterile Field," 2011). AST recommends a method in SOPIII-C that reads as follows:

> *"Small wrapped items, peel packs and suture packets should be opened and "flipped" onto the sterile field using aseptic technique. The glued area of peel packs and suture packets is considered the boundary between nonsterile and sterile. Items should be opened in such manner that the nonsterile person is not extending over the sterile field." ("Standards of Practice for Creating the Sterile Field," 2011)*

These procedures are similarly recommended in AORN's Recommendation VI and descriptions of several sterility studies are listed as supporting citations (*AORN Guidelines for Perioperative Practice*, 2016). AORN represents this concept with the following passage in VI-c and VI-e of their own recommendations:

> *"Sterile items should be presented directly to the scrubbed team member or placed securely on the sterile field. [5: No evidence]*
> *Items tossed onto a sterile field may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field."* (*AORN Guidelines for Perioperative Practice*, 2016).
>
> *"Peel pouches should be presented to the scrubbed team member or opened onto the sterile field by pulling back the flaps without touching the inside of the package or allowing the contents to slide over the unsterile edges of the package. [5: No Evidence]"(AORN Guidelines for Perioperative Practice, 2016).*
>
> The latter recommendation is also supported by AST:
> *Touching the inside of the package or allowing the contents to slide over the unsterile edges may contaminate the contents of the package."("Standards of Practice for Creating the Sterile Field," 2011).*

Guidelines are organized for comparison in Table 4.

Topic	AORN		AST	
Heavy items Puncturing the field	SRP Recommendation VI.c.1	Heavy items or items that are sharp and may penetrate the sterile barrier should be presented directly to the scrubbed team member or opened on a separate clean, dry surface.	Peel packs that contain a heavy or difficult item(s), eg pliers, multiple clamps, should not be opened and flipped onto the sterile field. The item could puncture the sterile cover. The item should be opened into a basin on a ring stand or preferably a non-scrubbed person should open the peel pack and pass the sterile item(s) using aseptic technique to the CST in the first scrub role.	SOP for Creating the Sterile Field III-3d
Opening packages	SRP Recommendation VI-c, VI-e	VI.c. Sterile items should be presented directly to the scrubbed team member or placed securely on the sterile field. [5: No Evidence] Items tossed onto a sterile field may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field. VI.e. Peel pouches should be presented to the scrubbed team member or opened onto the sterile field by pulling back the flaps without touching the inside of the package or allowing the contents to slide over the unsterile edges of the package. [5: No Evidence]	Small wrapped items, peel packs and suture packets should be opened and "flipped" onto the sterile field using aseptic technique. The glued area of peel packs and suture packets is considered the boundary between nonsterile and sterile. Items should be opened in such manner that the nonsterile person is not extending over the sterile field.	SOP for Creating the Sterile Field III-3c

Table 4 - Opening items to the sterile field, Standard comparison between AORN and AST

Schultz (1978) described *flipping* as a "jerking motion" which propels an item out of the package onto the field. According to Schultz (1978), many nurses contested the practice believing that "rapid, jerking movement of the hands and wrists, necessary to propel the object from the package to the sterile surface, may also propel skin debris and microorganisms onto the field." AST's guidelines (SOP III-c of Creating the Sterile Field) are at odds with AORN (Recommendation VI-c; Table 4), though the effect that either approach has regarding sterile transfer (or the lack thereof) remains to be objectively characterized.

AST also differs from AORN in that they explicitly state that a dropped package may be reused as long as it is packaged in an "impervious" material and that the integrity is not compromised.

2.6 **Corrective actions**

AST ("Standards of Practice for Creating the Sterile Field," 2011) lists in the "Rationale" section that surgical team members should point out perceived breaks in technique and communicate them to the rest of the surgical team, as well as take appropriate corrective actions. Although AST does not provide an example of the corrective action in the document, AORN gives an example in Recommendation VII.d of what a "corrective action" may entail:

> *"Corrective actions should include, at a minimum, removing the entire set and any other items that may have come in contact with the contaminated item from the sterile field and changing the gloves of any team member who may have touched the contaminated item. Additional corrective actions may be required subject to thoughtful assessment and the application of informed clinical judgment based on the specific factors associated with the individual event." (AORN Guidelines for Perioperative Practice, 2016)*

Aseptic technique is a sensitive process and is understandably conservative in nature. Yang et al. (2012) found that circulating nurses were effective at intercepting or otherwise mitigating errors committed by their peers. In Yang et. al's (2012) study, 28% of these mistakes were

related to aseptic technique. The authors concluded that circulating nurses, those in charge of managing the operating room, played a pivotal role in preventing OR errors and advocated "vigilance in the OR, especially in regard to aseptic technique and surgical prepping" (Yang et. al., 2012).

2.7 Packaging considerations

In addition to standards of practice, there are also guidelines for internal hospital packaging systems for reusable medical devices. These devices are re-packaged and re-sterilized in-house. AORN has a separate set of standards which go into more detail about the needs of OR packaging systems in *Recommended Practices for Selection and Use of Packaging Systems for Sterilization*. Among requirements related to sterilization are ease of opening, tamper evident sealing, allowing for identification of contents prior to opening, physical protection, and allowing for aseptic delivery of contents *(AORN Guidelines for Perioperative Practice, 2016)*. These points are supported by AST's *Standards of Practice for Packaging Material and Preparing Items for Sterilization (2009).*

In order to meet the needs of the healthcare providers, the packaging industry addresses similar requirements for packages used for disposable medical devices in the industry standard ISO 11607, which mandates that manufacturers of medical devices evaluate the integrity of seals and pouch materials, evaluate the appropriateness of materials for sterilization practices, and the ability of the materials to prevent microbial ingress. The focus of this dissertation is touched on in both industry and hospital standards with respect to packaging requirements: aseptic presentation. Before exploring packaging usage and delving into what aseptic technique means to the user, some OR packaging styles and their function are explored.

2.8 Packaging in these environments

Jennifer Neid Benolken has conducted several surveys and focus groups (live panels) of nurses at the Healthpack medical packaging conference spanning from 2008 to 2016 (Allen, 2010, 2011, 2012, 2013, 2015, 2016; Butschli, 2008). The findings, though only published in media coverage of the conference, provide some insights into the needs, complaints, and troubles nurses have with product packaging. Cai (2012) explored similar themes in usability issues, finding results consistent with the conference panels on topics such as the aseptic present-ability of header pouches, tearing issues, and difficulty of removing contents. Cai (2012) analyzed several common medical packaging styles used for disposable devices in the operating room and explored difficulties reported by healthcare providers through a series of focus groups. Cai used post-hoc content analysis methodology to identify themes in the data from discussions about packages including: trays, corner peel pouches, tear open pouches, double barrier pouches, chevron pouches, and header bags. The packaging styles will be discussed in tandem with perceptions that surfaced during her research.

2.8.1 Chevron pouches

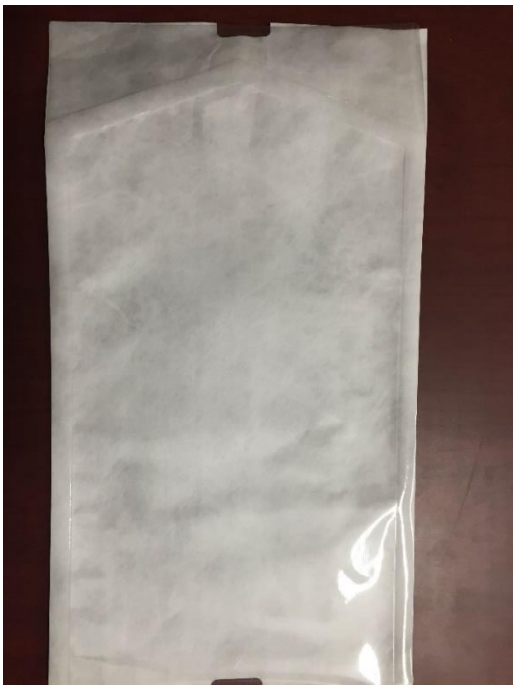


Figure 2- Chevron pouch (example)

Chevron styles are named for their "peak-shaped seal" at the end of the package (Figure 2), and are designed such that peel forces are distributed along narrow seals (Marotta, 1998). Marotta (1998) wrote that chevron designs were also used to mitigate the risk of fiber tear in paper-based backings. Cai (2012) reported, much in agreement with Benolken's studies, that the chevron was perceived favorably by healthcare professionals. The intent of the design is that the user begins peeling at the middle (just above the tip of the chevron), until the item can be removed or otherwise dispensed. When peeled in this fashion, the widths of the seals stay consistent throughout the path of peeling, in a straight downward motion that parallels the length of the pouch as the design intends. To gain familiarity with the relationship between seal design and opening force, the reader is encouraged to reference the dissertation of Javier de la Fuente (2013).

2.8.2 Corner peel packages

Figure 3- Corner peel pouch (example)

Marotta (1998) describes the utility of the corner peel configuration as providing "greater packaging space for a given size pouch, since seals can be made right up to the end." The design constrains the user to gripping a single corner to initiate opening. Corner peeled pouches may either be "flat" seals such as the image in Figure 3, or contain a small chevron for a low initiation peel force. Although Benolken often found that participants had a favorable opinion of corner peel pouches (Allen, 2010, 2011,2015), Cai, (2012) reported that the focus group participants considered the corner peel packs more difficult as they offered less control over the contents than a chevron. The pouch material's possibility of curling inward to contaminate the items was another consideration of corner peel packages reported in Cai's focus groups (2012).

2.8.3 Header pouches

Figure 4 - Header peel pouch (example)

Header pouches (Figure 4) are vented pouches that, according to Marotta (1998), are used to allow for "high permeability, ease of opening, and convenient product dispensing." The designs are created such that a small amount of Tyvek (Dupont-patented porous HDPE top web) is used for pouches that require ethylene oxide (EO) sterilization; a small section of Tyvek still allows permeation of gases into and out of the pouch while allowing less expensive films to be used for the majority of the pouch. In many cases, the user must peel off the Tyvek portion to allow access to the package contents, though some designs incorporate chevron peel seals at the opposite end of the pouch. Research done by Cai (2012) and a consumer panel conducted by

Benolken (Allen, 2015) call into question the ease of opening these packages. Cai (2012) reported that participants found it difficult to get the item out of a header pouch sterilely, with some participants stating that they were “similar to tear” pouches in that respect.

2.8.4 Tear open pouches

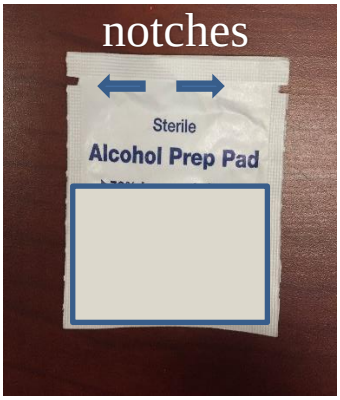


Figure 5- Sachet with tear notch (example, notches cut for illustrative purposes)

Similar to header pouches, participants from Cai’s study also reported sachets as inducing difficulty related to sterile transfer. Tear notches are used which require the user to rip the package into two pieces in order to access the contents. An example of such a notch can be seen in Figure 5. Cai (2012)’s participants converged on the idea that the tearing required too high of forces and it was difficult to identify the opening features of the sachets. One of the Healthpack panel nurses reported that she felt the tear strip “stick to an instrument” (Allen, 2010).

2.8.5 Thermoformed trays

Figure 6 - Thermoformed PET-G Tray with Tyvek lidstock (Example)

Semi-rigid trays (Figure 6) are used for high profile or irregularly shaped products as well as surgical procedure kits (Marotta, 1998). They are also used when the product requires extra protection or support, and are often lidded with porous, flexible materials such as Tyvek lidstock to meet sterilization requirements (Marotta, 1998). Concerns related to the design of lidded trays concentrated on difficulties with the item getting "stuck" inside the package (Cai, 2012). Cai's (2012) participants voiced the importance of being able to hold the tray stably in one hand in order to peel the lidstock smoothly. Panels at Healthpack suggested similar issues with accessibility (Butschli, 2008; Allen, 2015).

2.8.6 Double barrier packages

Figure 7 - Examples of double barrier packages, rigid inner pack (left) and flexible inner pack (right)

Double barrier packages are purported to be useful when extra assurance is needed regarding sterility (Eagleton, 1978). Double barrier packages were perceived positively in terms of "second chances" but negatively in that poor fit of the inner package to the outer package had the potential to cause accessibility issues (Cai, 2012). Conference panels similarly reported a preference for double barrier packages (Butschli, 2008; Allen, 2010, 2011, 2012), though recent panels have hinted at opposing opinions, whether it is simply not liking packages being contained within other packages (Allen, 2015) or just that single barrier packages are preferred for time-saving reasons (Allen, 2016). Double barrier packages have also been criticized as increasing the amount of handling (and by proxy, the potential for contamination (Crick et. Al, 2008) and that repeated openings over the field may compound the risk of introducing bacteria to the field (Smith et. Al, 2009). While there is no data to pinpoint the size and scope of the perceived pros and cons of any of the package styles, the lack of consistency in thenes is an

invitation for evidence based study of the effect of package design on handling and the ability to successfully transfer items to the sterile field.

For comparison of all package styles and opening methods, reference Figure 8:

Figure 8- Opening methods of six package styles (left to right) Chevron, Corner peel, Header pouch, tear notch, rigid tray

2.8.7 Other packaging related issues

Consistent themes from Benolken's panels and surveys are: the preference for double barrier systems (Butschli, 2008; Allen, 2010, 2011, 2012, 2013), the preference for clear packaging for content identification (Allen, 2010, 2011, 2012, 2013), and that packages must be able to be opened easily and in a timely manner (Butschli, 2008; Allen, 2011, 2012, 2013, 2015). Additionally, nurses consistently reported dumping or flipping items into the sterile field (Butschli, 2008; Allen, 2011, 2013, 2015, 2016). Many nurses reported that re-using a package dropped on the ground may be acceptable (Allen, 2011, 2012), which is in line with the Association of Surgical Technologists' guidelines so long as it is not placed back into sterile storage ("Standards of Practice for Creating the Sterile Field," 2011). The Association of Peri-Operative Registered Nurses does not have an official position on the issue, but discussion of the topic in a continuing education paper seems to agree with AST's position and cites surgical

journals which share the same line of thinking (Van Wicklin, Chambers, & Klacik, 2016). With respect to opening the packages, nurses often complained of the lack of opening features (Allen, 2011, 2013, 2015) and that there should be more signifiers for starting position (Butschli, 2008; Allen, 2013, 2015).

Forces required to open packages and the lack of gripping area were also converging themes from the participants discussing difficulties associated with sterile presentation (Cai, 2012). Long packaging and packaging with large or heavy products were viewed unfavorably due to control issues (Cai, 2012). Chevron packages (see Figure 2 on page 17) had the opposite influence on the perceptibility of control; Cai's (2012) participants reported that they were their "favorite" package to work with due to their ease of control. Aside from reporting their preferences, Cai's participants also expressed concern with contamination resulting from: items falling out of the field, items hitting something unsterile, breaches in packaging integrity, and problems identifying the correct product.

2.9 Summary

ISO 11607 part 1 mandates that designs allow the user to dispense the products aseptically. In this chapter, aseptic technique was discussed using nursing and surgical technology standards, which although similar, are not uniform in nature (See Table 1, Table 2, Table 3, and Table 4). The skilled usage of medical device packaging is acknowledged in ISO11607, but much is yet unknown about aseptic technique with respect to packaging and its role in assisting/hindering sterile transfer. As evidenced by the AORN standard, many of recommendations regarding sterile transfer have not been established with respect to the effectiveness of the techniques used and the ramifications for design use (or misuse) are unknown.

In the following chapters, this gap will be addressed with three studies.

- The objective of the first study is to determine if there is a statistically significant difference between pouch sizes and the source of the contaminant (i.e., hand versus pouch). This knowledge will help understand contamination hazards that may exist as a result of handling or as a result of dispensing over non-sterile edges of the packages.
- The objective of the second study is to understand the role design affordances have in the use of sterile packages, and what the package communicates to the user. A secondary objective of this study is to understand how aseptic technique is learned and applied. These insights will give designers insights into contextual factors which drive behavioral decisions (i.e., packaging use).
- The final objective is to explore opening forces and starting position as a potential cause of contamination using a simulated contaminant. These research

questions are explored using two Instron-based studies. First, peel force testing compared: a) three sets of pouches of three different strengths, and b) two sets of identical pouches peeled from different positions along the pouch, one of which was associated with higher opening forces. For the peel position study, qualitative data from surgical technologist interviews was analyzed to understand situations which may lead to peels being initiated at different locations along the pouch. Insights from this work provided a methodological basis for studying specific contaminants and provided support for the line of inquiry which ties opening forces to contamination.

3 Chapter 3: The contamination of sterile items during the usage of packaging

3.1 Background

A healthcare-associated infection (HAI), sometimes called a “nosocomial” infection, is defined by the Food and Drug Amendments Act as “an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital” ("Food and Drug Administration Amendments Act," 2007). HAIs have been a popular subject of study due to their impact in terms of increased length in hospital stays, financial burdens to patients, and mortality (Glance, Stone, Mukamel, & Dick, 2011). It is estimated that 1 in every 25 patients on any given day has at least one HAI (Magill et al., 2014). Magill et al. (2014) also estimated that there were approximately 722,000 HAIs in the US using data collected during the course of a year in 2011. Of the 722,000 infections, roughly 25.6% were device related (ventilator-associated pneumonia, catheter associated urinary tract infections, and central line blood stream infections) and 21.8% were surgical site infections (Magill et al., 2014). These two categories accounted for nearly half of the observed HAIs (Magill et al., 2014).

Siegel, Rhinehart, Jackson, and Chiarello (2007) identified two modes of transmission for HAIs: (1) indirect-contact transmission (transfer of an infection through a contaminated, intermediate object or person) and (2) direct contact transmission (between two people without an intermediate object). Herein, indirect contact transmissions, where packaging and packaging usage serve as a potential vehicle for transmission are investigated.

3.2 Published work investigating potential causes of infection

Investigators have studied transfer of contaminants through indirect routes from a variety of perspectives including: **glove integrity and the potential for gloves to serve as a reservoir for bacteria** (Beldame et al., 2012; Davis et al., 1999; de Oliveira & Gama, 2014; Giordano et al., 2014; Guo, Wong, Li, & Or, 2012; Kong, Sheppard, & Serne, 1994; Partecke et al., 2009; Rehman, Rehman, Rehman, & Freeman, 2013; Sørensen, Ejlertsen, Aaen, & Poulsen, 2008; Ward et al., 2014), **operating room traffic** (Andersson, Bergh, Karlsson, Eriksson, & Nilsson, 2012; Dalstrom et al., 2008; Lynch et al., 2009; Panahi, Stroh, Casper, & Austin, 2012; Pokrywka & Byers, 2013; E. B. Smith et al., 2013), **instrument sterility** (Chan-Myers, McAlister, & Antonoplos, 1997; Chu, Chan-Myers, Ghazanfari, & Antonoplos, 1999; Lipscomb, Sihota, & Keevil, 2008; Rutala, Gergen, Jones, & Weber, 1998; Southworth, 2014; Thompson et al., 2011) and **barrier** integrity (Kassarjian, 2011), **as well as hand hygiene** (Al-Damouk, Pudney, & Bleetman, 2004; Al-Tawfiq, Abed, Al-Yami, & Birrer, 2013; Arrowsmith & Taylor, 2014; Chun, Kim, & Park, 2014; Kirkland et al., 2012; Munoz-Price et al., 2014; Randle, Arthur, & Vaughan, 2010; Rowlands et al., 2014; Umit et al., 2014**).** All of these lines of inquiry have received due scrutiny in the literature. Although many indirect sources have been studied, packaging has not received much attention as a potential causal pathway for contamination. Further, there are only a few studies which investigate the interplay between user actions and packaging and how these relate to indirect transmission.

Medical researchers began the line of inquiry regarding packaging as a vessel of contamination. Crick et al. (2008) approached the topic with the intent of demonstrating that repeated openings of packaging (as is required with double barrier systems) increase the risk of contamination of orthopedic screws in comparison to traditional screw banks (containers

containing multiple screws). Crick et al. (2008) recruited 5 circulating nurses to present contents to a scrubbed-in "sterile" nurse. Each was to aseptically present 20 packages of individually wrapped screws and one screw bank with an undisclosed amount of screws. Contamination was measured using a simulated contaminant. Although Crick et al. (2008) provided limited formal analysis for the results, the methodology allowed for the nurse to remove items they felt were contaminated. Crick et al. (2008) found one instance of contamination of the inner package that the nurses themselves missed.

Smith et al. (2009) utilized microbes during opening of double barrier packets to measure the potential for contamination over the field. Smith et al. (2009) took two sets of measurements using a scrub and circulating nurse: culture swabs from the scrub nurse's hands, and measurements from petri dishes placed on the sterile field to capture potential growth after packages were opened over the field. Measurements were compared against controls. Smith et al. (2009) built upon Crick et. al.'s (2008) research; while Crick and colleagues provided evidence that clinicians may not always catch instances of contamination, Smith et al. provided evidence suggesting other methods of contamination via microbes falling from contaminated surfaces.

Smith et al. (2009) further investigated the microbe scattering hypothesis by using powdered salt as a coating in another study to measure the "scattering distance". The authors concluded that the scattering of the powder was "because of the force required to open the packets" although they did not provide complete information regarding the characterization of the peel force. Peel force as a potential contributor to contamination will be revisited in Chapter 5.

Trier et al. (2014) further investigated packaging, but unlike G. Smith et al. (2009) and Crick et al. (2008) who utilized picking presentation methods, single staff member presentations

were utilized by the nurses and surgical technologists in the study. Trier et al. (2014) studied three sizes of single-barrier chevron pouch sizes which were pre-filled with tongue depressors to a consistent surface area ratio (pouch-to-product) of 6.4. Leveraging the method developed by Crick et. Al (2008), Trier et al. (2014) coated both the pouch and gloves of participants with a simulated contaminant (Glitterbug cream) which illuminates under a blacklight. Echoing the concerns Crick et al. (2008) stated but did not specifically investigate, the authors hypothesized that increased handling would increase the risk of contamination (Trier, 2012). Analysis of frequency of hand movement (collected through post-hoc review of video data) suggested *handling* to be significantly higher ($P<0.001$) for each increasing pouch size, but the subjective nature of the data and the reproducibility of the counts left much to be desired.

With respect to the central issue—the contamination of sterile items during aseptic technique—the authors found that there was a significant increase in contamination rate between small and large pouches ($P<0.05$), but there was no evidence of a significant difference between the intermediary size and large or small pouches (Trier et al., 2014). The question of "where" or "how" things became contaminated was unclear based on the method employed, which used a single coating to represent contamination for both non-sterile surfaces (hand and pouch).

The present study hypothesizes that hand contamination is is the predominant mechanism for contamination in small pouches, and that the contaminations in large pouches will predominately be the result of contact with the pouch, itself:

HA_1: Contamination of items in small and large pouches varies by source of contamination (Hand vs pouch)

3.3 Methods

3.3.1 Participants

Prior to data collection, researchers obtained project approval from the Michigan State University Biomedical and Health Institutional Review Board (IRB# 13-383; see Appendix A for consent form and recruitment flyer). Participants were recruited at Association of Surgical Technologists (AST) conferences in New Orleans, LA in 2013 and Denver, CO in 2014. Participants were additionally recruited in 2015 by distributing flyers using an AST list-serv in the mid-Michigan area. Of the participants, 120 were recruited at conferences and 38 were recruited locally. A subset of the participants also participated in a guided interview (which will be discussed in Chapter 3). Those who participated without being interviewed received a $10 gift card for a gourmet coffee for their time, while those who were interviewed in addition to the opening study received $40 cash for participation. To participate, participants had to be at least 18 years of age, have no history of skin conditions (i.e. eczema, skin allergies, etc.), and be currently or formerly employed in a healthcare profession. Students with clinical experience were included in the eligibility criteria. Lastly, participants had to consent to be video-taped for the purpose of data collection.

3.3.2 Sample Preparation

Two sizes of pouch were utilized based on the prior study (Trier et al., 2014): 3”x 8” and 16”x 10.5”. Pouches were cut to these dimensions by Oliver-Tolas, the pouch manufacturer (Oliver-Tolas; Grand Rapids, MI) in order to maintain a constant aspect ratio of pouch surface area to tongue depressor surface area (aspect ratio). Pouches were filled with flat tongue depressors based on an aspect ratio of 6.4; one tongue depressor was filled into the small pouch, and seven were filled into the large pouch. Six-inch, non-latex tongue depressors (McKessen;

San Francisco, CA) were held together by being glued to a strip of paperboard using Gorilla Glue (Cincinnati, OH). Tongue depressors were held together to remove the confounding effect of multiple items per package. Pouches were sealed in a Sencorp thermal sealer (Clark, NJ) at 240°F with 50 psi pressure and 1.5 seconds dwell time. See Figure 9 for an illustration of the process.

Figure 9 - Filling and sealing process for large pouches

Two coating materials were used in a counterbalanced design to serve as simulated contaminants, the transfer of which signaled contact with a non-sterile surface contact (i.e., the outside of the pouch or hands). Glitterbug (Brevis; Salt Lake City, UT), which fluoresces under a black light and which has been used in prior studies (Crick et. al, 2008; Trier et. al, 2014), was selected as well as an ultramarine blue acrylic paint from Sargent Art (Hazleton, PA) (See Figure 10).

Figure 10 - Acrylic paint coating (L) and Glitterbiug coating (R)

Although the exact amounts of Glitterbug and paint were not consistent from trial to trial, efforts were made to keep it as consistent as possible. Each glove received one "pump" of Glitterbug per side of each hand or one "squirt" of paint per each side of each hand. Small pouches received one pump of Glitterbug or one squirt of paint per side. Large pouches received three pumps or three squirts of paint per side. Coatings were applied immediately before the participant opened the pouch on a flat surface using 1" foam brushes (made by Loew-Cornell (Erlanger, KY) and 9" rollers made by Rubberset (Cleveland, OH).

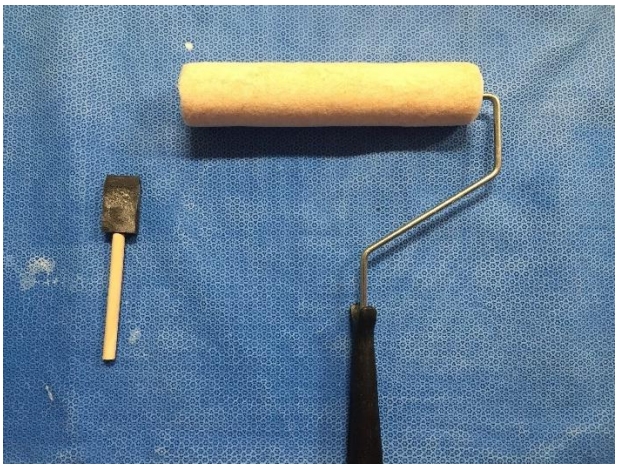


Figure 11 - Brush (L) and Roller (R) used to apply coatings. Paint rollers and brushes not pictured

The backs of gloves were coated entirely, except for the index finger and the bottom of the thumb. Pouches were coated approximately until the top 1.5 inches of the pouch (See Figure 12). Full coatings are avoided to prevent the pack from becoming slippery or artificially difficult to handle.

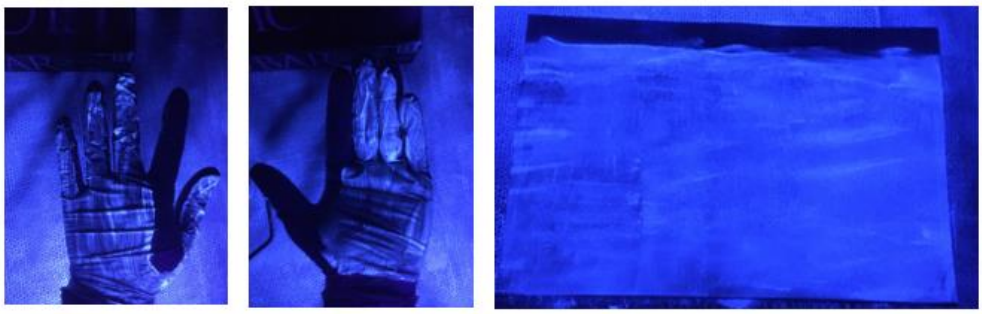


Figure 12 - Coating of back of hand (L), Coating of palm and fingers (M) and coating of pouch (R)

3.3.3 Statistics

Power calculations were conducted using Generalized Linear Mixed Models approaches at $\alpha=0.05$ to determine an appropriate sample size for the study, ensuring at least 80% statistical power to identify a differential source of contamination (hand or package) for large vs. small packages. The assumptions of rates of contamination were based on data previously gathered and analyzed (Trier, 2012). Percentage per source was estimated based on the hypothesis of the current study as data did not exist to assist in the estimation. Anticipated mean proportion of contaminations used, by treatment, to conduct power calculations are listed below. in Table 5:

	Pouch Size	
Source of contamination	***Small*** ***% of trials contaminated***	***Large*** ***% of trials contaminated***
Gloves	5%	5%
Pouch	1%	10%
Total	6%	15%

Table 5 - Estimated rates of contamination for power calculations

A type 1 error rate of 5% (α=0.05) was assumed. Calculations were performed with the desired power level was set to be 80% (β=0.2). A block variance of 1 and a whole plot (pouch size) variance was set to 0.5 based on the data generated from the master's thesis work of Trier (2012). Power calculations were conducted using a generalized linear mixed model procedure (PROC GLIMMIX) in SAS.

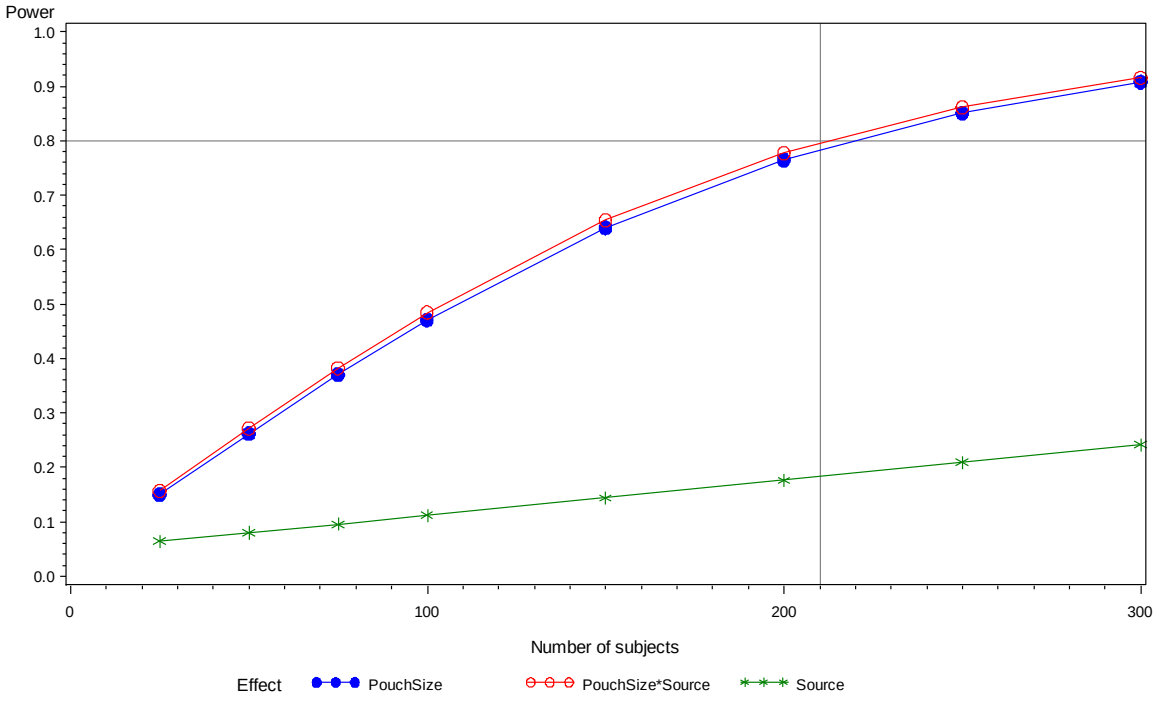


*Figure 13 - Power calculation of pouch size and pouch*source in PROC GLIMMIX*

The necessary sample size to detect a difference at 80% power and α=0.05 (PouchSize*Source interaction line) was calculated to be 210.

Each participant served as their own block. Every participant opened four pouches of two different sizes, coated in a randomized, counterbalanced fashion (Figure 14). Pouch run order within subject was randomized using SAS using PROC FACTEX with 210 blocks and 4 treatments per block.

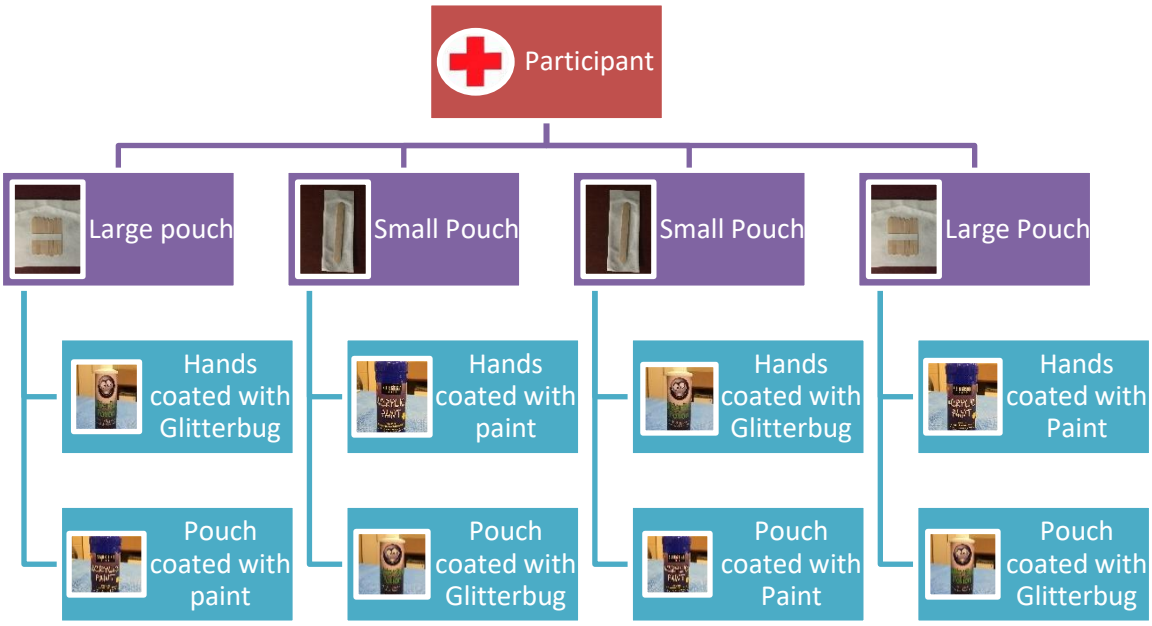


Figure 14 - Sample participant block run order

For statistical analysis, a generalized linear mixed model was fitted to the binary response "contamination," using a logit link function on a Bernoulli distributed random variable. The linear predictor in the model was assumed to include the fixed effects of pouch size (large vs. small), source of contamination (gloves vs. pouch surface) and contamination simulant (Glitterbug vs. paint), as well as all 2- and 3-way interactions.

3.3.4 Data collection

Cameras were positioned to capture the handling and opening of the package as well as the transfer of the tongue depressors to the sterile field. Table heights varied slightly depending on the location: at the AST conferences, the table was 30 inches tall, and 23" x 72" in size. At Michigan State, the table was 28 inches tall, and 24" x 72" in size. See Figure 15 for a diagram of the table dimensions.

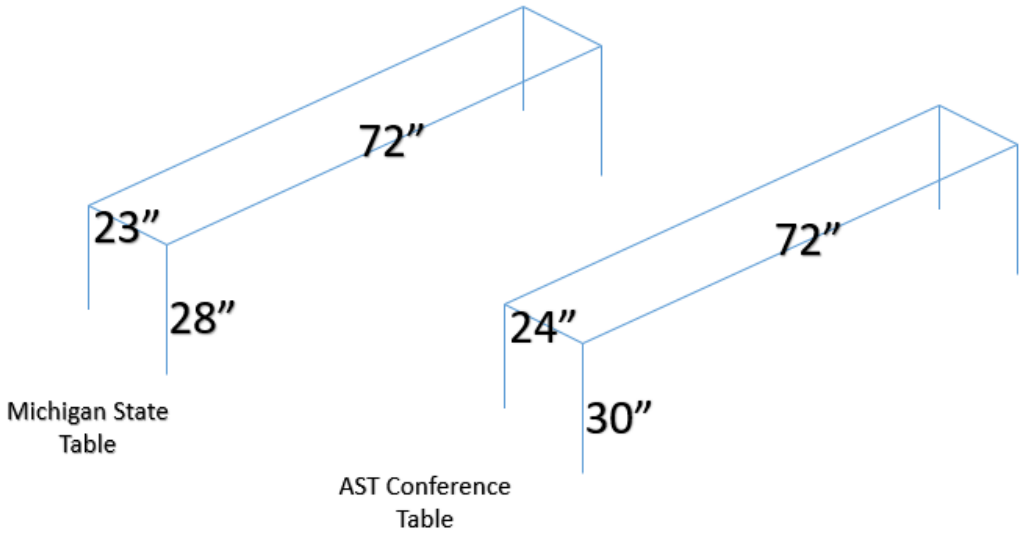


Figure 15 - Table sizes used in opening study

Before the study, participants filled out a work sheet which collected information regarding the participant's work history as well as their experiences opening packages (See Appendix B). Survey data was collected to gather work-related information including how many years of experience the subject had in their profession (free response), how many years specifically using aseptic technique (free response), how many packages they estimated they opened every shift (free response), how many packaged products per week they estimated they threw away (free response), and the reason they discard products when they do throw them away (multiple choice with a free response "Other" category).

Participants selected the size of glove they were comfortable with and changed nitrile gloves (Kimberly-Clark; Neenah, WI; See Figure 16) after every trial.

Figure 16 - Gloves used in contamination study

Each subject presented the contents of four packages, two large and two small (reference Figure 14). Participants were asked to aseptically present the tongue depressors to a 25" x 25" simulated sterile field, comprised of a drape from Medical Action (Arden, NC; See Figure 17).

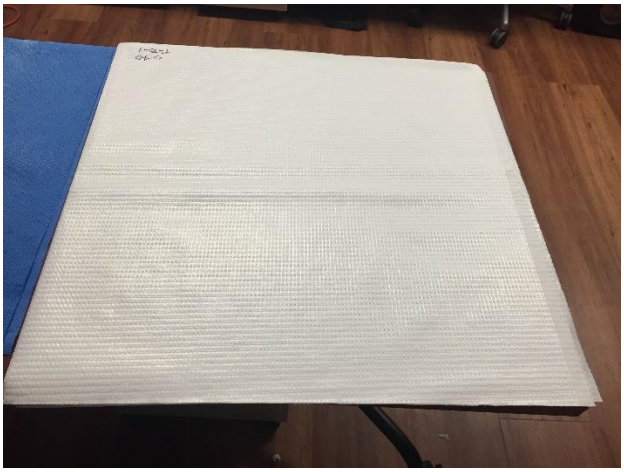


Figure 17 - Simulated sterile field

Immediately after each trial, the presented contents were scanned for contamination visually using a Glowbar black light to detect the Glitterbug in ambient lighting, and by visibly looking for traces of paint. Personnel involved in scanning scanned their gloves to ensure cleanliness prior to touching samples to mitigate the risk of cross-contamination. Contaminated gloves were removed and changed for a fresh pair. Contamination was scored in a binary fashion (yes/no) and the source of contact was recorded for the trial in a data collection sheet (see Appendix B).

To mitigate the likelihood of cross contamination, a single team member was tasked with handling the simulants while another was tasked with scanning tested devices (i.e., the tongue depressors). An additional researcher tasked with scanning wore gloves in order to minimize the risk of cross-contaminating trials. Scanning researchers were asked to scan their own gloves between inspections of dispensed items. In the event that only one researcher was available, the researcher changed gloves and ensured no Glitterbug or paint was present on the gloves before scanning and handling the dispensed contents.

3.3.5 Re-categorization of free response survey data

Due to the open-ended, free response structure of many sections of the survey (e.g., "10", "10-20", "10-15", "more than 10"), reported values were re-categorized by the researcher and data were fit ad-hoc to their corresponding category.

Values were categorized with the following rules, in this example, using the range "1-10" for demonstration purposes:

- If the participant reported a raw, discrete value (e.g., "10"), this was scored within that the appropriate range (e.g., 10 fell into the 1-10 range and was categorized as such).

- If the participant reported 5-10, the upper bound value was used to determine the value, placing it in the 1-10 category.
- If the participant reported “10 or more”, this value was scored in the next category above the reported value, “11-20”.
- If the participant reported “Less than 10”, the value was reported as if it were “9”.

3.3.6 Re-categorization of “Other” responses

The “other” option in response to the “Why do you throw away these products?” question was reviewed for responses that had common themes. These responses were condensed into additional categories. For example, responses such as “holes” or “channels” were categorized as “integrity issues”.

3.3.7 Re-categorization of professions

Participants were, for the purpose of data analysis, re-categorized into singular professions if they reported more than one. Re-categorization occurred as follows:

- If two professions were circled, the profession with the highest level of required education was chosen.
    - If surgical tech and first assistant were circled, the participant was categorized as a first assistant.
    - If surgical tech and nurse were circled, the participant was categorized as a nurse.
- One exception to the above rule is with the Student option. If “student” was selected by the participant as one of their profession choices, the participant was only categorized as a student. The rationale for this is to delineate students from practicing healthcare professionals in the analysis.

3.4 Results

3.4.1 Participants

A total of 159 healthcare providers participated in the study. Participants were predominately female (132 compared to 24 males, 3 not reporting) with an average of 11.4 years of experience (range 0-44 years). Participants had an average of 11.2 years of experience (range 0-44 years) presenting items to a sterile field. Participants were predominately surgical technologists (69%) with the next largest group being nursing students (9%; See Figure 18)

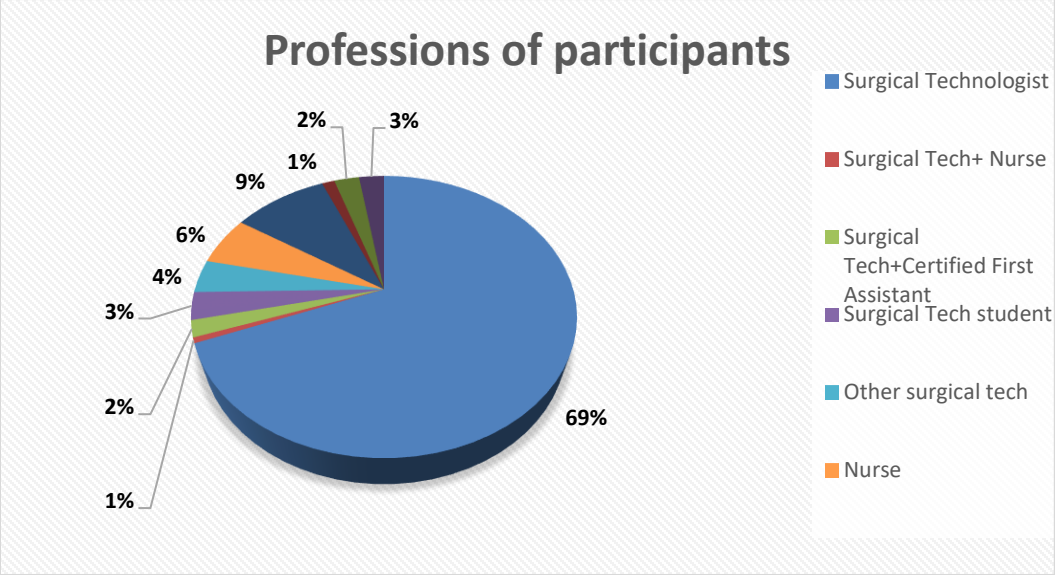


Figure 18 - Professions of participants before re-categorization

After re-categorization, the participant groups were divided as follows (See Figure 19):

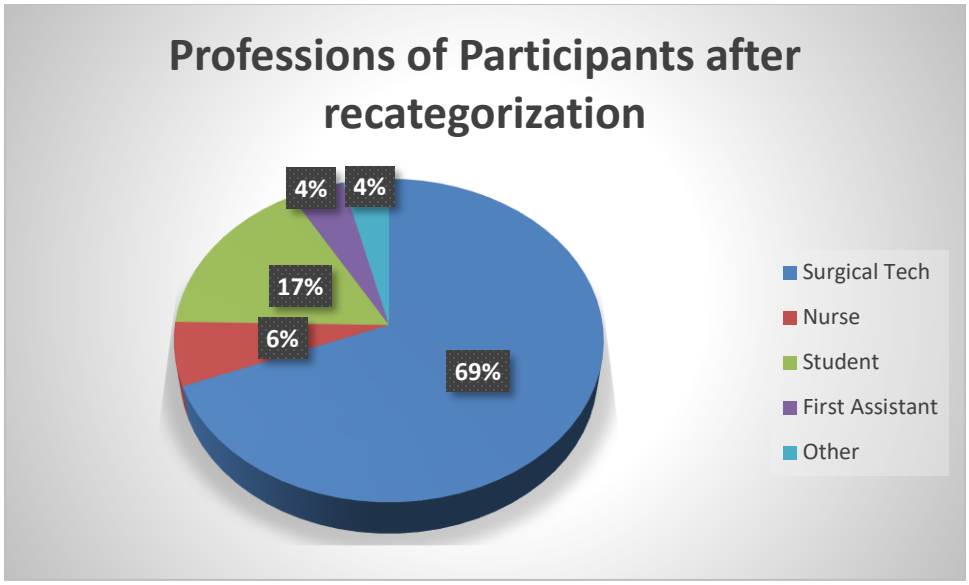


Figure 19 - Professions of participants after re-categorization

3.4.2 Packaging usage

The "total reporting" counts represent the number of participants providing responses in that particular survey question.

A total of 147 unique respondents reported number of packages opened per shift is reported in Table 6.

Pack Opened	Number of Participants Reporting
0	0
1 to 10	30
11 to 20	22
21 to 30	19
31 to 40	14
41 to 50	14
51 to 99	18
100 +	29
"A lot"	4
Total Reporting	**150**

Table 6 - Packages participants opened per shift.

The results of the categorization of number of products thrown away per week is presented in Table 7, Table 8, and Table 9.

Number of Products Thrown away	**Responses**
0 / None	7
1 to 10	106
11 to 20	14
21 to 30	4
31 or more	4
"A lot"	2
Total Reporting	**137**

Table 7 - Number of products thrown away per week for 137 respondents.

	ST	Student
0	0	0
1 to 10	9	15
11 to 20	16	2
21 to 30	17	0
31 to 40	13	0
41 to 50	13	1
51 to 99	16	0
100 +	28	0
"A lot"	3	0
	N=115	N=18

Table 8 - Packages opened per shift - surgical techs and students

	ST	Student
0	5	5
1 to 10	76	17
11 to 20	13	0
21 to 30	3	0
31+	4	0
A lot	2	0
	N=103	N=22

Table 9 - Packages thrown away per shift - surgical techs and students

147 unique respondents reported the rationale behind throwing away packaged products in.

Some respondents recorded multiple responses.

Reason for throwing away item	**Number of Participants Reporting**
Water	12
Expired	18
Package contacts item	110
Hand contacts item	83
Package Integrity	8
Dropped item	14
Remaining other responses	10

Table 10 - Reason for packaged products thrown away

Fifty-nine 59 respondents (40%) reported both the item contacting the hand and the item contacting the pouch.

3.4.3 Descriptive contamination information

The over-all frequency of contamination (irrespective of source or pouch size) was 2.4% of all test trials. This represents 31 total trials, with 5 contaminations occurring in small pouch openings and 26 contaminations occurring in large pouch openings (*Table 13*. Two participants, one a student and the other a surgical technologist, contaminated more than one opening trial. Contamination frequencies by profession (Table 11), location of study (Table 12), pouch size (Table 13), coating (Table 14), and source (Table 15).

Surgical Tech	Nurse	Student	First Assistant	Other	No profession reported	TOTAL
16/109	2/10	9/26	0/7	1/6	1/1	29

Table 11 - Number of participants in each profession who contaminated at least one trial. Denominator values are total number of participants within that profession.

New Orleans	Denver	MSU	TOTAL
8/320	14/160	9/156	31/636

Table 12 - Occurrences of contamination by location. Denominator represents number of individual pouch openings in that location.

Small Pouch	Large Pouch
4/318	25/318

Table 13 - Occurrences of contamination by pouch size. Denominator represents total openings of that size.

	GB	***PAINT***
Pouch	*3/318*	*12/318*
Hand	*8/318*	*8/318*

Table 14 - Occurrences of contamination by coating. Numbers represent total coatings per condition.

Hand	Pouch
16	15

Table 15 - Occurrences of contamination by source

3.4.4 Statistical analysis

The data were analyzed with a generalized linear mixed model. The dependent variable, contamination, was fit using a logit (log-odds) link, assuming a Bernoulli distribution. The probabilities were linked with a logit function in order to connect the probability of

contamination with the linear predictor. This linear predictor included five levels of Occupation (surgical technologist, nurse, first assistant, student, other), two levels of pouch size (small and large), two levels of coating type (Glitterbug and paint), two levels of contamination source (hand and pouch; see Figure 14). Additionally, for coating, contamination source, and pouch size, all two way interactions were fit to the model. Higher orders were not possible to fit with occupation due to category problems resulting from one level (first assistant) having zero contaminations. Random effects included subject nested within occupation. The random effects of test location, subject-by-pouch_size had variance components which converged to zero and were, as a result, removed from the model in analysis. To evaluate if variance components were greater than predicted with the model, overdispersion was evaluated. Maximum-Likelihood-based Pearson Chi-Square/DF was the method of estimating this overdispersion. As a result of the quasi-complete separation of datapoints (the categorical problem with occupation), a Laplace approximation to maximum likelihood was used in place of Residual Pseudo-Likelihood. Degrees of freedom in the model were approximated manually.

The model was fitted by using PROC GLIMMIX in SAS version 9.4 (SAS Institute; Cary, NC). PROC GLIMMIX is often used for generalized linear mixed models (fixed and random effects) and can be used with logit responses using link functions. Newton-Raphson with ridging was used as the optimization technique. Least square mean probability of contamination was calculated using LSMean, including the standard errors and estimated 95% confidence intervals. Pairwise comparisons were conducted with Tukey-Kramer or Bonferroni adjustments as appropriate to avoid an increase in Type I error from multiple comparisons.

There was sufficient evidence to reject the null hypothesis that pouch size did not affect the rate of contamination. Items presented from larger pouches [mean probability=0.0018 (or

0.18%), 95% CI (6.12 x 10^{-117},1)] were significantly more likely to be contaminated (P=0.0017) than smaller pouches [mean probability = 0.00034 (0.03%), 95% CI (1.17 x 10^{-117}, 1). The mean probability of contamination from the hand was 0.000827 [95% CI, (7.99 x 10^{-117}, 1) while the corresponding probability from the pouch was 0.000758 [95% CI, (7.32 x 10^{-117} , 1). There was insufficient evidence to reject the null hypothesis that source of contact (hands versus pouch; P=0.8736) was the same in both pouch sizes.

3.5 Discussion

3.5.1 Contamination during aseptic technique

There were two key aims of this study: to confirm and provide further evidence for the effect of pouch size on contamination during aseptic presentation, and to evaluate if there were sources of contact (via the hand or the pouch) that were significantly more likely to result in contamination. The dependent variable "Contamination" was measured in pouches that were two different sizes, utilizing two different simulated contaminants. The two simulants were used to identify two different sources of contact (hand or pouch) between the tongue depressors and each non-sterile surface per trial. There was insufficient evidence to reject the null hypothesis (P=0.87) that the ***source*** of contamination was statistically the same (hand versus pouch). Additionally, there was also insufficient evidence to detect a difference in ***coating***, or the occurrence of contamination where Glitterbug [mean=0.000605, 95% CI (5.84 x 10^{-117}),1] was present on the tongue depressors versus where Paint [mean=0.001035, 95% CI (1.0 x 10^{-116}),1] was present (P=0.32). Lastly, the was insufficient evidence to detect differences in probabilities of contamination in the different ***occupation*** groups (P=0.63). However, the ***size*** of the package did affect the probability of contamination (P=0.0017), where the probability of contamination was greater in the large pouch presentations than the small pouch presentations. Notably, after

adjustments in the model for coatings, sources, and subject variability (from the random effects), contamination estimates were 0.03% and 0.1% for the small and large pouch respectively.

All trials were providers noted difficulty with transfer were included in the analysis. This was done because the present study is interested in what factors facilitated (or hindered) the ability to transfer items successfully. It is important to note that Yang et al. (2012) demonstrated that circulating nurses were very effective at identifying breaches in aseptic technique, which in the case of identified contaminations, would mean that packaged products would usually be discarded by the healthcare professional and not used on the patient. However, Crick et l. (2008)'s study found one instance where a breach was not identified, suggesting that not every problem will be identified by healthcare providers even if they are disposing of the perceived contaminated products. The present work provides preliminary survey data which suggest that some packaged products are thrown away every week because the healthcare providers felt the contents were not sterile, and many reported that the decision to discard the devices is made because the device contacted the pouch or the hand during aseptic transfer of the products (110 and 83 responses respectively). The work also offers insights into the effect of pouch size on contamination, building on Trier et al. (2014)'s preliminary work which also found this to be the case. Specifically, items dispensed from large packages were significantly more likely to be contaminated as compared to small pouches ($P<0.05$), but the rates of contamination (when adjusted to account for subject variability) were quite small to begin with (0.1% vs 0.03% for the large and small pouches respectively). The raw percentages of small and large pouch openings (amount contaminated/total pouch openings of that size) which resulted in contamination were 1.3% (4/318) for small pouches and 7.8% (25/318) for larger pouches respectively. These values

were markedly lower than the values reported by Trier (2012), which were 7.2% (14/194) for the small pouch and 16.5% (32/194) for the large pouch.

These differing rates of contamination may have several explanations. One possible reason is the large variability involved in any testing done with human subjects who have different abilities experiences and approaches (and differ in size and strength as well). Additionally, the present study also addresses a limitation in Trier et al. (2014) in that tongue depressors in the large pouch were loose-filled in the previous study, and thus not representative of a single item being presented. This limitation made it difficult to attribute the contamination purely to pouch size, as biomechanical and behavior considerations were confounded (i.e., dumping out a single smaller item versus presenting 6 items that "flowed"). Although the final adjusted rates are low, the relationship in the present study is consistent with prior work even after the large pouch's loose contents were bound to a single unit.

3.5.2 Descriptive packaging usage

The number of packages opened per week, as estimated by the participant, varied considerably. However, the number of packaged products reported as being *discarded* per week was low with over 77% (106/137) being in the 1-10 per week range. Those who throw packaged products away reported that the sterile item contacting the hand (83 responses) and the sterile item contacting the pouch (110 responses) often were the reasons that the items were thrown out. Fifty-eight (58) participants reported *both* of these occurrences. Another notable element of the question is that package integrity issues (8 responses) and dropped packages (14 responses), though fewer in frequency, were issues that were introduced by the participants themselves, unprompted in the "other" space. Care should be taken to include these two phenomena in future work.

3.5.3 Limitations of opening study and survey work

Survey results, although interesting, must be interpreted conservatively as the convenient sampling is unlikely to represent the general population's experiences and attitudes. As such, statistical evaluation was not conducted. While the survey data do not allow us to paint a generalizable portrait of behavior in the OR, it does allow a window into the phenomenon and a preliminary idea of how aseptic presentation may tie in with operating room waste.

The clinical relevance of the opening study results are difficult to interpret with the low predicted probability of contamination. One should also consider that it is possible that the contamination was identified during the physical test, and had the healthcare provider a choice, they would have discarded the item instead of presenting it to the field. The survey data, in conjunction with the published literature and the results from the opening study, suggest that contamination may be an infrequent occurrence, which may further be mitigated by the keen eye of the healthcare provider. However, packaging studies published on the topic of contamination suggest that some instances of contamination may go undetected. Packaging opening studies, including the work herein, go further in building our understanding of how contamination can happen.

The present work has re-affirmed a previously published study in which package size may increase the frequency of contamination, though there was insufficient evidence to pinpoint the hands or the pouch as the culprit in either of the sizes. Even if these rare occurrences are noticed by the clinician, packaging designers must consider that package size may inadvertently lead to hospital waste, if not infections themselves. More work is needed to investigate issues such as material curling into the pouch and potentially contaminating contents, identifiability of breaches in package integrity, and how aseptic technique manifests in package styles other than

flexible chevron peel packs. Additionally, while the survey shed some light on the disposal of packaged products due to aseptic technique-related issues, the scope of the survey unfortunately does not give a good indication of general hospital practices. Work remains to be done with respect to national surveys which could further segment the issue by unique characteristics of individual hospitals.

4 Chapter 4: Aseptic technique and packaging – design communication and implications

4.1 Background

In the medical device industry, standards such as ANSI/AAMI/ISO 11607 play a prominent role in packaging design. The standard demands that packaging "allow sterilization, provide physical protection, maintain sterility to the point of use, and **allow aseptic presentation**" ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems ", 2006). The minimum packaging required to perform these functions is termed "sterile barrier system" (SBS) in ISO 11607 part 1. Additionally, in instances where the packaging is partially manufactured with the intent of being later filled and sealed, the term "preformed sterile barrier system" is used, and any additional packaging meant to protect the sterile barrier system is referred to as "protective packaging (AANSI/AAMI/ISO 11607-Part 1). In packaging validations, many requirements are set forth regarding maintaining sterility, preventing microbial ingress, and being able to survive customary distribution environments. With respect to usability, the role of the package is made explicit: "The sterile barrier system shall allow the product to be **presented in an aseptic manner**." (AANSI/AAMI/ISO 11607-Part 1). Aseptic presentation is then defined in the standard as the "introduction and transfer of a sterile product using conditions and **procedures** that exclude microbial contamination" (AANSI/AAMI/ISO 11607-Part 1).

Detailed procedures regarding the aseptic transfer of devices from their packaging are outside the scope of a broad standard of package design and not specified or referenced in the document itself. Standards which do focus on the process for achieving aseptic transfers involving packages are limited in their availability, and our review suggests that they are not

uniform in their recommendations for the same. For instance, they differ on the acceptability of tossing items into the sterile field (*AORN Guidelines for Perioperative Practice*, 2016; "Standards of Practice for Creating the Sterile Field," 2011). An example of detailed package-related procedures comes from the Association of peri-Operative Registered Nurses (AORN)'s guideline VI.e, which reads: "Peel pouches should be presented to the scrubbed team member or opened onto the sterile field by pulling back the flaps without touching the inside of the package or allowing the contents to slide over the unsterile edges of the package. [5: No Evidence]"(*AORN Guidelines for Perioperative Practice*, 2016).

4.2 Human factors methods for identifying tasks

In the *Human Factors design process for medical devices* standard, ANSI/AAMI HE74, the term *Human factors engineering* is defined as:

> "Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, equipment, systems, tasks, jobs, and environments to achieve productive, safe, comfortable, and effective human use" ("HE74: Human Factors Design Process For Medical Devices," 2001)

The process may involve numerous stages, including a stepwise analysis of tasks involved in the device's use, interviewing end users, observing the usage of similar items in a real context with minimal interference (contextual inquiry), and studying the usage of the device in real or simulated settings (HE74:2001). Medical device usability is typically covered in the pre-market approval phase of development. The FDA works with industry to approve of human factors plans and to review risk assessments associated with the use of devices ("Premarket Information - Device Design and Documentation Processes," 2016). Human factors evaluation is also required as part of 21 CFR 820 section 30, particularly sub-part C, F, and G. Sub-part G, regarding design validation, reads: "Design validation shall ensure that devices conform to

defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions" ("Design Controls," 2015).

The FDA recognizes several standards regarding human factors for medical devices, particularly AAMI/ANSI HE75:2009 "*Human Factors Engineering – Design of Medical Devices" and* ANSI/AAMI/IEC 62366-1:2015 "*Medical devices – Part 1: Application of usability engineering to medical devices".* When paired with ISO11697-1's requirements for aseptic presentation, human factors standards offer methods for understanding tasks involved in aseptic presentation of the devices, as well as the potential risks to the sterility of the item during the usage of the package. Three questions frame the present study:

- What formulates the skill "aseptic open-ability"?
- How does the package communicate information to the user during this process?
- How does context change the approach to usage?

To approach these questions, professional learning and skill acquisition literature were reviewed in addition to existing literature on the topic of affordances, which have long been used by designers to explain consumer behavior interactions between people and objects in the environment.

4.3 Aseptic technique as a professional skill

Dreyfus and Dreyfus (1986), in *Mind Over Machine,* re-introduced their 1980 paper which presented skill acquisition in a five-point model, ranging from novice to expert. In Dreyfus and Dreyfus's framework (1986), progressing from "novice" to "expert" involves increasing intuition based on practical experience; learners glean more information from the environment and move from dogmatic rules to situational models based on over-arching goals,

and finally to intuition (Dreyfus & Dreyfus, 1986). The Dreyfus Model is simply put as followed:

1. Novice – Adheres to rigid rule-based behavior.
2. Advanced Beginner – Person begins to notice patters, applying context-based rules.
3. Competent – Person begins to identify actions as part of a broader, higher-level goal.
4. Proficient – More analytical, sees actions as situationally dependent.
5. Expert – No longer reliant on rules, actions are intuitive.

Benner (1984) applied the Dreyfus and Dreyfus model to nursing, providing quotations from her interviews contextualizing, within nursing, each segment of the model. Benner (1984) also noted that experts can become novices in some respects, as "any nurse entering a clinical setting where she or he has no experience with the patient population may be limited to the novice level of performance if the goals and tools of patient care are unfamiliar." With respect to Dreyfus' model, this means a regression to rule-based behavior. The context is, therefore, a critical component of whether or not a situation can be navigated intuitively by the experienced healthcare provider, or if it will follow the "rule-governed behavior" of a novice.

Eraut (2000) described skill acquisition dynamically in that knowledge acquired from others and practical experience can both be at work. Eraut (2000) provided two situations to demonstrate this: not only can practical experience help clarify how semantic (general, non-specific) knowledge fits in a particular situation, but practical experience can also be contextualized into something more general through reflection. Eraut (2000) wrote that the ability to deliberate and reflect may be moderated by the environment; busy environments and

shortage of time lead to more intuitive actions. In addition to accounting for particularly busy or time-constrained conditions, Eraut (2000) cautioned that one must take into account the unique "learning histories" of the actors and the influences these histories introduce into a situation, as well as the influence of the situation on the learning histories of the individual actor. Eraut (2004) described that these learning careers are themselves dynamic, "flourishing" or "regressing" based on factors such as the extent "group members learn from each other, to what extent individuals of the whole group respond to the challenges of their work and support each other, and what additional learning opportunities for the group are located and developed." Indeed, Lave and Wenger (1991) and Le Clus and Volet (2008) each demonstrated that in group dynamics, learning can both be afforded with *access* or denied by coworker mistrust.

The communal aspect of learning is demonstrated by Lave and Wenger's (1991) work in situated learning. In their discussions of apprenticeship, they present a framework where learning is not simply an acquisition of a skill, but is the shaping of an idea within a "community of practice" (Lave & Wenger, 1991). Learning is influenced in part by anecdotes of "problematic or difficult cases" experienced by colleagues or senior staff members, and it is through these interactions that learning is "exceedingly rapidly and effectively" distributed (Lave & Wenger, 1991). Lave and Wenger even postulate that these interactions "may well be a condition for the effectiveness of learning" (Lave & Wenger, 1991). A summary of various learning research can be found in Table 16.

Author	Synopsis
Lave and Wenger (1991)	Learning facilitated and hindered by "access" to knowledge held by experienced colleagues.
Le Clus and Volet (2008)	Informal learning takes place spontaneously, in order to "keep up" with workplace acticities. Learning is positively and adversely affected by "social affordances", or relationships with colleagues.
Eraut (2000)	Experiences can lead to more generalized knowledge. Individuals have unique learning histories.
Eraut (2004)	Learning careers can flourish and regress based on opportunities for learning and support from colleagues.
Dreyfus and Dreyfus (1984)	Gradual transition from novice to expert, progression from rules to intuition.
Benner (1984)	Expert nurses can become novices in unfamiliar situations. Expertise is situation/skill dependent.

Table 16 - Situated Learning and Dreyfus Model synopsis

Sternberg et al. (2000) presented a framework of learning based on the memory organization work of psychologist Tulving (1972). This model was adapted by the author and presented in Figure 20. Three modes of memory were defined by Sternberg et al. (2000).

1. Episodic memory is comprised of “personally experienced events” (Sternberg et al., 2000) having, as Tulving (1972) put it, an “autobiographical nature.”
2. Procedural memory is composed of specific “condition-action pairings” (Sternberg et al., 2000). Tulving (1995) noted that this includes physical tasks such as balancing as well as cognitive tasks such as reading.
3. Semantic memory is general and “impersonal” (Sternberg et al., 2000). Semantic knowledge “transcends particular episodes (Sternberg et al., 2000) and it is from here that one generalizes (Tulving, 1972).

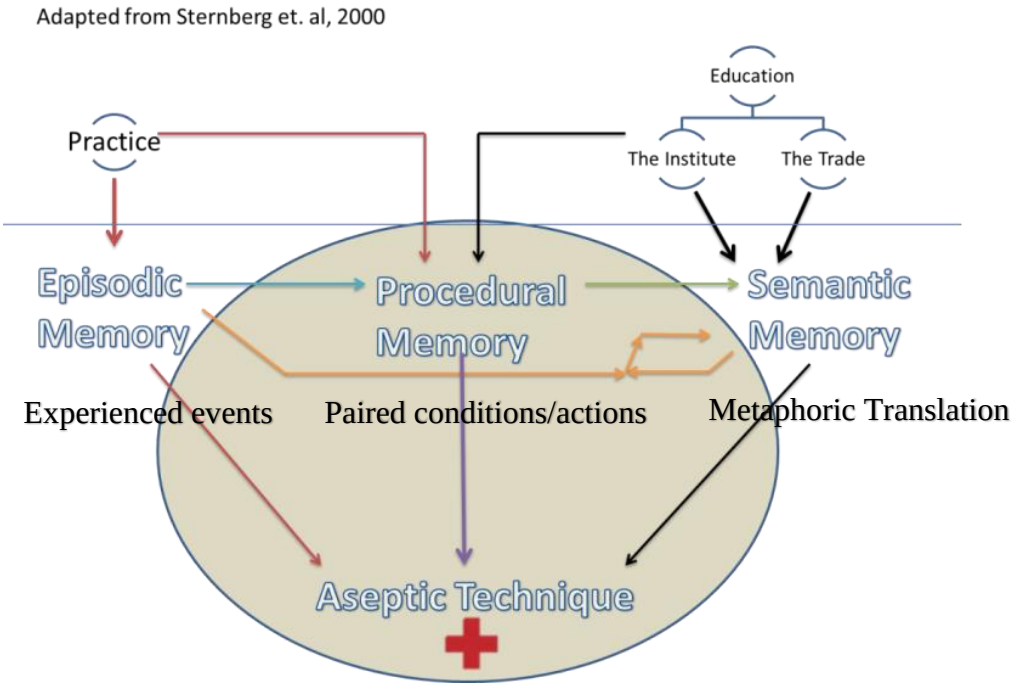


Figure 20 - Framework of memory, adapted from Sternberg et. al (2000) and Eraut (2000)

How people come to understand and employ aseptic technique may also be fitted to this model. Interactions with packages, according to this model, will over time form a condition-action pairing, which may also inform higher-level, broadly generalized semantic information. For example, enough experiences with fiber tear on pouches sealed to paper backings (episodic memory) may inform a certain method of peeling them, or the general rule (orange line) that "paper backings can cause fiber tear" regardless of pouch style (semantic memory). Whether the experience informs procedure or influences behavior directly, there is a practical, experience-based component in this cognitive model. Additionally, procedural and sematic memory can be directly acquired from others in the form of schooling or professional standards. Even colleagues in the workplace, such as a preceptor during clinicals, can be a source of directly acquired information.

4.4 Summary of learning literature

Multiple authors have framed learning and acquiring skills beyond the direct "book-learning" approach. Skills may be acquired through a combination of practical experience, coaching from colleagues, and sharing of experiences with others. Each individual learner has a unique learning history based on past interactions with others which are situated within their own contexts. It is because of this complexity that aseptic technique must be understood holistically when designing packages; decontextualized, codified procedures are comparatively simplistic compared to a framework that views each nurse or surgical technologist as a unique "work history." Each user has experiences that offer a window into aseptic technique's manifestation in practical situations. Many of the contextual factors are admittedly are outside the control of the designer, but the present study aims to understand how the user approaches aseptic technique when interacting with varied packaging designs—in other words, to understand how the package is effective or ineffective in practical situations. The designer can then modify the *designs to fit the needs* of the event.

4.5 Packaging communication

4.5.1 Affordances

The study of how an object (such as a package) might communicate with the user has a long, diverse history in the literature. Leveraging Husserlian philosophy, early 20th century Gestalt psychologists approached the concept with a phenomenology lens. Kurt Lewin wrote that needs (such as hunger) create a tension, leading to an organism seeking equilibration. Objects then gain what Lewin called an *Aufforderungscharakter* (Lewin, 1926). The German term, translated as *valence* in Rappaport's *Organization and Pathology of Thought* (Lewin, 1951) and as *demand character* in Koffka (1935), refers to an object's role in enticing action (Lewin,

p118). When one is hungry, food has a positive valence (attraction). The food entices, or as Lewin put it, *challenges* one to the action of eating (Lewin, p 117). Lewin demonstrated the concept of valences dissipating with a relatable example: "greatly tempting delicacies become uninteresting as soon as one is *satiated*" (Lewin p 120). In line with their phenomenological roots, it is the phenomenal apple which entices. It is not the mailbox which solicits one to drop a stamped letter into it, it is the phenomenal mailbox. This concept of solicitation is present in Dreyfus and Kelly (2007), a phenomenological paper which describes the solicitations as non-deliberative—that we are called to "give in" to their demands. Dreyfus and Kelly's (2007) example of this phenomenon is when one is standing too close to a large painting. Tension forms from being too close, and Dreyfus and Kelly (2007) describe the mitigating action as being "led" by the painting to stand at an appropriate distance, reducing the tension. Dreyfus and Kelly (2007) called these non-deliberative solicitations *affordances,* though they are much different from the *affordances* coined by James Gibson and used in the world of design.

In contrast to the Gestalt psychology writings at the time, James Gibson proposed an ecological perspective on the phenomenon in his theory of *affordances. Gibson (1979)* described this in terms of "what it *offers* the animal, what it *provides* or *furnishes*, either for good or ill." Gibson emphasized that affordances must be measured "relative to the animal" and that they are "unique for that animal" (Gibson 1979; p 127); they are not simply an amalgamation of physical properties. Gibson's example of a stone (Gibson 1979; p134) illustrates the difference between the *affordance* and the *demand character*: a stone may be used as a missile, a hammer, or a paper weight and carries all of these affordances simultaneously regardless of the actor's current needs. A glass of water will always afford drink-ability whether or not one is thirsty. It will not always challenge one to drink it.

Affordances were further categorized by Gaver, notably with tactile feedback and its role in communicating actionable possibilities to the user in tasks such as opening doors (Gaver, 1991). Gaver termed a *hidden affordance* as one without perceptible information, and a *false affordance* as perceptible information pointing to action possibilities that do not exist. Gibson himself acknowledged the latter concept in his review of Koffka, writing that "when Koffka asserted that 'each thing says what it is', he failed to mention that it may lie" (Gibson, 1979). Departing slightly from the Gibsonian position, Withagen, de Poel, Araújo, and Pepping (2012) argued that affordances are not just passive possibilities in the environment, but also have the ability *invite* an action or even *repulse* depending on the actor's personal history, moods, or the amount of energy required to complete the action. Withagen et al. (2012) contrasted the notion of an invitation with the phenomenological "solicitation" by incorporating agency, saying that "an invitation may be declined".

Don Norman adapted Gibson's affordance concept with a design lens in the book *The Psychology of Everyday Things,* which is now *The Design of Everyday Things (2013)* in its latest edition. While he disagreed with Gibson's stance that affordances are perceived directly, he adopted most of Gibson's definition of an affordance—that they are properties existing in the world regardless if one perceives them, and that they are *relationships* between the properties of an object and the individual's ability to interact with them (Norman, 2013). Norman (2013) built upon the roles affordances play in design by pairing them with a *signifier*, which he defined as a "perceivable indicator that communicates appropriate behavior to a person." Norman wrote that signifiers can be intentionally or unintentionally present, and may communicate whether or not there was an intention to communicate (Norman, 2013).

Highlighting the importance of *perceptible* affordances, Norman explained the signifiers as indicators of "where the action should take place" to complement "what actions are possible" (Norman, 2013). Winder's (2006) manifestation of this idea characterized affordances by their strength: weak affordances being less informative perceptual cues (consumer being unsure how to open the package), and strong affordances being obvious (Winder, 2006). In this paper, the author acknowledges that both the prominence and meaning of the signifier may vary in terms of clarity, but reserves the idea of "signal strength" for the signifiers rather than affordances. For example, a white tray with a blue tab would have a strong signifier as to where the action (peel-ability) should take place, while one with a white tab may be more difficult to notice. The affordance of "peel-ability", in discussion of packaging affordances, is not "weaker" when using a white tab. It is the signifier that is weak. For clarity, Winder (2006) acknowledged perceptual variability in discussing the individualistic nature of affordances.

The Gibsonian definition of affordance will be adopted: that they are possibilities for action in our world and that they are relational between the individual and the environment. Norman's emphasis on signifiers will also be adopted in framing this work: that affordances are independent of perception, and that when an affordance is perceived it is the signifier that is of interest; signifiers can be manipulated to encourage the user to take the appropriate course of action and are of premier interest to the design. Although there may be multiple, often disparate academic interpretations of invitations in affordances, this work only considers that some actions are more likely to be chosen than others.

4.5.2 Contextual use: situational affordances

Lewin (1951) presented two situations in which the context of the situation and the wants of the actor influenced which demand characters were present. First, a mundane office task such

as filing documents may afford a career advancement opportunity if the documents themselves are important (Lewin, 1951). In this case, a lack of value in the documents or a lack of ambition in the worker would cause this demand character to not entice the worker to file them. Another example from Lewin (1951) is that an intense hunger need may change an object's *negative* demand character (i.e., something one would find repulsive to eat) to a *positive* demand character (i.e., something one wants to eat). Lewin's example was, in this case, cannibalism, which would otherwise repulse the individual in most contexts other than a threat to survival. With respect to affordances, this suggests that the unique characteristics and desires of the individual are influential in determining what is being communicated. Deterding (2011), drawing on self-determination theory to explain the environment's influence on motivation, argued that the particular situation "shapes the usage, meaning, and consequential salient motivational affordances of the artifact in question." In other words, the situation itself will influence what an artifact (in Deterding's case, a video game) affords in terms of motivation. Although Deterding (2011) presents a theoretical spin on Gibson's original theory, particularly applying the theory to gamification, Deterding admits that the concept is a "theoretical sketch that leaves much to be asks for" and encourages investigation of the topic. One might even attribute the situated nature of affordances to Gibson himself, as the theory of affordances was developed with the idea that they are specific to what they afford an animal in its environment. Nonetheless, this paper emphasizes the environmental nature of an affordance beyond the "human-object" level.

The contextual importance of package interaction was explored in the dissertation of C. J. de la Fuente (2013), through a frame developed by the author termed the *Human-Package Interaction Model* (HPIM). The model presented by de la Fuente calls for a robust analysis of each stage of the user's experience. From a packaging perspective, de La Fuente J. de la Fuente,

Gustafson, Twomey, and Bix (2015) additionally advocated identification of affordances during the opening process. In the present study, we explore the experiences of surgical technologists and the possible design issues resulting from signifiers, which communicate intended and unintended actions.

The challenge of identifying a process tasks and subtasks (i.e., aseptic technique) through interview has been addressed by other authors. Chenitz and Swanson (1986) introduced *surfacing nursing processes* as a method of generating nurse-specific theory instead of appropriating external theories. Chenitz and Swanson (1986) advocated studying nursing processes as they existed in their situated, contextual practice in order to identify processes specific to nursing. Leveraging these ideas of probing practice to better understand the processes (or tasks) therein, the following objectives were established for this work:

- To identify characteristics of packaging that make it difficult to aseptically present items.
- To identify affordances perceived by the user, and signifiers which communicate this functionality for packaging designs common to healthcare environments.
- To better understand aseptic technique in a more social sense—how are approach and technique shaped, and challenged, in peri-Operative environments.

The method selected for this investigation was a semi-structured interview. To capture packaging-specific processes within the professional practice of surgical technologists and nurses, questions were designed to probe the experiences with and understanding of sterility in aseptic technique. Questions also probed the work environment and training of healthcare providers to understand how packaging-related issues were, to borrow Chenitz and Swanson's (1986) terminology, "submerged in practice". Interview transcripts were studied and abstracted

under the framework of affordances, signifiers, and the workplace learning literature presented herein.

4.6 Methodology

4.6.1 Materials

Interviews were recorded using an Olympus Digital Voice Recorder VN-7200 (Center Valley, PA) and a Sony digital camera. Six packages were presented to 15 participants. The six pouches (Figure 21) were intended to represent three groups: large packages (1 and 2), long packages (3 and 4), and double barrier packages (5 and 6). The packages included a Tyvek top web substrate sealed to an extrusion laminated film layer. Detailed information can be found in Table 17Table 24.

Figure 21 - Pouches used in the interview portion of the study. Pictured are large (1,2), long (3,4), and double barrier (5,6) pouches.

The measurements of each pouch were as follows:

Number	Pouch	Measurements (in x in)	Packaging materials	Package manufacturer	Packaged product
1	Large	16” x 10+1/2”	1073 B Tyvek, 48 ga PET/LDPE extrusion laminated film	Oliver-Tolas	Unfilled
2	Large	8+1/2” x 10+1/2”	1073 B Tyvek, unknown laminated film	DePuy Orthopedics	Unfilled
3	Long	**1/2**” x 18+1/8”	Unknown top web, unknown laminated film	Teleflex	Intermittent Catheter
4	Long	2+5/16” x 21”	Unknown top web, unknown laminated film	C.R. Bard	Foley Catheter
5	Double Barrier	10+1/2”x8+1/2”	1073 B Tyvek, unknown laminated film	Oliver-Tolas, Medtronic	Unfilled
6	Double Barrier	3” x 8”	1073 B Tyvek, 48ga PET/LDPE extrusion laminated film	Oliver-Tolas, Becton, Dickinson and Company	Syringe

Table 17 - Measurements, manufacturers, and materials of pouches.

4.7 Interview and coding methods

Participants were recruited via IRB-approved (IRB#13-383) flyers for the study (Appendix A), which took place at the Michigan State University School of Packaging. Participants were recruited from several hospitals in the mid-Michigan area via e-mail flyers. Inclusion criteria consisted of being 18 years of age, having no prior history of skin conditions (as a precaution for the observation package opening aspect of the study), and having prior experience as a healthcare provider. The first phase of the study was a package opening study

described in Chapter 2. The second phase of the work involved a semi-structured interview, which was video recorded to capture comments as well as physical gestures and demonstrations (i.e., picking up the package to show the research team something of interest).

Interview questions (Appendix B) covered a variety of topics, borrowing one package (i.e., double barrier peel pouch) that has consistently received positive reviews in conference panels and surveys conducted by Jennifer Neid Benolken and her colleagues (Butschli, 2008; Allen, 2010; Allen, 2011; Allen, 2012; Allen, 2013; Allen, 2015), and two problematic packages (i.e., large packages and long packages) from Cai's (2012) focus group research and. The "extremes" were chosen in order to represent critical incidents where the experience with packaging was likely to be memorable. Questions covered the use of long pouches, large pouches, double barrier pouches, as well as how the participant acquired knowledge about aseptic technique in general (See Appendix B). Questions were purposefully left vague in order to not imply that context should result in a different action or that the packages in question were particularly good or bad. The sections regarding long, large, and double barrier pouches were randomized in order to mitigate the effect of fatigue during the 30-minute interviews. The final section regarding aseptic technique always occurred last to minimize potential biases that result from thinking about "by the book" definitions before answering questions about packages. An example of questions by section can be found in Table 18, and the full moderator guide can be found in Appendix B.

Research Question (RQ)	*Interview question*
RQ: What are some contextual drivers for usage of specific package types?	How are the "large" packaged products typically introduced to the sterile field where you work? Or How would you expect these packages would be introduced, if things were different and you did see them in the OR? Can you please describe the process?
RQ: What packaging design elements may make things difficult or easy to remove the item aseptically?	What specific aspects about long pouches make things easy or difficult to remove aseptically?
RQ: Are there situations where one method is used over another?	Are there/Would there be any situations which "Single staff member" (flipping/tossing/dumping) are/would be more utilized for large pouches than "picking" (two staff member) techniques?
RQ: What is the does the user see when they first interact with the package? What signifiers stand out?	We talked a lot about packaging today. In general, how do you learn to open a new package?
RQ: What does aseptic mean to the user? Is there anything that stands out about packaging with respect to sterility? How did they come to this understanding of aseptic technique	Please detail what you think is meant by "aseptic transfer" of items to the sterile field specifically in terms of product packaging. For example, what assumptions do you make about the package, what you look for when opening a new package, and any other comments you wish to add on the topic.
RQ: How is this understanding formulated? Completely in school? At work?	Where did you learn this understanding of aseptic technique?

Table 18 - Sample questions from moderator guide

The interviewer utilized a strategy recommended by Glesne (Glesne, 2006) for interviewing participants. Discussion was prefaced by admitting and projecting naïveté on the subject matter in order to put the interviewee in the role of a "teacher" and the interviewer in the role of a "learner". An additional purpose of utilizing this method was to mitigate the risk of the participant defaulting to "by the book" answers. One researcher transcribed videos of complete interviews for analysis. Personal names and places of employment were replaced with a de-identified labeling scheme to protect the identity of the research participants.

4.7.1 Coding researchers

Two researchers coded the data that was transcribed by the primary coder. The primary coder (author of the present dissertation) had focused on aseptic technique and packaging for six years between two degrees. He had industry experience in the medical packaging field and had collected data at several conferences for nurses and surgical technologists. He had experience conducting human factors research while consulting for clients in graduate school, and had previous qualitative training. His background in the affordance literature, professional learning literature, and nursing literature provided much of the basis for the work in the study. The primary coder's role in the work was to participate in the first pass of coding, to meet with the secondary coder to generate the final code book, and to re-code the data with the shared understanding.

The second coder had some foundational understanding of medical packaging usage, though her research focus is unrelated to aseptic technique, which served to check the bias of the primary coder. Her research is similar in that it involves human-package interaction within the operating room, but dissimilar in that it focuses on waste streams instead of aseptic technique. The secondary coder was invited into the project by the primary coder and given background

instructions on the general research questions as well as the theoretical lens (i.e., situated learning and affordances). However, she was encouraged to code the data using her interpretation of the comments made. She was responsible for discussing her code with the primary coder after the first pass, and helped formulate definitions for re-coding the data.

4.7.2 Coding strategy

Data were analyzed using a thematic analysis as explained by Glaser and Strauss (1967). The software QDA Miner (Provalis Research; Montreal, QC) was used to assist in the construction of the thematic analysis. Themes were constructed using "codes", defined by Saldaña as "a word or short phrase that assigns a summative, salient, essence-capturing, and/or evocative attribute for a portion of language based or visual data." (Saldaña, 2009). Occasionally, entire paragraphs were coded in order to capture the context of the query for later review and analysis. The first pass of codes was collapsed into broader categories for the second cycle of coding (See Table 20).

Coders independently coded transcripts and compared themes, reconciling different interpretations through discussion. In reporting the data, researchers used participant voice to drive the narrative. Each coder read all of the transcripts before coding. The preliminary reading was done to formulate some tentative structures of the data before the first pass of coding. Coders met to discuss and construct some rough categories before the first pass of coding. Each coder was also tasked to add additional categories and codes as they felt was necessary. After the first pass of coding, codes were discussed, combined, and re-categorized until a final codebook was created. Coders compared codebooks and discussed the final code book until both were satisfied with the end product. After the construction of the final codebook, the primary coder re-coded all transcripts with the new definitions.

4.7.3 Organization of themes

For the purpose of discussion, codes that surfaced in ≥60% of interviews were labeled "Major Themes", while codes that surfaced in 40-60% of interviews were labeled as "minor themes". The cut-offs between "major" and "minor" were arbitrarily chosen in order to provide starting points for the analysis and to target the regularly recurring themes first. The major and minor distinctions were not designated to denote importance, just the prevalence of occurrence within the small group which was interviewed. Prevalence of codes was automatically tallied using QDA Miner's "Retrieve Segments" command, which is based on how many times the coder assigned a code to thoughts expressed in the transcript. Throughout the discussion, the code will be accompanied by a percentage of interviews in which it appeared. Discussions of codes in the results will be accompanied by quotations from participants which best illustrate the concept or idea.

4.8 Results

4.8.1 Participants

Although nursing students were recruited and interviewed as part of the packaging opening study, they were not included in the analysis. The experiences of the nursing students were out-of-scope with aseptic technique as it pertains to the peri-Operative contexts , therefore the interviews were not included so as to not lose focus of the target OR-based participant group. Participants were an average of 38.7 years of age (Std.Dev ± 9.4 years). One participant's age was not recorded. Participants had an average of 9.8 years of experience in healthcare (Std.Dev ± 9.5 years) and an average of 8.13 years of experience aseptically presenting items to sterile fields (Std.Dev ± 7.78 years). Fourteen of the 15 interviewees were female, and 13 of the 15 interviewees were surgical technologists with the remaining two being nurses. Table 19 provides the age, experience, gender, and profession of each interviewee.

Subject	Age	YE-Healthcare (years)	YE-Aseptic (years)	Gender	Profession
122	37	8	8	Female	Surgical Tech
123	41	13	13	Female	Surgical Tech
124	38	16	16	Female	Surgical Tech
125	51	30	3.5	Female	Nurse
126	23	0.5	0.5	Female	Surgical Tech
127	34	12	12	Female	Surgical Tech
128	Not Reported	1	1	Female	Surgical Tech
129	55	1	1	Female	Surgical Tech
130	38	9	9	Female	Surgical Tech
131	46	28	28	Male	Surgical Tech
132	51	2.5	3	Female	Surgical Tech
133	35	14	14	Female	Surgical Tech
134	24	1	1	Female	Surgical Tech
135	36	1	1	Female	Surgical Tech
136	34	11	11	Female	Nurse

Table 19 - Interviewee ages, experience, gender, and profession

In discussing the participant's responses, the participant will be labeled by their profession (e.g.,ST or N) followed by their participant number (e.g., ST133), and finally followed by their years of experience aseptically presenting items to the field (e.g., ST133-14). The de-identified format provided some contextualization of their answers via participant number, but maintained anonymity.

4.8.2 Code assignment

Codes were assigned and collapsed as needed. Table 20 provides some examples of how codes were assigned using the "material curling", which indicated that the material affected the ease of dispensing the product:

	Participant voice	Phrase of interest	First Coding Pass	Final Code
126	I guess similar to the other one. I'd break off the corner points and then I would start from the middle point and try to control the corners.	"control the corners"	"Try to control material"	Material curling
127	I would, If it's a sterile peel pack like this, I'd start at the middle and then like go [walking grips to far corner], say north or south on the package, and continue down the seams. So I could try to have a bit more control over the edges and keeping them away from the contents of the package.	"more control over the edges and keeping them away"	"Try to control material"	
128	Watch your corners… your corners is what gets you. On everything, no matter what kind of package it is.	"watch your corners...your corners is what gets you"	"Monitor material"	

Table 20 - Coding Process Sample

4.9 Overview of results

Themes in the data were tabulated by QDA Miner, an example of which can be referenced in Table 21. The plusses and minuses (+/-) in parentheses denote items that imply positive or negative opinions (e.g., double barrier (+) were positive perceptions about double barrier packaging).

Major Themes		Minor Themes
"Over the field" (80%)		Ease of dispensing - Size/shape of device (-) (53.3%)
Learning to use - "Just do it"/"Just look at it" (80%)		Differences between hospitals depends on procedure or use of kits (53.3%)
Learning Aseptic Technique - Clinical Experience (73.3%)		Differences between Hospitals - Same in all locations (53.3%)
Learning Aseptic Technique - Personal Experience (60%)		Perceptions of packaging as a risk to contamination (53.3%)
Dispensing by one's self - Staff Availability (60%)		Ease of dispensing - Rigidity (-) (46.7%)
Ease of Dispensing - Double barrier (+) (60%)		Learning to use packages by interacting with experienced colleagues (46.7%)
Ease of Dispensing - Size/shape of package (-) (60%)		Criticism of other's technique (46.7%)
Dispensing method - Picking: Size and shape of the device (60%)		Products rolling/dropping off field (46.7%)
Ease of Dispensing - Material curling (-) (60%)		"Watch each other" - Aseptic technique (46.7%)
		Learning aseptic technique from experienced colleagues (46.7%)
		"Watch yourself" - Aseptic technique (46.7%)
		Biomechanical limitations to dispensing contents (40%)
		Learning to use new packages by drawing upon packaging experiences (40%)
		Positive perceptions about seal strength of packages (40%)
		Packaging fiber tear issues (33.3%)*

Table 21 - Table of Major and Minor themes in qualitative analysis

Major themes emerged in the data which included negative perception of larger package sizes (60%), negative reports related to material curling issues (60%), the lack of staff availability influencing the chosen method of dispensing the contents (60%), the influence of product/package size (60%) for choosing to pick or dispense a product by one's self (i.e., larger items requiring assistance for removal), and topics regarding being over the sterile field (negative

perceptions as well as discussions of methods to do it "appropriately) when presenting (80%). Positive perceptions of double barrier packages (60%) and general positive comments about existing packages (60%) also surfaced in the data. The learning environment was largely reported as the same across interviews with participants reporting that they learned aseptic technique in school (100%), that knowledge was required while working in their hospital clinicals (73.3%), and by gaining personal experience (60%). Noteworthy is that most of the participants did not know which professional standard was used in their education, but largely felt that it was pretty much "the same" wherever they went.

Minor themes that surfaced in the data included elements of community, such as: watching others (46.7%) being critical of other's technique (46.7%), learning to open packages from experienced colleagues (40%), and learning aseptic technique from experienced colleagues (46.7%). Issues such as item rigidity (46.7%) and biomechanical limitations (i.e., length of arms and height) affecting the ability to use the package (40%) were among the minor themes. Although not meeting the definition of a "minor theme" as specified by the authors, the issue of packaging fiber tear (33.3%) is presented in Table 21 due to its role as an "automatic" contamination risk. Generally, aseptic technique was perceived to be the same across all hospitals in which the participants worked with differences being largely procedural in nature (e.g., surgeries having more or less set-up preparation, and more openings during the procedure in the latter case) (53.3%). The codes are first described within the context of the work and examples are given from the participants' interviews. The selected quotations are not meant to be representative of all comments within that theme, but rather as interviews which provide an example of how the theme manifested in the data. A categorical re-organization of Table 21 is referenced in Table 22. The order of discussion is as follows: the contextual influences on

method, the human-package interface and what designs afford to the user, and finally the community surrounding aseptic technique.

Organization of Themes by Topic
Packaging
Ease of Dispensing - Material curling (-) (60%)
Ease of Dispensing - Size/shape of package (-) (60%)
Ease of Dispensing - Double barrier (+) (60%)
Perceptions of packaging as a risk to contamination (53.3%)
Learning to use packages by interacting with experienced colleagues (46.7%)
Learning to use new packages by drawing upon packaging experiences (40%)
Positive perceptions about seal strength of packages (40%)
Packaging fiber tear issues (33.3%)
Device
Ease of dispensing - Size/shape of device (-) (53.3%)
Products rolling/dropping off field (46.7%)
Ease of dispensing - Rigidity (-) (46.7%)
Aseptic Technique
"Over the field" (80%)
Dispensing method - Picking: Size and shape of the device (60%)
Dispensing by one's self - Staff Availability (60%)
Differences between Hospitals - Same in all locations (53.3%)
Differences between hospitals depends on procedure or use of kits (53.3%)
"Watch yourself" - Aseptic technique (46.7%)
"Watch each other" - Aseptic technique (46.7%)
Criticism of other's technique (46.7%)
Biomechanical limitations to dispensing contents (40%)
Learning
Learning to use - "Just do it"/"Just look at it" (80%)
Learning Aseptic Technique - Clinical Experience (73.3%)
Learning Aseptic Technique - Personal Experience (60%)
Learning aseptic technique from experienced colleagues (46.7%)

Table 22 - Categorical organization of themes.

4.10 Contextual drivers for use

The issue of staff availability (60%) surfaced in the answers participants provided regarding which situations led to single- (dump) versus multiple-staff-member presentations

(pick). In other words, there were situations where AORN recommendations for presenting to the sterile field were not possible:

> ST134-1: "Any situation? Just if we're alone, really. That's the only reason I would want to do the dropping. I feel like it's a little…not more contaminations, but I drop more. That's it."

> ST127-12: "I would say it definitely depends on the staff availability and the amount of help we have to get the case ready. Um if there's just a nurse and a tech in the room, then that tech is mainly responsible for opening the room because the nurse is doing things at the computer, or finishing up charting, um… or he or she may be, you know, still be taking the patient down to the recovery room. So you have one person opening everything. And once in a great while, you can call for opening help and you'll get maybe three people to help open, yeah that's always an ideal and happy situation for everyone.

> ST124-16: "Um, there are times on the weekends when you're the only one getting the room [inaudible]… because, you know, the staff is lighter. Um, but like I said, in the instance that there is something that I'm questioning because I don't want to waste the dollars, I would rather hold it and say to my nurse or tech who I was—'hey [name], scrub in, can you open this to me?"

> ST131-28: "No, it just depends on how busy the person scrubbed in is. If they have—most of the time they will take it, but you know if they are holding the retractor in one hand and it's busy, they'll say 'just dump it on the field.'"

In addition to staff availability, time constraints (20%) surfaced in response to some of the questions from the moderator guide. The following example was a situation in which the availability of time was a driver for the choice of dispensing the item without assistance:

> ST130-9: "Like um in an emergent situation. Like if you have one who is scrubbing in really quickly to get something set up, you have one person-at least for me—in a separate basin away from the main sterile field, they'll just be dumping stuff into that just to get it ready really quick for you while you're over here getting stuff."

4.11 The packaged device interface – signifiers and affordances

4.11.1 Size and shape

Participants voiced the influence of size and shape of the device (60%) when communicating the package's dispensing functionality.

> N125-3.5: "Opening—well again, I would prefer to pick something long and cumbersome like this." (See Figure 21, packages 2 and 3).

> ST135-1: "For the most part, it depends on what's in them. If they get too large and something is too bulky, like a lot of them, especially in [redacted] or whatever, we get—they have drapes and stuff in 'em. And we'll just open them to another team member, what you call picking. You just—instead of trying otherwise, you'd fighting [sic] with it and you'd contaminate it. So it's just easier to do once you get past a certain size—or weight even—it's just easier to do the picking method."

> ST130-9: "Um I would say, at least for me, I like to do it—like to open it to somebody. I like to have someone pick it out of there. Um, just because of the curling sometimes, the awkward shape of what's in there, because they don't put the right stuff, you know what I'm—so I would say for me it's a picking thing."

4.11.2 Over the field

In the discussions with participants, the idea of being "over the field" (80%) while using packages was a prevalent theme.

> ST129-1: (In response to why they preferred flipping for opening double barrier pouches)"The arm that you are putting over the table is protected by the plastic. So you don't drop a hair or something from your arm on to the sterile field."

> ST131-28: "So even if you are over, again you're creating a barrier with [the pouch material] because inside is sterile and outside is not, and you have the outside against your skin and the inside is facing [the field]. It is a barrier between you and the sterile field."

Some participants were not as accepting of this as a proper practice.

> ST127-12 "Um, any unsterile, um, parts of the person opening it… any unsterile part of the package going directly over the sterile field. Those are all examples of poor technique."

N136-11: “I’m wondering if that’s even a good practice. Because we generally don’t open stuff over our sterile field. Because the outside of that item would not be sterile.”

ST124-16: “Um, you don't want to open over the field [shows inverting package over field], because you don't want this hand that's unsterile–because when you're openin' things, you're unsterile.”

4.11.3 Double barrier

Positive discussion of double barrier packages (60%) centered on the prospect of the “second chance” at opening things aseptically.

ST123-13: “I really like the double barrier, because then if the first barrier is somehow contaminated, or compromised, then you still can—you don’t have to waste the product because you can try to open it again because it is inside another sterile pouch.”

ST127-12: “I can’t see anyone having difficulty opening these things because they have two shots to get it right. You can get it wrong by yourself, but if you get it wrong the first time just put it to the side and just have someone else open it to you.”

ST130-9: “I like ‘em because there’s that—if someone were to contaminate the outside, especially for high price items, you still have that inner—inner layer there. So you’re not wasting thousands of dollars-worth of implants and stuff like that.”

4.11.4 Expensive items

Some participants voiced that the value of the product packaged within (26.7%) also influenced the method used to remove the item. The nature of opening affordances in this case extended beyond the simple physical profile and the abilities of the user:

ST125-3.5: “I work in orthopedics, so I open joint replacement, uh, implants. Very expensive things, so you’re always worried that you’re going to drop that on the floor. And those are like, thousands of dollars, so you have to be careful with those. And those we would open with the picking.”

Another participant contrasted high- and low-value products.

ST129-1: “Some of the longer ones…but that's just the nature of long packaging. You just have to deal with it. And I can't imagine that these [catheters] are that expensive, that if you drop one on the floor once a week–I bet I've dropped something on the floor once per week probably–something. It just happens. It's the way it is… and you know. But if it

gets to be something expensive, then you hear about it. You know. Or like one of those little eye…uh duct… you know what I was talking about, if you drop one of those, it's bad news. Because it's $1,000 you just dropped on the floor. Our cost."

4.11.5 Rigidity

The flexibility of the device (46.7%) was reported by participants to be a challenge for maintaining sterility during aseptic technique. While most of the codes pertained specifically to the product and not the package, the following example describes it more in terms of use of the package:

> ST135-1: "It's just a lot harder to control. So like, you're opening it, if you have a rigid item it's a lot easier to make sure you're, like, trying to brace it against your [arm]—trying to brace this so it's not floppin' around on you. It's easier if you have a rigid item, but if you have a flexible item this thing [points to bottom half of pouch] is just wobblin' around, so you're fighting against that and a rigid item is a lot less likely to bounce, once you peel the edge—it's a lot less likely to bounce out of the envelope and hit you in the hand than a flexible item is. We have battles [laugh]"

4.11.6 Packaging material as risk

In their discussions of packaging use, many participants mentioned packaging as a risk to sterility (53.3%).

> N136-11: "I knew as soon as I opened up the center, both corner pieces were going to fold in. I didn't feel there was a good way to open up a large package of this size unless I could open it up on a firm surface." (See Figure 22)
>
> ST132-3: "Look what's happening to the corners—they're folding in, and I have to be very careful with that when the object comes out, that those sides are not going to touch what's coming out, so it's just a matter of looking at it.

Figure 22- Material curling

Material curling was discussed more broadly in 60% of the interviews. Phrases such as "watch your corners" were present in answers to questions about their perception of "good technique." Additionally, one surgical technologist (ST132-3) provided an additional example of her experiences with packaging contaminating the sterile field:

> ST132-3: "I mean you kind of have to um peel it back as much as you can down here [bottom of pouch] because this is kind of still stuck there [at the bottom of the pouch], but you got to be careful. Because usually, it just falls right out…but you don't want this to happen [lets the long pouch go, it hits the table]. You don't wanna—this—because what can happen is when you peel this down, it can get to a point where this [material] will literally peel away. So you have your product coming out, but you have two pieces of the um, packaging and then it [pouch material] could fall on your sterile field."

4.11.7 Tearing issues

Tearing issues forpouches were brought up in one third of the interviews, predominately with respect to paper backings (4/15 interviews). This topic surfaced without specific prompts.

> ST122-8: “Like someone just went with claws, like, on your package. That's what it looks like sometimes. So then you have to go and try and go get all of those individuals or you've contaminated it and you've got to go get another one, so…”

One mention of the fiber tear surfaced as a response to what the participant considered bad technique for long pouches:

> ST130-9: That's bad technique? No, just when people try and use it–like when this paper on the back, sometimes it doesn't always peel off. Like it'll rip. And some people think it's okay to still use it, even though like–it flops over and it's touching the outside of that, even though it's not sterile on that side. So yeah, sometimes the integrity of the package isn't good and people try and use it. That's just a personal judgement.

4.11.8 Communication of starting peel position

Participants reported that the amount of material influenced their decision to begin peeling the pouch at a given location, whereby larger areas provided more area for grip (33.3%).

> ST123-13: “Well I, myself, typically if I’m not sure—let’s say I’ve never seen this [pouch 1, Figure 21]. I would pick it up and try to look for something—like this [grabs corner of pouch]. It’s got an easy-to-grab end piece that you could easily start to peel open, so that’s one of the first things I look for.
>
> ST129-1: “For me, I want to cover my arm as much as I can… I just tend to favor the corners. Maybe because they’re easier to see, easier to find. You can always go to a corner and find your way in… when you’re getting set up a lot of times, there’s pressure –come on hurry up, they’re waiting, get goin’.”

However, N136-11 discussed her decision to use the corner from a different perspective.

> N136-11: “This size [medium pouch] I could do in the center fine. This [pouch 1, Figure 21] size felt awkward to do it in the center, so I did it on the outside [corner]. But I feel like I should be opening it from the center … but just doing it like this [in the middle] I felt like both um, corners were going to fold in.”

In some cases, the chevron of the seal also served to indicate where the peel should take place (26.7%).

> ST126-0.5: “I guess because it’s at a point there and that’s the easiest part to get it, um, like to get it open there, because of the stickiness. … I don’t know. I guess I’ve just

always opened it at that point and felt that, um, if I tried to open it from the side it would be harder."

ST132-3: "You automatically know on a package this is what we're looking for [traces chevron seals with finger] the pitch of the package so it's easier. We know that this is the appropriate way to go, like when you look at a package and there's an arrow like 'open here' you get with the packages of stuff, it's the same concept."

For one participant, the poor fit of the product to the package guided that decisions.

ST135-1: "I usually, if I go kinda, kinda try to go against where the bulk of the weight is first. That way, what I'm opening isn't going to flip out on to the floor. And then I can try to more easily flip it on to the table, so that I can kind of peel it against myself, but depends on what's in it, I mean if it's taking up the whole package, then in the center. Not taking up the whole package, then against the weight first so I can flip it on to the table."

The choice of start location may also be based in the method the OR staff is using to dispense the items.

ST124-16: "I can start right here [near corner], I would rather--if I'm having somebody grab it I'm going to start from this corner [Far corner], okay? So I'm pulling away [from the scrub person]. But if it's me and I'm opening, I might start from this one [near corner] so it's not up against my arms, here [indicating that the package isn't resting against her arms]."

4.11.9 Biomechanical limitations

Participants voiced that there were anatomical reasons for packaging usage (40%). One participant relayed biomechanical reasons for being over the sterile field.

ST129-1: "And if you think about it, from an anatomical point of view, once you open it past this [Figure 23, A]—okay, opening it with my technique's fine. Well if I get any longer than that, I open it about here, I'm only half-open, and if I gotta go like that [Figure 23, B] that's not good. I'm leaning over my sterile field."

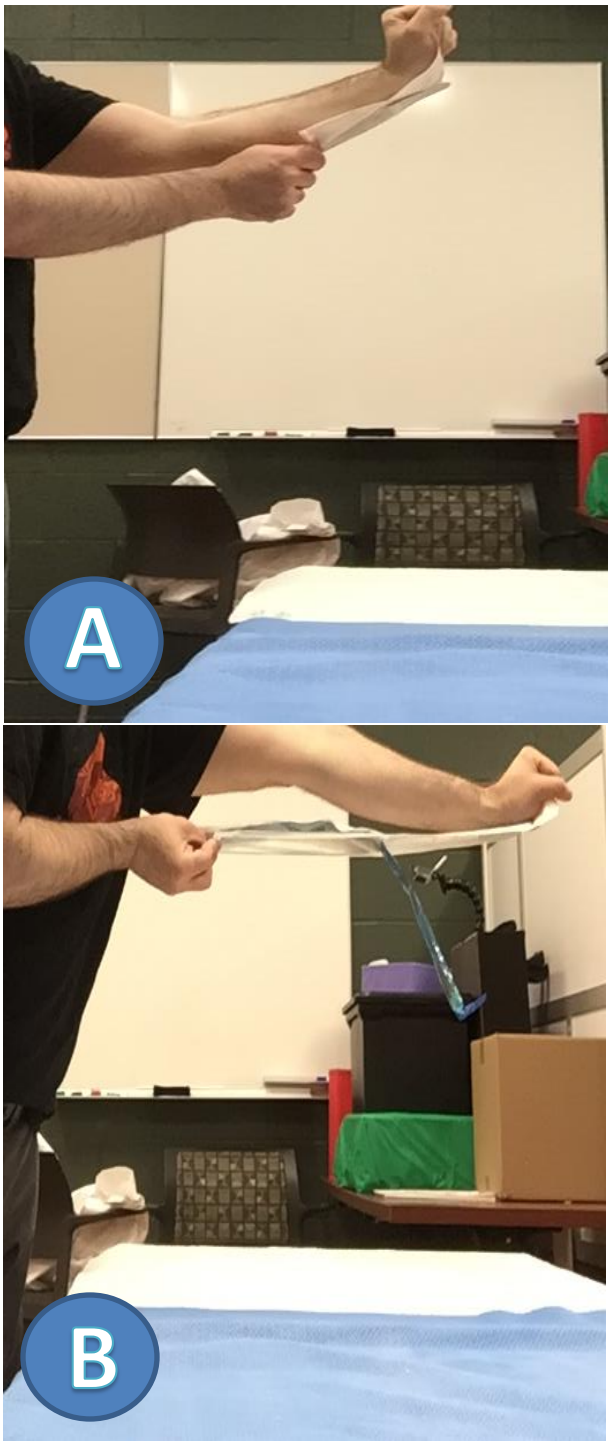


Figure 23 - Short package, not leaning (L), Long package, leaning (R)

Another participant described differences in table heights as influencing technique significantly.

> ST135-1: “Because different tables have different heights. I mean we have a, kind of a heart table that kind of rests up here [gesticulates in the mid-chest area], so to flip things on to that table is a little more challenging than to flip on this table”

4.11.10 Product fit

Many participants voiced problems with poor product fit to the package (53.3%). Most comments involved a package which was too large for the product.

> ST124-16: “That would be hard, especially because if you’re going to try to toss it, you have no control over where it’s going to really go.”

Additionally, products that were too tightly fitted to the package proved problematic.

> ST129-1: “There is consistently problems with the large staplers, um you get–you get the paper off, and then you're trying to pop it out of there and it won't drop out. You're trying to drop it on to the table, and then what you want–your instinct is to grab it somewhere in the middle and get it out of there but there's nowhere to grab. So you end up doing this thing the whole time [pushing on sides of tray to pop out device] trying to get it out of there. And then eventually you learn that wait and open it during the procedure, because then the circulator can do the–hand it to you and you can just take it out of there. Which is okay, maybe that is how it was intended to be and maybe that hospital's just po–policy's is to try and get it opened early. But I dropped one of those on the floor one time, and it was not a good thing. Because they're very expensive.”

4.12 Community of practice

4.12.1 Learning to use packages from experienced colleagues

Aside from the contextual drivers and the information gleaned from the product itself, participants described an environment in which their colleagues informed their packaging related behavior (46.7%). Most of these participants reported verbally interacting with their colleagues when learning to open packages.

> ST124-1: “It most happens if there’s a new product. And somebody, it comes from somebody who has had an experience, let’s say well, such-and-such ‘I opened this tubing and it doesn’t just fall out’, because sometimes you’ll have, like the plastic container I was saying, you go to dump it on the field and it doesn’t want to fall out. Like, the tubing

would fall, but it had a little attachment that would never fall, so it was basically by trial and error that we were able to talk and say 'hold this until somebody's scrubbed in'."

ST129-1: "That was really how I mostly learned how to do this. At the clinicals. Yeah, because you had one-on-one. Your preceptor was standing over you, or barking in your ear [laugh]. And uh, that's where you got practice because at first I was so afraid to open it, and I wouldn't, and she's like 'No, just go up and BOOM on to the table', you know?"

One participant described her experience observing others.

ST122-8: "It's kind of a 'see one, do one' kind of thing. Um, you watch other people do it, and um, they're having an easy time too, so you should not be having a problem opening up these packages."

4.12.2 Aseptic technique in the community

The mentorship from experienced colleagues was also applicable to aseptic technique itself (46.7%).

N125-3.5: "I work in surgery now, I used to work in critical care. So when I transferred into surgery, there was some education about that in my orientation to the department with the educator and with my preceptors, and my co-workers who were precepting me."

ST132-3: "When you get out into the field and you're doing the job, um, of course they're scaling you down. You know, 'you don't need to be 500 yards away throwing these'. You can—now you can come and they can critique it a bit more and show you how to present it a little bit better. I mean you have the general idea when you're in school but of course once you get out there, you're nervous, you're not sure and of course everyone else's experience comes into play and then they teach you a little bit more, and then you build on that."

4.12.3 Monitoring

Participants voiced that they watch (monitor) their colleagues' technique in the sterile theater (46.7%).

ST127-12: "If someone is looking like they are thinking about contaminating something, then it's my job to stop them and correct them. You know, correct whatever issues there may be or… yeah you gotta make it right. It's a very important job to be responsible for the, you know, sterility of an entire OR. And other people. You know, because it's not only yourself, but you have surgeons and circulators who are around the sterile field, you

know, med students who may not know what they can and can't do, you know in regards to sterile technique."

ST131-28: "I've always worked in surgery so… people will always point things out to you [laugh] … if they see something, they'll point it out, and you know you see something where they're at, you point it out to them. Everybody wants everything to be sterile for the best of the patient."

One participant, in discussing the monitoring role of the surgical tech, also described some reluctance on part of newer techs to do so.

ST132-3: "So anything we did, we had to put our critical thinking—and anybody who comes to your field, you have to babysit. You have to watch them, and if they've done anything that is not correct, you have to get them away. And it's—the surgical tech's position is extremely important and there's a lot of responsibility to it. So the school teaches you that, and makes you aware of that, so when you get out there—so funny as a student when you get out there in the clinicals, you are so programmed that you want to tell everybody what they're doing wrong! And you so don't do that. I mean because you're not—you're not supposed to do that. You just are baby birds flying for the first time. Yeah they prepare you quite a bit, quite a bit."

4.13 Discussion

4.13.1 Affordances – environmental cues and the packaging interface

Gibson (1979) wrote that an affordance is "what it [the environment] *offers* the animal, what it *provides* or *furnishes*, either for good or ill." J. de la Fuente et al. (2015) incorporated identification of affordances during task analysis for packaging design using observational methodologies. In the present study, semi-structured interview was used to identify affordances by probing the past experiences of the interviewees. Gibson's theory of affordances was rooted in *what the environment furnishes the animal*, therefore it is important to define what is meant by "environment" within the context of a surgical technologist or a nurse. The package in this discussion is framed as part of the provider's environment.

4.13.2 Gibson's relativity in a packaging context

One of the most prevalent themes in the conversations with the healthcare providers was the issue of being "over the field." Participants were generally cognizant of perceived risk of being over the sterile field, particularly leaning over it. However, many of those who shared their experience of presenting products demonstrated a method which they believed was good technique that had a curious contradiction—the participant's forearm was often extended over the field. The justification for this can be found in the responses of a few of the participants who describe one of the substrates as a shield for skin particles and/or hair. To borrow the "-ability" format from de la Fuente, the material substrate against the user's arm gains the affordance of "shield-ability". The perceptible part of this affordance, or the signifier, was voiced by one sole participant who described the delineation between what was "sterile" on the inside of the package (that would be facing the field) and what was not; that is, the plastic against the participant's forearm (Figure 23). As Gibson emphasized, affordances are unique to the animal (or the user, in this case), and thus it is understandable that this possibility would not be perceived by some participants. In this instance, one can observe perceived affordance differences between users who work in similar environments. Gibson's construction of affordances also includes what the object furnishes the user for *ill*. The package's tendency to curl was reported in most of the interviews, bringing to light the "negative" affordance *contaminate-ability.*

For packaging designers, these affordances and what signifies them should be considered carefully. If the package material itself communicates a risk to the user, then the tendency of extrusion-laminated materials to curl may carry more weight than just being a cosmetic nuisance. If the user must worry about packaging material simply dispensing a critical product, during an

already complicated and stressful procedure no less, then the package itself is potentially serving as another obstacle to successful transfer. Affordances, good and ill, may exist simultaneously within the same package. When considering something like ease-of-opening, focusing only on the positives may miss the negatives. Does the material curling communicate danger that designers are unaware of?

As Don Norman (2013) wrote, it is signifiers that are of interest to designers. Through the use of signifiers, designs communicate, intentionally or unintentionally, where action takes place. In the present study, the affordance of "peelability" was investigated by probing the starting peel location and rationale for choosing that location in large packages. As the start location varied, so did the reasons for choosing the location. For some, the chevron itself served to indicate the starting position, while for others the corner flaps which enabled gripping space served to signify that starting location. In either location, it is important to note that the affordance in either occasion (peelability) is the same, but that the signifier is different and guides the behavior to another portion of the seal. The signifiers again, in this case, did not make the affordance more or less perceivable, but changed the nature of the interaction by what was signified to the user.

4.13.3 Social construction of aseptic technique

Situated learning theory—legitimate peripheral participation—and the cognitive frameworks presented by Sternberg et al. (2000) and Eraut (2000, 2004) present several ways of considering the learning environment of the individual worker. Whether one explains learning environments using cognitive frameworks, or frameworks constructed by studying *apprentice-like* relationships, there is much to be gleaned from understanding the work-place relationships between end-users and their colleagues. In the present study, participants detailed their

interactions and how mentors and OR staff were part of their development. Additionally, participants described their own role in monitoring aseptic technique as part of their work.

Professional learning literature can give designers a window into the complexities behind what constitutes an "affordance." As Gibson (1979) put it, affordances are not something which can be measured as if it were physics. However, from the discussions with the interviewees, one finds a community surrounding aseptic technique; the interactions with colleagues may help shape what an individual surgical technologist or nurse sees as acceptable, whether it is "scaling down" the user or whether the user's mentor is demonstrating "*boom*, like that" on the field. Of course, while many participants voiced that aseptic technique is generally the same across all of the locations in which they've worked, there were clearly some procedures (e.g., peeling a pouch over the top of the field; Figure 23) which were more individually centered and contested by other users.

4.13.4 Meaning for packaging design

The interface was not, in the case of the present work, consistently interpreted by all participants. The perceived affordances of utility by some were perceived as breaches of sterile technique by others. What the chevron of the seal signified to one may be missed or overshadowed by another signifier for other participants. Additionally, characteristics specific to the device itself, such as item rigidity and product value, altered the nature of what is "dump-able" on to the field. Human factors processes, particularly contextual inquiries, may surface some of these affordances in addition to consumer interviews. It may also be useful to interview other colleagues from the same operating unit to see if variations exist among OR staff.

In an affordance-based design paper, de la Fuente et. al (2015) discussed using constraints to "optimize the perceptibility of affordances." The present study demonstrates the

relativity of what is considered an “affordance” and advocates that designers thoroughly study the implications of the constraint before focusing on one particular signifier for the affordance. For example, eliminating the gripping room at the corners of the pouch to force perceptibility of signifiers at the center of the pouch may inhibit some users who use the corners to “balance the weight of the item” as one participant described, or who open them at the corners in order to better facilitate presentation to another team member. Additionally, without a data-driven environment surrounding the opening methods utilized in the OR, designers are cautioned against presuming to know what is truly an “appropriate action”. Design constraints, while useful, may require that the designer work with several users before weighing the advantages and disadvantages of constraining the user.

Behavioral choices, such as that of presenting over the sterile field, may be difficult to control from a packaging design standpoint. The packaging designer can only understand the user’s goals (e.g. getting a wobbly device on to a field) and adjust the packaging to fit those needs. The packaging industry and the providers would benefit from the use of evidence-driven decision making regarding design and biomechanical technique when considering what is appropriate for aseptic presentation. For example, if evidence supported the idea that “packaging material as skin barrier” resulted in fewer contaminations of the sterile field, designers might ensure that widths of packages met anatomical specifications, such as the width of the forearm or designed in ways that non-sterile fingers could be “shielded” during use. Such insights can only be gleaned from extensive and thorough collaboration with the end user.

The present study has generated the following insights through interview of surgical technologist and nursing professionals:

- Affordances are, as Gibson put it, not properties of an object. Affordances are relational between a user and an object. As such, what may be afforded to one user may not be afforded to another—specifically, pouches afford a sterile barrier between the skin of the arm and the sterile field to some participants. Designers should be aware that if enough packaging material exists, this affordance may be acted upon and the user will be breaching the sterile plane. Whether or not this is a critical risk has little supporting data, though the insights from Smith et al. (2009) call into question the safety of the practice of opening over the field. For larger packaging sizes, interventions such as consumer education should be explored with the goal of mitigating openings over the field.
- The workplace influences what individuals consider aseptic technique, even if they feel that technique is mostly the same. Designers should consider that the outlined guidelines from professional organization may not be all-encompassing of what aseptic technique *is* to each individual clinician. Field study and/or interview may uncover topics such as acceptability of re-using dropped items (i.e., "second chance" double sterile presentations, breaching the sterile plane).
- Context is key: issues such as staff availability may influence the way an item is delivered to a sterile field. Designers should note that products that require picking, and may even be intended to smoothly facilitate picking, may not be as usable in a setting where the surgical tech is alone in the room or when the scrub tech is too busy to take it from the circulator. Each package should be designed for its specific and likely use, which can be learned from data acquired in ethnographic studies,

simulation, and empirical evaluation of the same. Packaging designers should consider how to best acquire this information for their design inputs.

4.14 Limitations and future work

This investigation was qualitative in nature, and the experiences of participants were used to contextualize existing theory within medical packaging. The personal accounts of the participants illuminate design communication when investigated through these lenses and direct researchers and packaging professionals toward understanding the user's needs and experiences. What this investigation does not purport to do is generalize these experiences to every surgical technologist and nurse. In the event that a risk analysis during the design failure modes and effect analysis (DFMEA) stage is being conducted, a more robust understanding of the *prevalence* of these experiences is warranted. It may be beneficial to conduct nation-wide surveys to understand the prevalence of some of these behaviors and thought processes, but such a feat can only be obtained with significant investments of time and resources.

The data was largely approached and interpreted by a researcher intimately familiar with aseptic technique and medical device packaging. While another coder assisted in construction of the codebook, the interpretations presented herein are from the perspective of a researcher sensitive to these issues. Additionally, the analysis was undertaken by a packaging researcher under the lenses of affordance theory, situated learning theory, and with a general understanding of work-place learning frameworks. The interpretation of the same data may be different if undertaken by a phenomenologist or a researcher with a strong background in education or nursing. Collaborations with researchers of other backgrounds may yield different interpretations, and should be pursued.

The interviews suggest that dogmatic rules (i.e., not extending over the sterile field per AST and AORN recommendations) may not be followed by experienced providers. However, without a more longitudinal, multi-interview relationship with each participant, we are missing information necessary to relate it back to the Dreyfus and Dreyfus model. For instance, is this dogmatic rule taught as dogmatic, if at all? Did each nurse or surgical technologist change their views over a period of time, or was it more instantaneous as they interacted with colleagues?

A final caveat to the present study is that the *necessity* of the recommendations set forth has yet to be established. Simply put, there are few studies which deal with topics such as presenting items over the field. A real-world connection to health outcomes has yet to be established. Packaging professionals and healthcare providers should further investigate the "cleanliness" of opening packages over sterile fields to understand the gravity of this usage issue and if either training interventions (i.e., getting providers to stop presenting over the field) or design interventions (i.e., making packages wide enough to present over the field "properly") prove to be the better route.

5 Chapter 5: User behavior and medical packaging design: a case study.

5.1 Introduction

In order to mitigate the risk of healthcare-associated infections (HAIs), nursing and surgical technologist organizations have put forth standards and recommended practices for many topics, including packaging usage (*AORN Guidelines for Perioperative Practice*, 2016; "Standards of Practice for Creating the Sterile Field," 2011). However, despite the attention to packaging in the professional guidelines of healthcare providers, little is known about which packaging design factors facilitate or hinder the aseptic transfer of items to the sterile field. Many clues about user behavior can be gleaned from the published literature, particularly those that study affordances and signifiers.

The chevron seal, as discussed in Chapter 1, was introduced to allow for a smoother peeling process, particularly in flexible pouches by distributing forces along narrow seals (Marotta, 1998). Presumably, the explanation is based on the highlighted region in Figure 24, where seals are narrow with relatively consistent peel width if the package is peeled as intended (pouch A); that is, using a straight path that begins at the top-center. This chapter explores what happens when users initiate the peeling process, particularly the forces exerted to open the seal and the relationship between pull direction and the resultant force profile as measured by a universal tester running in tensile mode.

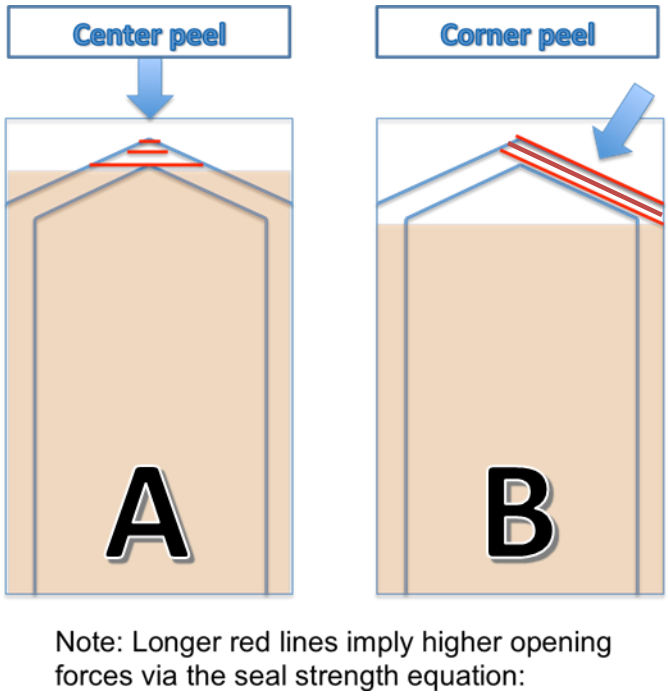


Figure 24 - Center Peel and Corner Peel – Comparison of seal widths along the peel pathway

G. Smith et al. (2009) hypothesized that opening forces influenced the scattering of surface contaminants about the sterile field. While Smith did not quantify the relationship, it does raise an interesting question: what is the relationship of the packaging seal and opening forces to the reactions of surface contaminants and, ultimately, the potential for contamination of the sterile field?

In the present study, two peel tests were conducted to investigate the issue of peel path, resultant forces, and the potential to induce the movement of contaminants *into* a sterile pouch during opening. Peel tests with simulated contaminants were conducted on two different starting positions for peeling (middle of pouch- See Figure 22 A versus corner of pouch- See Figure 22B) in the first study. In the second study, peel tests were conducted on pouches of three different seal strengths. The need to study these relationships is bolstered by our previous, unpublished work (Trier, Lee, and Bix; see Appendix D, page 171) which suggests that a fair number of

healthcare providers do not initiate the opening process for these pouches as intended (beginning at the top center). Review of the existing design literature which frames packaging as a communication medium for opening behaviors provides context as to why healthcare providers frequently initiate the opening process in ways that the package designer did not intend (i.e. from the corner of the pouch).

5.2 Design communication

In this discussion, design communication will be framed using Gibson's theory of affordances and Norman's pairing of affordances with signifiers, both of which are defined in Chapter 4. Norman (2013; p 14) summarized the concepts as they apply to design: "Affordances determine what actions are possible. Signifiers communicate where the action should take place. We need both." Chapter 4 introduced different ways users interpret the functionality of the package, and the present chapter will introduce how *signifiers* from the designs influence user actions to provide context for the lab-based work.

The design literature provides guidance as to how signifiers may be used. Three examples of design methods from Lidwell et al. (2010), identified by J. de la Fuente et al. (2015) as particularly salient to packaging, can be gleaned from Lidwell et al.'s (2010) *Universal Principles of Design.* These principles include: visibility (pg. 250), signal-to-noise ratio (pg 224), and recognition-over-recall (pg 200). The principle of visibility states that the design should clearly communicate *action* and *consequences* of the action (Lidwell et al., 2010d). In the case of the chevron pouch, this may be clearly communicating that the "center" starting location of the pouch is the "path of least resistance" with respect to peel-ability. The second principle from Lidwell is "signal to noise ratio", which suggests removing unnecessary information to create efficient designs; specifically, too many signifiers have the potential to disrupt or otherwise

obscure the communication of the intended signifier (Lidwell et al., 2010c). With the chevron pouch, this may mean limiting the number of "starting locations" signified (intentionally or unintentionally) by the design, for example the corners of the pouch (see Figure 22B). The principle of Recognition Over Recall (pg 200) states that users are better at recognizing previously experienced stimuli rather than recalling them from memory (Lidwell et al., 2010b). For example, a person may identify familiar opening signifiers (such as a differently-colored tab at the opening location and the appropriate peel path) with greater ease than if they were required to think about previous experiences with similar-looking designs.

An additional design principle suggested by Lidwell (2010) and discussed by J. de la Fuente et al. (2015) is the use of *constraints* to guide users to appropriate affordance behaviors (Lidwell et al., 2010a ; pg 60). Lidwell identified two types of constraints: physical and psychological. Physical constraints, as the name suggests, physically limit the possible ways that the user can interact with an object (Lidwell et al., 2010a). In the case of our chevron pouch, this may mean removing the corners altogether, guiding the user to a single peel path that is initiated at the center top of the pouch (see Figure 25, B). Additionally, one can use *psychological* constraints, which leverage perception and the cognition of the user (Lidwell et al., 2010a). An example of such a constraint may be labeling strategies that suggest that the user may only peel at the middle of the pouch (see Figure 25, C). One or more methods may be used if the designer does not want multiple access points (see Figure 25, A) to the package.

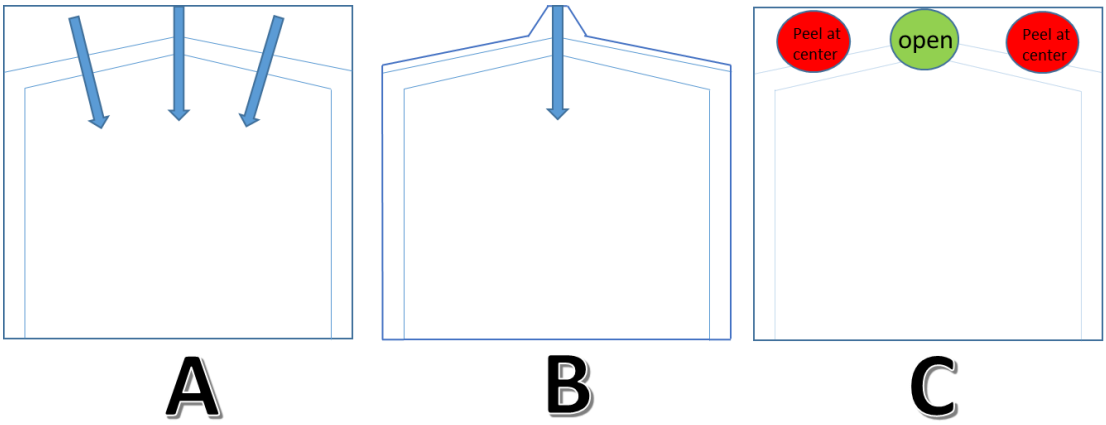


Figure 25 - Examples of constraints in package design. A represents an unmodified chevron pouch. B represents a Physically Constrained design. C represents a psychologically constrained design.

In short, designs should offer easily perceptible, clear information regarding the intended opening affordance and designers should consider "designing out" possible inappropriate actions. Caution should be exercised in defining an "inappropriate" action, however; if designers are to engineer-out specific affordances, such as initiating a pull from the corner of a pouch (Figure 24, B) in an attempt to prompt an intended behavior (pulling a straight path down the center of the pouch (Figure 24,A), it is important to understand the ramifications. de la Fuente et. al (2015) advocated a context-driven, field-work design strategy to identify actual affordance behaviors people employ. However, with respect to measuring affordance behaviors and the resultant forces from specific seal patterns, the studies are few in number.

5.3 Evaluation of peelable seals

When evaluating peelable seals on product packaging, common practice employs ASTM F88/F88M-09 (Figure 26; ASTM, 2009). In this test, one inch strips of the sealed pouch are cut and tested in replicate. The portion of the strips not held in the machine's clamps can either be unsupported (as in Figure 26), supported at 90 degrees (held in place by pinching the material

and holding it in position), or supported at 180 degrees with an alignment plate which firmly holds the material flush at 180 degrees. The standard does not advocate one approach over another, only that one record which is used in the test. Test strips are peeled at approximately 8-12 inches/minute in replicate. Seal failure method (e.g., if the test strips peel cohesively or if laminated layers separate) is recorded after each test by the evaluator. Data are reported primarily as peak loads and average loads depending on the interest of the lab study. Average load is often calculated between the "ramp up" (i.e., slack removing) period and the "ramp down" (post-seal separation) points of the data. The one inch strips are prepared to simplify subsequent calculations for Seal Strength (See Equation 1) by making the denominator "1".

Figure 26 – ASTM F88 Seal strength testing on Instron Universal Test Machine

$$Seal\ Strength = \frac{Force}{Unit\ width}$$

Equation 1 - Equation for seal strength

While this test has proven useful in determining the effect of changing processing conditions on package seal strength, the correlation of the performance of a single 1-inch portion of a seal to the peel functionality of an entire package is dubious at best. The current literature on opening forces has often investigated semi-rigid and rigid containers (e.g., trays and yogurt

cups), as discussed in the dissertation of C. J. de la Fuente (2013). However, much is left to be learned about opening forces associated with flexible packages, such as the chevron pouch in the present work. The literature has done much to answer *how* certain forces might be experienced (be it angle changes, user's chosen peel directionality, or seal design), but little has been done to establish *what it may mean*. As the body of literature has alluded, packaging tests such as F-88 do not accurately encapsulate the ramifications associated with package use. The present work ties self-reported user choices in packaging usage to objective evaluations of force during whole package opening.

5.4 Research investigating opening forces of product packaging and user behavior

A limited number of researchers have explored how varied factors impact opening forces; the primary stimuli studied have been lidded semi rigid systems utilized by the food and medical industries. Canty, Lewis, and Yoxall (2013) investigated the opening of yogurt cups using observational and video analysis techniques; specifically, researchers investigated the directionality of pull, the type of grip used, the angle of peel, and the force required to open the lid. The authors concluded that a lack of dexterity was likely to be a more significant issue than opening force (for older consumers). Additionally, the authors noted that the measured forces fluctuated throughout the test. The research team attributed a drop in the forces required after the initial opening to an uneven peel between both sides of the lid, or as the authors put it: one side "[opening] slightly, then the other side repeatedly" (pg. 8). The authors' brief description of the phenomenon is interpreted herein as an uneven separation of sealed lidstock during the opening process (See Figure 27)

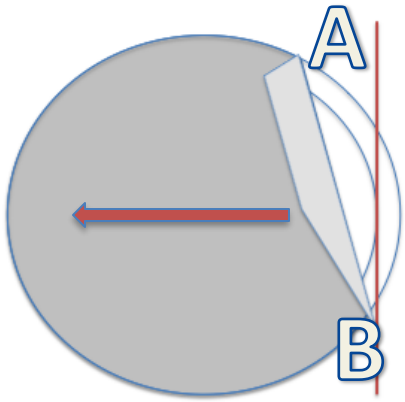


Figure 27 - Author's interpretation of Canty et. al's uneven of yogurt cups. Red line and arrow represent a user's peel path being right to left, with the sealed region peeling more rapidly on side A than side B

Liebmann, Schreib, E. Schlözer, and Majschak (2012), of Fraunhofer AVV, investigated peel angles and speeds on resultant forces with the goal of developing a whole package peel test standard for trays with lids. Using a group of volunteers, the authors reported that "when opening a peelable closure, the human hand intuitively chooses a tear angle greater than 90°, since this makes it easier to open the packaging" (Liebmann et al., 2012). The authors, though not specific with respect to where the angle was measured, likely defined the angle based on its relative position to the *previously sealed* edge (Figure 28). Liebmann et al. (2012) presented data suggested that of the three peel angles investigated (90°, 135°, 165°) the middle value was the lowest in force.

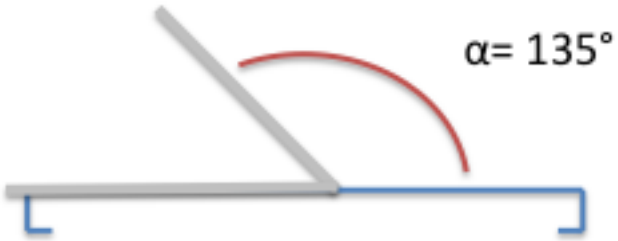


Figure 28 - Liebmann's peel angles. Note that the Figure's angle is only for demonstration purposes and may not be 135 degrees.

Although Liebmann postulated that the angles were intuitive, it was de la Fuente (2013) who quantified the suggestion. de la Fuente's work (2013) investigated user interactions with lidded trays typically used for medical devices, and utilized quantitative methods with a Qualisys kinematic system (motion capture) to capture the peel path utilized by participants. The forces resulting from the peel path were objectively characterized using an Instron Universal Test Machine, and de la Fuente (2013) compared both sets of data to shed light on the relationship between peel angle, peel path, and the forces they influenced. Using the motion capture system, de la Fuente (2013) found that users tended to employ average peel angles of 44° (st.dev 14°); employed peel angles were within, to use de la Fuente's words,an "optimal range" of 45°±15° that corresponded to a "sweet spot" of low forces (as recorded by the Instron). He noted this same phenomenon using the two methods with peel *paths*, or the path to peel the lidstock off of the container taken by the user during the opening process. Preliminary data collected using the kinematic system suggest that participants rotated the package during the opening process to change the peel path such that the length of the seal that was being peeled was as small as possible. The Instron recorded significantly lower forces when the widthof the area being peeled was the shortest possible width. Although the innovative study by de la Fuente suggested that users biomechanically optimize their peel paths, the present work draws upon previously gathered data (Table 31, page 171 in Appendix D) to see what happens when designs communicate alternative functionalities (see Figure 29).

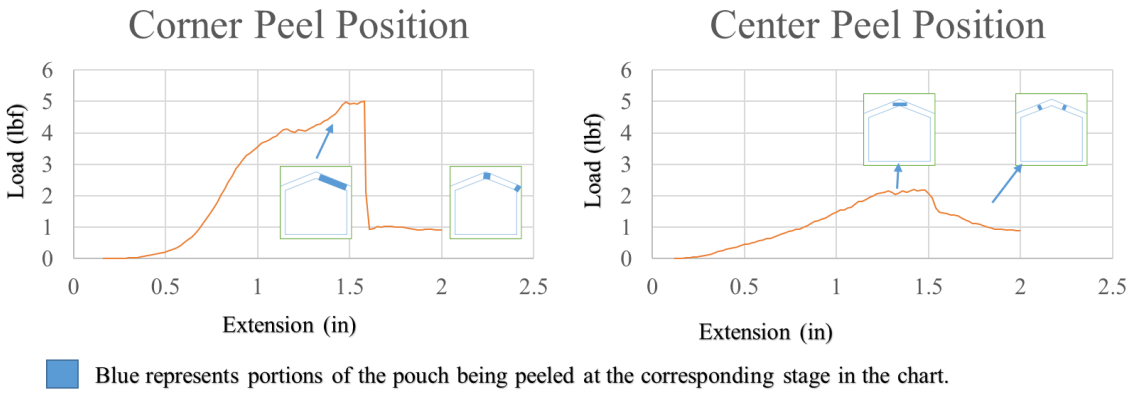


Figure 29 - Corner versus Center Peeling (for illustrative purposes). Corner peels result in a higher initial load and drop down to similar levels as the center peeled pouches when both are peeling along the smaller widths.

The peel path work done by de la Fuente suggests that omitting human behavior from peel tests may lead to data that do not capture key elements of use. In the case of the chevron pouch in the present work, the seal widths with which the users interact may be much larger, typically, than the widths evaluated in industry testing standards, namely ASTM F88.

5.5 Focus of the present study

The focus of this paper is the chevron pouch seal design that has been in use for years and was originally intended to create smoother, low force peel paths (Marotta, 1998). As discussed in Chapter 1, the chevron accomplished this by distributing forces evenly along the seals. de la Fuente (2013)'s work with lidded trays from medical devices suggests that users will optimize their peel pathways in order to generate the least amount of force required for opening; that is, they navigate the path so the length of the sealed material that they are working is minimized. Users may self-select the optimal peel pathway. In the case of the chevron, this means beginning just above the pointed peak of the seal and continuing with a straight path. However, the large corners have the potential to serve as a signifier that signals the affordance of *grip-ability*, and

our previous work quantifying the starting position of peeling for large chevron pouches (Appendix D, page 171) suggests that this is happening.

The varied approaches of the users and the multitude of factors with the potential to impact resultant forces make predictive modeling very challenging. As the work of de la Fuente has demonstrated, investigating the systemic and environmental influences on usage using qualitative methods, such as field observation (J. de la Fuente et al., 2015), can help identify the relationship between signifiers and affordances. Similarly, interview methods can provide valuable "user voice" data which grounds the decisions in the self-reported experiences of the users. Where observation can shine light upon the actions users take when using packaging, user voice can help pinpoint what the user is thinking as they are using the package. In the prior chapter, packaging afforded different things to different users based on their personal understanding of what constituted aseptic technique and what was not. In this chapter, signifiers are tied to user decisions and what those decisions may mean.

While user behavior can be studied academically, it is also important to explore the possible clinical relevance of behavioral choices. In the case of the flexible chevron pouch example, depending on the signified affordances for initiation and the peel path employed through the opening process, the width of the seal (and resultant forces) may be narrow and smooth, or fluctuate in width resulting in large differentials in force (Figure 24 - Center Peel and Corner Peel – Comparison of seal widths along the peel pathway). It is the hypothesis of the present work that these fluctuating peel paths may be associated with higher contamination of contents.

We are not the first to conjecture regarding the relationship between opening force and contamination. Smith et. al (2009) hypothesized that an observed disturbance of surface

contaminates (measured via scattering of the same into petri dishes placed throughout the experimental area) was caused by forces required to open the surgical pouch (though they did not formally test this hypothesis). However, the present work moves past the general umbrella of "force" that Smith conjectured as the reason for the scattering of the contaminants; the work herein investigates two factors that would lead to greater opening forces: seal strength differences, and peel pathways. Abrupt changes in force result in rapid changes in opening speed which results in a "jerking motion" with enhanced potential for contamination

5.6 Hypotheses

Using interview-based query, we investigate the idea that starting position is influenced by cues signified from the package and/or product

Using an Instron Universal Testing device, we quantified the relationship between the peel path, resultant forces and rates of contamination of contents as measured with a simulated contaminant. Our hypotheses regarding the Instron studies were as follows:

HA: Contamination of the interior of the packages is significantly greater when the pouches are peeled at 12 in/min starting from the corner position than when starting from the center position.

HA: Contamination of the interior of the package is significantly affected by the seal strength, with higher seal strengths resulting in more contamination.

As each of the three facets of this work (interview, position peeling, and the flat seal peeling) utilize a unique methodology for data collection, the studies will be presented one-by-one, and revisited together in the discussion.

5.7 Interview study

5.7.1 Interview methodology

5.7.1.1 Participants

Participants were recruited by sending a flyer (Appendix A) through a listserv of members of the Association of Surgical Technologists. Members of the organization were

included in the listserv if they lived within the mid-Michigan area and could commute to the site of the study, Michigan State University. Participants were additionally recruited from MSU College of Nursing via a listserv e-mail. Participants read and signed an informed consent form (Appendix A) which detailed the study and inclusion criteria, specifically: being at least 18 years of age, having no known history of skin conditions (e.g., eczema), having experience as a healthcare provider, being willing to be video-taped, and having transportation to the site of the study. Nurses and surgical technologists were recruited to open packages and share their experiences with medical device packaging (see Figure 21, page 68 from Chapter 3) from their work environment. Questions were asked from a semi-structured interview guide, which can be referenced in Appendix B.

5.7.1.2 Interview coding

Interviews were transcribed from audio recordings, and coded using QDA Miner (Provalis Research; Montreal, QC). In addition to speech, actions (such as physical gestures) during the interview were recorded in brackets to provide context to the accompanying speech. A portion of the interview data, pertaining to the choice of starting position on large pouches, was coded by a single reviewer.

5.7.1.2.1 Location

The coder first recorded the participant's verbal response regarding the starting peel position. Responses such as "in the center", "in the middle" were included as direct references to the center position of the pouch. Other starting locations were gleaned inferentially based on the user's response. For example, "where the divot is", "where the arrow is", or "at the peak" reference aspects about the pouch design that exist only in the center of the pouch. Location was similarly handled with corner peels. For example, "at the corner" was included as a direct

reference to the location whereas “extra lip” was inferred from the context of what the user was discussing.

5.7.1.2.2 Reason

The guiding reason for choosing the center and/or corners was inferred from the text of the transcript. Accompanying sample quotes from the participants, which illustrate the concept, were reported.

5.7.1.2.3 Affordance

Affordances were identified by a single coder and reported. Affordances were reported in a hyphenated format; the affordance was labeled as “action”-ability, where “action” pertained to a specific function. For example, if the participant noted that they select the corner of the pouch because there is more room to grip the material, “grip-ability” was recorded as the relevant affordance. The affordance recorded was simply which action was possible within the context of the discussion. Due to the inferential nature of the analysis, it is important to mention that the coder had significant familiarity with the literature pertaining to affordances as well as aseptic technique.

5.7.1.2.4 Signifier

Signifiers were inferentially identified based on the user’s response within the transcript in a similar manner as the affordances. A single coder (the same which coded the affordances) recorded what made the affordance perceptible to the user based on the participant’s response. For example, if the participant noted they start peeling the pouch in the middle because it is “where the arrow is”, then the chevron is listed as the signifier. Additionally, the type of feedback the signifier provides was recorded. In this case, the feedback is visual in nature since

the participant perceived it by seeing it. Other types of feedback may include: tactile, auditory, olfactory, or taste.

In summary, information provided by the participants was couched in theoretical frameworks to understand what influenced the decisions of the users interviewed in this study. The insights provided by the participants were studied alongside Instron-based bench data which explored possible consequences of those decisions. This bench data included an evaluation of contamination differences between different starting positions, as well as a comparison of contamination occurrences between three seal strengths.

5.7.2 Results: user responses

As the peel position portion of the present work in this chapter hypothesized that starting position may be correlated to contamination via surface contaminants, user data was collected to contextualize why different starting locations may be chosen. The recruited participants were an average of 38.7 years of age (st.dev ± 9.4 years). The age of one of the participants was not recorded by the research team due to not being captured on the recording of the interview. Most of the participants (14/15) were female and surgical technologists (13/15).

Responses are separated by start location. The rationale for choosing the center of the pouch is reported in Table 23, and the rationale for choosing the corner can be found in Table 24. Notably, some participants mentioned that they were taught to do it that way, or mentioned responses akin to “it just makes sense.” These are not represented in the following tables due to the general nature of the response and the lack of follow-up probing questions (i.e., “why does it just make sense) in the interview.

Location	Reason	Affordance	Signifier	Signifier type	Code Example
Center	"Where the arrow is"	Peel-ability	Chevron peak	Visual	"I would pick them up where the arrow is"
Center	"the divot"	Access-ability	Thumb notch	Visual	"And there's always a little divot where we… where it is, so."
Center	"if it was a single"	Flip-ability	Lack of inner package	Visual	"Well if it was a single [grabs medium pouch] I'd go right down the middle with this one."
Center	“it’s at a point” "stickiness"	Peel-ability	Chevron peak, Smoother peel	Visual Tactile	" I guess because it's at a point there and that's the easiest part to get it, um, like to get it open there [simulating peeling], because of the stickiness."
Center	"Control of corners"	Control-ability	Curling material	Visual	" Because I can get a better grip on the whole package itself. Like I can control both corners better. Like both corners I can clearly see are flipping out, like with this one if I do that it still rolls in and it folds over on itself. So better control."
Center	"if it takes up the whole package"	Flip-ability	Product fit to package	Visual	"I usually, if I go kinda, kinda try to go against where the bulk of the weight is first. That way, what I'm opening isn't going to flip out on to the floor. And then I can try to more easily flip it on to the table, so that I can kind of peel it against myself, but depends on what's in it, I mean if it's taking up the whole package, then in the center. Not taking up the whole package, then against the weight first so I can flip it on to the table."

Table 23 - User responses regarding usage of the center position of the pouch, and associated affordances and signifiers.

Location	Reason	Affordance	Signifier	Signifier type	Code Example
Corner	"cover my arm"	Cover-ability	Material space	Visual	"For me, I want to cover my arm as much as I can. Something like this [arm diagonal across pouch for maximum coverage, favoring corners]. This would be alright, with this one too. I just tend to favor the corners."
Corner	"easier to find"	Access-ability	Material space	Visual	"Maybe because, um, they're easier to see, they're easier to find. … Because you're…when you're getting set up a lot of the times there's pressure–come on hurry up, they're waiting, get goin'–so you don't have a lot of time to sit and look. You just kind of neat to…get a trustworthy spot goin', and get goin'."
Corner	"easier to control"	Control-ability	Material space	Visual	"It's just harder–so that's why I go from the corner [large pouch corner] 'cause I can control it better from one side."
Corner	"extra lip"	Grab-ability	Material space	Visual	"and it also gives you the extra lip of the material [grabs corner of pouch]"
Corner	"Not taking up the whole package"	Flip-ability	Product fit to package	Visual	"Not taking up the whole package, then against the weight first so I can flip it on to the table."

Table 24 - User responses regarding usage of the corner position of the pouch, and associated affordances and signifiers.

Two other reasons reported by the interviewees for using the corner of the pouch were difficult to couch in terms of affordances without more contextual probes or observation. In one

instance, the participant favored the corners because it was easier to present it to another person such that the pouch was away from the field. In another instance, the participant voiced that the opening starts smaller when they open it from the corner. The responses indicate diversity in the types of interactions the users had with the pouch, even when one narrows the review to a single peel positon choice. The present study first explores contamination as a result of starting peel position in lab-based tests. Starting peel position is of interest due to the higher opening forces users would experience in their first interaction with the package (as previously discussed using Figure 24).

5.8 Commercial pouches peeled at two locations

5.8.1 Commercial pouch peel study methods

HA: Contamination of the interior of the packages is significantly greater when the pouches are peeled at 12 in/min starting from the corner position than when starting from the center position.

In order to evaluate the hypothesis, 20 pouches were peeled using a fixture constructed for use with an Instron Universal Test Machine (Grove City, PA), which allowed for coatings on the clamps holding the material. The Instron tests were conducted at two starting positions (center, top of chevron; corner, middle of seal) to simulate two different peel pathways. Tests were standardized to stop shortly after the pouches were opened and contents would have been exposed to the environment, namely, after the Instron jaws had extended 2 inches. Sample preparation and details about the test fixture are described herein.

5.8.1.1 Sample preparation

5.8.1.1.1 Pouches

Large pouches (10.5” x 16”) were selected in this study because, during prior work (Trier, 2012), healthcare providers were observed to initiate opening at varied locations. Pouches

were constructed of a Tyvek layer and an extrusion-laminated 48 ga PET/LDPE layer. Pouches were sealed at the manufacturer (Oliver-Tolas Healthcare; Grand Rapids, MI) with unspecified conditions. In order to fit the commercial pouches into the clamps of the test fixture, the extraneous corner material of the right side of the pouch was removed. Samples were cut such that 3/4 of an inch of material was available (distance from the seal) to be placed into the clamps. An example of a cut pouch appears in Figure 30.

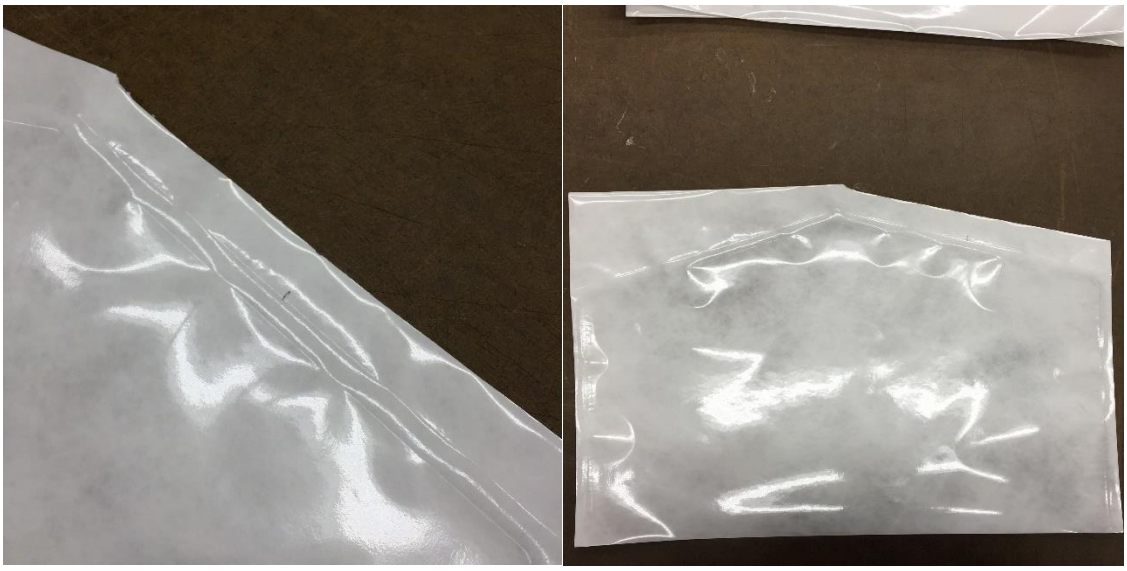


Figure 30 - Cut Commercial Pouches, marking in the middle (L), full view (R)

Pouches to be peeled at the corner position were marked 4+1/16 inches from the end of the seal (i.e., in the middle of the right side of the chevron; see Figure 30) in order to align the center of the clamp with the center of the right seal. All pouches [20 unmodified pouches (center pull), 20 cut pouches (pull from corner)] were conditioned in a controlled chamber at 23°C and 50% relative humidity for 48 hours prior to being tested using the Instron equipment.

5.8.1.1.2 Seal strength characterization of commercial pouches

To characterize the seal strength of the commercial pouches, unsupported 1-inch strip tests were performed according to procedural guidelines in ASTM F88. One-inch test strips were cut from the pouches (one strip per pouch) in the same location on the seal (middle of the broad seal, see Figure 30). Samples were peeled in an unsupported condition on an Instron Universal Test Machine model 5655 (Grove City, PA) with a 10kN load cell. Pouches were conditioned for 48 hours at 23°C, 50% RH prior to testing. Each strip was peeled at the 12 in/min recommended speed. Data were recorded by the Instron in CSV file format.

Average loads were calculated by averaging the middle 80% of the measured load data points. Approximately 10% of the data points were removed from the beginning and end of the test. This number was determined by taking the number of data points, dividing by 10, and rounding to the nearest whole number. The average of the middle 80% of data points were recorded separately and calculated in a grand average of all peel test samples. The seal strength was measured to be 0.90 lbf (st.dev=0.17).

5.8.1.2 Test fixture

A customized test fixture (Figure 31, specifications in Appendix D) which enabled whole package peel testing utilizing an Instron Universal Testing Machine model 5565 in tensile mode was used to characterize the peels as the packages were tested. The fixture enabled a consistent rate of peel and allowed the research team to capture force components such as absolute peak load. The wheel of the pulley was situated directly under the Instron's clamp such that the cotton string went upwards at a (visually approximated) 90-degree angle.

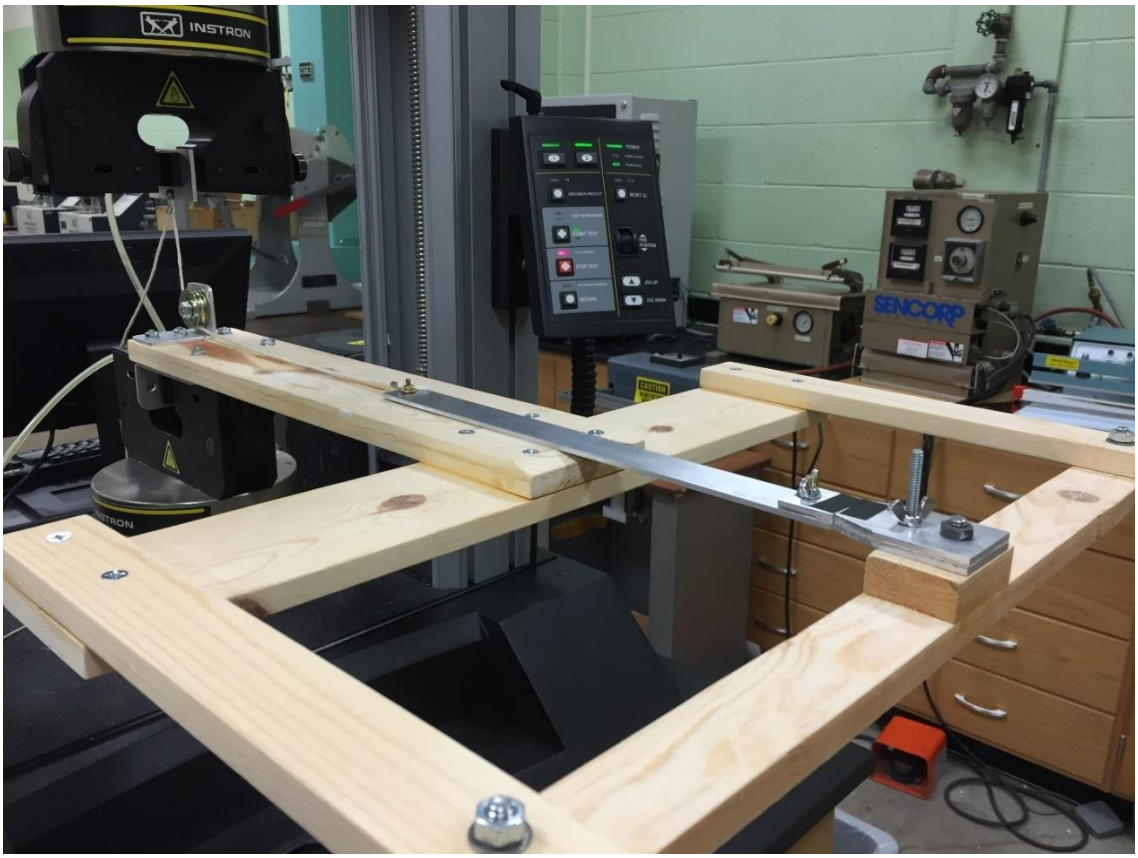


Figure 31 - Customized text fixture for full pouch peel testing.

In order to account for forces resulting from the clamp dragging across the surface of the wood, ten trials consider to be pilot were tested using the system (i.e., without an attached pouch) were performed. Average load was calculated per run, and all ten average loads were then averaged into a grand average. This value was ultimately subtracted from the reported force values obtained in the course of testing to account for the effect of drag.

5.8.1.3 Contaminant simulants

Contaminants were prepared in advance of the testing. Additionally, a 1” x 0.5” black sticker was placed on the clamps of the customized fixture to mark the coating area. This sticker served as a reference for the application area for the coating which was confined to the sticker’s surface. GloGerm powder, a melamine resin copolymer (Glo Germ Company; Moab, Utah), was

used as a simulated contaminant. The simulated contaminant served to provide evidence of surface contaminants entering the pouch during all test trials. The resin is a fine powder (5 microns in particle size) that fluoresces in the presence of a UVA blacklight. A GloBar (Brevis; Salt Lake City, Utah) was used to illuminate the particles. The fluorescing characteristic allowed the research team to identify small amounts of contamination that may not have otherwise been visually noticeable. 5 mg (± 0.5 mg) of power were pre-weighed using an Ohaus analytical balance into 80 individual sauce cups. Powder was emptied on to a spoon and spread across the 1" x 0.5" sticker manually until the researcher was satisfied with the consistency.

5.8.1.4 Peel tests

Peel tests were conducted at three rates of Instron jaw separation speed (6 inches per minute, 12 inches per minute, 18 inches per minute), in two different positions (center position peel, corner position peel) for each speed. The faster and slower speeds were used to pilot the idea that there is a relationship between peel speed and rates of contamination. Specifically, it was hypothesized that the faster rate of pull would result in the creation of a vacuum and thus lead to increased contamination rates. The peel speed analyzed statistically herein is the middle speed (12 inches per minute). The rate of separation was chosen since it is within the suggested test rate range within ASTM F88. The extension distance of 2" was chosen based on pilot tests which approximated how much the jaw needed to travel to open the seal partially in both the central and corner positions. The full design can be referenced in Table 25.

	Peel Location	
Peel Speed	Center (# of samples)	Corner (# of samples)
6 in/min	5	5
12 in/min	20	20
18 in/min	5	5

Table 25 - Samples per peel speed in the position (center versus corner) peel tests. The 6 in/min and 18 in/min conditions were pilot data and were not include in the statistical analysis. Due to a loss of one corner peel sample due to damage, a total of 39 samples were tested at 12 in/min.

Immediately after each test concluded, the interior of the pouch was scanned using a black light in ambient lighting conditions to illuminate particle contamination within the package. The black light was held close to the pouch without touching the pouch itself or the testing fixture. Powder on the surface of the clear film side of the pouch was brushed lightly with a gloved finger to verify that the contaminant was not on the outside surface of the pouch. Gloves were scanned prior to touching the samples to avoid adding additional contaminants to the outside of the pouch near the contaminated area. Contamination was scored in a binary fashion (yes or no). Any amount of contamination within the pouch (any powder that had entered the interior of the package past the seal area) was scored as a “Yes”. The inner seal area (inside edge) was chosen to demarcate contamination as the inner portion of the pouch is assumed sterile.

Figure 32 - Contamination scoring zone. Note that the bolded line is on the "sterile side" of the seal. The other side of the seal is where text fixture clamps would peel the pouch open.

After scanning, pictures of the contamination were taken for later reference in order to provide the potential for post-hoc assessment of the amount of contamination that occurred within the pouch. Packages were then removed from the apparatus and discarded. Residual powder was cleaned from the clamps and spoon using an alcohol swab.

5.8.1.5 Determination of absolute peak load

In order to quantify and compare possible differences in opening forces that occur during peels that begin from the corner as compared to those beginning from the center, absolute peak load was calculated from the Instron-recorded data points of load versus extension. Absolute peak load was selected because it simplified the comparison of maximum forces users might experience. Each absolute peak load in each plot was modified by the "dry run" (see 5.8.1.2, Test Fixture) adjustment before being compiled into a grand average.

5.8.1.6 Statistics

The target (dependent) variable in the analysis was the dichotomous variable CONTAMINATION; specifically, the presence of the simulated contaminant within the pouch. The sole categorical covariate in this particular test was starting position of the jaw (specifically, center versus corner). The reference value of this predictor was selected as the "center" peel condition.

One corner-peel trial was excluded as a result of being damaged by the research team between the conditioning and mounting onto the custom test fixture. The data of the included trials were analyzed using a binary logistic regression model in SPSS (IBM; Armonk, NY). The assumptions for using the model were checked and met:

- The dependent variable was measured on a dichotomous scale (yes or no). Contamination was scored in a binary matter irrespective of amount of contaminant.
- The measurements were independent of one another, as each pouch was measured once only.
- An independent variable, starting position, was incorporated into the model.

- Linear relationship between the continuous independent variables and the logit of the dependent variable. This condition was met by virtue of not using continuous variables (such as force) in this model.

5.8.2 Commercial pouch peel test results

5.8.2.1 Results of commercial package test

A total of 39 pouch trials were included in the statistical analysis, as the slower and faster peel tests were conducted solely for reference purposes. One pouch was torn due to an unrelated material defect such that the seals did not separate when the whole package was tested. This pouch was removed from the analysis. Frequencies (in pouches) of contaminated trials per condition can be referenced in Table 26.

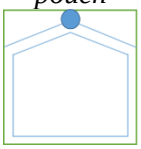
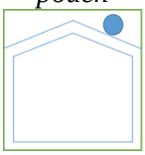
	Contaminated	**Not Contaminated**
Pull Initiated at the Center of the pouch 	3/20 (15%)	17/20 (85%)
Pull initiated at the Corner of the pouch 	16/19 (84.2%)	3/19 (15.8%)

Table 26 - Raw data of contaminated trials by peel position (center versus corner)

The Wald test was used to test the significance of each coefficient, namely the intercept and the independent variable, position (see Table 27). The odds for contamination were 30.2 times greater in corner peeled pouches as opposed to center peeled pouches. The Betas reported in the model represent the log-odds of contamination. Exponentiated betas, therefore, represent odds of contamination versus the reference value (center peel).

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	Position(1)	3.409	.888	14.744	1	.000	30.222
	Constant	-1.735	.626	7.673	1	.006	.176

Table 27 - Binary logistic regression of contamination data - Exponentiated beta indicates odds ratios of contamination in peels started at the corner position versus the center position.

5.8.2.2 Peak loads in each peel location

Absolute peak loads (see Table 28) were determined via Instron plots of load versus extension. An adjustment of 0.01666 lbf was subtracted from the absolute peak loads of each trial to account for the clamp dragging against the wood, and a new standard deviation was calculated. Raw and adjusted absolute peak loads can be referenced in Appendix D, page 169.

	Center position (N=20)	**Corner position (N=19)**
Mean	2.42535 lbf	5.39077 lbf
Standard deviation	0.33850 lbf	0.99179 lbf

Table 28 – Absolute peak loads of commercially sealed pouches, from 0 to 2 inches of jaw travel extension.

5.8.2.3 Results of slower and faster peel speeds

The results of the two pilot test speeds are presented in Table 29. Each number of contaminated trials is presented out of 5 total trials.

N= 5 samples per position	**6 in/min**	**18 in/min**
Center Contaminated	0/5 (0%)	0/5 (0%)
Corner Contaminated	3/5 (60%)	5/5 (100%)

Table 29 - Frequency of contamination in slower and faster peel test speeds. Center position versus corner position in commercial pouches.

Researchers observed that contaminated trials in the 6 in/min condition were usually limited to one contaminated location, whereas the faster peel speed had more contaminants scattered throughout the pouch's interior.

Figure 33 demonstrates a fairly typical amount of contamination in most of the contaminated trials across all 3 test speeds within this study. Contamination accumulated in small spots throughout the package, mostly near the opening of the pouch. Illuminating GloGerm spots are circled.

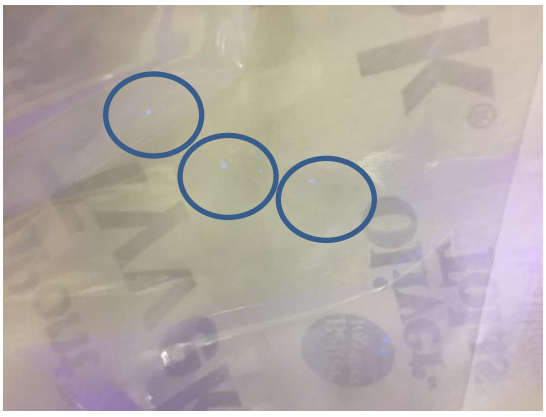


Figure 33 - Example of contamination illuminating under a black light

5.8.3 Square seal test

5.8.3.1 Pouch preparation

A total of 60 pouches were crafted to evaluate the effect of seal strength on contamination. The seal strength was of interest due to its effect on opening forces for the present study, This seal strength was manipulated by varying dwell time during the sealing process. The temperature was set at 145°F with 70 psi of pressure on an MD 2420 dual-shuttle tray sealer (Sencorp; Clark, NJ; Figure 34). The tray sealer was used in order to customize the seal design for the test pouches. A more detailed methodology for creating the custom seal gasket can be referenced in Appendix D, page 172.

Figure 34 - Shuttle sealer with square seal custom gasket.

Eight (8) one inch strips were created to benchmark the seal strength comparison across conditions. Average load was taken as with the commercial pouch seal strength evaluation; the load was taken between the ramp-up and ramp-down peaks as suggested by the standard. Please reference 5.8.1.1.2 on page 119 for a detailed methodology. An ANOVA with Tukey pairwise comparisons was conducted to compare the three sets of seal data in order to establish that the

seal strengths were different from one another when manufactured using the three different dwell times. The value measured for each testing condition can be referenced in Table 30:

	145F 70psi 0.75s	145F 70psi 1.50s	145F 70psi 3.00s
Mean	0.23 lfb (N=7)	0.63 lbf (N=8)	1.1 lbf (N=8)
Standard Deviation	0.077	0.21lbf	0.22 lbf

Table 30- Mean seal strengths for the 3 dwell time conditions. Note: One sample from 0.75s condition not peeled, sample damaged before testing.

5.8.3.2 Square seal testing conditions

Twenty pouches were created for each processing condition. The "opening flaps" at the top were sized to three-quarters of an inch to fit the peeling clamps. Prior to testing, each pouch was measured and marked in the middle to align the clamps to the center of the seal (see Figure 35).

Figure 35 - Square sealed pouch

Clamps in the study of seal strength were prepared in a similar fashion with contaminants as the positional study, detailed on page 120, section 5.8.1.3 . Jaws on the Instron were separated prior to test in order to fit the custom text fixture and the instrument was run at a speed of 12

inches per minute with testing automatically ceasing when the jaws extended 2 inches. The dependent variable of interest, the appearance of powder inside the pouch, was evaluated using a black light. As done in the positional peel study, contaminated areas on the film side of the package were lightly brushed with a glove finger to verify that the powder was not on the outside of the pouch. Any amount of contamination within the pouch (past the seals) was scored as a "Yes". Residual powder was wiped away after each trial with an alcohol pad.

5.8.3.3 Determination of average absolute peak loads from tested pouch samples

Data were recorded by the Instron into CSV files. In order to simplify comparisons between seal strength treatments, the research team recorded the average absolute peak load for each treatment. Peak loads were also selected post-hoc as a reference point, due to the peak load coinciding with a drop in measured load just as the seal is initially broken and continues along the side seals. The process of calculating the average absolute peak load was similar to 5.8.1.5 on page 124.

5.8.3.4 Statistics

For the multiple comparisons of conditions, a generalized linear mixed model was fitted with a logit link. The dependent variable, contamination, was a binary, Bernoulli-distributed variable. The sole independent variable was seal dwell time. To account for multiple, post-hoc comparisons, a Tukey pairwise comparison was used. Comparisons were made at the $\alpha = 0.05$ level to determine significance, and all three groups were found significantly different from one another ($P<0.001$).

5.8.4 Results of the square seal test

5.8.4.1 Descriptive results

The adjusted average absolute peak loads across N=20 trials per seal strength condition is represented in Table 31:

	145F 70psi 0.75s	145F 70psi 1.50s	145F 70psi 3.00s
Mean	1.30462 lbf	3.67522 lbf	5.05937 lbf
Standard Deviation	0.34338 lbf	1.22142 lbf	1.02051 lbf

Table 31 - Average absolute peak loads of the 3 dwell time conditions

.

The number of contaminated trials for each dwell time condition can be referenced in Table 32.

Seal Strength	**Contaminated**	**Not Contaminated**
0.23 lbf	8	12
0.63 lbf	12	8
1.11 lbf	16	4

Table 32 - Raw data of square seal peel tests.

5.8.5 Statistical analysis of square seal pouch contamination

As there were three levels of seal strength (.23 lbf, 0.63 lbf, 1.11 lbf), a generalized linear model was used to analyze the data. As the binary dependent variable contamination followed a Bernoulli distribution, the model was fit with a logit (log odds) link. Newton-Raphson was used as the mode of parameter estimation. The seal dwell time was the sole independent variable in the model. Bonferroni adjustments were made to account for multiple pairwise comparisons. The estimated means represent probability of contamination. Beta values represent log-odds, whereas the exponentiated beta represents odds-ratios between the condition and the reference value.

5.8.5.1 Generalized linear model of square peel tests

Three seal strength conditions were compared with pairwise comparisons. Mean contamination rates, standard errors, and 95% Wald confidence intervals can be referenced in Table 33.

lbf	Mean (probability)	Std. Error	95% Wald Confidence Interval	
			Lower	Upper
0.23	.40	.110	.21	.62
0.63	.60	.110	.38	.79
1.11	.80	.089	.57	.92

Table 33 - Mean contamination rates of square-sealed pouches, with standard error and 95% Wald confidence intervals.

The 0.23 lbf condition had a mean contamination rate of 0.40, 95% CI [0.21,0.62]. The 0.63 lbf (M=0.60, 95% CI [0.38,0.79]) and 1.11 lbf (M=0.80, 95% CI [0.57, 0.92]) both had increasing amounts of contamination. To evaluate this claim statistically, Bonferroni comparisons were conducted post-hoc on the data.

After conducting Bonferroni comparisons between each of the three dwell time conditions, a significant difference in contamination was detected between the 0.23 lbf and the 1.11 lbf seal strengths (P=0.014). There was insufficient evidence to detect a difference between the 0.63 lbf treatment and the lower (P=0.59) and higher (P=0.472) seal strength treatment. Figure 36 visually depicts the estimated mean contamination rates as well as the Wald 95% confidence intervals and Bonferroni comparisons.

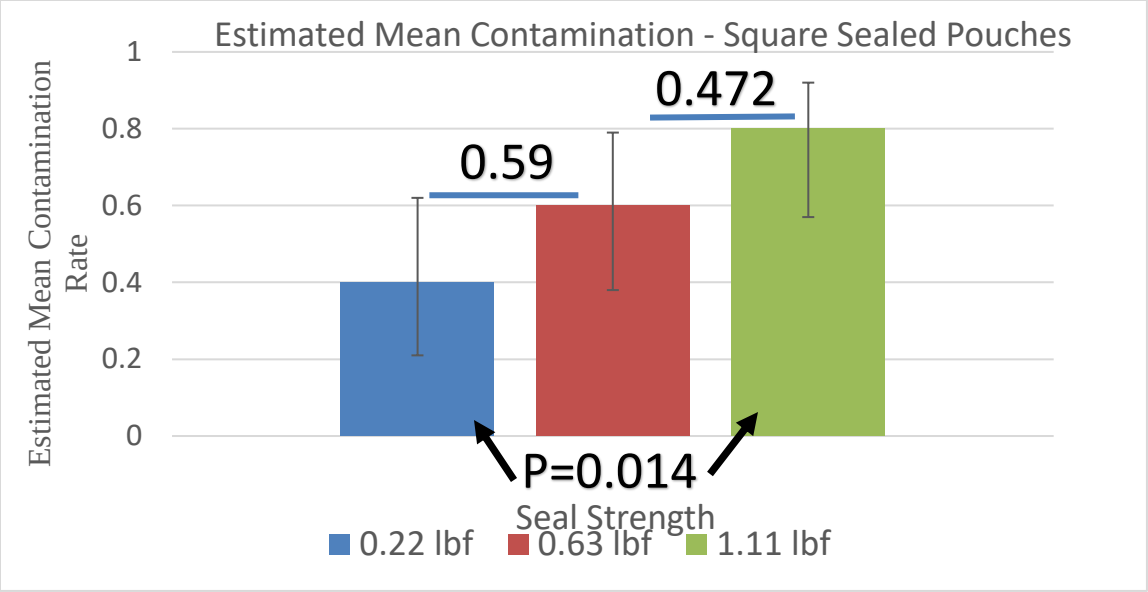


Figure 36 - Square seal pouch contamination rates with 95% Wald confidence intervals, as well as pairwise comparisons between the intermittent values.

5.9 Discussion

In this study, the choices of starting position were explored qualitatively. The investigation attempted to tie behavioral choices of the participants to packaging design by couching the experiences within the academic framework of affordances and signifiers. Regardless of its generalizability to all users of packaging, the work presented herein has provided a window into how designs, such as the chevron of a peel pack, may not be used in the way that the design is intended; although packages are often designed such that the peel forces are distributed evenly down the seals, an alternate peel pathway removes this benefit. The importance of design "misuse" in the case of starting position of the pouch was explored by two lab-based studies: the center peel position was compared to the corner position in terms of contamination, and three seal strengths were compared using square-sealed pouches.

Findings suggest that pouches peeled from the corner significantly increase the odds of contamination of the inside of the pouch occurring (see Table 27) when compared with those that

were pulled centrally (P<0.001). Seal strengths of the fabricated, square sealed pouches did not show evidence of a difference in contamination rates between the 0.63 lbf seal strength and the 0.23 lbf and 1.11 lbf conditions, but there was enough evidence to detect a difference between the lowest and highest seal strength condition (P=0.014). The two studies in tandem suggest that the opening forces hypothesized by Smith et. Al (2009) may indeed be the cause of the contamination. However, the precise reason for the contamination can only be speculated with the present data. The large drops in force present in the corner peel may be one driver of the contamination. Magnitude of force drops (per the square seal study) could be additionally important to the rate of contamination.

The original hypothesis, as postulated by Smith, was that the opening forces may be a cause of contamination of the contents of the package. Here, we find that chevron pouches peeled from the corner (broad seal, high force) have a significantly higher frequency of contamination. The odds ratio of contamination of pouches peeled at the corner compared to contamination of chevron pouches pulled from the center (chevron seal, low force) test is 30.222, 95% CI [5.305, 172.158] . This suggests that pouches peeled at the corner are over 30 times as likely to become contaminated as those peeled at the center, but the causal link has yet to be established. The second study, which utilized three processing conditions to generate three different seal strengths, provided evidence in support of Smith. Although the *why contamination occurs* question has been partially addressed by this work, the *how it happens* needs further clarification.

The packaging industry has long considered seal design from a usability standpoint, but much is left to be studied on how users actually interact with packaging. The present work builds on the understanding of affordances in packaging and how they are signified by design characteristics of these specific chevron pouches. Herein we find that the interaction with the

package is highly personalized; what one user perceives as an indication to open (e.g., the "arrow" of the chevron) may not be noticed by another. It is also worthwhile to consider that user needs may be affected by techniques they use to dispense the product in the context of a particular setting. Someone in an operating room may choose a specific location that helps the user dispense the product well after the initial pull on the seal. Also, the user may be relying on more than visually perceptible information to make their usage decisions, as was the case with the one participant who relied on the *tactile* feedback to determine where they should start peeling the pouch open.

The results herein suggest that human factors testing and packaging go hand-in-hand. Although the peel tests in the present work are not replicas of real world situations, they do shed light on to what user decisions may lead to with respect to surface contaminants. The corner peels resulted in higher contamination rates, and the 1.1 lbf seal strength treatment (average full pouch absolute peak load 5.1 lbf) resulted in significantly higher rates of contamination as compared to the 0.23 lbf seal strength (average full pouch absolute peak load 1.3 lbf). While the relationship between forces and contamination needs much more study to draw definitive conclusions, it does provide a starting point for discussion of the potential for improved health outcomes by objectively evaluating package designs that consider the user interface.

5.10 Limitations of the present study

Caution is encouraged when interpreting the results and drawing conclusions. The first issue lies in the amount of clamp surface contaminant per clamp (5mg), which may be much higher than a typical amount of pouch surface contamination. GloGerm powder likely does not represent the physical behavior of bacteria or dust, and must be taken for what it is: a model. The

methodology of Smith et. al (2009)'s, to use their words, "crude" demonstration was more refined in the present study, but is still far from a real-world example. Additionally, while the amount of powder applied per opening was measured prior to application, there are yet inconsistencies in the application of the GloGerm upon the surface of the clamp; the powder's fine grains did not lend themselves to a consistent, flat coating in the amount that was applied. Future work should consider comparisons which utilize comparisons of contaminants such as hair, blood, or microbes may help researchers understand how real-world contaminants can enter sterile packaging, and this study provides a basis upon which to build that line of inquiry.

To further investigate the effect of seal strength on rates of contamination, seal strengths of square pouches were varied by changing the dwell time (0.75 seconds, 1.5 seconds and 3.0 seconds). These dwell times had resultant absolute peak loads of1.3 lbf vs 3.7 lbf vs 5.1 lbf respectively. Although the peak loads were measured, the exact moment of contamination could not be identified in the videos. The force data, while interesting, could not in good faith be included in the model without evidence to tie it directly to the contamination; the contamination could have happened at any point after the pouch was opened, making it impossible to tie specific portions of the force plot to the contamination without evidence. Larger, more camera-recordable contaminants could assist in bridging this gap.

Additionally, the opening forces in the center-versus-corner peel test (i.e., where on the pouch the peel occurs) were different in each position, so opening forces were addressed in a cursory manner by conducting the square seal tests. Although conducting the square seal tests allowed for a targeted investigation of seal strengths, it is unclear whether the same amount of contaminations would occur between a chevron design and a square seal with the same opening forces; the two studies conducted in the present work (position and seal strength) are not able to

be easily compared with one another due to this discrepancy. Another experiment should examine chevron-seal contamination rates which vary in seal strength.

5.11 Research summary

Three key findings emerged from the work:

- Large pouches were significantly more likely to have contaminated contents when presented aseptically as compared to small pouches. This finding has been strengthened by addressing a limitation in Trier et. al (2014) regarding loose contents in the larger pouch.
- Aseptic technique is at least partially informed by other people in the workplace. What is "aseptic" may be left to interpretation: one may think that going over the sterile field is never acceptable, but others may find affordances in the packaging that justify breaching the sterile plane (i.e., the sterile interior of the packaging facing the field is covering your arm).
- The rationale for choosing different peeling locations may carry some clinical relevance, as indicated by the work presented in the starting position bench study. This, bolsters Smith et. al's (2009) postulation that opening forces may affect the contamination of sterile items. When opened, pouches with high seal strengths had more contamination than pouches with lower seal strengths.

However, caution should be exercised. The contamination results associated with the intermediate seal strength value were not found to be significantly different from the smaller or larger seal strength contamination rates. Also, there may be a positional effect of contamination (i.e., center versus corner), which was not analyzed concurrently with seal

strength. With the current peel study, the inferences about positional effect were limited by the fact that opening forces will be higher in the corner than the center when seal strength is the same.

A consistent theme across all three studies is that packaging design should be carefully considered in terms of usability. Designs do not necessarily communicate their functionality intuitively, and there may be consequences for ignoring this concept. Similarly, it is not enough to read standards of aseptic technique to understand it. Contextual drivers (e.g. staff availability, characteristics of the device, urgency of the situation, and type of procedure) may influence how a user interacts with packaged products. The connection to health outcomes was explored using simulated contaminants as part of an opening study as well as a bench test conducted with an Instron. In both studies, factors such as package size, peel location, and seal strength showed some correlation with increased contamination, though the causal link is yet to be defined. Additionally, perceptions of what is sterile and unsterile may vary. The practical significance of this is that opening pouches over a sterile field may not be necessarily "bad" from one user's frame of reference. If packaging design, such as a lengthy package for a catheter, enables or encourages this behavior, it is something that must be taken seriously and evaluated as a potential health risk. Barring that, the research community must establish that design is *not* a health risk, in order to better inform healthcare standards of practice. What the design affords to the user, in that one can breach the sterile field and still be "sterile", exists whether it is intended or not. Packaging designers and human factors engineers should work closely with healthcare providers (especially surgical technologists, who are not as highly represented in the literature) to understand contextual drivers for usage and if the design is communicating something it should not be communicating.

APPENDICES

APPENDIX A

Consent form and flyer

Research Participant Information and Consent Form

Title: An investigation of sources of contamination during simulated aseptic presentation of peel packs

Principal Investigator:
Dr. Laura Bix, School of Packaging, Michigan State University 517-355-4556

Secondary investigator:
Tony Trier, Grad. Student, Michigan State University, 989-860-6346

To participate in this research you must:

- be at least 18 years old
- have no known history of skin condition (e.g. eczema, latex allergy, etc.)
- be employed (currently or formerly) as a healthcare provider
- be willing to be videotaped presenting devices to a simulated sterile field
- **You have not participated in this experiment prior to now.**

Purpose of the research:
You are being asked to participate in a research study which investigates the link between package size and contamination during the aseptic presentation of a device to a sterile field. You are being asked to participate because you are a health care professional. The experiment will take about one hour to complete. From this study, researchers hope to develop packaging which eliminates contamination by making the 'opening process of packages' easier for health care professionals.

What you will do:
We will ask each subject to wear a pair of gloves and a lab coat (to help protect your clothes from non-toxic paint and/or coating that will be applied to some packages). Then we will video tape you while you try to open pouches/packages. We will ask you to open the packages a total of four (4) times.

All participants will be given small and large pouches, which are coated in Glitterbug® and/or Sargent Art® non-toxic acrylic paint. The gloves will be treated with either Glitterbug® cream, Sargent Art® or Speedball Ink to simulate contamination. In some instances the packages will also be treated. The Glitterbug cream is not visible unless ultra violet light is used.

Currently the researchers don't have any information that supports Glitterbug or Sargent Art paint are harmful to humans, as the paint is non-toxic and the Glitterbug cream is meant to be used directly on the skin in hand-washing exercises. Neither of these substances will be placed directly on your skin in this experiment. The gloves are non-latex, though we also screen for skin conditions for your safety.

We will ask you to present devices inside a series of four pouches to a simulated sterile field. When you are finished with the experiment, we will analyze the pouches and the gloves to determine if any traces of contaminant are visible. We are also analyzing items to determine if

the contents of the packages have become contaminated through the opening process. From these experiments we hope to develop better packaging which will result in packaging that creates 'less contamination' for use by health care professionals.

Then we will ask you to complete a survey regarding your professional background, years of experience within the healthcare field, years of experience presenting to sterile fields and experiences with packaging for medical devices.

We will also interview you regarding the prevalence and usage of certain package styles in your day-to-day work life as well as questions regarding aseptic technique. We will provide packages to serve as a visual example to assist you.

Benefit
Although there is no direct benefit to you for participating in this research, it is our hope that the data gathered can be used to understand the interface between healthcare professionals and packaging in order to create designs that will facilitate presentation of contents to the sterile field.

Risk
Risks associated with this study may include rash, blistering or other foreseen complications from exposure to the simulated contaminants. Glitterbug is an agent that is commonly used in infection control and hygiene programs aimed at healthcare providers and even children to provide information about appropriate hand hygiene. Sargent Art non-toxic paint was chosen as the other simulated contaminant. Neither of these will be applied directly to the skin, but to gloves and packages that that you interact with. There is a possibility your clothing may be stained or that your skin might become irritated from wearing the gloves. Further, you may be at risk of becoming embarrassed by being filmed in public or by your performance at delivering these items to the simulated sterile field.

Privacy & confidentiality
All information about subjects will be tied to a subject number and you will not be identified by name. The data for this project will be kept confidential to the maximum extent allowable by law. Information collected during this study will be stored in a password protected computer. These records will then be transferred and kept in a locked laboratory in the School of Packaging at Michigan State University for a minimum of three years. Research records will be accessible only to authorized researchers and members of MSU HRPP (Human Research Protection Program) at MSU.

Your rights to participate
Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time.

As part of this research study, all subjects are required to be videotaped. However, you have an option of allowing your video tape for public viewing in presentations of the study results or not. If you agree that your video tape may be used for public viewing, we will give you a yellow sticker, if not, you will be given a red sticker. The sticker will be attached to your lab coat during all research activities. Video tapes not used for presentations will be destroyed upon completion of the data analysis.

I voluntarily agree to allow the researchers to use the videotapes of the experiment for a presentation(s) of research results.

☐ Yes ☐ No Initials_____

Costs and Compensation
There is no cost for being in this study. You will be given $40 for participating in this study.

The right to get help if injured
If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *Dr. Laura Bix*, MSU, 517-355-4556, ext. 153 or Tony Trier 989-860-6346 with any questions or to report an injury.

Contact Information
If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Dr. Laura Bix, Laura Bix 517-355-4556; 153 Packaging Building East Lansing MI 48824 bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@ora.msu.edu or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI 48824.

Documentation of Informed Consent
Your signature below means that you voluntarily agree to participate in this research study.

_____ _____
Signature Date

You will be given a copy of this form to keep.

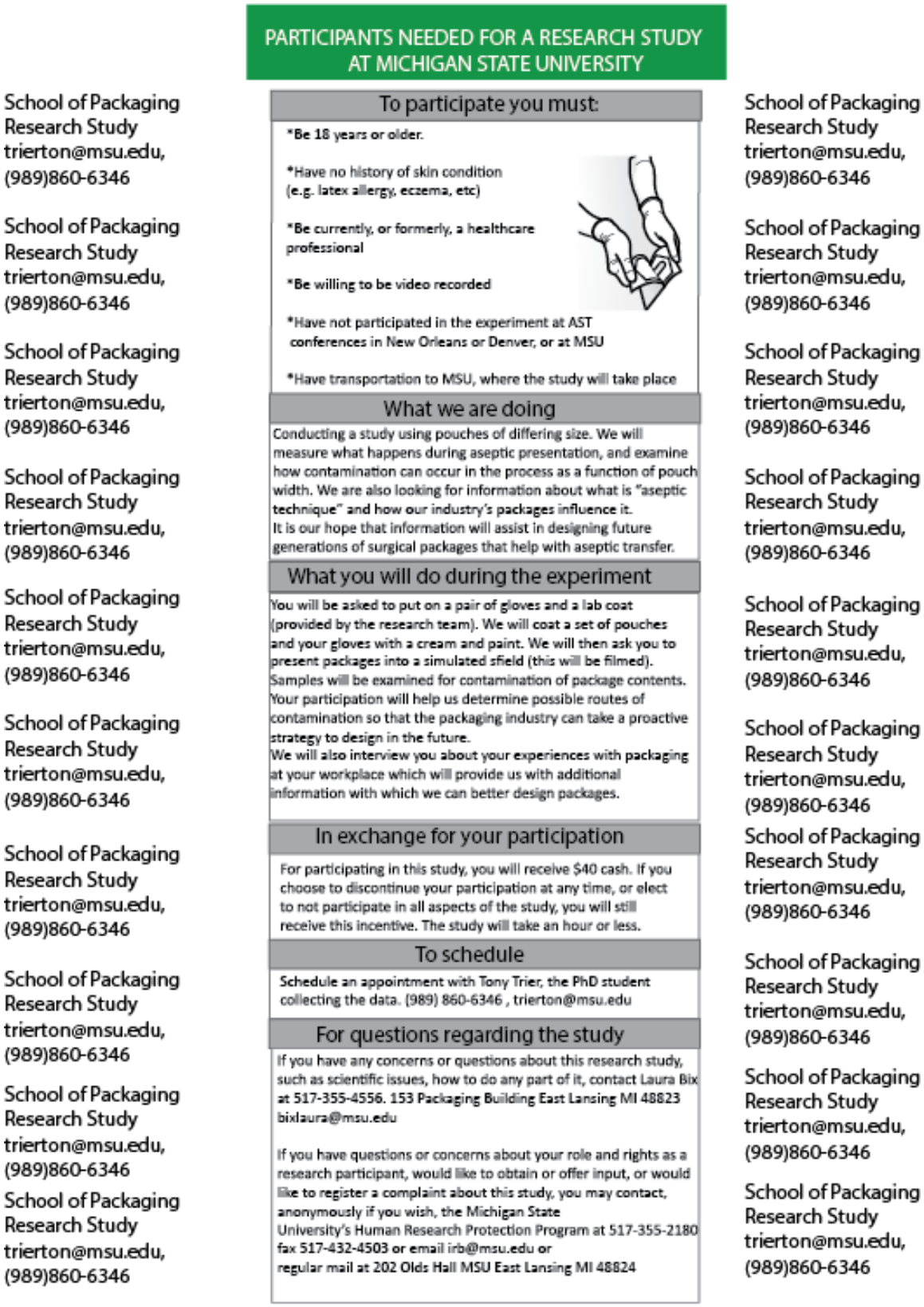


Figure 37 - Recruitment flyer.

APPENDIX B

Study documents

Subject # _____

Gender: Male Female Transgender Other

Profession: Surgical Technologist LPN RN CNA Nurse Anesthetist

Other (Please specify) _____

Years of experience: _____

Years of experience aseptically opening device packaging: _____

Dexterity: Left-handed Right-Handed Ambidextrous (Both)

What is the typical length of your shifts? _____

How many packages do you estimate you typically open during your shift? _____

What percentage of sterile packages do you open without assistance? _____

What type of medical product do you feel is the most problematic to get out of its package during your shift?

How many products per week do you estimate you throw away because you felt the contents were not sterile?

_____

Why do you throw away these products?

Water inside package **Expired product** **While opening, package contacted item**

While opening, item made contact with my hand **Other _____**

Date: _____
Location:_____
Interviewer: _____

Participant Number: _____ Age: _____

What we are doing in this survey is asking you about your opinions and experiences on packaging-related topics within aseptic technique. We, the research team, are admittedly not experts on the subject matter, so anything you can provide will be educational for us. There are no right or wrong answers, just answers that are based on your experience. We do not assign your answers with your name or workplace; the participant numbers are provided to disassociate your personal details from your answers and we will be deleting place names and personal names from the transcripts, so please answer as honestly as possible. If you do not wish to answer the question, you may decline to answer. If you do not understand a question or term, feel free to ask for clarification. I'll be asking you a series of questions and occasionally scribbling notes to myself to help our conversation along.

Definitions

First I would like to introduce a few definitions I will be using.

Dumping: One staff drops the item into the sterile field.

Flip: One staff member inverts the package and peels the film back to allow the item to drop into the field.

Toss: One staff member propels the item into the sterile field by "throwing" it from the package.

Picking: One staff member opens the package itself, and has another staff member remove the product.

Single Staff member techniques:

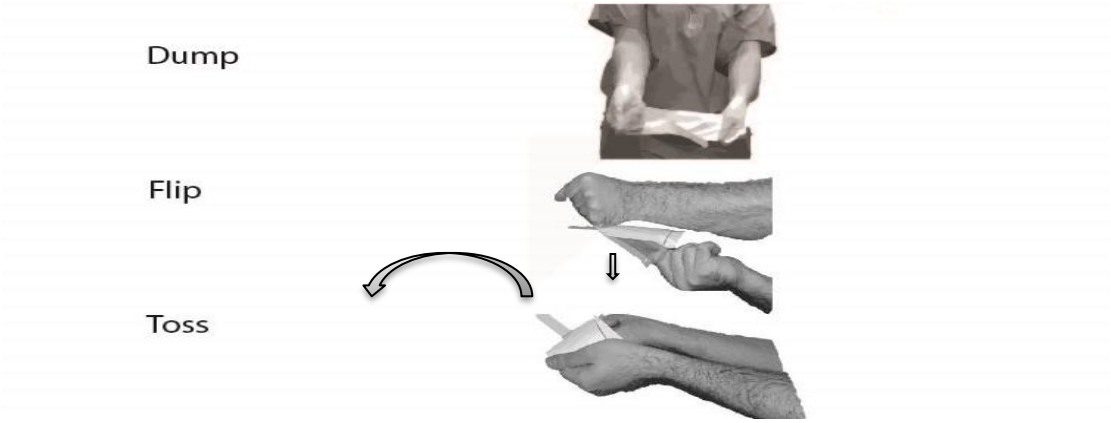


Figure 38 - Interview visual aid for presentations.

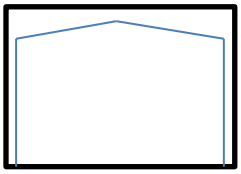
Section A – Large Packages

Please look at the packages with a [1] sticker on them. These will be considered "large" pouches in the following questions. The "large" aspect of the package only refers to size, so if you have any experiences with products/packages in other flexible pouches, please consider those as you answer the questions as well.

How many times in a month do you open "large" pouches or see them opened in the operating room?

Please detail any experience that you've had with "large" pouches *prior* to your participation in today's study. **If you *do not* have any experience, why do you suspect you do not see these pouches in the operating room?**

Where, on these packages (use the packages with the [1] sticker for reference), would you begin peeling the pouch open (where do you initially grab it), if you were to open the package? You can demonstrate if you like.
(Follow up: Why this location?) Also mark the location on the figure below the box.



Please mark (circle/X) on the figure where the participant would begin to peel the "large" packages if they were to attempt to open them.

*If participant's opening trials indicated they started at the corners but did not report it here

How are the "large" packaged products typically introduced to the sterile field where you work? Or **How**

would you expect these packages would be introduced, if things were different and you did see the in the OR? Can you please describe the process?

Are there/**Would there be** any situations which "single staff member" (flipping/tossing/dumping) are/**would be** more utilized for large pouches than "picking" (two staff member) techniques?

If tasked to open something like this, what do you consider is "good" technique?
What do you consider bad technique? (follow up: any stories which illustrate bad technique?)

To what extent do you agree that products in this style of package would be difficult to remove aseptically? (Follow up: Could I get you to elaborate on that?)

What specific aspects about large pouches make things easy or difficult to remove aseptically?

Section B – Long Packages

Please look at the packages with a [2] sticker on them. These will be considered "long" pouches in the following questions. The "long" aspect of the package only refers to size, so if you have any experiences with products/packages in other long, flexible (pouch) materials, please draw upon those as well.

How many times in a month do you open "long" pouches or see them opened in the operating room?

Please detail any experience that you've had with "long" pouches *prior* to your participation in today's study. **If you *do not* have any experience, why do you suspect you do not see these pouches in the operating room?**

How are the "long" package products typically introduced to the sterile field where you work, if at all? ? Or **How would you expect these packages would be introduced, if things were different and you did see the in the OR?**

Are there/**Would there be** any situations which "single staff member" (flipping/tossing/dumping) are/**would be** more utilized for large pouches than "picking" (two staff member) techniques?

If tasked to open something like this, what do you consider is “good” technique?
What do you consider bad technique? (follow up: any stories which illustrate bad technique?)

To what extent do you agree that products in this style of package would be difficult to remove aseptically? (Follow up: Could I get you to elaborate on that?)

What specific aspects about long pouches make things easy or difficult to remove aseptically?

Section C – Double Barrier Package

Please look at the packages with a [3] sticker on them. These will be considered "double barrier" pouches in the following questions. The "double barrier" aspect of the package only refers to the concept of a package containing an inner package, so if you have any experiences with products/packages in other flexible (pouch) materials, please draw upon those as well.

How many times in a month do you open "double barrier" pouches or see them opened in the operating room?

Please detail any experience that you've had with "double barrier" pouches *prior* to your participation in today's study. **If you *do not* have any experience, why do you suspect you do not see these pouches in the operating room?**

How is the inner package typically introduced to the sterile field where you work, if at all? Or **How would you expect these packages would be introduced, if things were different and you did see the in the OR?**

Are there/**Would there be** any situations which "Single staff member" (flipping/tossing/dumping) are/**would be** more utilized for large pouches than "picking" (two staff member) techniques?

If tasked to open something like this, what do you consider is "good" technique?
What do you consider bad technique? (follow up: any stories which illustrate bad technique?)

To what extent do you agree that products in this style of package would be difficult to remove aseptically? (Follow up: Could I get you to elaborate on that?)

What specific aspects about double barrier pouches make things easy or difficult to remove aseptically?

Section D – Aseptic Technique

We talked a lot about packaging today. In general, how do you learn to open a new package?

Are there any written instructions that you follow? What kind?

Please detail what you think is meant by “aseptic transfer” of items to the sterile field specifically in terms of product packaging. (Follow up if necessary: For example, what assumptions do you make about the package, what you look for when opening a new package, and any other comments you wish to add on the topic.)

Where did you learn this understanding of aseptic technique?

What standards do you follow at your workplace for aseptic technique, if any? Who determines the aseptic technique standards/methods you use at the workplace?

In how many different hospitals have you worked in a surgical capacity?

If you answered 2 or more, please describe any differences or similarities (without mentioning institution or educational institution names) between aseptic transfer of the items to the sterile field at each location.

If you received only one source of training (i.e., one institution did not teach aseptic technique), please make note of how you've applied that to the workplace.

Open ended: Are there any comments you wish to add? Things to clarify? Please use the space below to add any additional information you feel is important to our understanding of aseptic transfer. Please write below:

APPENDIX C

Statistical output

Kansas State University

Department of Statistics
Statistical Report #1:

Factors affecting contamination during sterile field presentation

Report prepared by: Nora M. Bello, Statistics, KSU
PI: Laura Bix, Packaging, MSU
Graduate student: Tony Trier, Packaging, MSU
Date: 03/31/16

Descriptive statistics

The frequency table below depicts an overall low frequency of contamination (2.4%).

CONT

CONT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1241	97.56	1241	97.56
1	31	2.44	1272	100.00

Frequency Missing = 8

A series of frequency tables are presented below to characterize the raw marginal frequency of contamination observed as a function of each of the factors considered in the study.

Table of CONT by Occupation

CONT(CONT) Frequency	CSFA-CFA	Nurse	Other	Student	SurgTech	Total
0	56	78	47	199	854	1234
1	0	2	1	9	18	30
Total	56	80	48	208	872	1264

Frequency Missing = 16

Table of CONT by Location

CONT(CONT) Frequency	Denver	MSU	NewOrlea	Total
0	306	303	632	1241
1	14	9	8	31
Total	320	312	640	1272

Frequency Missing = 8

Table of CONT by Size

CONT(CONT) Frequency	Large po	Small po	Total
0	610	631	1241
1	26	5	31
Total	636	636	1272

Frequency Missing = 8

Table of CONT by Coating

CONT(CONT) Frequency	Coating GB	Pa	Total
0	625	616	1241
1	11	20	31
Total	636	636	1272

Frequency Missing = 8

Table of CONT by Source

CONT(CONT) Frequency	Source Hand	Pouc	Total
0	620	621	1241
1	16	15	31
Total	636	636	1272

Frequency Missing = 8

The observed low frequency of contamination seems to be particularly problematic for Occupation, as at least one of the levels of Occupation shows no contamination (i.e. frequency = 0). This will be challenging when fitting a statistical model due to complete separation of datapoints (i.e. extreme category problem). Further, the overall low frequency of contamination in the dataset is likely to yield problems with estimation of higher order interactions between the factors evaluated in this study.

Probability of contamination

Statistical Analyses: A generalized linear mixed model was fitted to a binary response consisting of contamination, assuming a Bernoulli distribution. The logit link was used to connect the Bernoulli probability of contamination with the linear predictor. The linear predictor included the fixed effects of occupation (5 levels), pouch size (large vs. small), coating type (glitterbug vs. pain) and contamination source (hand vs. pouch) and all 2-way interactions amongst the latter 3 factors. It was not possible to fit any higher order interactions neither interactions with the occupation factor due to quasi-complete separation of datapoints (i.e. extreme category problem) and its implications for estimation and inference. Random effects in the linear predictor included subject nested within occupation. Random effects for location and subject crossed with pouch size yielded variance components that converged to zero and were thus removed from the model.

Overdispersion was evaluated using the maximum-likelihood based fit statistic Pearson Chi-Square/DF. No evidence for overdispersion was apparent. The final statistical model used for inference was fitted using a Laplace approximation to maximum likelihood; it was not possible to use Residual Pseudo-likelihood due to convergence problems associated with quasi-complete separation of datapoints for some factor level combinations. Degrees of freedom were approximated manually. The model was fitted using the GLIMMIX procedure of SAS (Version 9.4, SAS Institute, Cary, NC) implemented using Newton-Raphson with ridging as the optimization technique. Estimated least square mean probability of contamination and corresponding standard errors are reported in the columns labeled "Mean" and "Standard Error Mean" in the LSMean Estimates sections below. Estimated 95% confidence intervals are also presented under the columns labeled “Lower Mean” and “Upper Mean”. Relevant pairwise comparisons were conducted using either Tukey-Kramer or Bonferroni adjustments to avoid inflation of Type I error rate due to multiple comparisons, as appropriate in each case.

Results:

Model Information

Data Set	WORK.DATA
Response Variable	CONT
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix Blocked By	Subject(Occupation)
Estimation Technique	Maximum Likelihood
Likelihood Approximation	Laplace
Degrees of Freedom Method	Containment

Class Level Information

Class	Levels	Values
Subject	158	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 159 160
Location	3	Denver MSU NewOrleans
Occupation	5	CSFA-CFA Nurse Other Student SurgTech
Source	2	Hand Pouc
Coating	2	GB Pa
Size	2	Large pouch Small pouch

Number of Observations Read	1280
Number of Observations Used	1264

Response Profile

Ordered Value	CONT	Total Frequency
1	0	1234
2	1	30

The GLIMMIX procedure is modeling the probability that CONT='1'.

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	256.24
AIC (smaller is better)	280.24
AICC (smaller is better)	280.48
BIC (smaller is better)	316.99
CAIC (smaller is better)	328.99
HQIC (smaller is better)	295.16

Fit Statistics for Conditional Distribution

-2 log L(CONT | r. effects)	215.20
Pearson Chi-Square	681.41
Pearson Chi-Square / DF	0.54

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error
Intercept	Subject(Occupation)	1.0320	1.0256

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
Occupation	4	153	0.65	0.6304

Size	1	153	10.26	0.0017
Coating	1	310	0.98	0.3219
Coating*Size	1	310	0.18	0.6746
Source	1	310	0.03	0.8736
Source*Size	1	308	0.53	0.4658
Source*Coating	1	308	2.84	0.0930

Occupation Least Squares Means

Obs	Effect	Occupation	Mu	StdErrMu	LowerMu	UpperMu
1	Occupation	CSFA-CFA	1.74E-8	0.000012	0	1.0000
2	Occupation	Nurse	0.01095	0.01006	0.001763	0.06488
3	Occupation	Other	0.009013	0.01087	0.000820	0.09154
4	Occupation	Student	0.01949	0.01159	0.005959	0.06183
5	Occupation	SurgTech	0.008885	0.004691	0.003120	0.02504

Differences of Occupation Least Squares Means
Adjustment for Multiple Comparisons: Tukey-Kramer

Occupation	_Occupation	Estimate	Standard Error	DF	t Value	Pr > |t|	Adj P
CSFA-CFA	Nurse	-13.3629	661.26	153	-0.02	0.9839	1.0000
CSFA-CFA	Other	-13.1667	661.26	153	-0.02	0.9841	1.0000
CSFA-CFA	Student	-13.9485	661.26	153	-0.02	0.9832	1.0000
CSFA-CFA	SurgTech	-13.1522	661.26	153	-0.02	0.9842	1.0000
Nurse	Other	0.1963	1.3938	153	0.14	0.8882	0.9999
Nurse	Student	-0.5856	0.9182	153	-0.64	0.5246	0.9686
Nurse	SurgTech	0.2107	0.8587	153	0.25	0.8065	0.9992
Other	Student	-0.7818	1.2058	153	-0.65	0.5177	0.9667
Other	SurgTech	0.01444	1.1609	153	0.01	0.9901	1.0000
Student	SurgTech	0.7963	0.4987	153	1.60	0.1124	0.5018

Size Least Squares Means

Obs	Effect	Size	Mu	StdErrMu	LowerMu	UpperMu
11	Size	Large pouch	0.001808	0.2387	612E-119	1.0000
12	Size	Small pouch	0.000346	0.04579	117E-119	1.0000

Differences of Size Least Squares Means
Adjustment for Multiple Comparisons: Tukey-Kramer

Size	_Size	Estimate	Standard Error	DF	t Value	Pr > |t|	Adj P	Alpha
Large pouch	Small pouch	1.6543	0.5164	153	3.20	0.0017	0.0017	0.05

Coating Least Squares Means

Obs	Effect	Coating	Mu	StdErrMu	LowerMu	UpperMu
13	Coating	GB	0.000605	0.08001	584E-119	1.0000
14	Coating	Pa	0.001035	0.1368	1E-116	1.0000

Differences of Coating Least Squares Means
Adjustment for Multiple Comparisons: Tukey-Kramer

Coating	_Coating	Estimate	Standard Error	DF	t Value	Pr > |t|	Adj P	Alpha
GB	Pa	-0.5370	0.5413	310	-0.99	0.3219	0.3219	0.05

Source Least Squares Means

Obs	Effect	Source	Mu	StdErrMu	LowerMu	UpperMu
15	Source	Hand	0.000827	0.1093	799E-119	1.0000
16	Source	Pouc	0.000758	0.1002	732E-119	1.0000

Differences of Source Least Squares Means
Adjustment for Multiple Comparisons: Tukey-Kramer

Source	_Source	Estimate	Standard Error	DF	t Value	Pr > |t|	Adj P	Alpha
Hand	Pouc	0.08700	0.5463	310	0.16	0.8736	0.8736	0.05

Interpretation:

- Overall, the frequency of contamination during sterile field presentation was very low.

- There was no evidence for any main differences between occupations on the probability of contamination (P=0.63).

- We found evidence for a main effect of package size on the probability of contamination (P=0.0017), whereby contamination was more likely to occur when handling large packages as opposed to small packages. It is noted that, after adjusting for variability between subjects and any effects of coating and source, the marginal estimates of contamination were of very small magnitude (<1%), as expected given the low frequency of contamination observed. More specifically, the estimates were of 0.1% vs 0.03% for large and small packages respectively.

- There was no evidence for any main effect of coating (glitterbug or paint) on the probability of contamination (P=0.32).

- There was no evidence for any main differences between possible sources of contamination (hands vs. pouch) on the probability of contamination (P=0.87).

Additional Position Peel Test Output

Model Summary			
Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	33.483[a]	.410	.546

Table 34 - Position peel test model summary.

Classification Table					
	Observed		Predicted		
			Contaminated		Percentage Correct
			NC	Contaminated	
Step 1	Contaminated	NC	17	3	85.0
		Contaminated	3	16	84.2
	Overall Percentage				84.6

Table 35 - Position peel test classification table.

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Position(1)	3.409	.888	14.744	1	.000	30.222	5.305	172.158
	Constant	-.030	.444	.005	1	.946	.970		

Table 36 - Position peel test beta values.

Additional Seal Strength Statistical Output

Estimates

Mean	Std. Error	95% Wald Confidence Interval	
		Lower	Upper
.61	.067	.48	.73

Table 37 - Mean contamination rate of peeled pouches.

Estimated Marginal Means 2: DTime

Estimates

DTime	Mean	Std. Error	95% Wald Confidence Interval	
			Lower	Upper
0.75s	.40	.110	.21	.62
1.5s	.60	.110	.38	.79
3.0s	.80	.089	.57	.92

Table 38 - LS Mean contamination rates per dwell time condition.

Pairwise Comparisons

(I) DTime	(J) DTime	Mean Difference (I-J)	Std. Error	df	Bonferroni Sig.	95% Wald Confidence Interval for Difference
						Lower
0.75s	1.5s	-.20	.155	1	.590	-.57
	3.0s	-.40	.141	1	.014	-.74
1.5s	0.75s	.20	.155	1	.590	-.17
	3.0s	-.20	.141	1	.472	-.54
3.0s	0.75s	.40	.141	1	.014	.06
	1.5s	.20	.141	1	.472	-.14

Table 39 - Pairwise comparisons of flat seal pouches.

Pairwise Comparisons

(I) DTime	(J) DTime	95% Wald Confidence Interval for Difference
		Upper
0.75s	1.5s	.17
	3.0s	-.06
1.5s	0.75s	.57
	3.0s	.14
3.0s	0.75s	.74
	1.5s	.54

Table 40 - 95% Wald confidence interval for difference.

Overall Test Results

Wald Chi-Square	df	Sig.
8.095	2	.017

Table 41 - Wald chi-square of flat seal test.

APPENDIX D

Miscellaneous

Each squirt was approximately 4.59 (Std. Dev 0.71 g) determined from an average of 10 weighed amounts.

N=10 Samples ea	Average grams of cream per side (pumps)	Standard Deviation
Small pouch (1 side)	0.5735 (1)	0.3067
Large pouch (1 side)	2.0625 (3)	0.7606

Table 42 - Average grams of cream on a trial run of 10 pouch measurements.

	A	B	C	D	E	F
1	2.60833	6.23588		2.591669	6.219219	
2	2.48213	4.6046		2.465469	4.587939	
3	2.29012	5.0027		2.273459	4.986039	
4	2.6455	8.94476		2.628839	8.928099	
5	1.95432	4.88807		1.937659	4.871409	
6	2.76725	5.13946		2.750589	5.122799	
7	2.58042	5.49502		2.563759	5.478359	
8	2.30397	5.24287		2.287309	5.226209	
9	2.35294	5.38523		2.336279	5.368569	
10	2.48804	4.73514		2.471379	4.718479	
11	1.742	5.27792		1.725339	5.261259	
12	3.13207	5.75487		3.115409	5.738209	
13	2.63996	5.01998		2.623299	5.003319	
14	2.2046	4.55361		2.187939	4.536949	
15	2.62388	5.65882		2.607219	5.642159	
16	2.99932	5.94635		2.982659	5.929689	
17	2.55239	4.26209		2.535729	4.245429	
18	2.24979	5.01149		2.233129	4.994829	
19	2.01526	5.58229		1.998599	5.565629	
20	2.20793			2.191269		
21	CENTER	CORNER		CenterADJUST	CornerADJUSTED	
22	2.442011	5.407429	MEAN	2.425350	5.390768	
23	0.338502	0.991787	STDEV	0.338502	0.991787	
24						
25						

Figure 39 - Adjusted absolute peak loads. Columns A and B represent original values, D and E represent adjusted values for string interference on custom apparatus.

	A	B	C	D	E	F	G
1		0.75	0.75Adjust	1.5	1.5Adjuste	3	3.0Adjusted
2	1	1.30491	1.28825	3.26217	3.24551	5.85292	5.83626
3	2	1.34183	1.32517	3.00295	2.98629	6.05512	6.03846
4	3	1.39684	1.38018	3.08153	3.06487	4.7481	4.73144
5	4	1.40643	1.38977	4.97181	4.95515	4.33696	4.3203
6	5	0.93062	0.91396	3.78765	3.77099	4.94521	4.92855
7	6	0.86206	0.8454	3.18306	3.1664	4.71119	4.69453
8	7	1.01276	0.9961	4.32378	4.30712	4.00497	3.98831
9	8	1.47082	1.45416	5.25802	5.24136	3.2594	3.24274
10	9	1.34232	1.32566	4.68964	4.67298	5.29263	5.27597
11	10	1.41406	1.3974	1.42195	1.40529	4.26867	4.25201
12	11	1.07187	1.05521	1.54966	1.533	3.51869	3.50203
13	12	1.11142	1.09476	3.42745	3.41079	4.86046	4.8438
14	13	1.05455	1.03789	3.31713	3.30047	6.19629	6.17963
15	14	1.36099	1.34433	5.95224	5.93558	3.92985	3.91319
16	15	1.14838	1.13172	3.83455	3.81789	6.35739	6.34073
17	16	2.13691	2.12025	3.80912	3.79246	5.33404	5.31738
18	17	1.42707	1.41041	1.97946	1.9628	5.22156	5.2049
19	18	1.18744	1.17078	5.56711	5.55045	7.02608	7.00942
20	19	1.21629	1.19963	3.79576	3.7791	6.37173	6.35507
21	20	2.22812	2.21146	3.62257	3.60591	5.22941	5.21275
22	MEAN	1.32128	1.30462	3.69188	3.67522	5.07603	5.05937
23	STDEV	0.34338	0.34338	1.22142	1.22142	1.02051	1.02051
24							

Figure 40 - Adjusted absolute peak loads. Highlighted colums represent values adjusted for string interferences on custom apparatus.

Opening “first pull” locations taken from small, medium, and large chevron pouches. Observational data from Trier (2012). Manuscript preparation in progress.

	Near Corner	Center	Far Corner	Total
SMALL	11 (5.7%)	177 (91.2%)	6 (3.1%)	**194**
MEDIUM	50 (25.8%)	101 (52.1%)	43 (22.2%)	**194**
LARGE	70 (36.1%)	82 (42.3%)	42 (21.6%)	**194**

Table 43 - Frequency of occurrence of starting peel location by pouch size. Percentages are calculated out of 194 trials

Custom Gasket Creation Process

The standard tray gasket was removed from one cavity and replaced with a customized rectangular seal gasket. The finished gasket measured 6.30 in x 4.72 in (OD) in size, with an internal dimension of 5.0 in x 3.43 in, and with a gasket width of 0.31 inches. The design of the customized gasket was created using SolidWorks (Dassault Systèmes, Waltham; MA). After creation of the part in SolidWorks, the mold was 3D-printed with a fifth generation MakerBot Replicator (MakerBot Industries; Brooklyn, NY). The printing material chosen was a black-colored polylactic acid (PLA; Makerbot Industries; Brooklyn, NY) due to material availability and the ability of the material to resist warping during the cooling process.

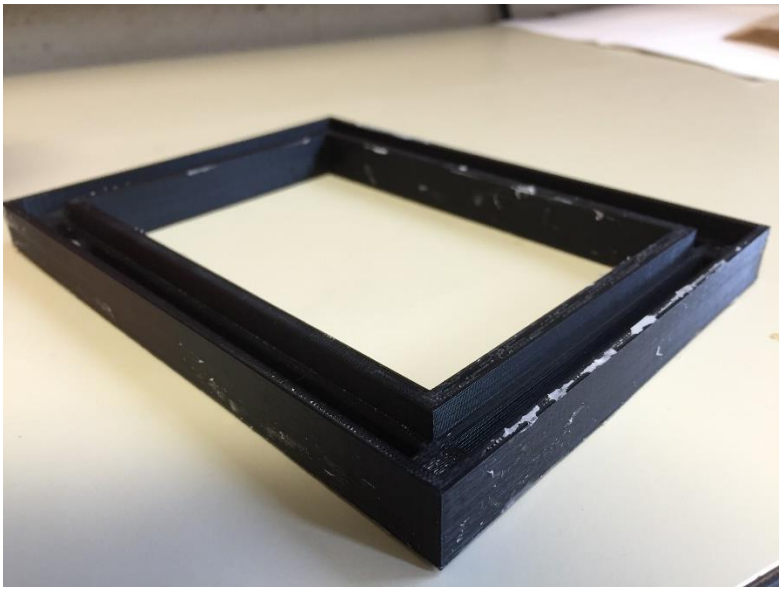


Figure 41 - Customized mold for sealing gasket.

After the mold was printed and the supports were removed, the printed mold cavity (see Figure 41) was filled with heated silicone (Silpak, Inc; Pomona, CA; Figure 42) and allowed to harden. To size the square seal appropriately, pegs on the bottom and right side were removed such that the hardened gasket could rest on the top of the tray sealer's cavity.

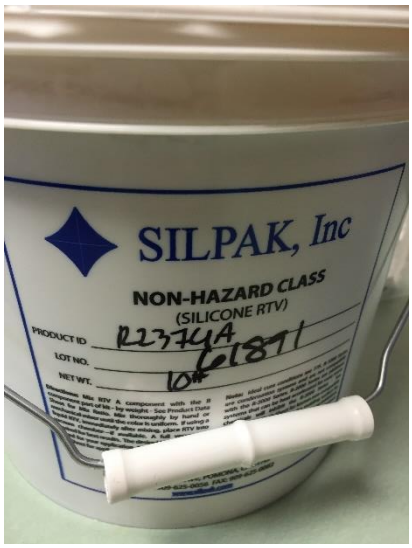


Figure 42 - Silicone for creation of seal gasket.

The customized gasket was used for three sealing conditions which varied in dwell time alone. The sealing temperature was 145°F with 70 PSI of pressure for all three processing conditions, with varied only in dwell times of 0.75 seconds, 1.5 seconds, and 3.0 seconds. Dwell times were arbitrarily chosen based on the 3.0 second condition since higher dwell times created seals that were welded or caused fiber tear. Since the top-most part of the seal dye was the most stable (locked into the cavity), that portion of the sealed pouch was selected as the end to be opened. Samples made using the gasket were marked prior to conditioning in order for the research team to identify the seals for later testing using the Instron Universal tester.

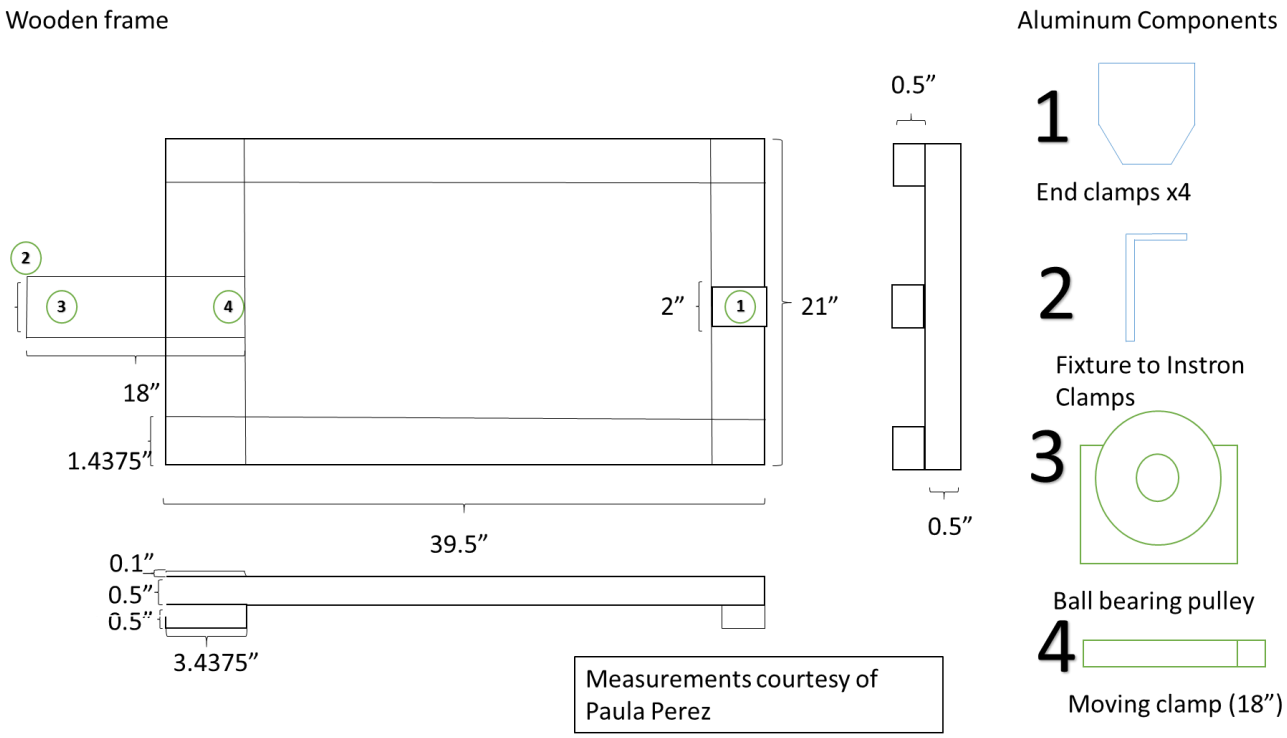


Figure 43 - Custom peel rig dimension

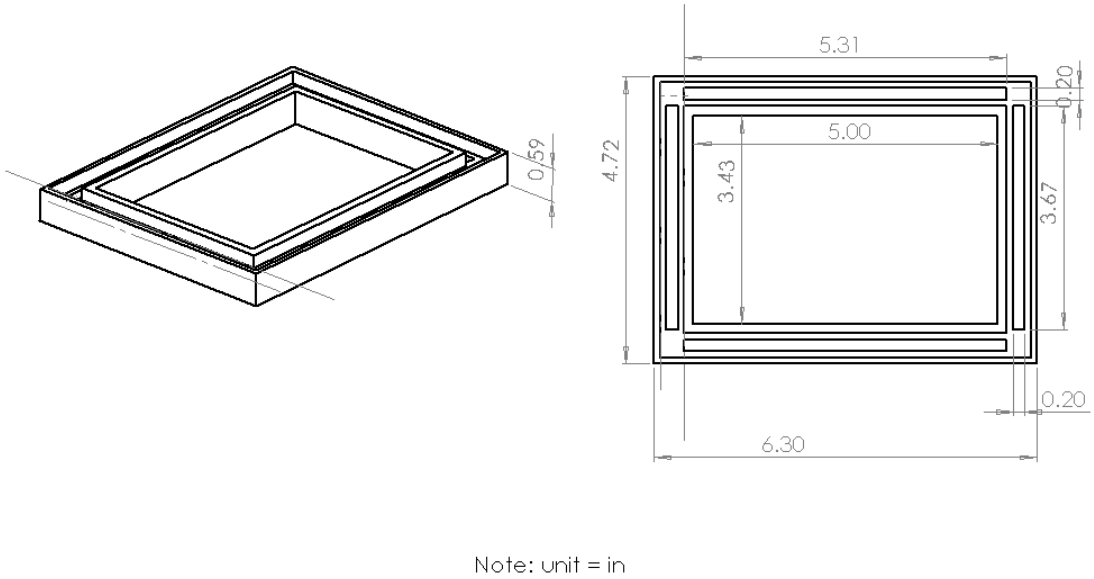


Figure 44 - CAD Drawing of Mold

APPENDIX E

Glossary

GLOSSARY

A

Affordance: Action possibilities that exist in the world which are unique to the characteristics of the individual regardless of whether or not they are perceived. (Gibson, 1979)

Aufforderungscharakter: Kurt Lewin's term meaning "demand character" which refers to the communication between a the phenomenal object and its perceiver in the presence of internal tension. (Lewin, 1951)

Aseptic presentation: Defined as "introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination" by the medical device industry. ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems " 2006).

D

Design element – General blanket-term referring to specific characteristics such as size, amount of gripping space, rigidity, and more.

E

Episodic memory – According to Endel Tulving, this part of the memory is comprised of personally experienced events. (Tulving, 1972).

H

Healthcare-associated infection: Infections acquired as a result of healthcare received. Not incubating or otherwise acquired prior to treatment. (Adapted from Food and Drug Amendments Act, 2007)

Human Factors: Application of human data, limitations, and insight into design (adapted from AAMI/ANSI HE75:2009 "*Human Factors Engineering – Design of Medical Devices)*.

P

Phenomenology: The study of experience, including emotions. This dissertation limits this scope to the Gestalt psychologists' take on phenomenology as it pertains to communication between an object and its perceiver.

Principle of Visibility: Lidwell's principle that designs should not only communicate *what to do*, but also *what happens when you do it.* (Lidwell, 2010).

Procedural memory: Memory that is bridged between actions and the conditions in which they take place (e.g., balancing while ice skating). (Tulving, 1995).

R

Recognition over recall: Lidwell's principle that designers should provide stimuli which are easily recognizable and do not rely on the user to recall them from memory. (Lidwell, 2010).

S

Semantic memory: Generalized memory whose scope is beyond individual events. (Tulving, 1972).

Signal-to-noise ratio: Lidwell's principle that unnecessary stimuli should be removed in order to make the intended design more noticeable. (Lidwell, 2010)

Signifier: That which indicates where an action should take place when the user is interacting with a package. (Norman, 2013)

Situated learning: Body of literature which generally states that learning is developed in part by context in which its learned. In this manuscript, Lave and Wenger's (1991) and Eraut's (2000,2004) professional learning work guide the framework in the qualitative piece of this work.

Sterile: An absence of microbes, particularly those which are viable (adapted from ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems ", 2006) .

Sterile barrier system: Defined as "minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use" by the medical device industry ("ISO11607-Part 1, Packaging for terminally sterilized medical devices—Part 1:Requirements for materials, sterile barrier systems,and packaging systems ", 2006).

V

Valence: The characteristic of attraction or repulsion with an object and its perceiver (e.g., an apple to a hungry person).

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