PERCEPTIONS OF MEDICAL DEVICE PACKAGING USED BY OPERATING ROOM PERSONNEL

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ABSTRACT

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Medical device packaging plays a vital role in patient health and the intensive user environment. When little conscious thought is given to packaging, it has the potential to compromise patient outcomes.

Seven focus groups consisting of total of 21 operating room healthcare personnel were conducted in the greater Lansing and Cleveland areas and analyzed with a coding scheme. Research objectives were: to identify common problems associated with medical device packaging in order to provide a basis for future research. The most promising research avenues were identified by organizing focus group data into qualitative “thought units” based on their frequency, salience and relevance to medical packaging design. Different packaging features were ranked by their importance level.

Participants’ responses to focus group questions (N=1095 thought units) converged around the themes of: opening and aseptic presentation, quick identification and packaging waste. Findings suggest opening and aseptic presentation were of primary concern to respondents; 49.7% of total thought units were categorized as opening and aseptic presentation while 16.4% of recorded units focused on the identification of contents. Congruent with these findings, participants ranked grip space, preopening integrity, seal/peel strength and easy to read label as most important.

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CHAPTER 1
INTRODUCTION

Due to medical device packaging's vital role in patient health and the intensive user environment, when little conscious thought is given to packaging, it has the potential to compromise patient outcomes (Sherman, 1998). Although the packaging of medical devices have some of the same burdens as their commercial counterparts, the critical nature of the contents demands emphasis on aspects of design that are different from retail packages. For instance, designers of device packages must create designs which will facilitate sterilization, maintain sterility throughout distribution and handling and also enable the presentation of a product into the sterile theater aseptically.

I. THE PRIME FUNCTION OF MEDICAL DEVICE PACKAGING

Medical device packaging must provide the same functions as the packaging of other products, but has a different emphasis due to the specialty of the contents and the criticality imposed by the environment and task. For medical devices, there are five basic goals that the packaging must accomplish or facilitate: sterilization, protection, identification, environmental friendliness and ease of use (Sherman, 1998) (Pilchik, 2003).

i. Sterilization compatibility

For each sterilization process used, appropriate selection of material is imperative. Material properties should be able to withstand the worst-case process

conditions and not be adversely affected (Edmund A. Leonard, 1996) (Sherman, 1998) (Nicolette, 1996).

ii. Protection

More than simply containing the products for purposes of unit identity or shipping, protection in medical device industry has two meanings: providing an adequate sterile barrier if the devices are needed in a sterile application; and minimizing physical damage to the product throughout its entire life (Sherman, 1998). For these reasons, packaging materials and package construction are carefully chosen so that the medical device is protected from microorganisms and physical damage. Packages are designed such that there is a high degree of assurance that the sterility of the contents is maintained until the package is opened (Nicolette, 1996) (Ramona Conner, 2006). More specifically, the packages are required to provide protection from shock and vibrating, crushing, puncturing, tearing, bursting, cracking, splitting, humidity, heat, so that integrity could be maintained (Ramona Conner, 2006) (Laura Bix, 2009).

iii. Identification

The US Food and Drug Administration (FDA) governs the label copy that appears on medical devices that are distributed in the US. In order to prevent errors that are potentially caused by look-alike medical device packages, the package serves an important role in the differentiation of products (Sherman, 1998) (Laura Bix, 2009). Critical information including: product type, size, product code, instructions for use, expiration date and precautions must be clearly marked, or affixed to the package (Sherman, 1998). In addition, the quality of printing must be legible, accurate and clear (Sherman, 1998) (Laura Bix, 2009).

iv. Environmental friendly

Thorough design considers the entire-life circle of the package. The solid waste the package generates has raised concern among healthcare professionals since the packaging materials constitute a large volume of hospital waste (Sherman, 1998). It has been estimated that medical waste generates about 600,000 to one million tons of waste annually and is increasing each year (Valenti, 2000).

v. Ease of use

Although quite dependent on the setting of use, for many medical device packages, quick and easy opening and sterile removal of contents from primary packaging is crucial (Laura Bix, 2009). The need for asepsis, coupled with the sometimes chaotic conditions of use, mandate human factors considerations (Sherman, 1998). Packaging materials should be strong enough to be opened without tearing, yet facilitate manual opening without imposing excessive stress on the device or user (Sherman, 1998) (Laura Bix, 2009). The user environment should be taken into consideration since it has a big influence on desirable packaging features. For instance, a transparent component is frequently designed into packaging in an attempt to assist providers with rapid identification of the package contents. Packages using slippery

materials or that are asymmetric in terms of their weight distribution can be hard to hold, resulting in difficulty with manipulation, and, ultimately, opening (Pilchik, 2003). Within the intraOperative environment (see section entitled OR Personnel), it is paramount that sterile medical devices be removed without contamination (Laura Bix, 2009). That particular need has led to the development of sterile barrier systems (SBS)[1] which permit the aseptic presentation of contents.

Research into SBS has primarily focused on the areas of sterilization (Hackett, 1996) (Scholla, 1999) or maintenance of the SBS (Laura bix, 2004) (Hackett E, 2000); far less is known about package design and asepsis (Kwong SJR, 2012). The needs of the healthcare provider (including the ability to aseptically present) are an area in need of study.

This project has two primary objectives:

- To investigate the attributes of packaging for medical devices that are desirable to the healthcare personnel involved with the operating room environment.

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[1] ISO 11607 Part I defines the Sterile Barrier System (SBS) as the “minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.”

- To gather insights regarding these attributes through shared anecdotes.

II. OR PERSONNEL

To better understand the packaging needs of OR healthcare personnel, a general job description of the OR healthcare personnel and their work environment are given.

i. Job description

Operating Room (OR) personnel that frequently handle packages include Surgical Technologists and OR nurses. Surgical Technologists are often referred to as scrub technicians, or surgical technicians (US Bureau of Labor Statistics, 2010). They are unlicensed, assistive personnel working as a part of the team delivering surgical care, under the supervision of a Surgeon and Registered Nurse (RN). They have requisite skills in sterile and aseptic presentation. OR nurses are referred to as Perioperative[2] Registered Nurses to more accurately reflect the duties during the preoperative, intra-operative, and postoperative phases of the patient's surgical intervention (Operating room nursing: Perioperative role, 1975). They use the nursing

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[2] AORN defines Perioperative as the "Surrounding the operative and other invasive experience, ie, before, during, and after"

process, develop a plan of nursing care and then coordinate and deliver care to patients undergoing operative or other invasive procedures (Ramona Conner, 2006). They possess skills and knowledge for: patient assessment, the creation and maintenance of a safe, sterile surgical environment, and provide ongoing monitoring of the patient's physical and emotional well-being. There are several roles that perioperative nurses fill to ensure quality patient care in the operating room and beyond.

a. Scrub nurse

The scrub nurse contributes his or her ability to anticipate, plan for, and respond to the needs of patient, surgeon, and other team members (Ramona Conner, 2006). They perform a surgical hand scrub and aseptically don a surgical gown and gloves (P, 1991). The scrub nurse is cognizant of patient responses to a series of surgical events and contributes to the overall well-being of a patient by being vigilant in assessing the patient's condition and visually monitoring devices (Groah, 1983). They work directly with the surgical team within the sterile field by anticipating and passing the necessary instruments, sponges, and other supplies during the surgical procedure (Groah, 1983) (Rothrock, 2003).

b. Circulating nurse

Circulating nurses works outside the sterile field. They are responsible for managing nursing care within the OR by observing the surgical team from a broad perspective, coordinating patient care and case flow of the surgical suite and assisting the team in creating and maintaining a safe, comfortable environment (McGarvey, 2000). Additionally, they assess the patient's condition before, during and after the operation (P, 1991).

c. Registered Nurse's First Assistant (RNFA)

The RNFA is a perioperative registered nurse that has gone through additional extensive education and training to deliver surgical care. The RNFA works in collaboration with the surgeon and health care team members to ensure an optimal outcome for the patient (Ramona Conner, 2006). In surgery, RN first assistants function in an expanded perioperative nursing role. They are allowed to use instruments/medical devices and handle or cut tissue in the surgery while the other nursing and technologist roles do not (Ramona Conner, 2006) (McGarvey, 2000).

d. Surgical Technologists

Surgical technologists perform the duties of both the circulating and the scrub roles. They assist the surgical team and operating staff in preparing and cleaning the OR and collaborate with the team to ensure a safe operating environment and the proper functioning of all equipment. They help set up, break down and clean the operating room and aid the surgical team in preparing instruments, scrubs, medications, and other supplies that will be necessary during the surgical procedure (US Bureau of Labor Statistics, 2010). They perform basic tasks such as checking patient's medical charts and consent forms, preparing sterile dressings, and closing incisions.

ii. Working Environment

The OR has three different areas: Pre-OP, Intra-OP and Post-OP. Pre-OP is primarily used for the preparation of the patient for surgery from both a physical and psychological perspective. Specific activities that happen preoperatively include: identification and verification of patient details, safe positioning of the patient specific to

their operation, preparation of equipment and instruments (L.J., 2004) (Kneedler J.A., 1991).

The Intra-OP period occurs from the time the patient is transferred from Pre-OP to the operating table (located within the OR) to the time they are admitted to the recovery area (L.J., 2004). The Intra-OP area is the place where patients have surgery, so maintaining the sterile environment to reduce the likelihood of infections is paramount (L.J., 2004) (Kneedler J.A., 1991).

The Post-Op period begins with the admission of patient to the recovery area and ends when the surgeon discontinues follow-up care (L.J., 2004) (Kneedler J.A., 1991). The range of nursing activities include: communicating information about the patient's surgery to the appropriate personnel within the recovery area and ensuring that the patient has a safe recovery from surgery (McGarvey, 2000). It is more common that the medical device products used in Pre-Op and Post-Op do not have the sterility requirements compared with those used in the Intra-Op portion of the process (L.J., 2004).

Within the OR, or the intra-operative environment, the setting is generally clean, well-lit (though this may not be the case for certain procedures) and cool. Operating Room personnel are required to stand for long periods of time and remain alert during surgery. The traditional shift length for OR nurses is eight hours. However, several reports suggest that OR nurses are working longer hours with fewer breaks and often inadequate time for rest between shifts (Page, 2004). Twenty-four hour call shifts are cited as becoming more common which leads to concerns for patient safety due to the fatigue and performance degradation caused by sustained work hours (Ramona Conner,

2006) (Rogers, 2004). It has also been suggested that nurses are directed to work beyond their scheduled work shift to augment staffing requirements, meet unexpected patient needs, or satisfy organizational expectations. This is primarily listed as a problem in hospitals.

III. ASEPTIC TECHNIQUE

Aseptic technique refers to “procedures that are performed to minimize microbial contamination and reduce patient risks for surgical site infections” (Dougherty L, 2004). This is encompassed in procedures such as preparing a wound dressing or performing an invasive procedure (e.g. inserting a urinary catheter). Preventing surgical site infections in the OR is a primary goal of the surgical team, and the principles of aseptic technique play a vital role toward this end. Activities involving creating and maintaining a sterile and safe surgical environment, including the presentation of medical devices into the sterile field aseptically, are performed to support the asepsis of the operating room environment (Standards, recommended Practices and Guidelines, 2006).

Aseptic technique involves the way the healthcare personnel handle packages and their contents. It should be noted that the reduction in tactile sensation and manual dexterity that occur when wearing gloves has been noted to increase the difficulty personnel experience when presenting items to the sterile field, particularly if the gloves are pulled tightly over the finger tips (Dodds, 1990). Largely as a result of concerns related to allergens, there is an increasing prevalence of non-latex gloves in use in healthcare settings.

As mentioned previously, research into sterile barrier systems (SBS) has primarily focused on the areas of sterilization (Hackett, 1996) (Scholla, 1999) or maintenance of the SBS (Laura bix, 2004) (Hackett E, 2000); far less is known about package design and asepsis.

As such, a discussion of the recommended practices regarding aseptic technique is quite germane to this topic. Numerous healthcare settings have their own policies and procedures regarding aseptic presentation which are varied. Both the Association of perioperative Nurses (AORN) and the Association of Surgical Technologists (AST) have overarching guidelines for the process as well. The recommended practices of aseptic techniques, developed by the AORN Recommended Practices Committee, are guidelines that are intended to provide direction and information (Ramona Conner, 2006); they include the following principles.

i. The function of scrubbed persons within a sterile field

Only the sterile members, or scrubbed personnel, can work directly in the surgical field. Scrubbed personnel are defined as those who will perform a surgical hand scrub prior to donning their sterile gown and gloves (Fogg, 2003). Scrubbed persons must wear a sterile surgical gown, mask, scrub attire and gloves at all times within the sterile field (Mangram, 1999). Once the scrubbed person dons the sterile surgical gown, the gown's sterility is limited to the gown portions that are directly viewed by the scrubbed person. These sterile areas include the gown front, from chest to the sterile field level, and the sleeves from two inches above the elbow to the cuff (Ramona Conner, 2006) (Mews, 2000).

ii. Sterile drapes are used to create a sterile field

Sterile surgical drapes are handled only by scrubbed personnel to establish an aseptic barrier to minimize the passage of microorganisms from non-sterile to sterile areas. Under no circumstances should the sterile drape be removed or rearranged once the drapes are positioned (Fogg, 2003) (L.J., 2004). After the patient and operating room tables are draped, only the top surface of the draped area is considered sterile. The 1-inch outer edge of sterile field is usually considered non-sterile (Mews, 2000).

iii. All items used within a sterile field must be sterile

To avoid cross contamination that may occur between sterile and non-sterile items/areas, only sterile items are presented to the sterile field (Ramona Conner, 2006). AORN considers the sterility of a package to be event-related, rather than time-related (Connor, 1994). According to AST recommended standards of practice, effective October 2009, the concept of event related is related to “how sterile packages are handled and that contamination is event related rather than time related”. An event is “any damage to a package, or incident that compromises the sterility of the content”. To ensure sterility, all sterile items should be thoroughly inspected immediately for seal, package integrity and inclusion of a sterilization indicator, as well as expiration date, prior to introduction onto the sterile field (Ramona Conner, 2006) (Japp, 1997). Any sterility indicators that are present are inspected to verify the appropriate color change for the selected sterilization process. Any package which has been compromised or outdated should be considered contaminated and not be allowed to use (Ramona Conner, 2006) (Japp, 1997) (B Gruendemann, 2001).

iv. All items introduced onto a sterile field should be opened, dispensed, and transferred by methods that preserve sterility and integrity

The sterile items should be either presented directly to the scrubbed person or placed on the sterile field securely to maintain the integrity. "Flipping," a technique in which sterile items are tossed onto the sterile field, is not recommended because of the potential contamination it may cause like penetrating the drape, or rolling off the sterile field (Fogg, 2003) (L.J., 2004).

Sharp or heavy objects should be presented directly to the scrubbed person or opened on a separate surface to avoid the penetration of the sterile drape, or displacement of other items on the sterile field if dropped (Fogg, 2003) (L.J., 2004).

The materials that form each side of a peel pouch should be rolled down with the inner contents toward to the scrubbed person. The inner edge of the heat seal of the package is considered "the line separating the sterile from non-sterile" (Fogg, 2003) (L.J., 2004). Contamination can occur when the edges of the package curl or the contents slide over the unsterile edge.

Rigid container systems should be opened on a separate surface. The lid should be lifted toward the person opening the container (Ramona Conner, 2006).

Each institution should determine how to handle double packaged items; specifically, a decision needs to be made regarding whether one or both packages will be opened prior to presentation to the sterile field.

IV. MEDICAL DEVICE PACKAGING TYPES

Medical device packaging varies in sizes, materials, opening features, and shapes according to its intended use and the sterilization methods that are utilized. Medical device packaging is commonly separated into two categories: flexible pouches and lidded thermoformed trays (Sherman, 1998).

i. Flexible pouches

Flexible pouches have been widely adopted by the medical device industry to fit the needs of a diverse range of products. Flexible pouches are commonly chosen for low-cost, high-volume and lightweight devices including: gloves, catheters, tubing, dressing and others (Sherman, 1998). They also can offer the advantage of transparency.

The usual construction of pouches includes adhesive coated paper to paper; coated or uncoated paper to film; coated or uncoated Tyvek® to film; coated Tyvek® to Tyvek®; and coated or uncoated film to film. It should be noted that not all types of pouches are suitable for all sterilization methods. Pouches fabricated from porous materials, like paper and Tyvek®, can be used with sterilization methods which need gas to pass through the package, such as ethylene oxide (EtO). Tyvek®, however, is limited to low temperature methods only (L. Jones, 1995) (Brunch, 1993). Pouches composed entirely of non-porous materials (e.g. film to film) are usually limited to radiation sterilization or (under controlled-conditions) steam autoclaving (Sherman, 1998) (Nicolette, 1996).

A discussion of different commercially-available, flexible packaging types follows, including: flat pouches, gusset pouches, paper bags, vented bags, header bags

and chevron header pouches (Sherman, 1998). Chevron pouches, corner peel pouches, tear pouches represent the three typical opening features in medical device packaging. Chevron, corner peel pouches, are peel-to-open while tear pouches are tear-to-open.

a. Chevron pouch

The most popular form of peel pouch is known as the “chevron” pouch (Sherman, 1998). The peak-shaped chevron seal at one end of package is designed to distribute peel forces along the relatively narrow seals that generally parallel the length of the package. This concentrates the opening force at the tip of the peak so the healthcare personnel have a better control when presenting contents (Figure 1) (Sherman, 1998). This is particularly vital for packs of medical or surgical items.

Figure 1: Chevron pouch

(For interpretation of the references to color in this and all other figures, the reader is referred to the electronic version of this thesis.)

b. Corner peel pouch

A corner peel pouch is formed with the incorporation of a seal across one or two corners of the pouch. This approach leaves a peel tabs at the corner (Figure 2) (Sherman, 1998). The use of a stud embossed in one of the two webs can be added in

an attempt to separate the webs, in the interest of aiding the user. For a given size pouch, corner peel opening features can provide greater inner space since the remaining seals are at the outermost edges of the package (Sherman, 1998).

Figure 2: Corner peel pouch

c. Tear pouches

Tear pouches are generally squared at the corners and incorporate a notch which catalyzes the tearing of the pouch as the mechanism for opening (Figure 3). Tower® Tear is one solution to the tear-open medical device packaging. Tear pouches were first used in 1962, then a U.S. federal trademark registration was filed for Tower Tear by AMCOR FLEXIBLE INC., in 2008. They feature a linear-tear capability as an integral part of the packaging which is usually incorporated into pouches and bags. This patented feature, built into the film during its formation, enables the user to tear the packaging open cleanly along a straight, sharp line, without the irregular tearing that is typical of plastics. This eliminates the need for scissors or other instruments to open the package, and is used as an alternative to peel-able pouches.

Figure 3: Tear pouch

d. Header bags

Header bags are designed with a porous material such as a peel-able paper or Tyvek® strip running completely across the top (Sherman, 1998) (Figure 4). Compared with the normal chevron pouch, which uses the Tyvek® web as an entire face, header bags offer cost savings by reducing the amount of Tyvek® material present in the pouch. Aseptic presentation is possible for header bags when careful technique is employed (Sherman, 1998).

Figure 4: Header bag

e. Chevron header pouches

Being inspired by the concepts of header bags and chevron pouches, Duet introduced a new hybrid design which is called chevron header pouch to the market in 2007 (Figure 5) (Operating room personnel input critical to new peelable chevron header pouch, 2007). By borrowing the “header” concept from the header bag, the amount of Tyvek® typically found in a chevron pouch is reduced, thereby removing the cost. The chevron header pouch is composed of two portions with different materials. The top web is constructed by sealing a Tyvek strip to a polyester/extrusion-coated sealant. The bottom web is composed of polyester/poly. Different from the typical chevron pouches, dual chevron opening features are created at the bottom of the pouch with the polyester/extrusion-coated layer extending beyond the polyester/poly film side to create access tabs at both corners. This, in theory, provides an easier opening method and facilitates aseptic presentation in the OR.

Figure 5: Chevron header pouch

ii. Lidded thermoformed trays

Trays have become a standard form of packaging for surgical procedure kits and, unlike pouches, are ideally suited for high-profile, irregularly shaped products. Trays are also known as three-dimensional packaging (Sherman, 1998). Two styles of trays are commonly used in the industry: rigid and flexible.

a. Lidded rigid trays

Due to their rigidity, rigid trays (Figure 6) are less prone to puncture and can provide enhanced product protection, which make them particularly suitable for high-profile, heavier or products consisting of multiple components which are likely to require support or physical protection, such as procedural kits. The materials and forms of rigid trays can be manipulated to accommodate a wide range of instrument sets and intended uses. Common materials are high density polyethylene (HDPE), polyvinyl chloride (PVC), polystyrene (PS), polycarbonate (PC), polyacrylonitrile (PAN), polypropylene (PP) and polyester copolymer (Sherman, 1998) (Laura Bix, 2009). Lids can be fabricated from varied stocks, including: paper, Tyvek®, or a film (Sherman, 1998). Lids are commonly coated with a heat-sealable, peel-able adhesive. The trays can be obtained from a manufacturer specializing in thermoforming or may be formed right on the filling line using a form-fill-seal (FFS) process.

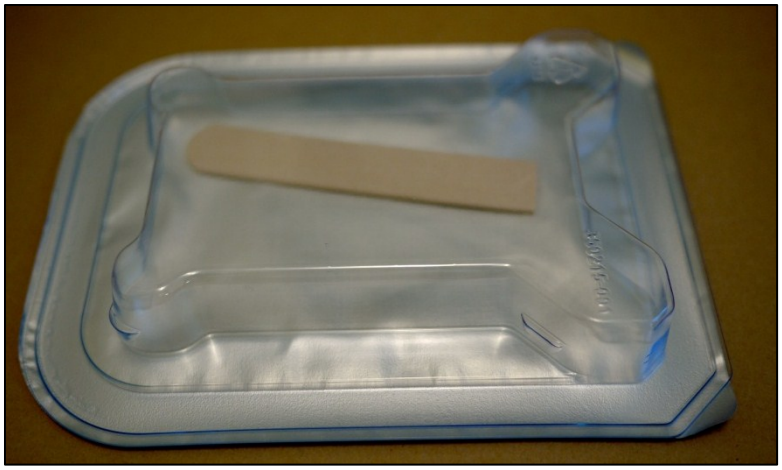

Figure 6: Thermoformed lidded rigid tray

b. Lidded flexible trays

Flat style flexible trays are available in a variety of structures and are usually the combination of two or more plastics (Sherman, 1998). The lidded flexible tray is also referred to the “three-dimensional flexible trays” (Figure 7) (Sherman, 1998). Flexible bottom webs are made from a less diversified group of plastics than the rigid. For several years, laminations of nylon to polyethylene or formable polyester to polyethylene have been the standards of formable “soft” bottom webs. Since the flexible tray is not self-supporting, the only way to use the flexible material in three-dimensional packaging, other than bags, is via the form-fill-seal process. For devices that do not require barriers to gas or moisture, the top webs most commonly used with flexible trays are papers and Tyvek®; this is the case regardless of whether they are sterilized with ETO or radiation. When barrier to gasses or moisture are required, typical top webs include paper/foil/heat seal (H-S), film/foil/H-S, paper/film/H-S, or metallize film lamination (Sherman, 1998).

Figure 7: IV start kit as Lidded flexible tray

CHAPTER 2
LITERATURE REVIEW

I. GENERAL PACKAGING NEEDS OF HEALTHCARE PERSONNEL

The little literature that is available on this topic suggests several issues generate frustration for healthcare personnel that have the potential to result in inappropriate or ineffective packaging (Sherman, 1998). This is especially true in a high-stress, life or death situation. Understanding provider needs and the roles each play with regard to packaging is a critical need.

In 1998, Reichert Consulting published one chapter titled “Packaging needs for the Health-Care Facility” in the Medical Device Packaging Handbook (Sherman, 1998). Concentrating on sterile single-use items, they claimed that healthcare providers want the following from packaging:

- labeling that allows quick identification to select the right product;
- packaging that requires minimal storage space;
- simply illustrated use directions;
- packaging materials impervious to environmental contamination;
- package designs that allow for aseptic presentation;
- packaging materials that are environmental friendly (Sherman, 1998).

As the users’ first introduction to the product, labeling plays an important role in conveying important product information to the healthcare provider. It must be recognized that the three distinctive “users” within the healthcare facility- the receiver,

the store room personnel and the clinical user have totally different needs for the labeling (Sherman, 1998). Clinical personnel are those people who are responsible for selecting and opening the product aseptically at point of use. They need to be able to quickly scan the items on the storage cart to differentiate the right item from others. The name and the size of the products are the two main pieces of information when searching for the wanted item (Sherman, 1998). Reichert also noted that additional information, like whether any companion product needs to be used, was desirable. Designs which facilitate the ability of healthcare providers to differentiate products are also very important. According to one report published in AORN Journal in 2007, look-alike packages frequently caused medication errors on a daily basis (Beyea, 2007). The report indicated that, “When medications have similar names, labels, or containers, it could be confusing.” (Beyea, 2007).

Armed with this information, Reichert recommended a unique label for medical device packaging that would allow instant recognition while ensuring required information is incorporated efficiently. These labels should consider, “font type, point size, label color, size, and placement of the information.” (Pilchik, 2003) (Sherman, 1998).

Highlighting and color coding systems are two popular ways that are intended to assist healthcare personnel in the selection of the correct product from an array of choices (Sherman, 1998). However, color coding systems have also been indicated to be problematic when not standardized across the industry. For example, when different colors carry different meanings for various manufacturers (Sherman, 1998). Due to the great variety of products, the limited number of colors that have the potential to be

effective a danger exists that this type of approach could cause errors if the system becomes a shortcut for reading printed information. The critical information for correct product selection, like the name and the size of the products, should be designed to be visible and not be blocked, or misleading, when stored. When designing packages, how the packages will be stored should be taken into consideration to ensure the visibility of the important information to fulfill the needs of quick and correct product selection (Sherman, 1998).

Reichert's document also emphasized the importance of considering storage spaces during the design process; efficient utilization of limited storage was considered a highly desirable aspect of design by this team (Sherman, 1998). Critical information (e.g. sizes and names of the products) should not be blocked when stored. When visibility of this information is precluded, for instance, when pouches are stacked or hung, a method that will hold or secure several units with an additional information tag, including name and size of products, should be provided and attached to each unit (Figure 8).

Figure 8: Medical device units with information tag in hospital

Opening instructions of the package are expected to be easily understood by the healthcare personnel and should consider the intense working environment. As instructions are designed, designers should assume the end user has no previous experience with the product (Sherman, 1998). Further, they suggest validating proposed designs for effectiveness prior to actual usage situations.

To offer the highest assurance of sterility, the integrity of medical device packaging must be maintained until the package is opened and the sterile product is aseptically presented (L. Jones, 1995). The packaging material is expected not only to be durable and impervious to environmental contamination, but also easy to present aseptically (Sherman, 1998) (Ramona Conner, 2006). Packages with strong seal strength, unusual sizes, and unclear opening features which could affect the usability of the package all have the potential to add to the difficulty of the aseptic presentation. It has been recommended that human factors evaluation should play an important role in healthcare system (Gosbee JW, 2006).

When the package is opened, the sterile device is immediately exposed to potential microbial contamination by the environment, people, and by the microorganisms that have been statically attracted to the surface of medical packaging (Ramona Conner, 2006). To reduce the probability of using contaminated devices, some sterile packaging designs have attempted to recognize aseptic transfer as a feature (Sherman, 1998). Another approach that attempts to mitigate the likelihood of contamination during primary package opening to the sterile field is the use of a double barrier package (Eagleton, 1997). The outermost packaging layer is removed just prior to the packaged items' entrance into the sterile environment. However, Dr. Brad Crick

(Crick B, 2008) has published research which suggests that double barrier packages may increase the risk for potential contamination of sterile field contamination rate.

Trends of waste reduction and pressures to reduce the volume of trash being contributed by packaging may adversely impact the prevalence of double barrier design (Sherman, 1998). Therefore, packaging designs that minimize waste or packaging materials that are biodegradable or those can be recycled are preferred by the healthcare personnel (Sherman, 1998).

II. PACKAGING NEEDS OF OR PERSONNEL

The ramifications of poorly designed packaging for Operating room personnel are undoubtedly significant. Yet, surprisingly, there has been limited research published in this area. A review of such studies follows.

A survey about the medical device packaging needs of operating room nurses was conducted by Neid in 2008 (Butschli, Surgical nurses survey medical device packaging, 2008). More than 200 OR nurses responded to the survey. The majority of respondents were 51 or older with more than 21 years of experience (Butschli, Surgical nurses survey medical device packaging, 2008) (Don't miss the nurses, 2010). Among the respondents, nearly 60% identified themselves as Registered Nurses, 37% as having a Bachelor of Science in Nursing, and about 2% as Licensed Practical Nurses.

Overall themes that emerged from the analysis of the responses are summarized in Table 1.

Table 1: Major findings of the survey about medical device packaging needs of OR nurses conducted by Neid

1	Sterility indicators and expiration dates were ranked to be very important in labeling medical devices.
2	Consistent color coding and expiration date formats were indicated among the approaches to design that would be beneficial.
3	Medical device packaging must be simple to open. As nurses age, trays with snaps become more difficult to open. Header bags are hard to open. Chevron-style pouches are not understood by some nurses.
4	Easy removal of the medical devices from packages is preferable.
5	"Dumping" or "flipping" a product from its package onto the sterile field was seen as an acceptable technique or practice by more than half respondents. (Though this is not encouraged by the AORN guidelines), however, the opening technique varies from facility to facility.
6	Both inner and outer packaging should be sturdier to resist potential physical damage.
7	Double-barrier packages were preferred nine to one compared with single barrier package for long-term implantable devices.
8	Recyclable packages or packages that create less waste were valued.

Neid surmised that survey information suggested that the nurses were not always clear on terminology used to describe various medical device packaging, indicating a need for education and clarification between the packaging and nursing communities.

In a panel discussion of OR nurses at a major medical device packaging conference in 2008, panel participants expressed that the end user of the packaged device (e.g. nurses and surgical techs) should be consulted during packaging development. The nurses expressed their concern over hard to open packages, and they worried about breaching the sterile field during their struggle. Ultimately, they

suggested that ease of opening receive more attention in the design of future medical device packages (Butschli, Surgical nurses survey medical device packaging, 2008).

During the panel, OR healthcare personnel reportedly favored double-barrier packages for sterile medical devices because maintaining sterility was the top concern in operating room (Butschli, Surgical nurses survey medical device packaging, 2008) (Don't miss the nurses, 2010). For that reason, single barrier packages are acceptable as long as it meets the sterility requirement. This is likely because intuitively, one might surmise that compared with single barrier packages, double barrier packages can better guarantee the maintenance of product sterility.

However, according to a study conducted at the Royal Brisbane and Women's Hospital between February and July 2004, it was suggested that single barrier packages carry no greater risk of bacterial contamination than double barrier packages (Webster Joan, 2005). Four-hundred packs containing 1 safety pin, 1 gauze-square and 1, 3-cm piece of silicone tubing were prepared for the testing. Half were packaged in double barrier packaging and half in single barrier packaging (Webster Joan, 2005). Fifty single barrier packages and 50 double barrier packages were placed in one of four designated holding areas around the hospital. On the first day of each two week period, 20 items were randomly selected from each area, placed on a trolley, and moved to another location to simulate handing. After 1 hour, they were returned to their original location; this process was repeated four times. Every two weeks over a five month period between March and July 2004, three double barrier and single barrier (n=24) were removed from each of the holding areas and transported in a clean, sealed plastic bag to the microbiology laboratory for testing. Results suggested that the number of

times packs were handled had no effect on whether or not the contents became contaminated, nor did the location at which packs were stored. No significant difference was evident in the levels of bacterial contamination when the two packaging types were compared (P=0.64). Authors concluded that the two packaging types performed equally well in protecting sterile items from contamination during transport, storage and handling (Webster Joan, 2005).

Another study conducted by Dr. Brad Crick suggested that having double barrier package could even increase the potential of contamination of sterile field due to the repeated opening motion. Five theatre nurses opened 20 double wrapped screws after bathing their hands in the Glitterbug cream which could be detected under ultraviolet light. Samples were considered contaminated if there was any fluorescence under ultraviolet light. They identified contamination in one of 100 screws which was believed by them that it exceeds acceptable limits (Crick B, 2008).

Duet Company garnered insights regarding the packaging of medical devices with OR personnel who were organized into focus groups. The focus groups were conducted with OR physicians and nurses from the Austin, TX area. The frequent complaint of the focus groups suggested the healthcare providers had difficulty understanding opening features, and the nurses felt that the structural indicators didn't make opening intuitive. It was also suggested that nurses were dissatisfied with the lack of availability of a single option for opening (Operating room personnel input critical to new peelable chevron header pouch, 2007) (Peelable header pouch, 2007). The other concern of the nurses was that incorrectly opening a package could compromise the sterility of the contents. Based on the focus groups results, a new-generation pouch was

developed by Duet, called a “chevron header pouch” (Figure 6). The new design combines elements from both header bag and chevron pouch designs (Operating room personnel input critical to new peelable chevron header pouch, 2007). This hybrid design aims to ease pouch access and improve aseptic presentation. To fulfill the nurse’s needs of having more opening options, dual chevron opening features were created at the outer edges of both bottom corners. In doing so, it was reported to be easier for operating room personnel to open and remove challenging three-dimensional objects without flaps potentially compromising the aseptic presentation. Different from the traditional chevron bags, the chevron header pouch was manufactured three-side sealed with bottom chevron access seals already in place and top area left unsealed for the later loading purpose.

The studies conducted by both Neid (Butschli, Surgical nurses survey medical device packaging, 2008) and Duet (Operating room personnel input critical to new peelable chevron header pouch, 2007) have been echoed in observations obtained during simulations conducted at Michigan State University and debriefings of the healthcare providers that immediately followed. During a 2 day conference conducted during the fall semester of 2010, a complete provider team from the intra-Op environments conducted a simulated hernia repair on a state of the art simulator. Following the simulation, healthcare practitioners debriefed the experience in front of the conference audience and discussed issues that they had with medical device packaging.

During the simulation, Melissa Gray, RN, pointed out that unclear opening feature slowed nurses (Simulations focus on Packaging Usability, 2010). “I could not

find a corner to open on the tube packaging," recounted Melissa Gray, "I believe it was meant to be a corner peel, but you need the ability to get your thumb under the flap to open, and it needs to be at least the width of your thumb." Further research into the contexts of use and application of formal data relating to anthropometrics and anthropomorphic was recommended. When asked about the frequency with which packaging contributes to sterility problems, a single panelist suggested that one out of every five procedures contains complications related to packaging which leads to a discard (Simulations focus on Packaging Usability, 2010) (Butschli, MSU examines how packages operate in ER, OR environments, 2011).

CHAPTER 3
RESEARCH METHODS

I. OBJECTIVES

The goal of the study was to investigate the medical packaging needs of Operating Room personnel so that future packages can be improved by manufacturers.

More specifically, the objectives were:

- To examine the relationship between context and design in healthcare environments, specifically, the Operating Room
- To determine the key features of medical device packaging as indicated by operating room personnel so that guidelines and designs can be developed to address specific needs
- To identify common medical packaging problems and begin to develop a sense of their severity and frequency

II. METHODS

To accomplish these objectives, OR healthcare personnel were recruited for a series of focus groups (See Appendix G for a discussion of focus groups). A focus group methodology was chosen because this technique is known to be useful for exploratory research where rather little is known about the phenomenon of interest (Krueger & Casey, 2009). All procedures were conducted in accordance with those approved under IRB #11-242. Recruitment of the participants started 3 months before a focus group was conducted. Flyers were designed (See Appendix F) and sent, via

email, to nurses from the East Lansing area and personnel at Right Med Label (West Lake, OH). Participants were also recruited through word of mouth advertising. Two reminder emails were sent to each participant, a week prior to the testing and one day prior to the focus group. The focus groups were conducted in two locations: the School of Packaging at Michigan State University and the Westlawn square office building in Cleveland.

To be included in the study, participants needed to be either currently employed as, or have a history of employment in, the operating room environment. Prior to beginning a focus group session, informed consent was obtained using both written consent form and an oral description of the study (see Appendix B for a copy of the approved consent form). In the consent form, participants also needed to indicate their willingness to have images shown in public. Videotaping was requisite to participation due to the fact that they were reviewed post hoc to create an accurate transcript. Those that indicated willingness to have their images shown in public were given yellow placemat which gave the researcher the right to use the video clips in public for educational purposes. Those who did not this were given red placemat. In that case, there would be a permanent marker in camera indicating the videos can only be used for recalling details of the session. After the consent process, basic demographic information including: age, gender, and work experience were recorded (See Appendix D for a copy of the demographic form). After introductions were made, the discussion began with a series of warm up questions regarding typical shifts and traits of people that work in OR settings (See Appendix A for a copy of the moderator guide).

Seven focus groups, consisting of 21 OR healthcare personnel were conducted with at least 2 participants in each focus group session from August to December in both East Lansing area and West Lake, OH area (see Table 2).

Table 2: Focus groups recruiting information

Focus Group	Size (N)	Date	Location
1	2	30-Aug-2011	East Lansing, MI
2	2	27-Oct-2022	East Lansing, MI
3	6	19-Nov-2011	West Lake, OH
4	4	19-Nov-2011	West Lake, OH
5	2	14-Dec-2011	West Lake, OH
6	2	14-Dec-2011	West Lake, OH
7	3	15-Dec-2011	West Lake, OH
Total	21		

According to the demographic survey (see Appendix D) collected during the focus groups, within the 21 participants, 90.5% of participants (n=19) were female, 61.9% of participants were above 40 years old. 90.5% (n=19) of participants were reported more than 10 years healthcare system experience and 71.4% of participants had more 10 years OR experience (see Table 3).

Table 3: Composition of Focus group

		Size (n)	Percentage (%)
Gender	Male	2	9.5
	Female	19	90.5
Age	<30	1	4.8
	30-39	2	9.5
	40-49	4	19

Table 3 (Cont'd)

		Size (n)	Percentage (%)
Age	>49	13	61.9
Healthcare system Experience	<10 yrs	2	9.5
	≥10 yrs	19	90.5
OR Experience	<10 yrs	6	28.6
	≥10 yrs	15	71.4

III. MATERIALS

Three different package types were shown and introduced to the participants in the study. The study purposefully include the most common medical device packages presently used in operating room: pouches, trays and double barrier packages. All the three package types were shown to the participants in the education section (see Appendix A: Moderator guide) along with the educational document (see Appendix E). In an attempt to develop common language for discussion, a brief description of each packaging type was given to all the participants by the moderator in that session. Later on, in the session of opening and aseptic presentation (see Appendix A: Moderator Guide), chevron pouches and double barrier packages (tray in a corner peel pouch) were distributed to each participant to open. Then in the session of problematic and good designs (see Appendix A: moderator guide), all the packages were displayed on the table for the participants to discuss.

i. Flexible pouch

Flexible pouches with four different opening features including chevron seal, corner peel, tear strip and header bag (see pictures in Chapter 1) were introduced to the participants of the study during the educational section (see Appendix A: Moderator Guide) though the use of the educational document (see Appendix E).

a. Chevron seal

The chevron seal pouches were a combination of PET/LDPE lamination and Tyvek®. Pouches were 13 in by 10 in and 2.5mil thickness provided by Oliver-Tolas, Grand Rapids, MI.

The manufacturer's seal was created using a CeraTek model 24-AS/1 (Serial No. 06-04236) heat bar sealer (SenCorp, Hyannis, MA). Sealing parameters were 275 F, 60psi, and 1.5 seconds of dwell time. A tongue depressor was sealed within each pouch. After sealing, pouches were visually inspected for any defects. Those with identified seal defects were removed from the study. The chevron peel pouch was first shown and explained to the participants in the education session (see Appendix A: Moderator guide) and later on passed to each participant so that they could present the tongue depressor into the sterile field during the beginning of the session "opening and aseptic presentation" (see Appendix A: Moderator guide).

b. Corner peel

The corner peel pouches were 100GA Biax Nylon (0.001), 0.0007 LDPE, 0.002 HDPE Coex pouches (Lot#; H150978/1/A) with dimensions of 7.25 inch x 9.50 inch (Mangar industries, Inc., New Britain, PA).

Pouches were sealed using a CeraTek model 24-AS/1 (Serial No. 06-04236) heat bar sealer (SenCorp, Hyannis, MA). Sealing parameters were 275 F, 60psi, and 1 seconds of dwell time. After sealing, pouches were visually inspected for any defects. Those with identified seal defects were removed from the study. A tongue depressor was sealed within each pouch for purpose of Aseptic presentation. The corner peel pouch was shown and explained to the participants in the education section (see Appendix A: Moderator guide).

c. Square seal with tear strip

The tear open pouches used in the study were 48 ga. PET/ 0.0007 White LDPE/0.00035 Foil/0.0007 EMAA/0.0015 LLDPE-EVA with dimension of 6 inch x 9.75 inch (Mangar industries, inc., New Britain, PA). Due to the limited amount of the samples, the tear open pouches were merely shown during the education section (see Appendix A: Moderator guide) of the focus group.

d. Header bag

Two header bags were distributed to the participants. One had a chevron opening feature located at the center of the bottom edge, and the other one was a standard header bag which required participants to peel the top to open. Due to the limited amount of the samples, the header bags were shown and explained during the education section of the focus groups (see Appendix A: Moderator guide) along with the educational document (see Appendix E: educational document).

ii. Trays

Three types of trays including: lidded rigid trays, flexible trays and surgical kits (see pictures in Chapter 1) were introduced to the participants of the study.

a. Rigid tray with lid

Corner peel trays were shown during the course of the study. The tray body was "Medronic Inc. Outer Tray Part No. 350215-001" 0.025 inch blue tint uncoated polyethylene terephthalate (PETG) (Perfecseal, Mankato, MN). Trays were sealed with LKF-002 Paper/PE/Foil/ PE/HSC die cut lids (Amcor Flexibles Healthcare, Madison, WI) using a CeraTek Model MD-2420 shuttle-style heat sealer (SenCorp, Hyannis, MA), fixtured with a Teflon impregnated fiber glass barrier blanket. There were nine sealing positions that were recorded for each tray run. Sealing parameters were: 300 F, 70psi, 2.5 seconds of dwell time. After sealing, trays were visually inspected for defects. A tongue depressor was sealed into each tray as a simulated medical device. The lidded rigid trays were shown and explained during the education section of the focus groups (see Appendix A: Moderator guide) along with the educational document (see Appendix E: Educational document).

b. Flexible tray with lid

Flexible trays showed in the study used for the contained IV start kit manufactured by Medline Industries, Inc. (Mundelein, IL).

c. Surgical Kits

The moderator explained the terminology of surgical kits during the education section of the focus group (see Appendix A: Moderator guide) along with the educational document (see Appendix E: Educational document).

iii. Double barrier package

Double barrier package systems (see Figure 9) were created by sealing rigid lidded trays within a flexible pouch. The sealed, lidded rigid trays were placed inside corner peel pouches. Pouches were then sealed using a CeraTek model 24-AS/1 (Serial No. 06-04236) heat bar sealer (SenCorp, Hyannis, MA). Sealing parameters were 275 F, 60psi, and 1 seconds of dwell time. Each double barrier tray was first shown and explained by the moderator during the education section (see Appendix A: Moderator guide) along with the educational document (see Appendix E: Educational document) and then delivered to each participant so that they could present the contents at the beginning of the session “opening and aseptic presentation” (see Appendix A: Moderator guide).

Figure 9: Double barrier package (tray in a pouch)

iv. Others

a. Sterile drapes

The sterile towel drapes used in the study were manufactured by Kimberly Clark and had dimensions of 18 x 12 inch to simulate the sterile field during aseptic presentation of the medical device into the sterile field.

IV. PROCEDURES

Each focus group lasted no more than two hours and was guided by a series of questions that comprised the IRB approved moderator guide (see appendix A). In addition to the moderator, one or two other members from the research team attended sessions in order to take notes and handle videotaping during the whole process. Because of research suggesting a lack of consistent terminology regarding medical packaging (Butschli, Surgical nurses survey medical device packaging, 2008), participants received the document with relevant terminology relating to medical device packaging features (see Appendix E) during the education section. Also, according to their willingness of having images shown in public which has been indicated from the consent from (see Appendix B for a copy of the approved consent form), the participants will be given either red or yellow placemat. After the general introduction which included: a definition of focus groups, study purpose and some basic rules, the discussion started with several warm-up questions like self-introduction and work load. Afterward, the education session was conducted. Packaging samples with different opening features were set on the table, and then presented to the group one by one when explaining each terminology in the educational document (see Appendix E). The terms that we in packaging use for certain things (e.g. header bag) were introduced to

each group to generate a common understanding of the varied designs and the terminology used. The participants were advised to use the educational documents with terminology and images as a reference for later discussion.

The moderator then asked the participants to describe their work environment, mainly focusing on noise, lighting and work space. The potential packaging problems related to the work environment were discussed. After that, the session of general packaging review began with a few questions about packaging. During this portion of the focus group, participants were asked about the common package types they deal with and the number of packages they open during a typical shift. Still within that session, the participants were asked to list the features that they think should be of central consideration to packaging designers. From the list generated from the brain storming, the participants chose the 10 most important aspects and ranked them from 1 to 10 with 1 being the most important of the group and the 10 being the least important.

In accordance with the moderator guide (see Appendix A) the following sections included: product identification, packaging opening, aseptic presentation and disposal of packaging waste. Participants were asked to score the importance of quick identification, ease of opening and aseptic presentation on a scale of 1 to 10 (1=not important at all, 10=very important). In the session of identification, the storage types, organization of devices and the relevant packaging features were discussed. Then, several medical trays and pouches with different opening features were distributed to participants. Participants were asked to present contents into a simulated sterile field. The participants were later asked about the common opening ways and the features related to the ease of opening approaches. Additionally, features related to the aseptic

presentation were discussed. During packaging waste section, the participants were asked to discuss the issue of the product disposal as the result of a problem with packaging and also estimate the frequency.

At this point, discussion was directed to specific packaging problems. Individual participant experiences with the problematic packages were shared. Suggestions for improvements were discuss. This was followed by a brief summary about the common reasons that packaging failed. Based on the list, the participants were asked to evaluate the frequency of failures. In the end, good designs were discussed. Similar with the discussion about the problematic designs, the participants shared their experience with the good designs and pointed out the specific features that they thought have been very helpful.

CHAPTER 4
METHODS FOR ANALYSIS

Both qualitative and quantitative methods were used to analyze the collected data. Open-ended questions collected during the focus groups were subjected to qualitative analysis and were later converted to a summarizing, quantitative method known as content analysis. The three activities captured with collection sheets (see Appendix C) were analyzed separately. Employing both quantitative and qualitative methods provides varied epistemological properties within the same context of research (Rossi & Freeman, 1999).

I. ACTIVITY 1: RANKING ORDER

During activity 1, participants were asked to choose the 10 most important packaging features from a list generated by the group and then rank them from 1 to 10, with 1 being the most important and 10 being the least important (see Appendix C). Data collection sheets were gathered at the conclusion of the focus group.

To analyze the data, frequency counts were conducted which quantified the number of participants who ranked each packaging feature at each point on the scale. Mode and median values for each packaging feature were also computed. Since there are more than 10 packaging features on the list, the data was then filtered by total frequency of each packaging feature. The top 10 packaging features with the highest total frequency value were extracted from the list and were considered as the 10 most

important packaging features wanted by the OR personnel. Median ranking and the mode of the ranking of each of the top 10 packaging features were computed.

II. ACTIVITY 2: RATING OF IMPORTANTCE

Activity two (see Appendix C) asked participants to indicate on a scale of 1-10 (1 was least important, 10 was most important) how important that they thought varied aspects of package features are. Mean value, standard deviation, median, mode values and frequencies for each score were computed for each packaging function.

III. ACTIVITY 3: RATING OF HOW OFTEN A PACKAGING PROBLEM OCCURS

Activity three (see Appendix C) attempted to gauge the frequency with which specific problems (generated in the course of focus group discussion) occurred. During the focus groups, a research assistant generated a list of packaging problems based on discussion specific to that group. Just prior to activity three, this list was transferred to a flip chart and participants copied the list onto the form distributed as part of activity 3. They were then asked to rate each problem at one of four levels of frequency: never, sometimes, frequently and always. The lists were synthesized as part of a note-based discussion, and the research assistant only chose a few problems for participants to rate as a result the lists varied from focus group to focus group. For a complete overview of the focus group contents, content analysis which is based on the focus group transcripts was applied.

For the purposes of analysis of activity 3 data, each problem was listed on the data collecting sheet activity 3 (see Appendix C: data collecting sheet) by the research assistant during the focus group for participants to rate how often the problem occurs is

considered as a problem unit individually. Frequency counts were conducted on the number of participants who checked each packaging problem at each level of report (never, sometimes, frequently, and always). Then, all the problems were aggregated. After that, similar packaging problem units were grouped together. Those similar problems from different focus groups were considered as one unique problem unit. In doing so, a list of consisting of a condensed number of unique packaging problem units was generated. Frequencies of problem units were tabulated. The last step was that the problems were further categorized into "problem type" as aseptic presentation, opening, labeling, environmental and storage, others. The number of problem units within problem type was counted and the percentage was computed.

IV. CONTENT ANALYSIS

Content analysis was conducted to create a quantitative assessment of the qualitative data by classifying statements, or "thought units," into common categories (Neuendorf, 2002). Common themes that emerged from the comments and discussions were reported following a reduction process of the videotape recordings, and focus group transcripts. A coding scheme was created to help group similar thought units together for discussion and analysis. In grouping this way, the inputs can be coded into categories to build inferences and analyze frequency of themes. Analysis consisted of 3 main processes: unitization, coding and discussion.

i. Unitization

To prepare for the unitization process, each participant was assigned a number and a full transcript of each focus group was created verbatim by the researcher upon review of the videotapes (Krueger & Casey, 2009). An abridged transcript was created

by removing questions and statements made by moderator and any irrelevant conversations. The abridged transcript was then broken into thought units and added to the coding sheet (see Appendix H) that was organized during the coding process.

ii. Coding

The coding process groups similar thought units together. Data were analyzed by utilizing a coding scheme that cataloged data into 3 overall categories (general packaging, work environment, and packaging issues), overall categories were comprised of 10 sub-categories. Corresponding questions in the moderator guide were used to help define each sub-category (see Table 4).

Table 4: Coding Scheme

Overall Category	Secondary Category	Code	Example
General Packaging: Any statements about the quantity of packaging opened during a shift, and common approaches to opening	Opening Quantity: ➡How many packages do you open during a shift?	OQ-1	➡"easy a hundred, one and two." ➡"you can open anything from 10 to 50 items for one surgery."
	Common Type: ➡What's the common way to open packages?	CT-2	➡"header bag is not very common"
Work Environment: Any statements about physical work environment in the OR.	Noise: ➡Is the OR usually noisy? ➡Does noise ever cause distractions when working with packages? ➡What kind of things happen?	NOI-3	➡"very noisy" ➡"we have to concentrate on that, but the noise doesn't matter" ➡"the nurse either doesn't hear him or misunderstand what he says, they open the wrong thing,"
	Lighting: ➡How's the lighting in the OR? ➡Does the light vary across the department? ➡Have you ever had any packaging difficulties that are the result of lighting?	LIG-4	➡"it is usually very bright" ➡"I would say yes, the light varies across the department" ➡"I think at my age, the lighting with any instructions is really important and color contrast of the instructions is very important."

Table 4 (Cont'd)

Overall Category	Secondary Category	Code	Example
Work Environment (Cont'd): Any statements about physical work environment in the OR.	Work Space: ➡Is the OR ever crowded? ➡Does your work space ever cause difficulties when working with packages?	WS-5	➡"Especially when you are in a teaching hospital, it's very crowded." ➡"the packages which are big and hard to open. you have to make sure no one's around you"
	Storage: ➡Types of storage where you might have to go to look for a medical device. ➡Are the medical devices consistently placed so that they can be quick identified or easily located?	ST-6	➡"we have closets, drawers" ➡"we have multiple storage rooms, but they are not the same."
	Other: ➡Any work environment statements don't fit into the above categories	OWN-7	➡"sometimes the OR is stressful" ➡"organized" ➡"it's fast pace"

Table 4 (Cont'd)

Overall Category	Secondary Category	Code	Example
Packaging Issue: Any statements about packaging problems and possible or suggested solutions	Identification: ➡problems of identifying desired product or information regarding the product and suggested solutions	IDE-8	➡"…because a lot of nurses… we just read sterile. and we don't have time to read the whole thing" ➡"they should circle and slash the not sterile" ➡"different color? that will be sweet"
	Opening & Aseptic presentation: ➡What packaging problems related to procedures of aseptic presentation have you ever had? Provide suggestions you have to solve these problems	OPE-9	➡"easy to open is huge." ➡"I don't like these tear open packages, when you rip them, you can't tell what's going to touch where" ➡"for the long skinny part, you have to hold that first, then flip quickly" ➡"if they color coded the corner where I should peel, and leave other corners white"

Table 4 (Cont'd)

Overall Category	Secondary Category	Code	Example
Packaging Issue (Cont'd): Any statements about packaging problems and possible or suggested solutions	Packaging Waste: ➡In what instances might you dispose of a product before it is used on a patient? ➡How frequently does this occur? ➡How frequently does this occur as the result of a problem with packaging ➡How do you dispose of a product that fails before being used? Where do they go? ➡Who pays for them?	PAW-10	➡"when it flips out on the floor, you have to throw it away" ➡"probably 1 or 2 times a day at least." ➡"goes to trash, sometimes we have a mission bin too." ➡"the hospital pays for that"

a. General Packaging

The general packaging category included statements about the frequency of openings per shift, and common package opening techniques. Detailed statements regarding specific packaging problems were not included in this category and will be coded into the category of work environment or packaging issue (see table 4).

Discussion regarding the frequency of opening was prompted with the question, “how many packages do you open during a shift?” (see Appendix A: moderator guide). Responses to the question included behavioral actions (e.g. “laugh”), explicit answers, (e.g. “easy a hundred, one and two.”), and qualified statements (e.g. “depending on how big the cases we are doing [are].”).

Common types were defined primarily by their opening features (e.g. “I will say the chevron and corner peel”).

b. Work Environment

The second major category used to code the discussion involved the working environment. Statements related to work environments were defined as those involving the physical environment in the OR. The broad category was divided into 4 sub-categories related to specifics about working conditions: noise, lighting, work space, storage and “other.” Comments that were coded in the noise category included any statements (directly or indirectly) made following three questions from the moderator guide (see Appendix A): “Is the OR usually noisy?” (e.g. “very noisy”); “Does noise ever cause distractions when working with packages?” (e.g. “we have to concentrate on that, but the noise doesn’t matter”) and “What kind of things happen?” (e.g. “the nurse either

doesn't hear him [the surgeon] or misunderstands what he says, they open the wrong thing,") (see Appendix A: Moderator guide).

Statements regarding the questions "How's the lighting in the OR?" (e.g. "it's usually very bright"); "Does the light vary across the department?" (e.g. "the light varies across the department"); and "Have you ever had any packaging difficulties that are the result of lighting?" (e.g. "I think at my age, the lighting with any instructions is really important and color contrast of the instructions is very important.") were all categorized under the heading lighting (see Appendix: moderator guide).

Similar to the previous 2 sub categories, the work space heading included statements which answered "Is the OR ever crowded?" (e.g." it's very crowded") and "Does your work space ever cause difficulties when working with packages?" (e.g. "the packages which take a lot of space" and "they are harder to open, you have to make sure no one's around you") (see Appendix: moderator guide).

Statements that referred to the types of storage where you might have to go to look for a medical device (e.g. "we have closets, drawers"), "are the medical devices consistently placed so that they can be quick identified?" (e.g. "we have multiple storage room. but they are not exact the same.") were categorized in the "storage" category (see Appendix: moderator guide).Statements regarding work environment that didn't fit into the above 3 sub-categories were subcategorized as other (e.g. "it's fast paced").

c. Package Issues

Package issues were defined as statements relating to packaging problems that the participants have, along with suggested solutions or discussion of examples of good

design. This category was divided into 4 sub-categories: identification, opening and aseptic presentation, packaging waste and other (see table 4).

Statements regarding problems of product identification relating to locating desired product(s) or specific information within a label were categorized as thought units under the identification subcategory (e.g. “because a lot of nurses we just read sterile and we don’t have time to read the whole thing”) and its suggested solutions (e.g. “they should circle and slash the not sterile”).

Statements relating to packaging features that they felt facilitated or hindered the opening process (e.g. “you see how tiny the grabbing space is”) or the process of aseptic presentation (e.g. “I don’t like these tear open packages, when you rip them, you can’t tell what’s going to touch where”) and suggested solutions (e.g. “if they color coded the corner where I should peel, and leave other corners white”) were aggregated into the “opening and aseptic presentation” category. Additionally, statements that answered the question of “do you check the integrity of packaging before you open” (e.g. “yes, if it’s paper,” “you check there’s no hole”) (see Appendix A: Moderator guide) were included here as well.

The “packaging waste” subcategory included statements answering the question, “In what instances might you dispose of a product before it is used on a patient?” (e.g. “when it flips out on the floor, you have to throw it away”); “How frequently does this occur?”; “How frequently does this occur as the result of a problem with packaging”; “How do you dispose of a product that fails before being used? Where do they go?” (e.g. “goes to trash, sometimes we have mission bin too.”); “Who pays for them?” (see Appendix A: moderator guide).

“Other” referred to packaging problems or suggested solutions which didn’t fit into the above secondary categories (e.g.” easy to store”).

iii. Decision rule

Due to the large amount of data collected and the multiple categories in the coding scheme, decision rules were devised to assist in placing units of analysis within the most appropriate category. A unit was first categorized in work environment, then packaging issue, and then the remaining categories which means if a thought unit could fit into both work environment and packaging issue, it should be categorized into work environment. For example, a thought unit talking about the labeling within dark environments, according to the definition of the overall category, could be categorized into either the work environment (lighting related packaging issue), or the packaging issues (subcategory: identification issue). However, according to established the decision rules, it was subcategorized as “work environment”.

iv. Data reporting principle

Direct quotes related to each category were selected based on three criteria: 1) consistent representation of idea/issue across groups; 2) salience of the idea/issue (multiple responses gave the issue prominence); and 3) the potential for the idea/issue to require attention and/or correction from the medical device industry targeted to OR personnel.

CHAPTER 5
RESULTS AND DISCUSSION

Seven focus groups, consisting of a total of 23 participants were conducted. Two people who reported no OR experience were removed from group. Thus, analysis included the responses of 21 participants. Within the 21 participants, 90.5% of participants (n=19) were female, 61.9% of participants were above 40 years old. 90.5% (n=19) of participants had more than 10 years healthcare system experience and 71.4% of participants had more 10 years OR experience. As mentioned in the methods section, this work was comprised of four different sections:

- Activity 1: Ranking of Desired Features for Packaging Medical Devices (see Appendix C)
- Activity 2: Rating the Importance of Varied Packaging Features (see Appendix C)
- Activity 3: Rating the Frequency of Specific, User-Generated Packaging Problems (see Appendix C)
- Content analysis of the discussion that occurred during the course of the sessions

I. ACTIVITY 1: RANKING ORDER

Responses from all 21 participants were used in the analysis of data collected as part of activity one. Table 5 analyzes the results of this activity four ways: the frequency of respondents who ranked varied features of packaging at the differing levels of rank;

the total frequency of responses for a given packaging feature (subjects only ranked 10 items from a list of fourteen and could also write in others); the median[3] and mode[4] ranking value for each packaging feature (see table 5). The four features that received highest number of responses at any rank by the group are shaded in grey. Within this set, the features that were most frequently ranked as important were:

- sufficient gripping space
- preopening integrity
- seal/peel strength and
- easy to read labeling

These items had the lowest median and mode values of ranking as well (in response to listing the items from 1-10 with 10 being the least important). When the features were compared using the median value and mode value, package integrity before opening was ranked highest (14/21 people ranked it No. 1), followed by easy to read text/font labeling (9/21 people ranked No. 2), then enough gripping space and

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[3] In probability theory and statistics, median is described as the numerical value separating the higher half of a sample, a population, or a probability distribution, from the lower half.

[4] In statistics, the mode is the value that occurs most frequently in a data set or a probability distribution.

seal/peel strength. Convenient to store and rigid or flexible packaging material were ranked to be the least important among the ten aspects with the median value of 9.00.

Of the ranked features, seven out of ten concerned opening and aseptic presentation, while two were about quick identification, and one was about storage. Packaging waste was not included the top 10 most important packaging features, suggesting that, relative to opening, aseptic presentation and quick identification, packaging waste was less important.

Table 5: Frequency of participants who ranked packaging features using a scale of 1-10 (1= Most Important; 10= Least Important)

	Enough gripping space	Package integrity before opening	Seal/ peel strength	Easy to read text/font labeling	Fast opening
Most Important	3	14			
2.00	5		1	9	3
3.00	2	2	4	2	3
4.00	1	1	6	1	1
5.00	6	1		3	1
6.00	1	1	3		2
7.00	2		1	2	4
8.00	1	1	3	1	1
9.00			1		
Least Important			1	1	1
Total Frequency of participant responses	21	20	20	19	16
Median Ranking	3.50	1.00	4.00	2.50	5.00
Mode of Ranking	5.00	1.00	4.00	2.00	7.00

Table 5 (Cont'd)

	Visibility of the product inside	Opening instructions on package	Double barrier	Convenient package size	Convenient to store
Most Important	1		1		
2.00		1	1		
3.00	1	1			
4.00	2	1	2	1	
5.00	1	3	1	1	1
6.00	2		1	1	1
7.00		1	2	4	
8.00	2	2	1	2	2
9.00	3	4	1	2	2
Least Important	2	1	3		5
Total Frequency of participant responses	14	14	13	11	11
Median Ranking	6.00	7.00	6.50	7.00	9.00
Mode of Ranking	9.00	9.00	10.00	7.00	10.00

II. ACTIVITY 2: RATING

During the second activity, subjects were asked to rate, on a scale of 1-10, the importance a packaging feature from a list that was provided to them (1 not important at all and 10 very important). Raw data from activity 2 is depicted in Table 6 and summary data with the frequency of how many people provided a rating to a packaging feature, median and mode values can be found in Table 7.

Table 6: Rating results with mean and standard deviation

Group #	Subject #	Quick identification of product	Ease of opening	Present device aseptically
1	1	10	10	10
	2	10	10	10
2	3	10	10	10
	4	9	10	10
3	5	3	2	1
	6	2	3	1
	7	10	10	10
	8	1	3	2
	9	2	1	3
	10	10	10	10
4	11	9	9	10
	12	10	10	10
	13	10	10	10
	14	10	10	10
5	15	10	10	10
	16	10	10	10
6	17	10	10	10
	18	8	10	10
7	19	10	10	10
	20	10	10	10
	21	10	10	9
	Mean	8.29	8.48	8.38
	St. Deviation	3.18	3.12	3.32

Table 7: Distribution of frequency of how many people provided a rating to a packaging feature

Rating	Quick identification of product	Ease of opening	Present device aseptic
1.00 (least important)	1	1	2
2.00	2	1	1
3.00	1	2	1
4.00	0	0	0
5.00	0	0	0
6.00	0	0	0
7.00	0	0	0
8.00	1	0	0
9.00	2	1	1
10.00 (most important)	14	16	16
Total Frequency	21	21	21
Median	10.00	10.00	10.00
Mode	10.00	10.00	10.00

The median and mode values were both reported to be 10.00 for all these three packaging features (see table 7). These values support the findings from activity one which suggest quick identification of the product, ease of opening and the ability to aseptically present sterile devices to be very important to the participants.

High standard deviations were noted and explored; these were largely attributable to focus group three (subject #5, 6, 8, 9); the other 17 people all gave the three features very high number from 8.00 to 10.00 (see table 6). It is likely that subjects in this group misunderstood the directions by providing a ranking from 1.00 to 3.00 (without duplication) instead of rating (How important is this feature on a scale of 1-10). This misunderstanding was further supported during the review of the transcripts. It is likely that there were issues of instruction due to the fact that this occurred in an isolated group.

III. ACTIVITY 3: RATE OF HOW OFTEN PACKAGING PROBLEM OCCURS

For each focus group, a list of problems was written on the data collection sheet prior to activity 3 (see Appendix C: data collecting sheet) based on the group discussion to that point. Each listed problem on the sheet is considered as a "problem unit" individually. Fifty-eight specific problem units with thirty two unique problem units were recorded to the problem lists by the research assistant during each focus group (see Table 8). Similar problems were grouped, into sub-categories called "problem types", which included: aseptic presentation, opening, labeling, environmental issues, storage, and others.

The most problem units were categorized into "aseptic presentation." This comprised 41.4% (n=24) of the total problems. 31.0% of the total identified problems were categorized as opening problems and 19.0% were categorized as labeling issues. Environmental and storage issues represented only 5.2% (n=3) of the total problems (see table 8).

Table 8: Frequency and percentage by problem types

Problem Type	# of Problem Units	Percentage of total problems
Aseptic presentation	24	41.4%
Opening	18	31.0%
Labeling	11	19.0%
Environmental and storage	3	5.2%
Other	2	3.4%
TOTAL	58	100.0%

Consistent with reports collated from activities one and two, problems coalesced around the same topic areas (aseptic presentation/opening and labeling). This was

determined by two factors: how many types of unique problem units were included and how many focus groups discussed that specific type of problems. Problem types were further broken down to explore the categories in greater detail (see Table 9, 10, 11, 12, 13).

Table 9: Aseptic presentation problem breakdown

Unique Problem Units	# of focus groups listing this issue	# of participants reported	How often the problem occurs			
			never	sometimes	frequently	all the time
Oversized packages make it harder to present contents aseptically	4	12	0	7	3	2
Softness of the tray body could cause contamination	2	4	1	2	1	0
Seal strength contributes to damage or contamination	4	13	1	6	4	2
Corner peel makes aseptic presentation harder since it can only have 2 sides open	1	2	0	1	1	0
Perforations can't be used for sterile content	1	6	1	0	4	1
Same package used for sterile and non-sterile content causes confusion	1	6	0	3	3	0
Header bags make aseptic presentation difficult	1	4	2	1	0	1
Paper/foil ripping	6	19	0	10	6	3
Material durability is not good enough and allows sharp content to penetrate	2	9	0	0	5	4
Paper fiber contaminates products	1	2	0	1	1	0
Tacks on pouch make aseptic presentation difficult	1	2	0	0	1	1

Table 10: Opening problem breakdown

Unique Problem Units	# of focus groups listing this issue	# of participants reported	How often the problem occurs			
			never	sometimes	frequently	all the time
Not enough gripping space	3	10	0	4	4	2
Opening location is hard to detect for corner peel	2	5	0	1	4	0
Corner peel causes difficulty in opening	1	2	0	1	1	0
Opening location is hard to detect for tear pouch	2	6	1	3	0	2
Film curls back contaminates product	1	2	0	2	0	0
Hard to separate two webs	2	5	0	2	3	0
Opening of atypical packaging and opening instructions are not obvious	2	6	1	2	2	1
Package slips because the hands are too dry	2	4	0	3	1	0
Foil layer cuts fingers	1	2	0	1	1	0
Content sticks to film	1	3	0	1	2	0
Contents are difficult to pop out of rigid tray	1	3	0	1	2	0

Table 11: Labeling problem type breakdown

Unique Problem Units	# of focus groups listing this issue	# of participants reported	How often the problem occurs			
			never	sometimes	frequently	all the time
Hard to determine expiration dates	4	9	0	4	5	0
Important information is not clear	4	16	1	12	1	2
Non-standard labeling	1	6	0	2	1	3
Inconsistent locations for important information	1	2	0	0	2	0
Cluttered writing on package makes finding needed information harder	1	4	0	2	2	0

Table 12: Environmental and storage problem breakdown

Unique Problem Units	# of focus groups listing this issue	# of participants reported	How often the problem occurs			
			never	sometimes	frequently	all the time
Double barrier increases trash	1	6	0	2	4	0
Too much trash	1	4	0	1	3	0
Package changes don't fit on shelves	1	2	0	1	1	0

Table 13: other problem breakdown

Unique Problem Units	Combined unit(s)	# of participants reported	How often the problem occurs			
			never	sometimes	frequently	all the time
Not enough leverage	1	2	0	1	1	0
Can't tell where product is in the package	1	2	0	2	0	0

Packaging issues regarding ripping, size, seal/peel strength etc. were mentioned by more than 3 focus groups; these issues which are involved in opening and aseptic presentation were also considered to be problematic by more participants. Compared to the number of unique problem units in opening and aseptic presentation, labeling had only 5 types of unique problem units, but with 2 unique problem units mentioned by 4 focus groups. By contrast, environmental and storage problems, together, garnered only 3 unique problem units, with each one having 1 focus group mentioned which suggested it was not a concerning to the participants during the discussion.

Results collected during the course of activities one and three were largely parallel. The packaging features with highest ranks in activity 1 were: sufficient grip space, preopening integrity, seal/peel strength and easy to read labeling (see Table 5).

IV. CONTENT ANALYSIS

As mentioned, focus groups, by their very nature, provide qualitative results. Results are group-driven with medical device packaging features of the greatest salience to OR nurses emerging as a means to identify key issues for further exploration.

Focus groups followed a moderator guide (Appendix A) which broke sessions into 3 categories for discussion. Recordings taken during focus group sessions were reviewed post-hoc to identify and categorize “thought units” into a coding scheme. A total of 1,095 thought units were categorized according to the coding scheme based on the moderator guide (see Appendix A and Table 14). Units coded in the broad category, “packaging issues,” accounted for 72.6% of the collected data (n=795/1095). The work

environment accounted for 20.8% of the data (n=228/1095) while the general packaging accounted for only 6.6% of the enumerated thought units (n=72/1095).

Table 14: Distribution of thought units

	n(% by category)	(%) by total units
General Packaging		
Quantity opened	33 (45.8)	3.0
Common Types	39 (54.2)	3.6
Total General Packaging Unit	***72***	6.6
Work Environment		
Noise	59 (25.9)	5.4
Lighting	49 (21.5)	4.5
Work Space	57 (25.0)	5.2
Storage	39 (17.1)	3.6
Other	24 (10.5)	2.2
Total Work Environment Unit	***228***	20.8
Packaging Issues		
Identification	180 (22.6)	16.4
Opening & Aseptic presentation	544 (68.4)	49.7
Packaging Waste	68 (8.6)	6.2
Other	3 (0.4)	0.3
Total Packaging issue Unit	***795***	72.6
Total Units	**1095**	100.0

Consistent with findings of other activities detailed herein, a majority of the discussion (as identified through analysis of the total thought units generated) focused on: opening and aseptic presentation (49.7%), followed by identification (16.4%).

i. General packaging

The “general packaging” category addressed two questions: typical opening quantities and common packaging types.

The general perception was that OR personnel could open “up to hundreds” of packages during a shift. This frequently led to discussions regarding the large amounts of packaging waste generated in the OR which was further explored through guided discussion in the “Packaging Issues” category (see Moderator Guide Appendix A and Table 14). Among the packaging opening features discussed, chevron pouches (see Figure 1) and corner peel pouches (see Figure 2) were recognized as the two most common types of packaging used in the OR setting.

The performance of commonly used packages played an important role in respondents’ ability to execute activities. Nurses reported that poorly designed corner peel or chevron pouches significantly increased difficulties.

ii. Work environment

The overall category of work environment accounted for 22.5 % of the total thought unit data (see Table 14). The findings of each sub-category (noise, lighting, workspace, storage) are presented as follows.

a. Noise

Most participants reported that the OR was very noisy a majority of the time. “People noise” and “equipment noise” were consistently reported as noise sources. Even though the OR was identified to be a noisy setting, a majority of participants indicated that while opening packages noise “didn’t bother” them. However, many

participants sensed that the main problem of the noise was that some confusion could be caused when they couldn't hear what the surgeon was asking for if it was noisy.

b. Lighting

In general, lighting was reported to be "very good" in the OR. However, many nurses reported inconsistent lighting, based on procedure. In certain cases, it was indicated that the lighting "stinks", causing difficulty in both reading and locating needed information on packages. This became an issue especially if the package was not familiar to participants.

c. Work space

Most participants felt that operating room is crowded, largely as the result of the varied equipment for most of the time. Further discussions revealed that the problem of crowding was compounded at teaching hospitals, where students are also present. Not surprisingly, there was a sense that having many people move around in the room increased the difficulty of aseptic presentation. Big packages were indicated to be particularly challenging to open in a crowded environment.

d. Storage

Many participants indicated that things are relatively well organized and properly labeled in the storage room within the OR, where items that are routinely used tend to be stored. In contrast to this, they reported that central supply commonly has things placed in the wrong bin, and, as a result, incorrect or inappropriate items can be selected.

Another primary concern for the participants was the constantly changing storage location of medical devices and a lack of communication between OR nurses and logistics.

Based on the findings in the work environment, most reported in the broad category “environment issues” were not related to the packaging. Two packaging features: convenient packaging size and quick identification of wanted information were the only relevant issues within this category.

iii. Packaging issues

Across all seven focus groups, a total of 795 thought units were identified during the “Packaging Issues” portion of the focus group (See Table 14 and Moderator Guide Appendix A). Within the “packaging issues” category, 68.4% (544/795) of thought units were sub-categorized as opening & aseptic presentation; identification accounted for 22.6% (180/795) of the thought units in “packaging issues.” While packaging waste issues accounted for 8.6% of units collected during the “packaging issues” discussion (68/795) (see table 14).

a. Identification

Nurses identified themselves to be very busy: they either “don’t have time to read” at all or to complete the message in its entirety. To cope with this fact, two packaging needs were expressed by the participants: packages that nurses don’t need to read and the presence of critical information in a format that can be quickly identified and read. Table 15 and table 16 concluded the major comments and findings associated with these two needs.

Table 15: Findings associated with need of "don't need to read"

Need	Possible Solution	Problems associated with solution
Don't need to read	Transparent packaging to allow quick identification of contents	
	Diagrams	
	Color coding systems	Needs to be consistent and universal
	Different opening features (apply to the sterility information)	

1. Don't need to read

Based on the first need, four features were recommended by the participants (see Table 15): transparent packaging to enable quick identification of contents; diagrams on the packaging; color coding systems, with emphasis on size and material; and using different opening features to indicate the sterility of the contents.

- Many participants suggested transparency (see Figure 10) was desirable, enabling quick identification of inside contents and a correct choice of product within a short time. When transparency is not an option, having a diagram (see Figure 11) on the outside package was indicated by some participants to be helpful, particularly with regard size and shape.

- A "universal" color coding system was indicated by many participants to be very helpful to quickly identify a product when applied to "size" and "material". It was also suggested that the consistency (or standardization) of the color coding was the basis of the success of this method, or could cause the confusion.

- Different opening features were suggested to be used for the identification of sterility of the product. For example, the tear open package (see Figure 3) implied the inside contents were not sterile, while peel packages, such as the chevron (see

Figure 1) or corner peel (see Figure 2) implied to participants the sterility of the inside contents.

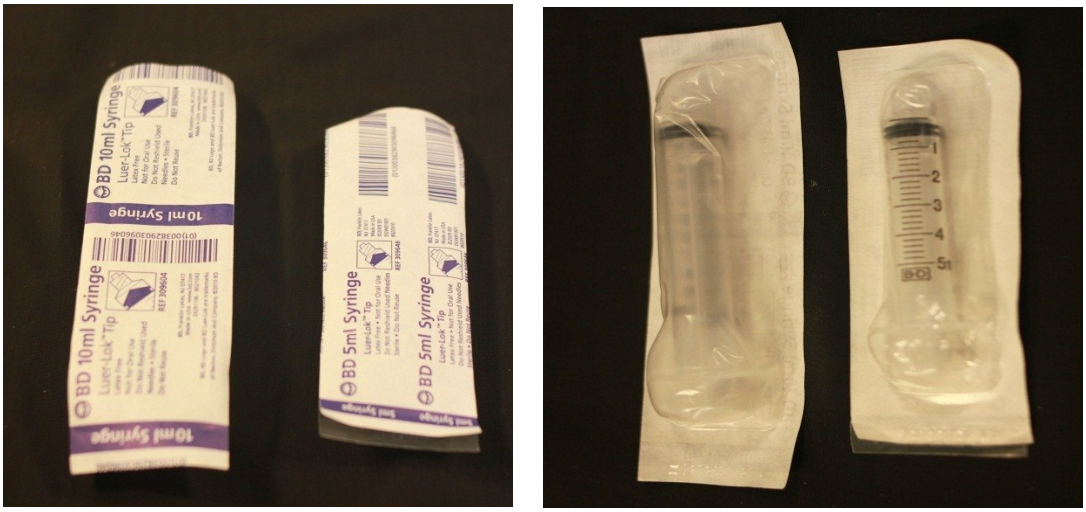


Figure 10: Example of transparent packages

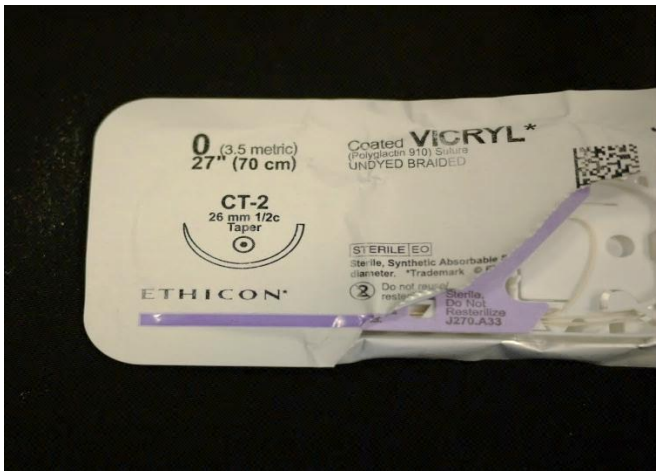


Figure 11: Example of a diagram on a package

Among these four possible solutions mentioned by the participants, each one had certain limitations. Using different packaging opening features to indicate the sterility of the inside product is not currently applied commercially. This suggestion was

made largely due to the fact that some opening features create difficulty of presenting the product aseptically, for instance, the tear open pouch (see Figure 3). Nurses indicated that tear open packages should not be used for sterile product at all; this discussion was continued during the “packaging issues” portion of the moderator guide (see Appendix A).

The use of color coding systems was the most controversial solution proposed. Some participants suggested that such a system can result in confusion if the color coding was not consistent. Other issues include the fact that decipherable color options are limited.

2. Critical information must be quickly identified and readable

Most participants reported difficulty in finding critical information on packages (see Table 16). As discussed in the previous section, nurses expressed a desire for designs which eliminate the need to read. They suggested that where this is not possible (the information has to be obtained by reading), a second need should be met: having the critical information facilitate quick identification and be easily read.

Thought unit analysis suggested that irrelevant information interferes with the accessibility of critical information. Nurses recommended four pieces of information as critical to them: expiration date, product name, latex free and sterility.

Table 16: Findings associated with need of "critical information"

Need	Challenges		Solution
Critical information must be quickly identified and readable	non-critical information gets in the way making it harder to find the wanted information (see Figure 12)		get all the wanted information together, highlight the critical information
	expiration date	No standard location	standardize a location for this information
		Light colors	make it dark and black or bold, bright color
		Font sizes	use larger font
	latex free	Lack of any information regarding latex status causes confusion regarding its presence or absence	
		latex free info not provided	
	sterility info for double barrier	the sterility info is sometimes printed on the inner package	the outer package should have the information
		font size	use bigger font size
		wrong highlighting of sterility for unsterile item	use circle and slash

Figure 12: Example of non-critical information gets in the way

- Many participants suggested that all the critical information should be placed together and in a single location.
- It was also suggested that techniques should be applied to make the critical information stand-out such as: bolding, underlining, and bright colors.
- Expiration dating was reported to be “very important”. Most participants indicated that they had hard time finding or reading the expiration date (see Figure 13).
- Complaints of poor contrast were not limited to packaging systems that relied on embossed expiry dates (see Figure 13). Participants also suggested that printing of minimal contrast, light colored text, gave them difficulty. Small font was also reported to be an issue for most of the participants.
- The inconsistent location of the expiration date was another issue for OR nurses and made them feel frustrated frequently. Having a standardized location for expiration date was highly recommended by all the participants.
- Latex information was considered to be important due to increases in the prevalence of latex allergies. Lack of ANY information on the presence of latex caused confusion.
- Most participants indicated that the sterility information was very important especially for double barrier package due to the associated contamination issue.
- It was suggested that when sterility information was marked on the inner package (instead of the outer), there was increased potential for contamination because needed information wasn’t present until they dumped the inside package into the sterile field.

- Not surprisingly, small font sizes for sterility information were indicated to be a challenge for many participants (see Figure 14).
- A packaging example that was brought into the focus group indicated “the inside package is not sterile” with the word “sterile” bolded. This led to the assumption that the inside was sterile since this single word was bolded. This led to the suggestion that a circle and slash should be used on the word “sterile” if the inside contents are NOT sterile.

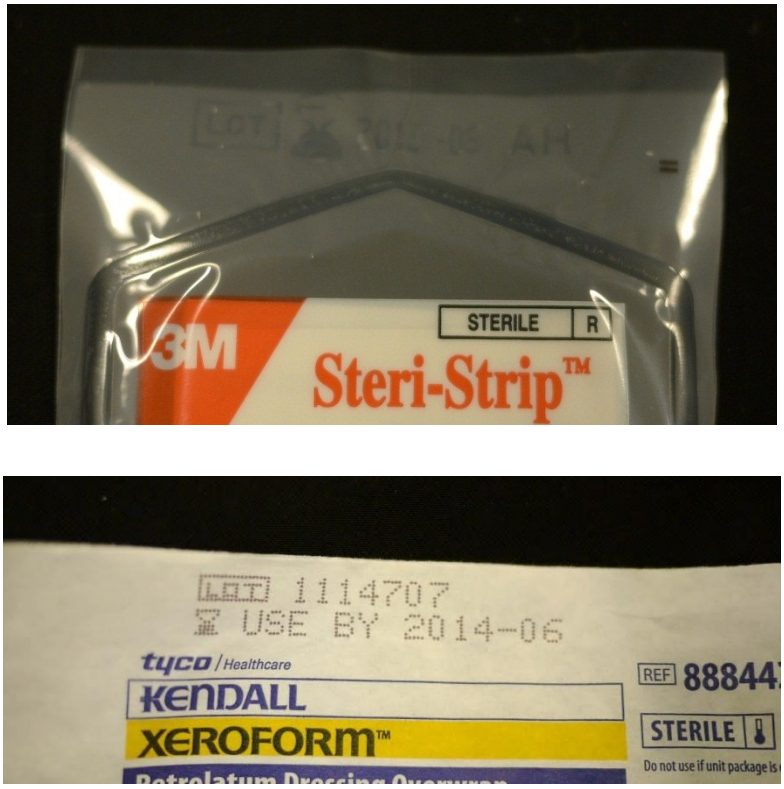


Figure 13: Example of packages with hard-to-read date (Top) and with clear expiration date (Below)

Figure 14: Example of Large font size applied to package

b. Opening & Aseptic presentation

Five-hundred and forty-four thought units were categorized under the heading "opening and aseptic presentation." (see Moderator Guide Appendix A and Table 14) Due to the large amount of thought units within this category, under the major category "packaging issues" (see Table 14), several sub categories were further split out (Identification, opening and aseptic presentation) aseptic presentation was further subdivided into 10 major themes reported by the participants.

1. **Findings of opening and aseptic presentation issue types**

The number of thought units under each issue type is reported in the table 17; within each type, the number of thought units of each was counted, and presented from highest frequency to the lowest frequency in the table (see table 17). Nonspecific expressions such as, "packages can be hard to open" were categorized under the broad heading, "broad comments".

Issues specific to certain packaging types, were also noted and counted within each main packaging issue type for later analysis (see table 17), so that comparisons could be made (see table 18).

Table 17: Distribution of thought units of packaging issue types under subcategory Opening and Aseptic Presentation

		N	(%) Total Percentage
1.Removing contents sterilely		**105**	19.3
corner peel		33	
tear open package		27	
chevron		16	
rigid tray		14	
header bag		8	
double barrier		6	
broad comments		1	
2.Hard to open		**91**	16.7
peel/tear strength		39	
	tear strength	10	
	strong peel strength	15	
	weak peel strength	7	
	broad comments	7	
sufficient opening room		40	
	corner peel	11	
	chevron	6	
	tear open package	3	
	broad comments	20	
tack		8	
	chevron	5	
	corner peel	3	
broad comments		4	
3.Package design should consider contents		**80**	14.7
double barrier		22	
long/skinny/flexible		18	
big/heavy		13	
sticky		11	
multiple loose items		9	
sharp		3	
small		2	
broad comments		2	

Table 17 (Cont'd)

	N	(%) Total Percentage
4.Sturdy material	**71**	13.1
ripping of material during opening	53	
rigidity of rigid tray	11	
broad comments	7	
5.Hard to separate interfaces	**60**	11.0
thumb notch	23	
extended material	10	
same material of 2 webs	8	
rough edge	6	
missing material in rigid tray	4	
broad comments	9	
6.Convenient package size	**54**	9.9
rigid tray	33	
oversize package	15	
broad comments	6	
7.Quick identification of opening features	**44**	8.1
solution	16	
corner peel	7	
rigid tray	3	
chevron	2	
tear open package	5	
header bag	1	
broad comments	10	
8.Slipperiness of packaging material	11	2.0
rigid tray	11	
9.Packaging provides added protection	9	1.7
double barrier	9	
10.Another opening option	3	0.6
corner peel	3	
Total Units	544	100.0

Among the 10 themes that were subcategories (see Table 17), the 7 packaging issues with the highest frequency of recorded thought units were:

- Removing contents sterilely

- Hard to open
- Packaging design didn't take the inside contents into consideration
- Packaging material is not sturdy enough
- It is hard to separate two webs
- Package size causes problems
- Opening features didn't allow quick identification

1.1 Removing content sterilely

Packaging issues relating to difficulties in removing contents sterilely were reported to be a major concern by most participants. Data suggests that the issue is dependent on package type (see table 17). Corner peel pouches (see figure 2) received the most of the negative comments. The tear pouches (see figure 3) received the second most of the negative comments, however were indicated to be the least favorite packaging type when applied to sterile products. Rigid trays (see figure 7) accounted for 14 comments (all negative), followed by header bags (see figure 5) and double barrier packaging, all with negative comments. Chevron pouches (see figure 1) had all positive comments. Many participants indicated that products could be easily reached and removed (sterilely) from Chevron pouches.

Nurses generally indicated that removal of sterile contents from tear pouches (see figure 15) was usually associated with contamination and, as mentioned previously, suggested this to be the hardest design to successfully present sterilely. Reasons for this generally fell into two categories: "no sterile boundary for tear open pouches"; and a lack of control of what the contents would contact during opening. Most participants felt that it would be preferable if the tear pouches were "only used for non-sterile items". For

the same reason, the tear pouch was considered by some participants to be unsuitable for the outside package of double barrier system, but a possible option for the inner package.

Figure 15: Tear Open Pouches

Comparisons were made between corner peel pouches (see Figure 2) and chevron pouches (see Figure 1), the two most common packaging types used in OR. When comparing the two packaging types, all the participants showed great favoritism for the chevron pouches. Participants suggested that chevron pouches were superior to corner peel pouches for aseptic technique in three regards: getting three edges of the pouch open; control of the package and product; and even opening.

Participants generally agreed that personnel need to “have three edges of a pouch open” for things to be presented sterilely, something which was hard to do with a corner peel design. To achieve this for a corner peel, the nurses indicated that they generally move their hands, which they believed increased the chance of contamination since the hand might “touch” the contents. At this point, it was indicated to be very easy

to get three edges of the chevron pouches open. According to many participants, contamination could also be caused when opening large corner peel pouches since the “flaps might curl back” and “touch the product.” Many participants suggested that contents would easily “slide over” and “touch the edges,” due to limited control of the product when opening corner peel pouches. They suggested that opening chevron pouches, on the other hand, offered “more control” of the product and less curling of the material. And unlike chevrons, many participants complained that they couldn’t “peel the corner evenly” which could make them lose control and increase the contamination risk.

Rigid trays (see Figure 7) received 14 comments. Discussion focused on opening and removal by “popping” contents from the package. Participants reported occasional cases where the content got stuck and couldn’t be popped out. A single participant expressed concern about the popping technique, due to the potential contamination. Expanding concern in this topic suggested that rigid trays were frequently “made for one person to pop out” because there was “no room” for someone to “get fingers in and grab the item out”. The topic was illustrated by a participant who claimed difficulty with the package for ping pong. The device was contained in a thermoformed tray, with no room for another person to get the fingers in and grab the ping pong out. The nurse reported difficulty in “popping” the item from the package, rendering the contents stuck.

The “peel up” header bags (see figure 16 and Appendix E) were also reported to result in difficulties associated with removal of contents sterilely. It was stated by some participants that “similar to the tear pouches”, getting the sterile items out was a big issue for “peel up” header bags. However, “when a tray was packaged” within the header bag there were not as many complaints.

Figure 16: Peel up Header Bag

Six negative comments were recorded with regard to double barrier packaging and sterile removal. A tray within a tray was noted to be a particularly problematic system. Two focus groups noted that occasionally, “the outer package was just a little bit bigger than the inner package”, so they “don’t have enough thumb room to get the inner tray out sterilely”. One existing packaging feature of “putting a little paper tab” in the inner tray was indicated to be helpful since the inner tray can then be easily lifted. A suggestion of “having a corner cut for them to grab” was also mentioned.

1.2 Hard to open

Thought units discussed during the “hard to open subsection” were further divided into: peel/tear strength; enough opening room; and tack. Of these, peel/tear strength 42.9% (39/91) and enough opening room 44.0% (40/91) gathered the majority of thought units (see table 17).

Peel/tear strength was indicated to be “a big issue” for most participants. In addition to the questions of sterile presentation discussed in previous sections, participants also indicated that tear open packages sometimes couldn’t be torn or be

torn all the way through (see Figure 17). Several participants indicated that the slit on the tear open packages was too short, which increased the difficulty of tear open.

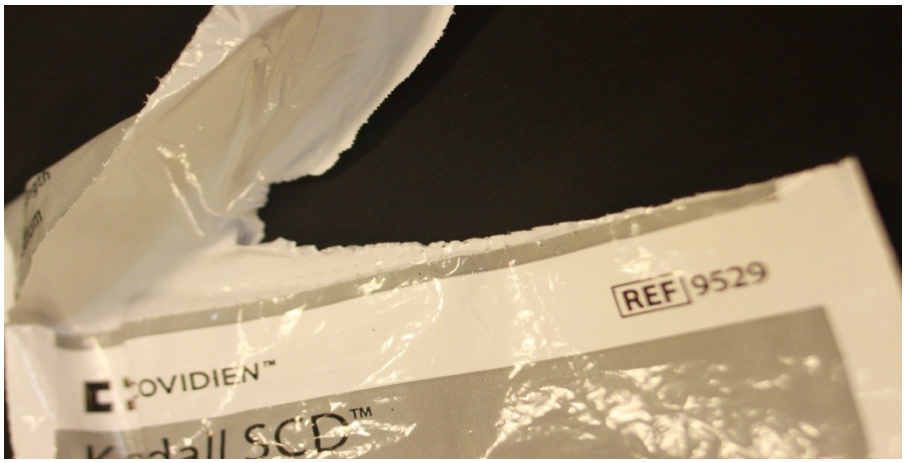


Figure 17: Example of tear pouches didn't tear all the way through

Discussion regarding peel pouches suggested that peel strength that was "too strong" and "too weak" generated problems. Strong peels could not only cause opening issues, but also had the potential to contaminate because the package required "extra effort", frequently causing contents to "jump out of the package". Weak peel strength was perceived as a problem, too. When peeling packages, "certain tension" was expected, in the event that it wasn't present, contents could also jump from the package when it peeled too easily. Weak seals also raised concerns related to sterility of the contents.

Most participants consistently expressed their need for sufficient grabbing room. People suggested that the depth of the holding room should be made "at least as deep as man's thumb" (see Figure 18). Three packaging types were specifically mentioned when talking about sufficient opening room: corner peel, chevron, and tear open pouches. Not having enough gripping space was submitted to be a more common in

corner peel pouches (see Figure 2) than chevrons (see Figure 1). Chevron pouches were generally perceived as having large spaces for gripping.

Figure 18: Example of corner peel pouch with big open corner

Tacks (see Appendix E) were reported as problematic by a few participants, who indicated that the presence of a tack(s) increased the difficulty of opening on chevron and corner peel pouches. It was also reported by some participants that they usually "separated the tacks before" peeling the package to cope with their presence (see Appendix E).

1.3 Package design should consider contents

Packaging was discussed in relation to the medical devices within. Participants reported problematic issues when device properties were not taken into the consideration when selecting packages. Six main content types were discussed: (1) long/skinny/flexible; (2) big/heavy; (3) small; (4) sticky; (5) multiple loose items; (6) sharp profiles (see table 17).

It was reported that the long/skinny/flexible contents had more chances of "leaning to the package edge" and getting contaminated (see Figure 19). Similar

problems were reported for big/heavy contents. Compared with the big contents, not surprisingly, small items were reported to be easier to control.

Figure 19: Example of long/skinny/flexible contents with its package

It was reported that sticky contents (see Figure 20) “always” required a scrub nurse to pick the item with the circulator holding the package. Non-adherent dressing was a common example given by the participants. After opening the package, the dressing is always stuck to the inside of one web which requires another person to peel it off.

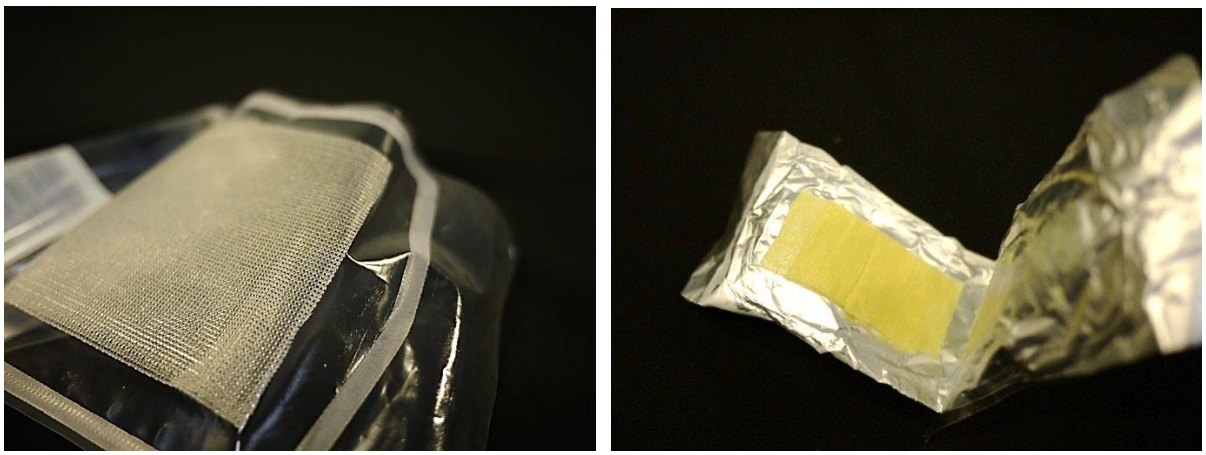


Figure 20: Example of Sticky contents with package

Many participants complained about packages with multiple loose parts inside. According to the participants, the parts could either be “easily missed” or “fly out in

different directions", hit the fingers and become contaminated upon being presented to the sterile field. It was suggested to the tie all the loose contents together to one unit.

Sharp contents (see Figure 21) were mentioned to have safety issues since it could be dangerous to the scrub nurse.

Figure 21: Example of sharp items with its package

Many participants mentioned double barrier packaging as a suggested solution to many contents related issue: long/skinny/flexible; sticky items; multiple loose items; and sharp items.

1.4 Sturdy material

Ripping issues (see Figure 22) inspired many thought units (53/71 for the "sturdy materials category; 74.6%) and the need for sturdy material that wouldn't rip was consistently expressed by many participants (see table 17 "sturdy material subsection"). It was reported that the ripping of foil and paper-based packaging happened on a "daily basis" in the hospital. Most participants expressed their concern about the sterility of products once ripping occurred. Concern centered on the fiber that was generated

during ripping and other factors. Respondents generally felt that coated paper had more resistance.

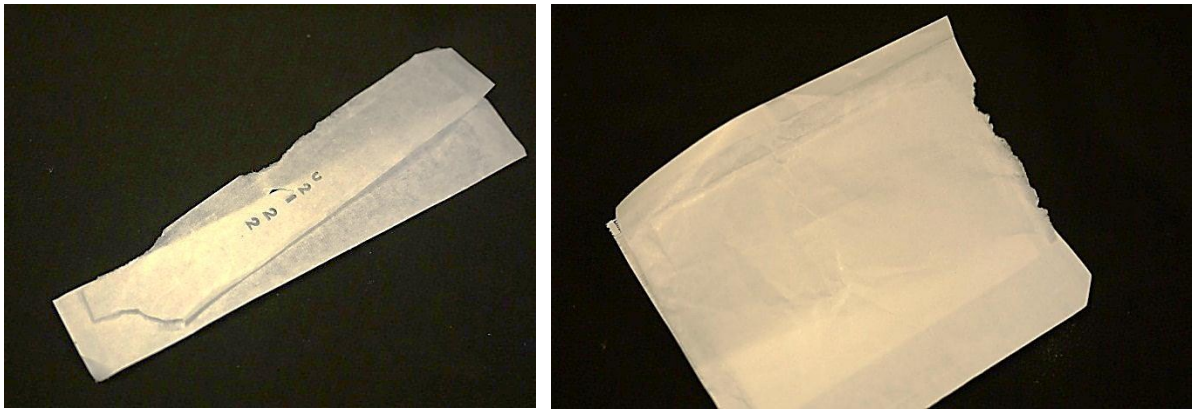


Figure 22: Example of packaging ripping issue

Several participants pointed out that when the tray bottom was not rigid enough (see Figure 23), contamination could be caused when the tray was turned over and contents were presented.

Figure 23: Example of rigid tray with flimsy bottom

1.5 Hard to separate an interface

Sixty thought units were categorized under the heading of separation of an interface (two webs for flexible or a lid from a tray) (see table 17 “hard to separate an interface subsection”). This was said to be particularly problematic when the materials were the same. Four existing design features that the participants thought could be helpful were discussed: thumb notches (see Figure 24); “extended material” (see Figure 25); “rough edges” (see Figure 26); and missing material in rigid tray (see Figure 27). Thumb notches were given the most positive thought units by most participants. Extending a web beyond the other and increased friction of the webs were also reported to be helpful by some participants.

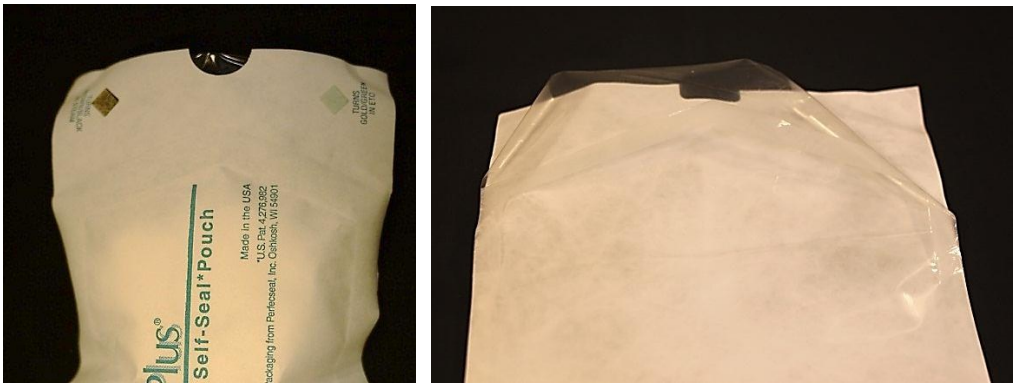


Figure 24: Example of Package with thumb notch

Figure 25: Example of package with extended material

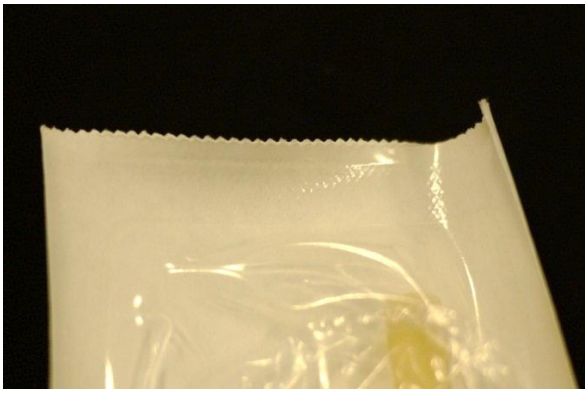


Figure 26: Example of package with rough edge

Figure 27: Example of missing with extended material in rigid trays

1.6 Convenient Package size

The importance of a convenient package size accounted for 54 thought units; of these, 33 regarded rigid trays and 15 related to oversized packaging (see table 17 “convenient packaging size subsection”). Discussion of convenient package size seemed to concentrate on the rigid tray.

The primary concern in rigid trays was that if the trays were able to be held by “one hand” (see Figure 28). It was consistently indicated that if the trays could be held by one hand, it would be safer since the “fingers would be away from the contents”, and “more stable” during opening. When the tray was too wide to be held, nurses indicated

that they have to “sit the tray down” to open and claimed this was much harder designs that facilitate one handed openings. Grip was also mentioned to be extremely important for contents that had to be “pulled from the package” because the circulating nurse needs to be enabled to hold the package tight while the scrub nurse removes the product. For wider trays, it was suggested that some grip areas should be designed into the tray body for people to hold.

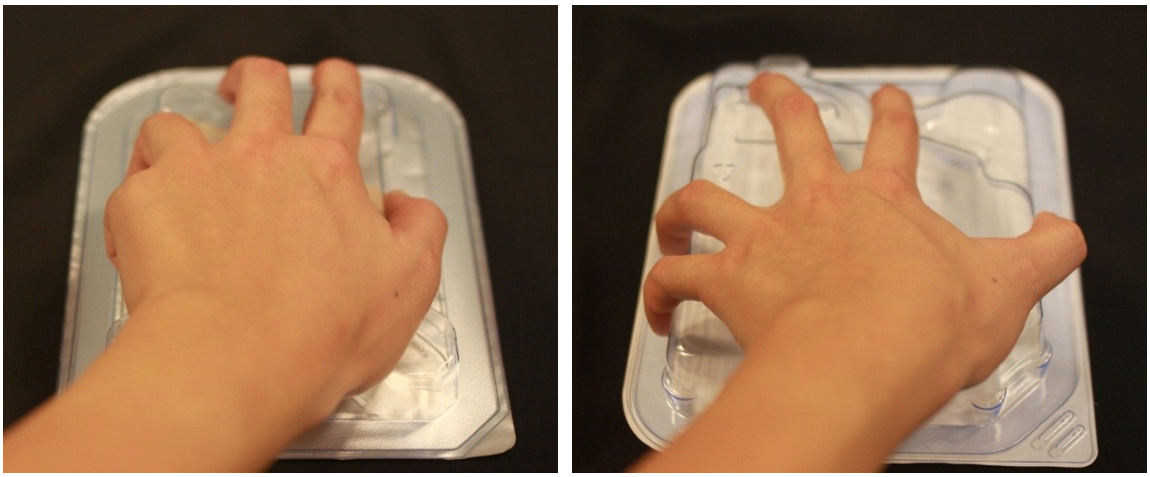


Figure 28: Rigid tray with convenient size that can be held by one hand (Left); Rigid tray with size that can barely be held by one hand (Right)

Oversized packages were consistently identified as a common reason for contamination by many participants; participants suggested that “free space” in the package (see Figure 29) enabled the contents to lean to the edge. Suggestions were made to make the package more “fit” to the content.

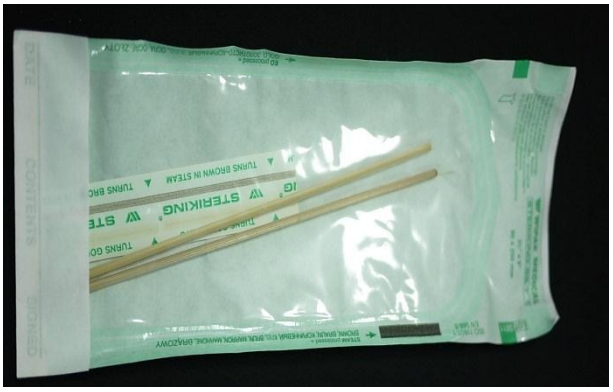


Figure 29: Example of package having “free space”

1.7 Quick identification of opening features

Many participants reported that they had difficulty finding where, and how, to open medical device packages. Thought units (44/544=8.1%) regarding these issues and suggested solutions were quantified (see table 17 “quick identification of opening features” subsection). Among the packaging types discussed, participants indicated that they had the most difficulties locating the opening corner in corner peel pouches. Tear open packages were also reported as problematic, due to short slits. Participants reported that finding the slit was a problem. Inconsistent location of the slits caused frustration, as did depth and quality, even for the same type of medical device.

By contrast, finding the opening for chevron pouches (see Figure 1) was not reported as problematic for participants. It was indicated that the “big V shaped opening feature” made the opening spot on chevron pouches obvious. Some participants indicated favor to trays formed in different shapes (see Figure 30) where opening could be quickly identified.

Figure 30: Example of package cut into different shapes

Participants suggested three design solutions for the problem of locating the opening. (1) Color coding the opening spot (see Figure 31) or (2) the use of symbols, like arrows, others suggested (see Figure 31) (3) employing simple open instructions like ”peel here” in a large font size (see Figure 31).

Figure 31: Example of packages with color coding opening spot, symbols and open instructions

1.8 Other

Three other issues related to opening and aseptic presentation were discussed (see table 17). The major findings within these three issues were:

- The slipperiness of material made the two webs hard to separate.
- The slipperiness related contamination was found to be a common issue for rigid trays. “Grab space” and “ridges” were suggested by some participants.
- Double barrier package was considered to be nice since it always gave the personnel a “second chance” to present items aseptically.
- It was reported that dual opening features such “two open corners” in corner peel pouch was favored (see Figure 32).

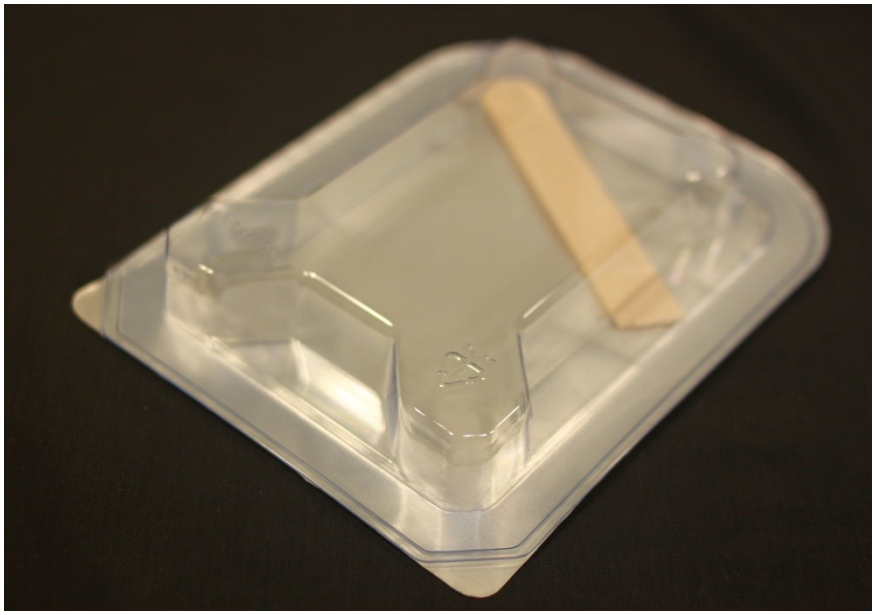


Figure 32: Example of package with two open corners

2. Findings of Packaging types by opening and septic presentation issues

Thought units were also characterized by package design (see Appendix E), shown in table 18. Negative and positive comments were enumerated separately.

Table 18: Distribution of thought units of packaging types under Opening and Aseptic Presentation

	Rigid Trays		*Corner Peel Pouches*		*Tear open Pouches*		*Double barrier*		*Chevron Pouches*		*Header Bags*	
	Neg.	Pos.	Neg.	Pos.	Neg.	Post.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.
Sterile Removal	-14		-33		-27		-6			16	-8	
Peel/tear strength					-10							
Sufficient opening room			-11		-3					6		
Tack			-3						-5			
Package design should consider contents								22				
Sturdy material	-11											
Convenient package size	-33											
Quick identification of opening features		3	-7		-5					2		1
Slipperiness of Packaging material	-11											
Packaging provides another protection								9				
Another opening option				3								
Total number of thought units	-69	3	-54	3	-45		-6	31	-5	24	-8	1
	72		**57**		**45**		**37**		**29**		**9**	

As shown in the table 18, rigid trays, corner peel pouches and tear open pouches received the global comments. These three types of package also received the most negative comments while the double barrier package and chevron pouch received most of the positive feedbacks. Only nine thought units related to the header bag, with eight of them negative.

As would be expected, each package design had specific issues. Rigid trays, received negative comments relating to convenient sizing. The discussion was focused on if the tray could be held by one hand, and most participants expressed the importance of this ability. Other concerns relating to rigid trays were the slipperiness and rigidity of the tray body. Participants felt that soft trays and trays which easily slipped were more likely to be contaminated during asepsis.

Within 45 comments, discussion regarding tear open pouches primarily related to sterile removal, a subject which accounted for 27 negative comments. This was the reason that participants suggested this packaging type not be used for sterile contents. Tear strength and quick identification of the opening features were also suggested to be a big issue for tear open pouches. Strong tear strength reportedly increased the difficulty of opening and the inconsistency of the tear slit made it hard to locate the opening.

Corner peel pouches inspired many comments; many of which were negative. Negative comments focused primarily on three aspects: hard to get the product out sterilely; not enough gripping room; lack of the ability to quickly identify the opening feature. As discussed earlier, participants indicated that they had less control when peeling corner peel pouches which could lead to contamination. Not having enough

gripping room and difficulty finding the opening corner were issues that were mentioned more for corner peels than other package designs.

On the contrary, the comments for double barrier packages and chevron pouches were mostly positive. When talking about the packaging difficulties regarding the properties of different contents, double barrier package was considered to be a very effective solution. Among the positives, participants mentioned that the use of double barrier systems provided extra protection and a second chance for asepsis. Concerns included sterile removal for double tray systems when insufficient gap space was provided.

In terms of getting product sterilely, chevron pouches got 16 positive comments and no negative comments. Most participants concluded that the chevron package was their “favorite” package and very easy to work with. Participants found that they had the most control of the product and package when opening the chevron packaging.

Header bags only obtained 9 thought units in total, with 8 negative comments and 1 positive. The 8 comments were all about how to get the product out sterilely.

c. Packaging waste

Packaging waste accounted for 8.6% (n=68/795) of thought units within packaging issues (see table 14). Across the focus groups, many people expressed their concern about the large amount of trash the hospital generated. There were many situations that could lead to the disposal of products before it was used on patients. These included:

- Products that fell out of the sterile field
- Products that hit something unsterile which caused the contamination

- Products that were expired
- A break in integrity or questionable integrity
- The wrong size of item was opened due to the similarity of the packages

Some participants indicated that the situation (disposal of a product prior to use) happened “at least once a week”; while some indicated that it happened “on a daily basis”. Many participants stated these things happened because of packaging only “once or twice a day”.

Products which got contaminated but were not used were reportedly defined as “clean trash”. Several avenues for “clean trash” were provided. These included:

- Return to the company for credit, refund, return or re-sterilization, particularly for expensive items.
- The use of a “mission bin” or “med-wish” system, for the purpose of providing products to those in need. Recycling is not very common for medical devices. There are only few recycling programs in hospital and mainly for plastics.
- The cheap ones, disposable ones, and uncounted ones will go to the trash.

Despite the fact packaging waste was ranked to be less important compared to other packaging features and only had 9.5% of the though units within packaging issues, it was still pointed out by some participants that it’s worth the serious consideration due to the large amount of trash packaging generated.

CHAPTER 6
CONCLUSIONS

Seven focus groups consisting of 21 OR healthcare personnel were conducted to explore common themes related to packaging features, packaging types, and how the OR environment affects packaging utility. Three activities comprised a good portion of the focus group. These activities were: (1) The rank ordering of different packaging features, (2) The rating of varied packaging aspects (quick identification, ease of opening and aseptic presentation), (3) development of a "problem list" from the group discussion and scale reporting of the frequency of each. A content analysis was conducted from abridged transcripts of the seven focus group sessions.

Activity one results (the ranking activity) suggested that quick identification, ease of opening and aseptic presentation were quite important to OR personnel. All of these factors in activity two (the rating activity) rated as a number higher than 8 (with 10 being the most important).

Ease of opening and aseptic presentation comprised 7 of the top 10 features ranked. "Labeling" and "visibility of the product", which both were related to quick identification were selected by the participants as the top 10 important packaging features. Environmentally friendly packaging and storage issues were less of a concern for participants than the issues of ease of opening; aseptic presentation and labeling that were previously discussed. A similar pattern was found in activity 3, which evaluated the problem units associated with opening, aseptic presentation, identification, environmental and storage issues. A large number of problems concerned opening and

aseptic presentation (see Table 8). Although the topic quick identification did not have as unique problem units as those associated with opening and aseptic presentation, it was an important issue during the discussion that was mentioned by many focus groups. As with the activity one rankings, environmental issues received less attention compared to the other two but were discussed.

The content analysis of the thought units suggests that participants have some difficulty with different packaging features, and the various packaging types. Participants generally agreed that, medical device packaging should be conveniently sized and facilitate quick identification due to the lighting and work space issues in the operating room.

Quick identification was a big issue for participants. Participants expressed the desire: to not read or to only read limited information. Participants suggested that they currently have difficulty finding the needed information, including: expiration date; latex free; and sterility information.

The ten packaging issues (related to opening and aseptic presentation) that participants reported with the highest frequency were: difficulty in aseptic removal; hard to open packaging due to peel/tear strength; lack of opening room, and tacks; inappropriate packaging type for certain specific contents; material is not sturdy enough which caused ripping issue; hard to separate an interfaces; not convenient packaging size; opening features does not allow quick identification; slipperiness of packaging material; packaging provides another protection; and another opening option.

Based on the findings of the content analysis, different packaging types perform differently in the OR. Chevron pouches and corner peels are the most commonly used

OR packages. Chevron pouches were selected as a favorite packaging, with focus group participants suggesting they were superior to other packaging types because of: quick identification of opening features, ease of aseptic presentation. By contrast, OR personnel reported that corner peel pouches had many problems including: difficulty in aseptic removal, lack of gripping space, difficulty identifying the opening corner.

Given the emphasis on sterility and sterile technique that are imperative in this environment, it is not difficult to understand why tear open pouches and header bags received a lot of negative comments (see Table 18).

If the rigid tray's size allows them to be held by one hand is considered by the participants to be a very important feature for the rigid tray and could influence the ease of opening and aseptic presentation.

In general, double barrier package was considered to be nice by providing another protection and suitable for certain contents.

CHAPTER 7
RESEARCH LIMITATIONS

As with any study, several limitations exist. The current sample size of 21 is not large enough to generate statistically reliable results of the three activities. Larger sample size recommended for future studies to more completely assess differences.

In activity 2, it's likely that the 4 participants out of 21 participants ranked the quick identification, ease of opening and aseptic presentation instead of rating them which contributed to the inaccuracy of the rating results and was the possible reason for the high standard deviation of the results data.

Focus groups are, by their very nature, subject to group dynamics. Additionally, moderators guide focus groups with a moderator guide. The use of said guides enables consistency among the groups, and limits the amount of off-topic discussion. That said, potential influence regarding the course of discussion is inevitable and thought units will largely reflect the guide.

Although frequencies of the categories of thought units were counted, this does not necessarily indicate that the important level of topics discussed. For example, some topics were discussed more than others. This may be because they happened more frequently as opposed to participants considering them to be more the most important. It was apparent that sometimes an important topic may have only been mentioned a few times, but with extreme intensity. As much as possible powerful comments were noted and recorded.

CHAPTER 8
FUTURE RESEARCH

Based on the packaging issues reported by the participants, a survey could be developed regarding packaging issues and their frequency, important packaging features.

Further study is recommended to quantify the impact of varied packaging features. For example, the relationship of packaging size to storage and aseptic presentation can be further studied. Quantification of the relationship between design (e.g. corner peel and chevron pouch) on contamination rates is also recommended to explore the nurses' suggestion that there is higher contamination risk associated with corner peels. This same type of work is also recommended to explore how tear open pouch designs impact contamination rates (Nurses suggested that tear open designs should not be used for the sterile contents). The relationship of seal strength and contamination is also recommended for further study.

Recommendations for future study are not just limited to design factors; it is also recommended that focus groups be repeated with others within the hospital, for example, members of central supply, and the emergency department. Comparative studies would help to optimize package design and further hone new directions of study.

Other recommendations for future research include optimization and redesign of packages for medical devices. Based on the results of this research, new designs should consider: gripping area so that the packaging could be held and pealed easily and optimal placement and presentation of information for quick identification. Other

factors that were suggested to be important included: one handed presentation, particularly with large trays; as aseptic presentation of sticky or skinny flexible devices. Participants' suggestions for such designs can be found herein.

APPENDICES

Appendix A:

IRB approved Moderator Guide

Focus Group Moderator Guide

GOALS

We are trying

1) To get a sense of what OR and ED personnel experience when using varied designs of medical device packages.
2) To gain better understanding of the needs of these people with regard to medical device packages.
3) To evaluate how the current medical device packaging features work for OR and ED personnel.

Note

Time allotted for each section is as follow:

Section	Minutes
Introduction	5
Warm-up	5
Education	5
Work Environment	15
General Package Review	10
Identification	10
Opening and Aseptic Presentation	15
Packaging Waste	10
Problematic and Good Design	40
Conclusion	5
Total	120

INTRODUCTION

Hello everyone, my name is Monica Cai. I'm a graduate student in the school of packaging at Michigan State University. First, I'd like to welcome all of you coming here, sparing your precious time and helping us with this focus group. Basically, a focus group is just a group of people getting together and talking about one specific topic. The group will last for approximately two hours until every question has been answered and everyone has said what they want to say. Our whole purpose here today is for you to voice your opinions and share your the experiences you've had with medical packaging.

I will be your moderator today and here with me are the members of our research team, XX and XX. They are going to help taking notes and taking care of the cameras. Today, we are going to focus our discussion on issues related to the design of medical packaging. I need to confess that I'm not an expert in this area and I don't know much about it. Since everybody here is from the medical profession, your perceptions will be extremely valuable to our research. My job here is to help keep the discussion flowing and to make sure everyone gets the chance to talk. If I need to interrupt, it will only be to ensure that we can cover all the topics within our time frame or to make sure that those that have not had an opportunity to do so if they wish. I apologize that my english is not that good, so if you don't understand my questions or what I'm saying, please feel free to ask me to clarify.

We want everyone to feel comfortable to share their opinions, but still, there are some rules for the discussion

1. There are no right or wrong answers.
2. Everything you say is very important to us.
3. Feel free to disagree or agree with other's opinions. We expect people to have different opinions.
4. Please try not to interrupt each other.
5. I might skip over you if you have talked a lot or I might call on you if you haven't talked at all. Our goal is to hear everyone's thoughts.

We will be videotaping this talk so we can remember what was said. For those that have indicated it is OK, we may use video clips in conference presentations and the

classroom. In doing so, we would like to share learnings that we gain with students as well as the medical device industry, so that future packages are improved.

Any questions? Thank you for being here and let's begin.

I. WARM-UP

1. I'd like to begin by having each of you tell us your name, what your current position is, and how long you have been employed as part of the healthcare system.
2. How many hours do you work on a typical shift? And how do you feel about your work load?
3. Do you think there are certain traits that people working in ED/OR settings should have?

II. EDUCATION

(Set the package samples on the table, show the packages one by one to nurses)
Now, I'm going to show you some medical device packages, and teach you some words that we, in packaging, use to describe the design features. So that we can all be on the same page, and minimize misunderstanding, if you could use these terms as we get into discussions, that would be helpful. I brought several packages with different features.

1. Flexible pouch
    1. Chevron
    2. Corner peel
    3. Header bag
    4. Tear strip
2. Rigid tray with lid
    2. Porous lid
    3. Nonporous lid
3. Flexible packaging with lid

II. WORK ENVIRONMENT

1. What's the environment of the ED/OR like?
2. Physical environment

PROBES

a. Noise
   -Is the ED/OR usually noisy?
   -Does noise ever cause distractions when working with packages?
   -What kind of things happen?
b. Lighting
   -How's the lighting in the ED/OR?
   -Does the light vary across the department?
   -Have you ever had any packaging difficulties that are the result of lighting?
c. Work space

-Is the ED/OR ever crowded?
-Does your work space ever cause difficulties when working with packages?

III. GENERAL PACKAGING REVIEW

1. How many packages do you open during a shift?
2. What common package types do you deal with?
3. Let's brain storm. List the features or aspects that you think should be of central consideration to package designers.

Activity

Please choose the 10 most important aspects from this list, and order them from 1 to 10, with 1 being the most important of the group and 10 being the least important.

IV. IDENTIFICATION

1. List all the types of storage where you might have to go to look for a medical device. (carts, drawers, pockets, closets etc.)
2. Are the medical devices consistently placed so that they can be quickly identified or easily located, or are they in variable locations/orientations?
3. What packaging features do you think is relevant to the identification of product?
4. How important do you think quick identification of the product in ED/OR is? Scaled 1-10 with 10 being very important and 1 being not important at all.

V. OPENING AND ASEPTIC PRESENTATION

Activity

Distribute medical trays and pouches with different opening features to the participants. Then ask them to open the packages on a sterilized field.

1. What kinds of opening features have you used?
2. What's the most common way to open packages?
3. Do other people assist you to open the packages? How is this done?
4. What packaging features do you relate to easy of opening? (e.g. specific design, weight, shape, etc.)
5. How important is the ease of opening for you? Scaled 1-10 with 10 being very important and 1 being not important at all.
6. Do you check to make sure the package is unopened and completely sealed before you open it? What other things do you check?
7. What packaging features do you think are related to aseptic presentation? SIze?
8. How important it is to present things aseptically in the ED/OR? Scaled 1-10 with 10 being very important and 1 being not important at all.

VI. PACKAGING WASTE

1. In what instances might you dispose of a product before it is used on a patient?
2. How frequently does this occur?
3. How frequently does this occur as the result of a problem with packaging (e.g. open the incorrect product, fail to present to the sterile field)

1. How do you dispose of a product that fails before being used? Where do they go?
2. Who pays for them?
3. Are there times when package disposal is a challenge?

VIII. PROBLEMATIC AND GOOD DESIGNS

(Set the problematic and good packages on the table)

1. Problematic designs

Activity

Everyone will share their experience with the problematic packages they brought or talk about package features that they think don't work.

PROBES

a. What's the problem that you encountered with this package? Identification? Opening? Aseptic presentation?
b. Under what circumstances did this problem become an issue? Were you short of time?
c. How did you deal with the short comings?
d. Do you have suggestions about how this package could be improved?

2. Summary of common package failures

We have talked about a lot of problems caused by problematic designs, so let's make a brief summary, of what we have discussed.

PROBES

a. What are the commonalities in our discussion of packaging problems in the ED/ OR?

3. Activity

Based on the summary of the problems we concluded in question 2, I will hand out some sheets with tables containing two parts, one indicating if they believe this to be an issue in their facility and, two, how often this problem occurs.

4. Good designs

Activity

People will share their experience with the good packages they brought or talk about some packaging features they consider to be very helpful.

PROBES

a. What works well with the design?
b. In what instances might you think those features become extremely helpful?

XI. CONCLUSION

Thank you for taking time and participating in our discussion group today. Your opinions will help us improve the medical packaging. And I will try to let the people who make those packages hear your voice. Have a wonderful evening.

Appendix B:
Consent Form

MICHIGAN STATE
UNIVERSITY

Benchmarking medical device packaging used by Operating Room and Emergency Department Personnel with Focus Groups

Monica Cai, School of Packaging, 517-898-9515, caijingz@msu.edu

Consent Form

You are invited to take part in a research study regarding the impact of medical packaging design on the performance and opinions of OR and ED personnel. In exchange for your participation, you will receive a $20 Starbucks gift card.

What the study is about: This study is designed to

1) Get a sense of what OR and ED personnel experience when using varied designs of medical device packages.
2) Gain better understanding of the needs of these people with regard to medical packages.
3) Evaluate how current medical packaging features work for ED and OR personnel.

What qualification you must have: To participate you must

1) Be 18 years old or older
2) Currently (or in the past) work in an OR or ED setting
3) Be willing to travel to the School of Packaging at Michigan State University
4) Be willing to bring examples from your work environment that represent good or problematic medical packages
5) Be willing to be video taped while you participate in the study

What you will be asked to do: As a participant, you will be asked to participate in single focus group session which will last no more than two hours. You will be asked to fill out some general demographic information regarding yourself. The group will then be presented packages with different types opening features; we will also introduce the terms that we in packaging use for certain things (e.g. chevron pouch) so that we have a common understanding of the varied designs and the terminology used. During the course of the focus group, we will cover topics that include: work environment, identification of products, package opening, aseptic presentation and disposal of packaging waste. The group will be asked share the medical package problems and successes that have experienced.

Taking part is voluntary: Taking part in this study is completely voluntary. If you choose to be in the study you are free to withdraw at any time without consequences of any kind. If you are bothered by any question or activity, you may skip them or stop participating all together.

Risk and Benefits: Possible risks, although considered to be minimal, include the chance that you may feel uncomfortable speaking openly in a group or embarrassed when sharing your experiences. Although there is no direct benefit to you for participating in this study, it is our hope that the insights garnered can be used to generate medical packages that will better perform in the hands of OR and ED personnel in the future.

Your answers will be confidential: The whole focus group process will be recorded using video cameras. Video will be used to recall details of the focus group. For those that consent (below), video clips may be used for educational purposes (class room and conference settings). In the event that your clips are used, you will only be identified by first name. Only the research team and the MSU HRPP will have access to the data.

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 Dr. Laura Bix, associate professor of School of Packaging at Michigan State University at 517-355-4556 or bixlaura@msu.edu. If you have any 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 research study, you may contact, anonymously if you wish, the Michigan State University Human Research Protection Program at 517-355-2180, FAX 517-432-4503, or email irb@msu.edu, or regular mail at: 207 Olds Hall, MSU, East Lansing, MI 48824.

Statement of Consent: I have read the above information and have received answers to any questions. I consent to take part in the research study of impact of medical packaging features on OR and ED personnel.

☐ I consent to using the video clips of myself in public for educational purposes. (Conferences/classroom settings. You will only be identified by first name in the video.)

☐ I **DO NOT** consent to using the video clips of myself in public for any purposes. (In this case the video tape will be used only for recalling details of the session and will only be viewed by research personnel and will not be used in classroom/conference settings.)

☐ I have received my $20 Starbuck's Gift Card.

_____ _____

Participant's Signature Date

MICHIGAN STATE
UNIVERSITY

Benchmarking medical device packaging used by Operating Room and Emergency Department Personnel with Focus Groups

Monica Cai, School of Packaging, 517-898-9515, caijingz@msu.edu

Consent Form

You are invited to take part in a research study regarding the impact of medical packaging design on the performance and opinions of OR and ED personnel. In exchange for your participation, you will receive a $40 Target gift card.

What the study is about: This study is designed to

1) Get a sense of what OR and ED personnel experience when using varied designs of medical device packages.
2) Gain better understanding of the needs of these people with regard to medical packages.
3) Evaluate how current medical packaging features work for ED and OR personnel.

What qualification you must have: To participate you must

1) Be 18 years old or older
2) Currently (or in the past) work in an OR or ED setting
3) Be willing to travel to the Law Offices of Joseph M. Patton
4) Be willing to bring examples from your work environment that represent good or problematic medical packages
5) Be willing to be video taped while you participate in the study

What you will be asked to do: As a participant, you will be asked to participate in single focus group session which will last no more than two hours. You will be asked to fill out some general demographic information regarding yourself. The group will then be presented packages with different types opening features; we will also introduce the terms that we in packaging use for certain things (e.g. chevron pouch) so that we have a common understanding of the varied designs and the terminology used. During the course of the focus group, we will cover topics that include: work environment, identification of products, package opening, aseptic presentation and disposal of packaging waste. The group will be asked share the medical package problems and successes that have experienced.

Taking part is voluntary: Taking part in this study is completely voluntary. If you choose to be in the study you are free to withdraw at any time without consequences of any kind. If you are bothered by any question or activity, you may skip them or stop participating all together.

Risk and Benefits: Possible risks, although considered to be minimal, include the chance that you may feel uncomfortable speaking openly in a group or embarrassed when sharing your experiences. Although there is no direct benefit to you for participating in this study, it is our

hope that the insights garnered can be used to generate medical packages that will better perform in the hands of OR and ED personnel in the future.

Your answers will be confidential: The whole focus group process will be recorded using video cameras. Video will be used to recall details of the focus group. For those that consent (below), video clips may be used for educational purposes (class room and conference settings). In the event that your clips are used, you will only be identified by first name. Your confidentiality will be protected to the maximum extent allowable by law and only the research team and the MSU HRPP will have access to the data.

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 Dr. Laura Bix, associate professor of School of Packaging at Michigan State University at 517-355-4556 or bixlaura@msu.edu. If you have any 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 research study, you may contact, anonymously if you wish, the Michigan State University Human Research Protection Program at 517-355-2180, FAX 517-432-4503, or email irb@msu.edu, or regular mail at: 207 Olds Hall, MSU, East Lansing, MI 48824.

Statement of Consent: I have read the above information and have received answers to any questions. I consent to take part in the research study of impact of medical packaging features on OR and ED personnel.

☐ I consent to using the video clips of myself in public for educational purposes. (Conferences/classroom settings. You will only be identified by first name in the video.)

☐ I **DO NOT** consent to using the video clips of myself in public for any purposes. (In this case the video tape will be used only for recalling details of the session and will only be viewed by research personnel and will not be used in classroom/conference settings.)

☐ I have received my $40 Target Gift Card.

_____ _____

Participant's Signature Date

Appendix C:
Data Collecting Sheet

Figure 33: Data collecting sheet

ACTIVITY 1 Choose the **10** most important aspects from this list,
Order them from **1 To 10**. (**1** being the **MOST** important of the group, **10** being the **LEAST** important)

☐ Easy to read text/font labeling	☐ Color coded labeling	☐ Opening instructions on package
☐ Package integrity before opening	☐ Double barrier	☐ Convenient package size
☐ Rigid or flexible packaging material	☐ Fast opening	☐ Enough gripping space
☐ Seal/peel strength	☐ Fiber-free peel	☐ Visibility of the product inside
☐ Least amount of packaging waste	☐ Convenient to store	☐ _____
☐ _____	☐ _____	

ACTIVITY 2 How important you think the following features are?
Scaled **1 To 10.** (**10** being **very important** and **1** being **not important at all**)

☐ Quick identification of product

☐ Ease of Opening

☐ Present devices aseptic

Figure 33 (Cont'd)

ACTIVITY 3 From your experience
Indicate the frequency of the common package problems

	NEVER	SOMETIMES	FREQUENTL	ALL THE TIME

Appendix D:
Demographic Survey

DEMOGRAPHIC SURVEY
For Operating Room Personnel

The information is being collected by School of Packaging at Michigan State University for the purpose of study of Benchmarking Medical Packaging used by Operating Room Personnel through Focus Group.

1. What's your gender?

___ Female ___ Male

2. In what year were you born?

_____

3. What's your race/ethnicity? (check all that apply)

___ American indian/Alaskan Native ___ Asian or Pacific Islander

___ Black, non-Hispanic ___ Hispanic

___ White, non-HIspanic ___ Multiracial

___ Other/unknown

4. What's your education background?

___Doctor Degree

Please indicate what are(s)_____

___Masters Degree

Please indicate what are(s)_____

___Advanced Practice Nurse certificate

Please indicate what are(s)_____

___Bachelors Degree

Please indicate what are(s)_____

___Associate's Degree

Please indicate what are(s)_____

5. What is your family's total household income before tax?

___ Under $20,000 ___ 20,000-39,999 ___ 40,000-59,999

___ 60,000-79,999 ___ 80,000-99,999 ___ More than 100,000

6. Are you currently employed in an OR/ED environment?

_____

7. If yes to question 6, Which department are you working in?

___ Operating Room ___ Emergency Department

8. What's your current position in your department?

_____

9. If you answered no to question 6, were you formerly employed in a healthcare setting? If so, please briefly describe when this was and what type of setting you worked in.

_____

_____

10. How many years, in total, you have been employed in the healthcare industry?

_____ years

11. How many years you have been working in E.D. or O.R.?

_____ years

12. How many hours do you work PER WEEK?

_____ hours per week

13. How many hours do you work PER SHIFT?

_____ hours per shift

14. Identify your CURRENT employment setting(s)

___ Acute Care Hospital ___ PHysician's office

___ Ambulatory/Day Surgery Center

___ Nursing home/long-term care facility

___ Public/community health

Other _____

15. Identify any employment setting(s) that you have worked in PREVIOUSLY

___ Acute Care Hospital ___ PHysician's office

___ Ambulatory/Day Surgery Center

___ Nursing home/long-term care facility

___ Public/community health

Other _____

16. Which of the following do you perform/have you performed as part of your job responsibilities:

___ Room preparation ___ Identify appropriate products for patient

___ Open packages

___ Aseptically present products to sterile field

___ Dispose of products

___ Dispose of Packages

Other tasks related to packaged devices

_____

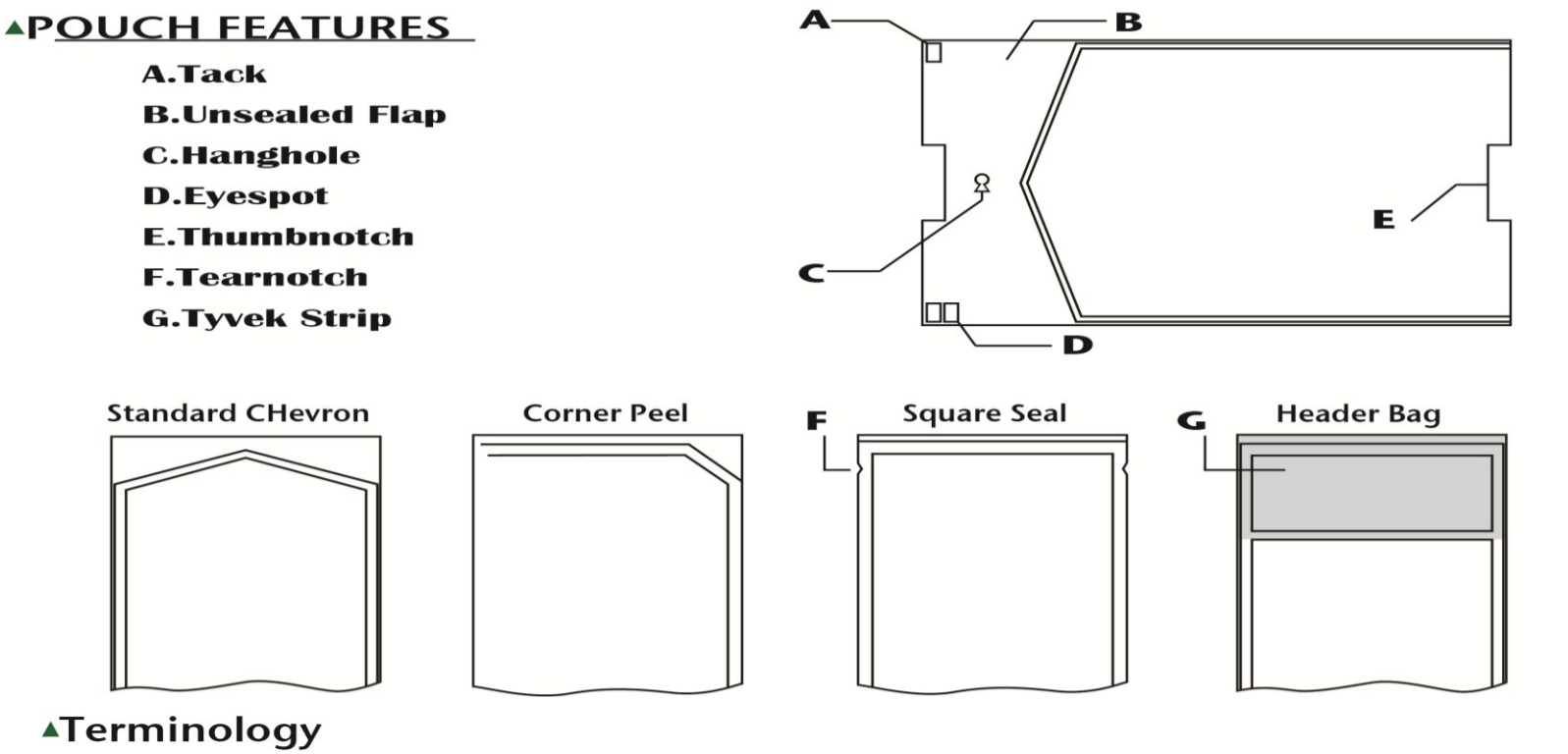
_____

_____

Appendix E:

Educational Document Used in Focus Group

Figure 34: Educational document regarding pouch terminology



A.Tack - Spot Seal at Chevron of pouch to keep unsealed flap together

B.Unsealed Flap - Unsealed space between seal and edge, used to grip to open

C.Hanghole - Hole punched through both webs to hang packaged products in storage

D.Eyespot - Printed mark used to register copy on pouch. Distance betwen eyespot in web direction determines pouch length

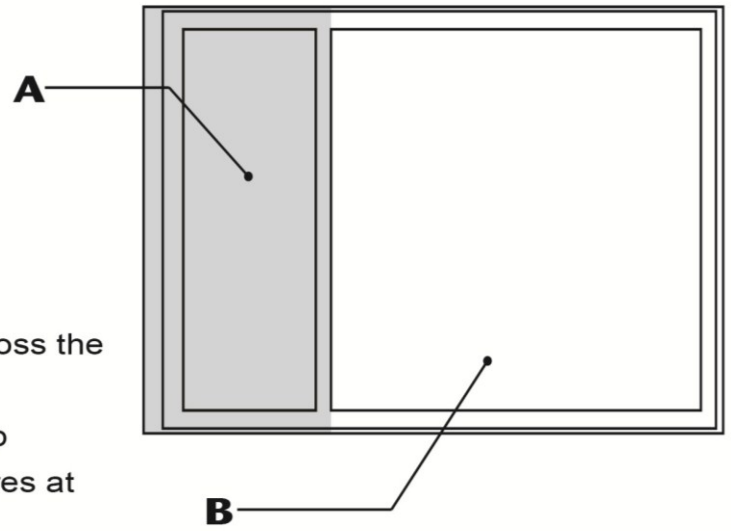
E.Thumbnotch - Notch in one web to faciliate web separation for both products loading and package opening

Figure 35: Educational document regarding header bag terminology

▲HEADER BAG FEATURES

A.Tyvek Strip

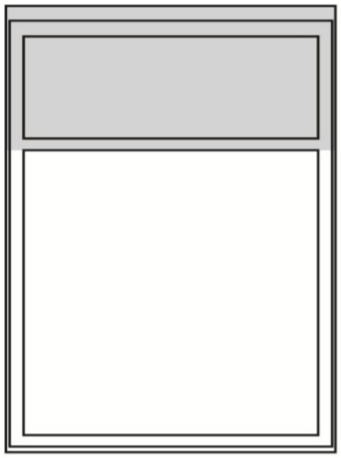
B.Film Portion



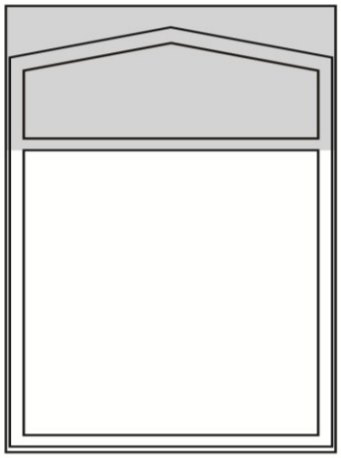
▲Terminology

Header Bag -	Have Tyvek strip running across the top
Chevron Header Bag -	Have chevron opening on top
Chevron Header Pouch -	Have chevron opening features at both corners of the bottom

Standard Header Bag



Chevron Header Bag



Chevron Header Pouch

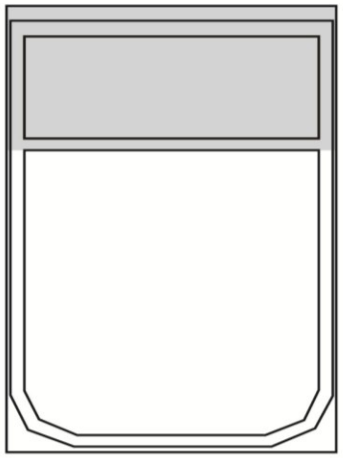
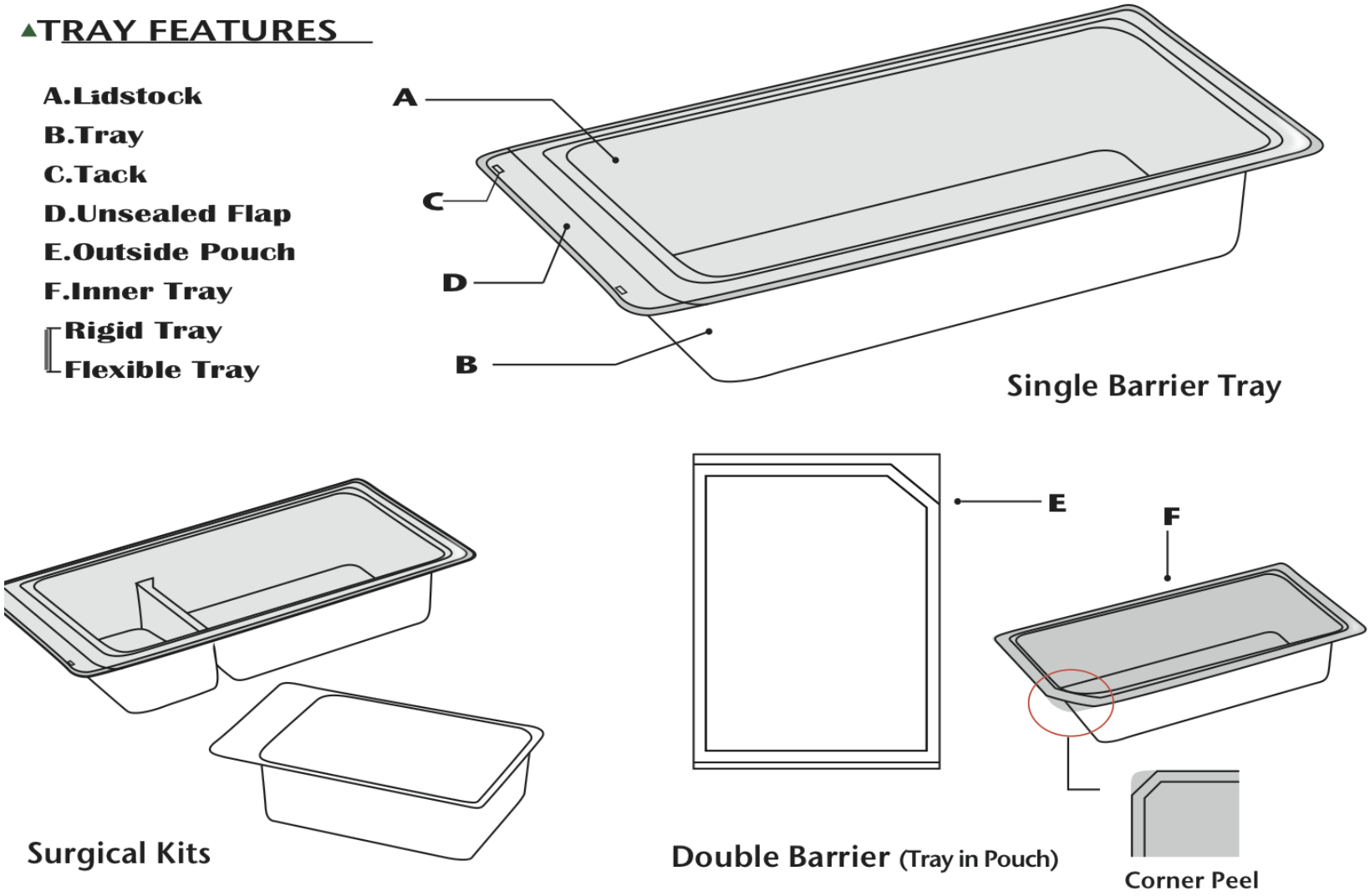


Figure 36: Educational document regarding tray terminology



Appendix F:
Recruitment Flyer

Figure 37: Recruiting Flyer

Medical Packaging
Your VOICE is Needed

MSU School Of Packaging
Is conducting a research study of Medical Device Packaging Used by Operating Room and Emergency Department Personnel using Focus Groups.

To Participate, You must:
Be 18 years old or older
Work in or have worked in, the OR or ED
Be willing to be videotaped
Have transportation to the study location
Be willing to bring good or problematic packages

Why: The intention of the study is to better understand your needs of Medical packaging so future packages could be improved. In exchange for your participation, you will receive a **$20 Starbucks Gift Card**.

Where: School of Packaging at Michigan State University

Time: No more than 2 hours

Join the Study Now!

By sending an e-mail to cajjingz@msu.edu with the following information:
Name, Gender, Age, E-mail, Experience in O.R. or E.D.

Appendix G:
Discussion of Focus Group

Focus groups are a special type of group in terms of purpose, size, composition and procedure (Krueger & Casey, 2009). It is mainly considered to be a form of qualitative research method since the most times the data including participants' perceptions, opinions, beliefs and attitudes towards a product, service, concept, or packaging are collected through open-ended questions (Henderson, 2009). A carefully planned series of discussions designed to obtain perceptions on a defined area of interest are usually prepared in advance. The focus groups are held in a permissive, nonthreatening environment to ensure the atmosphere of the discussion is relaxed, and participants enjoy sharing their ideas and perceptions (Krueger & Casey, 2009). The traditionally recommended size of focus groups is 6 to 12 people (Krueger & Casey, 2009) (Stewart & Shamdasani, 1990).

Focus groups provide a number of advantages relative to other types of research:

- Group discussion produce data and insights that would be accessible with interactions found in a group setting--listening to others' verbalized experience stimulated memories, ideas, and experiences in participants. This interaction helps participants compare their own personal realities to those of others. In this case, the similar experience the nurses have with the medical device packaging may stimulate them to talk more.
- Also because the interaction is allowed during the focus group discussion, the researcher has chances to interact directly with respondents which provide the opportunities for clarification of responses, for follow-up questions (Krueger & Casey, 2009) (Stewart & Shamdasani, 1990).

- Compared with individual interviews, focus groups can provide data from a group of people much more quickly and at less cost.
- The results of focus groups are verbal responses which are quite easy to understand for both researchers and decision makers.
- Although the focus group has been proven to be a valuable research tool with a number of advantages, it does have its limitations:
- Because the groups are made up of individuals, intra-personal influences on group process should be taken into account. Each participant can no longer be considered as an independent individual due to the possibility that each group member's actions are determined in part by other group members which could restrict the generalizability of results (Krueger & Casey, 2009) (Stewart & Shamdasani, 1990).
- The results obtained in a focus group may be biased by one or several very dominant participants, leaving other group members hesitant to talk.
- The responses to open-ended questions obtained in the focus groups can make summarization and interpretation of the results difficult.

The composition of the focus group must be selected strategically, with homogeneity as the key to a successful session (Krueger & Casey, 2009). By homogeneity, we mean the participants have something in common that the researchers are most interested in. Human behavioral studies have consistently proven that only when people share a common bond, will they reveal their innermost thoughts to others (Shaw, 1981).

Appendix H:
Coding Sheet With Example

Figure 38: Coding Sheet

Code	Group	Speaker	Unit
OPE-9	3	4	Easy to open is huge

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