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A RETURNABLE CONTAINER SYSTEM FOR MEDICAL DEVICE COMPONENTS

By

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ABSTRACT

A RETURNABLE CONTAINER SYSTEM FOR MEDICAL DEVICE COMPONENTS

By

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Returnable containers are widely used in logistical packaging. It was found that there is currently no returnable container system available for the medical device industry. A case study analysis was initiated during an Internship with Medrad, Inc., a medical device company in Pennsylvania.

A feasibility study including a financial analysis was performed to identify cost drivers and to find a cost efficient solution for shipping injection molded syringe barrels.

The research goal is to develop a returnable container system for syringe barrels that exceeds industry standards of product protection, utility, communication, and low cost. The returnable system can yield a reduction in material and labor cost by facilitating automation during barrel assembly, increasing product quality due to reduced particulate, and an efficient inventory management system by using bar codes. The implementation of a returnable system requires a large initial investment that needs to be integrated in the total system costs.

DEDICATION

I dedicate this research to my family in Germany, especially my parents, for their patience and great support for which I will always be thankful.

ACKNOWLEDGMENTS

Almost two years ago, I came to the United States as a Fulbright scholar from Berlin, Germany. My adventures at Michigan State University began in Packaging. My family and friends always asked me "What is Packaging?". At the beginning, I thought it is just boxing, but after all these great packaging courses, I am amazed to what extent packaging affects everyday life and finds its place across all industries.

My studies and living in the US had a tremendous impact on my life. I received overwhelming support from people I wanted to acknowledge and thank.

First, I thank all members of my graduate committee, Diana Twede, Paul Singh, Ted Stank, and especially Hugh Lockhart and Eugene Gelblum. I sincerely appreciate your support during my entire research at Michigan State University and Medrad, Inc. This research would not have been possible without the contributions of Medrad, Inc. and its supplier K&W who participated in this case study. I thank Ralph Wolstenholme for his time and insight, as well as Carl Ciampoli and Denis Olson who always pioneered and envisioned new advanced packaging development projects at Medrad.

Second, my deepest appreciation and thank to my parents (Erika and Klaus-Peter Block), my three brothers (Martin, Stephan, and Matthias), my sister Gabriele, and "old" friends in Germany, especially Gabi, Eddy, Peter, Franke, and Uwe, my new friends in the US, Dr. Jack and Linda Allen, Dr. Robert LaMoreaux, Emmy and Scott Marshall, DeLynne and Torben Siggaard, Charles Frangis, Donald Wolf, Joseph Szaley, and Gerald Eckman, and to the German Fulbright-Kommission in Bonn. Without your belief in my strengths and capabilities, this great experience would not have happened! I will always carry the Fulbright spirit, being a German ambassador for peace, friendship, networking for Women in Packaging and human rights.

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LIST OF ABBREVIATIONS

ABC ..... Activity-Based Costing
AIAG ..... Automotive Industry Action Group
ANGIO ..... Angiology - study of lymph and blood vessels
ASTM..... American Society for Testing and Materials
CFR ..... Code of Federal Regulations
CIP..... Cost Improvement Project
Ctn ..... Carton
EDI..... Electronic Data Interchange
EPS..... Extended Polystyrene
FDA..... Food and Drug Administration
FDC ..... Food, Drug, and Cosmetic Act
FLS ..... Front Load Syringe
FR..... Federal Register
GMP..... Good Manufacturing Practices
HDPE..... High Density Polyethylene
HIPS ..... High Impact Polystyrene
ISTA..... International Safe Transit Association
JIT..... Just-In-Time
LTL..... Less than Truck Load
MHIA..... Material Handling Institute of America
MRI ..... Magnetic Resonance Imaging
MSU..... Michigan State University
NIOSH ..... National Institute for Occupational Safety and Health
NPV ..... Net Present Value
PIRA ..... Packaging, Printing and Publishing Institute and Research Association
Plt ..... Pallet
PS..... Polystyrene
QA..... Quality Assurance
QFD ..... Quality Function Deployment
QM..... Quality Management
SAP AG..... Systeme Anwendungen Produkte Aktiengesellschaft
TL ..... Truck Load
WMS..... Warehouse Management System

1. INTRODUCTION

The idea for this thesis was developed during an internship with a medical device manufacturer, Medrad, Inc., Indianola, PA in 1998. The task was to propose a packaging strategy to improve the company's Packaging Performance Excellence of the Sterile Disposable Enterprise. A situation analysis was performed investigating internal and external packaging requirements to establish a basis for the implementation of a returnable container system.

Medrad produces medical diagnostic equipment and related disposable products. It is organized in four business units: Vascular Injection (injectors), Magnetic Resonance (MR image coils), Sterile Disposables (syringes and accessories), and Services (maintenance for Medrad medical equipment). The company's organization is following the Quality for Life philosophy (QFL). It has established five corporate goals that guide each research & development project: 1. Exceed financial objectives; 2. Grow the company; 3. Improve quality and productivity; 4. Improve customer satisfaction; and, 5. Employee growth and satisfaction.

The main objectives of the investigations prior to this thesis research were to identify improvements related to packaging processes, equipment, materials, testing and inspection methods, to recommend new or modified designs for a universal syringe package, and to interface with equipment manufacturers, material suppliers and external customers (hospitals). Several areas were identified as potential projects and integrated as a Packaging Strategy for cost improvement projects (CIP). The strategy provided the company with technical and organizational recommendations for future packaging process changes. Short and long term projects were summarized in an evaluation matrix (APPENDIX A). After evaluating all packaging issues, seven projects were

introduced to Medrad's Manufacturing Quality Council. The decision making criteria were: 1. Project necessity; 2. Time; 3. Cost/savings; 4. Quality/marketing benefits; and, 5. Testing opportunities at The School of Packaging (Block and Castro 1998).

The development of a returnable container system for medical device components was chosen since it offered the most areas for cost, quality, and productivity improvements. It was seen as a challenge to switch from an expendable to a returnable packaging system. In a long term perspective, a returnable container system can contribute to Medrad´s leading market position in the medical device industry.

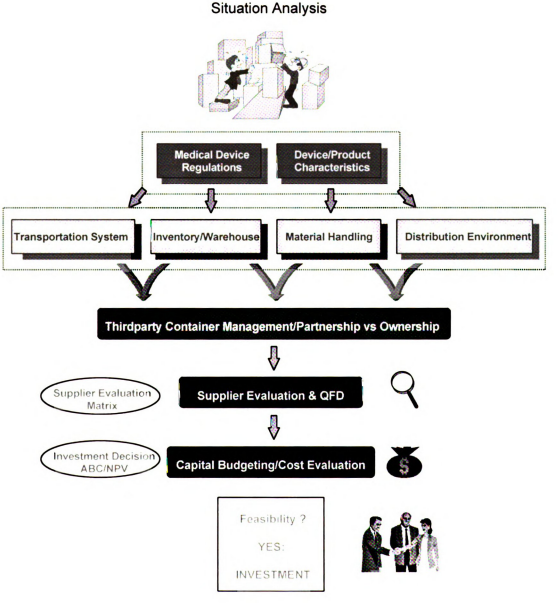
This project is a pilot project in the medical device industry and of value for similar case studies. The financial analysis is a critical part to adjust packaging and other investments and must be always included in the early stage of a project. This case study approach involves Medrad and several returnable packaging supplier participants. It strives to provide answers to the following key issues:

1. What are the requirements of a returnable container system for medical devices?
2. What kind of returnable package should be used?
3. What are the manufacturing, logistical and material handling requirements?
4. What cost-drivers should be considered when choosing between alternative returnable container systems?
5. How are the returnable packaging investments evaluated and integrated in the overall system cost?

The second chapter includes a literature review and provides background information to answer these questions. A model was developed to guide this project. It includes the situation analysis, a research of medical device and returnable container

characteristics, the transportation system, distribution and material handling requirements, inventory and warehouse management issues, ownership vs third-party container management, a supplier evaluation analysis of container configurations, quality function deployment for supplier selection, and a cost analysis (Figure 1). The conclusions are presented as a summary and recommendations for future research.

Figure 1 Returnable Packaging Development Model



2. Literature Review

This research is a development and feasibility case study to analyze design criteria for medical device packaging and the cost associated with a returnable container system. This case study followed the packaging development guideline introduced during the Internship period at Medrad, Inc. (APPENDIX B).

In this chapter, a basic literature review of books, journals, seminars, databases (PIRA, Teltech, CFR, FR) and lectures will guide the development of a returnable container system for medical device components. A conversion analysis, planning and implementation checklist will be described. In addition, the subjects (see Table 1) were selected from a returnable/reusable logistical packaging framework (Kibler 1997) to create an advanced model for logistical device packaging.

2.1 Medical Device Regulations

The product to be packaged and shipped in a returnable container system is a syringe barrel. It is a medical device component that will be assembled to an unfilled MRI or ANGIO syringe for human use in hospitals. These barrels are not sterilized before assembly. The final product is a front load syringe (FLS) which will be filled with a contrast media. With the help of the injector, the contrast media is injected into a human body. To understand the product and its packaging requirements, the following paragraph will introduce important aspects of devices such as history, legislation, definition, medical device packaging, classification, good manufacturing practices (GMPs) including the GMP regulation 21 CFR 820 (Code of Federal Regulations), and packaging-related recalls.

Table 1 Framework for Reusable/Returnable Device Packaging Development

Subject	Project Questions
Medical Device Regulations	Which medical device regulations must be considered? How do they affect the package?
Medical Device / Package Design Characteristics	What are the product protection requirements for medical devices? What is the proposed package system (molder-manufacturer)? What type of returnable packaging should be used? How many crates are required? How many types are required? How many barrels per crate?
Material Handling and Operational Requirements	What is the proposed material handling process? Where and how will the packaging components be cleaned? What would be an optimized crate for automated barrel presentation? How many layers of wrapping are required? How clean is the wrapping? Can the wrapping be automated? What material is the wrapping?
Inventory and Warehouse Management	How do inventory levels influence effective inventory management? What are the criteria to evaluate the appropriate inventory level? What would be the cost impact of various inventory levels?
Transportation System	What are the modes of transportation, the cost of shipping? What are the additional costs due to more material handling? What would be the changes in the distribution system? TL/LTL shipments? What is the truck size for optimized space utilization?
Distribution Environment, Product Protection, Efficiency	What is the stack height? How much compression strength is required for product protection? What is the most efficient package design which offers the best product protection?
Third Party Container Management vs Ownership	Which type of ownership should be considered? What are the characteristics and trade-offs? What are the cost drivers and risks, if any?
Supplier Evaluation	Are there any medical device related returnable packaging solutions available? What are the best crate, tray and cleaning solutions for medical devices? What are the latest trends?
Quality Function Deployment	How is QFD applied to evaluate the performance of returnable crates from various supplier?
Capital Budgeting and Cost Evaluation	What are the savings from returnable vs expendable? What is the lifespan of a crate/tray? What are the overall system costs including savings/expenses, development costs, capital investment (cleaning, automation, container, tooling). What are the material handling/operational costs?

The History of Medical Devices and Legislation

In 1906, the Food and Drug Act was enacted. It is the act under which medical devices fall. Medical devices were not regulated by the federal government until 1938 when they became officially part of this Act for the first time. However, the Act and its legal power were limited in scope. At the end of 1969, a medical device study group was formed to conduct research on new device legislation. A report was made public to show the need for new legislation because there were more than 10,000 injuries reported over a 10 year period regarding medical device misuse. According to this report, on May 28, 1976, a new Medical Device law was added to the Federal Food, Drug, and Cosmetic Act of 1938 which provided the Food and Drug Administration (FDA) with a more powerful law to regulate medical devices. This amendment made the greatest impact on medical device manufacturers in this century. The goal was to assure safety and effectiveness of medical devices, including diagnostic and laboratory products, and to upgrade the regulatory authority over devices. Some of the key issues were to classify devices with graded regulatory requirements due to the diversity of the device market, and establish registration, device listings, pre-market approval, investigative exemptions, good manufacturing practice (GMP) regulations, records and reporting requirements, preemption of state and local regulation of devices, and performance standards (O´Brien 1990). This amendment was followed by a number of regulations to enforce it. These regulations can be found in the CFR updated by the Federal Register (FR). The CFR includes 50 titles. The regulations of interest regarding medical device packaging are listed under the title 21 CFR 820.

The FR is a government publication that publishes new, changed, or proposed regulations of federal agencies which become of legal standing and official with their

appearance in the FR. A regulation is a statement by the governmental agency and describes how the agency is applying the legal authority given through laws passed by Congress. Proposed regulation can also be found in the FR and these invite public comment. A petition to the FDA commissioner can be filed by an individual, firm, or organization requesting that certain actions be taken regarding a regulation that should be changed, revoked or revised.

Copies of the CFR, FR, and proposed regulations are found on the Internet (for web address, see bibliography) or as hard copy in libraries, court houses, and federal office buildings. It is important to mention, that the Food and Drug Act as well as other acts are not the law but statute. Until an act is adjudicated in a court of law, it will remain an act and is not the law.

Definition of a Medical Device

A device is defined in the Food, Drug and Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, part, or accessory which does not achieve any of its principal intended purposes through chemical reaction within or on the body of man or animals, and which is not dependent on being metabolized for achievement of its principal intended purpose". It is differentiated from a drug because it is defined not to be metabolized nor to undergo chemical reaction. In addition, a medical device is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them. It falls under this definition and is "intended for use in diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure or any function of the body of man or other animals..." (FDA 1989).

Classification

Due to the great diversity among devices on the market, the classification into three classes provides a system to regulate all devices depending on their degree of importance to public health. Class I, general controls, is applied to all devices. It requires appropriate labeling, registration, product listing, pre-market notification, record keeping, and compliance to GMP. Class II, performance standards, set standards for specific devices for which general controls would be not sufficient, i.e. it relates to construction, components, ingredients, tests and properties of the device to assure safety and effectiveness beyond class I. In this case study, the device belongs to class II. Class III, pre-market approval, is applied where class I and II are insufficient to provide public safety. The manufacturer must obtain performance data and have it reviewed by FDA prior to market introduction. These include more sophisticated devices such as heart pacemakers (O´Brien 1990).

Good Manufacturing Practices

The GMPs for medical devices are one of the most important regulations for medical devices which include objectives for developing a quality assurance program. They include requirements for methods, facilities, and controls used in manufacturing, packing, storing, and installing medical devices. Three basic GMP principles for quality assurance are: 1. Product quality, safety and effectiveness must be designed and built into the finished product; 2. Quality cannot be inspected or tested into the finished product; and, 3. Each step of the manufacturing process of the device must be controlled to assure that the finished product will meet all specification requirements on quality and design (O´Brien 1990).

The returnable container system is a logistical package that is considered part of the medical device. Therefore, the design, testing, and manufacturing process must be FDA approved and continuously controlled by a medical device manufacturer.

The Device Good Manufacturing regulations include an overview of the GMP regulations 21 CFR 820 related to medical device packaging. With respect to medical device packaging, the most important ones for this case study are 21 CFR 820.20(a)(2), and (4), 820.25, 820.40, 820.60, 820.100(a)(1), 820.115, 820.120(b)(c), 820.130, and 820.181 (FDA 1987).

Table 2 provides a description of each section of the regulation. 21 CFR 820.130 and 820.181 are more of interest and will be discussed in chapter 4.

Due to the complexity of this issue, it is strongly recommended to develop a checklist to meet all GMP requirements, to be consistently reproducible and to keep accurate records of exact specifications. If the medical device belongs to class III a premarket evaluation is necessary that needs to be reported to FDA.

Packaging-Related Recalls

A recall is a voluntary action by a manufacturer or distributor to remove a product from the market and correct the products that the FDA considers to be in violation of the law in which the agency would initiate regulatory action, e.g., seizure (FDA 1998). Packaging-related recalls make up to 10% of all medical device recalls. About 7.6% of these are related to design and process problems, and another 7.6% are related to packaging and labeling mistakes (O´Brien 1990).

Table 2 Device Good Manufacturing Practices (FDA 1998)

GMP	Description
21 CFR 820.20(a)(2)	Development of procedures to approve or reject all incoming packaging materials.
21 CFR 820.20(a)(4)	Quality assurance check on incoming and finished packaging.
21 CFR 820.25	Personnel training regarding new operations (training on the job by experienced employees or by contracting specialists).
21 CFR 820.40	Design of packaging storage and operations areas to prevent contamination by particulate and microorganisms; to facilitate cleaning and maintenance and to prevent mix-ups.
21 CFR 820.60	Appropriate design, construction, placement, and installation of equipment, ease in maintenance, adjustment, and cleaning.
21 CFR 820.100(a)(1)	Installation of a QA system to assure the design basis for the packaging and its translation into approved specifications.
21 CFR 820.115	Establishment of reprocessing procedures to assure that a reprocessed device will meet the approved specifications including evaluation of the effects on the package.
21 CFR 820.120(b)(c)	Separation of packaging-labeling operations to prevent mix-ups. Inspection of the packaging-labeling area must be done before another operation begins to assure that no items remain from previous operations. Establish written cleaning, maintenance and area inspection procedures, and audit their use.
21 CFR 820.130	Medical device packaging design and material requirements.
21 CFR 820.181	Medical device specifications including methods and processes to include in the device master record, or reference is to be made to their location.

2.2 Medical Device Characteristics and Packaging Design

The new version of the GMPs from 1998 defines the medical device package as a component of the device. As of last year, this has been approved but not published in the new GMPs. If the package is an active part of the device, the package needs to be developed along with the device (Lockhart 1998). This is an important statement for the medical device packaging development whether it is a logistical or a consumer package to follow 21 CFR 820.

A returnable container system can consist of various types of returnable plastic containers and load bases. Most common are totes, bulk boxes, bins, crates, pallets, and dunnage used to transport loose or prepackaged items in a reverse logistics system where the container and dunnage are returned for reuse. Dunnage can be defined as a packaging material used to protect loose, fragile parts during transportation (MHIA 1999). It can be a thermoformed plastic tray, a plastic corrugated partition, or a hard foam made from extended polystyrene (EPS) or other foam materials. There are many types of materials for designing a returnable container system available (Kulwiec 1998) depending on the product characteristics, environmental hazards, legislation, regulations, and monetary value of the final container design.

When designing a returnable container system for medical devices, it must be understood that packaging is a socio-scientific discipline to deliver goods in the best condition. The package operates in a complex system of product, packaging, and distribution within the physical, atmospheric, and human environments. The functions of packaging—protection, utility, and communication—are critical aspects to fully meet the environmental requirements. This relationship can be described as a matrix where the functions interact with the environments (Lockhart 1997). The designer of a returnable container system for medical device components must consider these functions and the product characteristics, its value, and the hazards of the distribution system. The physical product characteristics, i.e. size, shape, weight, durability, fragility, and environmental stability determine the degree of package protection required and what types of reusable packaging designs can be used. With respect to the package requirements, the main goal of designing a package is to provide the "right" amount of protection by using the most cost-effective materials (Shires 1995).

The physical environment includes vibration in transport, shock from impacts, drops, and crushing from stacking and compression during shipping and warehousing. The fragility and durability of the syringe provide criteria for use in protecting the product from breakage. In general, failure can occur in two modes: brittle and ductile (Burgess 1998). In this case, the syringe is a brittle product. The fragility of a product can be determined after the ASTM standard D-3332-94a (ASTM 1994). It depends on the received shock impulse measured by the peak acceleration and shock duration.

The atmospheric environment considers the stability of product and package when exposed to various environmental conditions. These factors include environmental stresses such as temperature (heat, cold), chemicals and microbial stability (liquids, gases, and vapors), and ultraviolet sensitivity (direct sun light). The package must be stable to resist these conditions to protect the product. For example, ultraviolet light from exposure to sun can destroy the package and/or product due to environmental stress cracking and degradation of plastic materials. Chemical reactions and biological activity can be accelerated or decelerated by heat or cold. The plastic's glass transition temperature is an indicator of whether the material will be brittle or glassy at a given temperature, and whether if temperature changes will affect the material's properties.

The human environment is one of the most unpredictable factors. Each person has a different perception of vision, forgetfulness, or reliability. Cleanliness is one of the most important factors in medical device manufacturing. The more human handling the more likely it is that package and product will be contaminated. This is one of the reasons to design a package for the most reliable product protection in terms of cleanliness and package handling. Liability, legislation and regulations play an important role in the human environment which are defined by governmental agencies.

Finally, to design an economical and cost efficient returnable package, the product value is important. A product of high value will need higher protection and will justify higher package cost. Overall, material investments and development cost are factors that can decide whether an investment is feasible or not.

Package protection considers the product characteristics and all logistical hazards. It is important that the package protects the product from the environment and the environment from the product (Twede and Parsons 1997). Utility is the function that makes the product useful or easier to handle, i.e. product containment, stackability, easy to move and open, etc. Communication is traditionally interfaced with the needs of the end user. In logistical and medical device packaging, it is important that the package content is easy identifiable and traceable by appropriate labeling. A matrix (Figure 2) was developed by Lockhart to summarize all package functions linked to their environmental requirements (Lockhart 1997). This matrix is used in chapter 4 to determine the package characteristics for the returnable container development.

Figure 2 Generic Environment Matrix (Lockhart 1997)

		Environment		
		Physical	Atmosphere	Human
Function	Protection	Cushioning Hazardous Materials	Barrier Film Wet Strength Corrugated	Child Resistant Tamper Evident Warnings
	Utility	Stretch Wrap Bar codes	Wet Strength Corrugated	Directions, Shapes Legibility
	Communication	Printed Shipper Bar codes	Time/ Temperature Indicators	Legibility, Warnings Directions Product Name

2.3 Project Management for the Conversion from Expendable to Reusable

In most applications, returnable containers will replace corrugated containers in the current packaging system. Converting the operations to a reusable plastic packaging system can be a complex process. Many companies have problems in planning, tracking and controlling their logistical packaging. To ensure a smooth transition from expendable packaging to reusables, the current packaging and material handling system must be analyzed. All requirements must be taken into account to develop a conversion plan which includes people and processes of the facilities (supplier, manufacturer) and shipping loops. Therefore, it is necessary to investigate how the returnable containers can be integrated into the current system and what changes are necessary to implement the new material handling process.

There are several steps in conversion planning and implementation to consider. All steps can be seen as critical control points. The following plan in Table 3 is used as a checklist for the conversion process. Container suppliers offer assistance in conversion planning (Buckhorn 1996).

2.4 Material Handling and Operational Requirements

A situation analysis evaluates plant readiness for reusable containers and identifies requirements for change, i.e. for container storage space, changing workstations, installation of cleaning equipment, automation, and labor planning. A walk-through of the facilities and a flowchart of the material handling process (Figure 3) can help to identify key areas for improvement, i.e., effective labor placement, efficient material flows, facility changes for faster loading/unloading of containers and higher space utilization in transportation vehicles (Miller and Hehn 1998). Table 4 lists reasons for container tracking and requirements for material handling and operations.

Table 3 Checklist for Conversion Planning

Action Item	Description
Team Building	A cross-functional team consisting of engineering (packaging, product, facilities), purchasing, transportation, suppliers (product and container suppliers) is assembled to direct all activities.
Project Plan	A team leader is assigned to update team members with project status and timelines, to establish project guidelines for container selection (weight limitations, size requirements, standardization, return ratios, costs) and supplier performance evaluation.
Prioritization	The team is defining goals for conversion to reusable packaging, i.e., reduce packaging cost, increase product protection, ergonomics, handling efficiency, facilitate automation, etc.
Packaging/Product Analysis	Based on the company's requirements for reusables, each part in the facilities is evaluated by container type(s)/size(s), dunnage requirements for trays and cushioning, handling methods, etc.
System Changes	The plant readiness is evaluated for reusables to identify areas of change (container staging space, workstations, cleaning areas).
Analysis of Current Processes	A walk-through of the facilities helps to identify areas for improvement such as production rate, material flows, number of suppliers.
Economic Analysis	For each product, the economic feasibility will be evaluated. The expendable packaging cost, system changes, shipping charges, operational cost, and changes of the material handling system are calculated (spreadsheet) as savings and expenses of the conversion process. Theft, loss, repairs or production increase should be included in an activity-based cost analysis.
Action Plan	The team decides whether the project is feasible or not, and evaluates the benefits and payback. The action plan includes material validation, scheduling and assigning responsibilities.
Container Options and Cleaning	It is determined the container type, dunnage or trays, wrapping, closures, labeling, and cleanliness requirements. Benchmarking helps to find the best container and dunnage solution.
Quantities and Inventory	The container and dunnage quantities are calculated to determine proper inventory levels. Several methods can be used effectively to manage inventory, i.e. KANBAN (Kamiske 1996).
Material Handling, Container Control and Tracking	A material handling system must be established to ensure efficient container flow. Transportation routes must be planned for full and empty containers. Tracking and identification programs using bar codes for proper container control from suppliers to workstations are recommended for installation.
Third Party Container Management or Ownership	With an increased container and dunnage use, piece-price negotiations with suppliers for packaging materials can lead to a reduction in capital investment. Purchasing and ownership is an option when smaller container quantities are needed.
Maintenance Plan	Theft, loss, or repairs must be included in operational and material handling planning.

Table 4 Material Handling and Operational Requirements

Issue	Description
Container Use	Returnable containers must be efficiently placed (right time and place) in the facility to assure an optimized container flow and to avoid container delivery delays—internally to the next workstation and externally to suppliers.
Container Tracking	A flexible container tracking and identification system to control container use and availability must be installed. This system should be easy to adjust for additional product coverage. It avoids volume fluctuation per cycle (one loop between manufacturer and supplier) and cycle time.
Inventory	The amount of containers needed in the system must be determined. This depends on the company's inventory level to satisfy external delivery and internal production flow (Meagher 1998).
Application	It is recommended to apply a returnable container system for a consistent volume flow and short cycle times. If a high inventory level on returnables will be kept the cycle time is long and the number of containers needed will increase.
Investment	The investment in containers and dunnage depends on cycle time, production flow, and a fast return of empty container to suppliers. The number of containers will be increased as required to match the longest cycle with each fluctuation in volume per cycle (Thompson 1996).
Recommendations	To avoid any type of variation in the system and to improve the efficiency of the returnable cycle, the cycle time should be shortened by reducing inventory levels and faster returns. A tracking guideline for returnable container was developed by the US automobile industry to optimize shipments and reduce cost (AIAG 1991).
Material Handling Systems	Computer programs, manual tracking, visual control, external pull system control, and inventory management (Trudeau 1995).
Bar Coding	The use of bar codes facilitates container tracking via automated scanning and transfer into a computer system for analysis (LaMoreaux 1995). It supports the trend towards material and information moving simultaneously.

Tracking Systems

Container control and tracking is a non value added as well as a complex and time consuming issue within the material handling process. Companies have realized that the use of computer programs and services from third-party logistics providers, i.e., Systeme, Anwendungen and Produkte AG (SAP) can offer tremendous savings. These companies provide services and training, install programs, help to optimize container management along the supply chain. Tracking systems can be categorized as manual

or computer based. Manual tracking is used for simple container systems by manually keeping records of incoming and outgoing containers by shipper and receiver. It does not require high initial investments but it is labor intensive and will not provide enough records in case of shipping problems. Human error is also more likely in manual systems. Another product flow system to limit in process inventory is KANBAN (Kamiske and Brauer 1995). This method was developed in Japan and uses small lot sizes and quick inventory turns. Visual controls such as different container colors, colored labeling and other signs are used to easily identify products, containers, trucking information, lot numbers, or other system information to provide easy control and identification in the container movement process from packaging through material storage. Visual controls are easy to install and have low initial investments such as labeling but a well understood communication system is needed among all users and records must be carefully kept (MHIA 1999).

Instead of a manual system, computer technology can be used to track returnable containers. Electronic data interchange (EDI) can be used which is a computer-to-computer exchange of data, documents, and instructions between companies (Melnyk 1997). Inventory can be best managed by computer controlled tracking systems and these work best for complex distribution systems. They have the best capabilities to link different computer systems among several suppliers to interface with other material and logistics systems, i.e. truck, rail, air, ocean container shipment information, container allocations, transit times, shipment receipts etc. They offer the most benefits in shipping cost reduction by avoiding additional freight movement for adjusting additional containers due to out-of-stock container situations. Due to the higher complexity it also require additional training of personnel.

External pull systems are used for small lot sizes in returnables and manually handled containers with visual controls and a closed loop transportation system. It is controlled by a trigger mechanism where material shipments occur on a regular (almost daily) basis to replace material at the location of use. This system can be advantages because it eliminates waste, increases quality in production, and reduces lead times due to constant and regular delivery (Kibler 1997). It must be strictly controlled to avoid any out-of-stock situations, it requires standardized containers, and an optimized placement of resources including labor and material handling equipment (fork lift trucks, manual hand lifts).

Container control can also be done by financial transaction of supplier shipments when the company's shipping container are used. The supplier is financially responsible for returning the container after use. For each missing container, the supplier has to reimburse the company. Also, the parts supplier may own the containers and bill the company each time a shipment is received. This is the opposite where the company is billed for each missing container (Kibler 1997). The advantage of this system is that the container owner is protected against any risk of loss. It may risk loosing container identification and wrong billing in case of container loss, and the cost of bookkeeping is higher because they are required to keep track of correct records, billing and deposits or debits. Finally, inventory and warehousing management is most often used for container tracking which is an inventory control method described in the next section.

2.5 Inventory and Warehouse Management

Returnable containers are continuously shipped and returned on a routine basis. All partners of the supply chain have to inventory containers after predetermined time periods to assure that the right amount of containers is still cycling. Adjustments will be

made due to changes in production schedules, i.e. an increase in sales volume that requires more containers in the system or a faster return. Initial investments in this system are relatively low but it can be a disadvantage if there is a lack of cooperation between all members of the supply chain. Otherwise, container loss can significantly reduce investment benefits. An integrated inventory and warehousing management system can help to coordinate a reverse logistical system (Bojkow 1991).

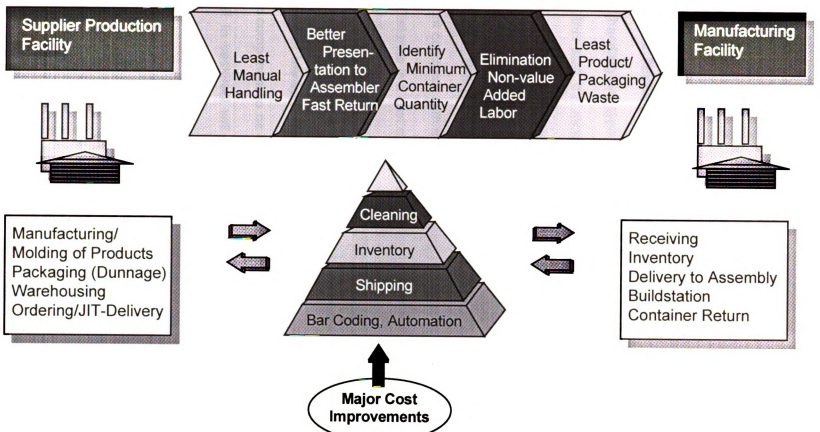
Inventory management systems (IMS) of returnable containers controlled by a computer system allow container management and material stocks by quantity and value. Planning and data entry of container movements are recorded in the form of documents. The physical inventory is used to compare physical stock against the book inventory balance. All transactions are made in real time and the physical stock shown is always accurate. The users are able to obtain an overview of the current stock level at any time. Real time accuracy is an important advantage in container tracking. The system recognizes container movements and updates stock values automatically. Each material document posted for a movement can be printed as a receipt with a bar code if needed to manually carry out physical movements within a warehouse.

A warehouse management system (WMS) supplements an IMS including all material movements. It manages storage bins in complex warehouse structures and has become imperative for efficient processing of logistics (SAP AG 1994, Trunk 1998).

2.6 Transportation System

Efficient shipment of returnables in a reverse logistic system depends on four issues: Transportation mode, distance between locations, Truckload (TL) vs Less Than Truckload (LTL) shipping, and the cooperation between supply chain partners (Kibler 1997).

Figure 3 Material Logistics Planning



The package design decision will be made depending on the transportation mode and function of the package. Product protection must be determined. Vendors can provide test data regarding shock, vibration, stacking and compressing capability of their products.

Currently, road transportation is the most common mode used for returnable packaging. It offers many advantages due to high availability of roads and carriers, route planning and flexibility to easily adapt other modes if intermodal transportation is needed, handling any type of containers and compatibility to current receiving facilities. On the other side, it is more expensive compared to rail and water transport because of higher variable cost mentioned earlier (Twede and Parsons 1997). Due to the fact of high transportation cost of road transportation, returnable packaging design is focused on using all available container cube and weight capacity. It is recommended to design lightweight container with minimum cube utilization (Robertson 1994).

Distance is a cost driving factor which most influences the overall system cost of operation since containers have to be returned to the place of origin. Return shipments (empty containers) is not value-adding and will directly contribute to the variable cost component of transportation consisting of labor, fuel and maintenance. Distance is a dynamic component to be considered in the calculation of transportation cost per mile. The cost to backhaul will be reduced per mile, but the longer the trip, the cost will decline at a decreasing rate (Bowersox and Closs 1996). It is not a constant decrease in cost and can be a major drawback in the financial analysis for a low value product if there are not other economies of scale to reduce cost. The use of collapsible container with a high return ratio is recommended to decrease the return volume. In a closed loop system, the shipper can use the additional cube for other items to ship back to the place of origin. Other case studies have shown that shorter distances will decrease

transportation cost due to lower backhaul cost (Twede and Parsons 1997, DeGiorgio and Palmer 1998, Romanski 1992).

For returnables, TL shipments are preferred compared to LTL shipment. During TL shipments, the trailer is loaded for minimum damage, maximum cube utilization, and minimum packaging use due to the fact that packages support each other in a stack (Blasius 1988). TL was evaluated to be less expensive (Faucett Associates 1991).

The type of carrier is another issue to consider when evaluating transportation issues. Shipping carriers are organized on a private, contract, or common carrier basis.

2.7 Distribution Environment, Product Protection and Efficiency

The logistical environment during transportation can be challenging because of many distribution hazards that can occur. Product damage in-transit may be caused by several factors such as handling and storage, shock and vibration during shipping and environmental conditions such as temperature changes or moisture influence. These factors decide how the returnable package will be designed to assure product protection.

To ensure product protection and a high lifespan of returnables, transit testing or an accelerated life cycle analysis (Singh 1998) must be included in the returnable container development. It is important to analyze distribution hazards, select corrective actions, and test the returnable container system. Main transit testing procedures are ASTM D-4169 and ISTA 1 and 2A which can be compared to ISO 4180/2-80. They give positive reactions regarding less product damage (Brana 1993, Fiedler 1995, ISO 1980/1 and 1980/2, 1994a). Compression strength must be considered when products are stacked. Several design considerations can increase compression strength such as using strong raw materials (steel, wood, and HDPE), considering that the product

supports the load (only used if the product is allowed to support the load) or by adding headspace which allows the load to compress the package but not bearing the load on the product.

The weight, size, shape, frequency of returnable containers determine the method of material handling. Heavy parts over 51 pounds (25 kilogram) cannot be handled manually by one person, and need at least two persons, mechanical assistance such as hand trucks and forklifts, or part redesign. The National Institute of Occupational Safety and Health (NIOSH) published manual lifting guidelines and recommendations for returnable packaging design and ergonomics (NIOSH 1998).

Cost efficiency and protection level must be evaluated parallel. Maximizing protection should always be the goal but also means using more material. It is recommended to reduce package weight, density, and size because carriers determine freight cost by weight and cube. A greater cube utilization and lower weight is more cost efficient than higher weight and lower cube utilization.

2.8 Third Party Container Management vs Ownership

When considering investing in a returnable container system, the question of ownership and handling significantly influences the investment decision and availability. There are three possibilities of ownership: Ownership by the shipper or consignee, partnership or part service ownership and leasing, or third party ownership. In the first case, returnables are owned by a shipper or the consignee; second, a partnership with part ownership and leasing of returnables is possible; and third, a third-party owns the container and provides services to the customers regarding tracking and controlling containers.

The ownership question depends on several factors: The price of service per units, availability of contractors, flexibility of partnering, the amount of containers needed, cleaning requirements, and frequency or cycle time. The amount of container components is a factor that can decide whether it is feasible to invest or to lease a service. If the container price and amount of containers needed, as well as variable cost will not exceed the leasing service, cleaning, tracking and control cost, than the investment and direct ownership of containers should be pursued. If the amount of containers used is very high, the investment and other variable costs will also increase and become more difficult to control the system. Direct ownership requires the company to track and maintain its containers themselves which may add cost.

With the increasing complexity of the supply chain, and more suppliers being involved in the returnable containers system, third-party container management or partnering is a better solution (DeGiorgio and Palmer 1998). Partnership is given in a vertical marketing system where the shipper and consignee are linked by ownership, strategic alliances, administration or contracts under the control of one firm (Bucklin 1970). In a partnership, it is important that the tracking and repair functions will be coordinated and might be performed by more than one company. It depends on the organization and structure of the returnable program as well as the industry that uses the container.

Certain industries may require a particular cleanliness requirement, i.e. the medical industry (pharmaceuticals and medical device) with distinct cleanliness and particulate requirements following governmental standards on good manufacturing practices (Pellizzi 1993) which do not existing, i.e. for the automotive industry. The cleanliness of the container in direct contact must be controlled and more container washing and cleaning is required which can significantly increase service cost. The

federal standard 209E, "Airborne particulate cleanliness classes in cleanrooms and clean zones" is required to be considered by manufacturers that have to meet good manufacturing practices guidelines for device manufacturers. It also complies with international regulations and standards. Therefore when choosing a partnership it is recommended to coordinate within the same industry.

In the case of a medical company, more frequent cleaning of returnable dunnage is required to comply with the GMPs. Partnership or third-party management compared to ownership can be considered if the total cost of cleaning does not exceed the investments in cleaning equipment, development cost, labor, maintenance, and material handling (Gelblum 1998).

For each returnable container system development case, the benefits for each ownership model must be analyzed and justified individually. A cost evaluation is recommended to incorporate the cleaning costs in a spreadsheet analysis for the net present value (NPV) analysis.

2.9 Supplier Evaluation

Evaluating the sources of supply is a process by which potential and existing suppliers are evaluated in terms of price, quality, reputation, location, service, flexibility, and financial strength. Selecting a vendor is a purchasing function normally called vendor analysis or supplier performance evaluation (Stevenson 1993). The criteria for supplier evaluation are described in Table 5.

Due to the complexity of returnable suppliers (Kulwiec 1998), a supplier evaluation is used to analyze the performance of a returnable packaging vendor. The goal is to find a supplier who can provide the best crate and dunnage solution with respect to price, quality, reputation, and service. Supplier performance can be compared

with the standards and specifications of the manufacturer who wants to use returnables, or, who wants to design its own customized containers. A supplier evaluation will help to understand the returnable container market and can be used as a part of the selection step of Quality Function Deployment (QFD) discussed in the next paragraph. For returnables that are designed for medical device applications, it is required that suppliers are selected and evaluated based on their experience in the medical industry. Furthermore they must provide design and performance capabilities based on current container system technologies and FDA approved materials.

The length of time for a supplier evaluation should not exceed more than two weeks for low volume products and should be less than four weeks for high volume products to make the evaluation cost effective. The evaluation should not include more than 3 suppliers because of evaluation costs.

Table 5 Criteria for Supplier Evaluation (Stevenson 1993)

Criteria	**Description**
Price	The price of a product is the most obvious selection criteria and may include discounts. Prices are determined by price lists, competitive bidding for large orders of standard products, and negotiation.
Quality	The quality of products must meet or exceed customer demands with respect to material and technical specifications and product functions. ISO certified companies and qualified manufacturing programs may insure high product quality.
Reputation	The supplier's reputation can be determined from past experience, reputable engineering programs and recommendations through networking associations, publications, and information services.
Location	Location of a supplier can impact delivery time, transportation costs, and response time for expediting orders. Local buying is recommended to support the local economy and avoid additional costs.
Service	Special services can be important in selecting a supplier, i.e. for replacement and repair of defective parts, and technical support.
Flexibility	Flexibility can be determined as the ability to respond to demand and design changes quickly and provide sufficient production capacity.
Financial Strength	The supplier's financial strength, the ability to purchase raw materials, and manufacture on demand is evaluated by credit reports.

2.10 Quality Function Deployment (QFD)

A QFD analysis can provide a good understanding of the performance of suppliers as a result of the supplier evaluation which selects the best companies to compare with each other (ReVelle, Moran and Cox 1998). QFD is a method used for a systematic planning process to develop new products or services. It helps to summarize all customer demands, to translate the demands into design targets and quality assurance points to be used throughout the manufacturing process. The goal is to 100 percent satisfy the customer by delivering a quality product (Daetz, Barnard, and Norman 1995). The need to use the QFD method was driven by two objectives: To convert the customer demands for a returnable crate into substitute quality characteristics at the design stage. To deploy the quality characteristics identified to the production or manufacturing activities of the crate supplier, thereby establishing the critical control points prior to the purchase order.

The QFD method follows a systematic approach and builds a QFD matrix (Figure 9, page 51). In general, the QFD matrix consists of 12 parts (Guinta and Praizler 1993) which are explained in Table 6.

Table 6 QFD Elements

QFD Matrix Element	Description	Application
Objective Statement	Goal description or problem statement of the project.	To find the optimum, cost efficient returnable crate solution (see chapter 1).
"Whats"	Characteristics of the packaging solution.	Easy to load trays, puncture resistant, easy to move, etc.
Importance Rating	Weighted values assigning the "Whats" and indicating the relative importance.	Values are 1, 3, and 9 (see matrix).
Correlation Matrix	Relationship between the "Hows". It covers conflicts between the "Hows".	Not used.
"Hows"	Ways of achieving the "Whats".	Stackable, collapsible, light weight, durable crate, etc.
Target Goals	Indicators whether the "How" should be increased or decreased.	Not used.
Relationship Matrix	Identifying the relationship level between the product characteristic ("What") and the way achieving it ("How").	Middle part of the matrix showing the importance ratings correlated to the "Hows"; values 1, 3, and 9.
Customer Competitive Assessment	Review of competitive product characteristics with the selected product.	Assessment of container supplier by performance comparison.
Technical Competitive Assessment "How Much"	The customers engineering specifications for each "How" and the competitor's.	Not used.
Probability Factors	Values indicating the ease to achieve the "Hows".	Not used.
Absolute Score	Sum of calculated values for each "How" or column in the Relationship Matrix.	Sum of all calculated values.
Relative Score	Sequential numbering of the "Hows" according to its absolute value.	Numbering ranges from 1 (highest absolute score) to 10 (lowest absolute score).

2.11 Capital Budgeting and Cost Evaluation

The use of returnable containers in the U.S., especially by manufacturer in the automotive industry, is constantly growing. Recent trends have shown that also other industries such as the grocery industry in the U.K. are becoming more interested in the benefits of returnables (Twede 1999). Many automotive companies such as Chrysler, Mercedes Benz or Ford Windsor have reported their success stories about the change from expendable to returnable packaging as the best solution to satisfy their logistical packaging and material handling needs (Auguston 1997, Forger 1998, Goetze 1998, Randall 1998). However, all companies had carefully to justify their investments in a returnable container system before they invested.

A national non-profit organization found that companies can reduce their container material used for shipments by 70.6 percent if returnable corrugates are used at least five times. The number goes up to 98.5 percent if returnable plastic container are used up to 250 times (Witt 1997, Table 7). Most companies do not accurately present their accounting system by which they have calculated their cost savings. Many returnable crate suppliers justify a container purchase only by the savings in expendable cost (Blasius 1991). However, it is important to show the overall system cost and cost drivers (Kolbach 1993).

Table 7 Life Time Cost Comparison Reusable Plastic vs Corrugated Container

Criteria / Container	Corrugated One-Way	Corrugated Reusable	Plastic Reusable
Estimated Life (Number of Trips)	1	5	250
Initial Cost	$0.53	$1.06	$11.03
Cost per Trip (average)	$0.53	$0.21	$0.044
Cost Savings	$0.00	**70.6%**	**98.5%**

Some companies still use traditional cost accounting. Many businesses have already switched to activity-based costing (ABC) which represents a different and better concept, especially for manufacturers.

Before investing in returnable containers, organizations always ask "How much does it cost and will this project be feasible under considerations of the total system cost and not only considering returnable vs expendable". Several case studies for the automotive and furniture industry and other literature in business journals have been reviewed which have used capital budgeting techniques to show the feasibility of their projects (Uxa 1994, Rosenau 1996 and Kibler 1997). Most commonly used techniques were ABC and Net Present Value (NPV) which will be used to show the effect of returnable packaging investments in this medical device case study.

During a cost analysis, the real cost that matters is the cost of the total process, and that is what ABC considers. Its basic premise is that manufacturing is an integrated process that starts when supplies, parts, or materials arrive at the plant's loading dock and continues even after the finished goods reaches the end user. Service is still a cost of the product. Therefore, ABC is an accounting method that assigns identifiable costs and allocates common costs to specific product lines or business segments. By using this method, a company can determine the profitability or profit contribution that each activity, segment, and product line brings to the company as a whole (Drucker 1995). ABC is important to evaluate the overall system cost and not only to compare the investments in returnables with the savings from expendables. The variable factors involved in this cost analysis are listed in spreadsheets (see Table 13-22). Using ABC can substantially reduce manufacturing cost by about one third or more. It shows the impact of changes in the costs and yields of every activity on the results of the whole process (Drucker 1995).

After all costs, savings and investments are summarized, the proposed capital investment in returnable packaging must be evaluated. Companies typically measure their investments in fixed assets. NPV is recommended and presents in corporate finance the present value of an investment in excess of the initial amount invested. In a spreadsheet analysis, the NPV sums all cash flows (CF) over the life time of a project and discounts them by the cost of capital at the moment of investment. The investment cost is subtracted form the discounted CF. The present value represents the value of cash to be received in the future expressed in today's monetary value.

When an investment has a positive NPV, it should be pursued; if negative, it should not be accepted (Twede and Mazzeo 1998).

Most companies use the payback method in combination with NPV. It calculates the time how quickly an investment pays back. It involves constructing a table of the NPV of the project by year until it reaches zero. In general, the shorter the payback period the better the investment opportunity.

3. Research Method

It was found during an informal survey of several returnable crate suppliers that a returnable container system for medical device components does not currently exist. Therefore, a single case study involving a medical device manufacturer was used to develop a returnable container system for syringe barrels and perform a feasibility study investigating possible solutions for a returnable crate.

The single case study approach was chosen to define a theory for future returnable packaging developments in the medical device industry. A case study describes the characteristics of a praxis oriented real-life event such as an organizational or a managerial process (Yin 1994). In comparison to a survey research, a case study does apply analytical results, not statistical generalizations. These analytical results can be applied to other returnable packaging development projects within the medical device industry. Each medical device case has its own characteristics, but there is a potential to advance the development endeavors by creating a packaging development guideline as shown in APPENDIX B.

This case study analysis includes several steps as shown in the project schedule (APPENDIX C) and project outline (Figure 4). The outline indicates all actions taken including basic research, supplier evaluation, QFD, cost analysis, design and prototyping, prototype fabrication, testing and specifications. All available resources were used such as literature search in libraries, attending seminars and conventions, interviews with packaging professionals, professors at MSU and industry, as well as several field trips including a walk-through demonstration at Medrad and its syringe barrel supplier.

A medical device company, Medrad, Inc., provided the practical information to formulate the single case study. In cooperation with the Manufacturing Manager at Medrad and its syringe barrel supplier, K&W, the research included the comparison of the current package to other returnable logistical packaging solutions.

Currently, Medrad is shipping 150 syringe barrels as bulk in corrugated boxes. At this point, the company had not considered any returnable packaging systems yet. The idea to find a returnable packaging container system was introduced because the company searched for an automated barrel loading system for the syringe assembly line. A robotic pick-up was considered to load the syringe barrels on the line. The current shipping configuration—unorganized syringe barrels in bulk bags—was not a useful configuration for a robotic pick-up. The task was to find a standardized crate or tray configuration to facilitate automated barrel loading and other manufacturing, material handling and logistical operations. The manufacturing manager was convinced that automation of the barrel loading operation would increase productivity and labor savings due to less material handling, and increase product quality due to standardized processes and less particulate created from shipping in bulk bags and corrugated.

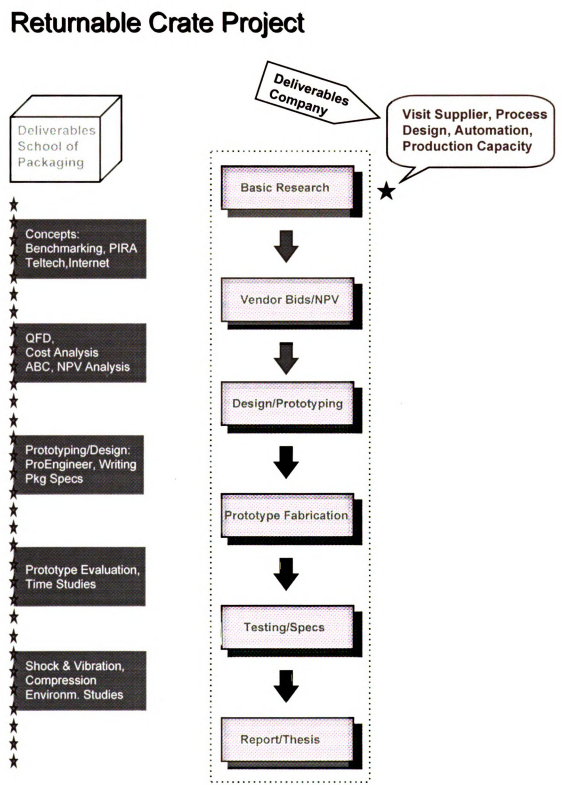
First, all product and package characteristics for the new returnable logistical packaging solution were defined and grouped as a QFD matrix to evaluate their importance and reduce development time. Secondly, a purchasing analysis was carried out to find returnable crate suppliers and thermoforming companies to deliver a tray and crate suitable for medical device components. Three major crate suppliers and one thermoforming company were found and evaluated by a supplier performance analysis (see APPENDIX D, only crate suppliers). Third, a feasibility study was performed as a spreadsheet financial analysis to compare the current and proposed returnable container system. The investment in crates and trays is evaluated to project the Net

Present Value of the overall project including capital investment, savings, expenses, and start-up or development cost. Three inventory scenarios show the influence of an efficient inventory management system.

Fourth, a preliminary tray design was developed. The package requirements were documented in a package specification that included all parts of the returnable container system (APPENDIX E). The specifications were given to three crate suppliers and the thermoformer. Crate samples and tray prototypes were provided to Medrad to conduct a walk-through demonstration and perform time studies to evaluate the labor impact.

Considering other cost analysis studies, it is not an unusual case in the industry that savings from the current package alone cannot be used to justify the use of returnable crates and trays. This is because the expendable material savings are not exceeding the combined investments in returnable crates and trays, a cleaning system, automation, and the increased material handling cost. The challenge, therefore, is to show whether there are direct and indirect labor and quality savings, as well as a reduced scrap rate to justify the investments. In order to find these impacts, activity based costing is used to uncover the hidden cost drivers for particular activities and to make a final project decision based on the net present value for each container alternative.

Figure 4 Project Outline



4. Case Study Results

Chapter two followed a model consisting of important criteria to be used for returnable packaging development for medical device (Figure 1, Returnable Packaging Development Model). This chapter will describe the results of this case study approach guided by this model.

4.1 Medical Device Packaging and Regulations

The product to be packaged and shipped in a returnable container system is a syringe barrel. It is a medical device component that will be assembled to an unfilled MRI or ANGIO syringe for human use in hospitals. These barrels are not sterilized before being assembled. The final product is a front load syringe (FLS). It will be filled with a contrast medium. With the help of the injector, the contrast medium is injected into a human body.

This case study is strongly regulated by the device good manufacturing practices published by the FDA. The returnable container system is a logistical package that is considered to be a part of the medical device during transportation between the syringe barrel supplier and the manufacturer of syringes. The syringe barrel is classified to belong to class II. Therefore, it is not necessary to obtain the package design with FDA approval before it will be used as logistical package. However, it must comply with the device good manufacturing practices.

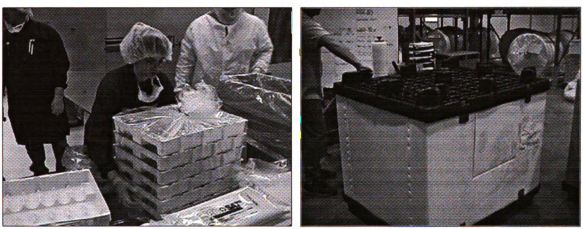
During design, testing, and manufacturing of these syringes, the medical device manufacturer is responsible for complying with the FDA regulations given in the GMPs. It is emphasized to comply with the GMP regulations as described in Chapter 2.

4.2 Medical Device Characteristics and Packaging Design

The size and geometry of the syringe determines how much space is required to set up the package dimensions, to optimize truckload capacity, and reduce shipping cost. The syringe barrel is light weight and does not require much cushioning. Syringe barrels do not provide as much compression strength, so they cannot be used as load bearing devices supporting a compressive load.

The following design requirements were considered to develop the returnable package system which consists of thermoformed trays and a collapsible container (Figure 5 and APPENDIX E).

Figure 5 Returnable Tray and Crate (Prototypes)



1. No sharp edges of the returnable container that can cause damage of the wrapping;
2. The syringe barrel should not support the load and should not be in contact with another barrel to prevent generation of any particulate during transportation.
3. The container in direct contact with the syringe will enter the cleanroom at the molder and manufacturer, and must comply with the cleanliness requirements of a class 10,000 cleanroom. It should provide product containment, be stackable, nestable when empty, provide enough stacking and compression strength to be

stacked 14 trays high, made of an FDA approved material that does not generate particulate, is flexible and resistant to temperature changes in distribution and warehousing, should be compatible to the cleaning process.

4. The outer container should be stackable, collapsible to minimize the return ratio, lightweight, easy to handle by one employee. The design should minimize any contact phases where particulate can accumulate. Therefore, open edges must be taped when plastic corrugated sleeves are used.
5. The tray should hold up to 14 barrels. It might be reduced because the flanges of the barrels are rubbing against each other which should be avoided to not generate any particulates.
6. The container system does not need to consist of a sterilizable material but it must be resistant to moisture or chemical contamination.
7. No sharp edges of the returnable container that can cause damage of the wrapping.
8. The syringe barrels should not support the load and should not be in contact with each other.
9. Wrapping material should be compatible to the package system, provide puncture resistance to protect the syringe from particulate.
10. A closure solution must be provided to close the wrapping.
11. A labeling solution must be provided to trace each syringe barrel lot molded by a particular molding machine. Labels must be placed on each packaging container element or a packaging unit, i.e., a stack of trays packaged in a bag. Labels must be tamper evident and legible throughout the distribution system.
12. A cleaning system should be recommended and in place to provide proper cleaning of the container elements that enter a cleanroom environment.

Appropriate packaging materials were investigated for the returnable container design, i.e., suppliers were asked to provide material specifications for their products to evaluate the compliance with GMPs and compatibility to the packaging and material handling process. In addition, packaging materials were requested to be recyclable.

A packaging specification (APPENDIX E) was written to provide a guideline for package design, prototyping and manufacturing for the returnable crate suppliers and thermoformer. It was used to evaluate prototypes during the walk-through demonstration and is subject for continuous change. The specification is kept on record for future reference to compare the delivered package components.

In this case study, the medical device packaging development, material handling and cleaning of trays, labeling of the crates and trays for traceability purposes must comply with the device good manufacturing practices. During the design stage, it must be assured that all team members responsible for the returnable package development (syringe tray in direct contact with the syringe barrels, see next paragraph), must communicate and cooperate with other team members who are responsible for materials, equipment selection, process validation, and quality control. It is recommended to work with companies who are experienced in the area of medical device packaging and who are familiar with GMPs and other FDA regulations mentioned earlier.

In Figure 6, all functions of the medical device package are summarized and linked to its environmental requirements. The matrix follows a system developed by Lockhart (Lockhart 1997).

Figure 6 Environment Matrix for Returnable Packaging Development

		Environment		
		Physical	Atmosphere	Human
Function	Protection	Compression/Stacking Hazardous Materials Vibration/No friction	Cleanliness/No Particulate Temperature Resistant UV-light Resistant	Tamper Evident Label Handling Instructions No Sharp Edges (Trays)
	Utility	Pallet Lock System Drop Doors	Flexible Material Corrugated	Access/Folding Instruction Hand Holes, Ease of Use
	Communication	Printed Crate Bar codes Label Holder	Storage Warnings Transportation Labels Opening Warnings	Legibility, Warnings Inventory Information Lot Number

4.3 Material Handling and Operational Requirements

At the beginning of the project, the company provided the process design and automation requirements for automated device loading at the manufacturers assembly line. The proper fit of the tray to the automated barrel loading robotic pick-up was the most important issue at that point. This was the main factor on the package design requirement list. Other information and requirements were gathered at the plant trip and a "wish list" for the QFD matrix was made.

Next, a plant visit at Medrad's molder facility in Westfield, PA (K&W), and Indianola, was arranged to investigate the current material handling flow using corrugated containers. Several possible returnable crate designs and dunnage/tray solutions, as well as a preliminary tray drawing and prototype were introduced to the supplier to visualize the new packaging solution. The walk-through demonstration of the facility was made by reviewing the molding process (cleanroom), barrel packaging in corrugated containers, releasing of full containers outside the cleanroom for palletizing and storage for shipment.

The loading dock capacity was reviewed and it was found that the ceiling height was not enough to handle two crates in a stack for efficient truck loading. The forklift

truck was able to carry only one crate at a time and place the crates inside the trailer on top of each other. It was found that this would dramatically increase material handling labor. A possible solution was to increase the loading dock height. However, it was decided not to do any construction at this point until the feasibility study was done. Another option was to use containers that are shorter in height.

Furthermore, overall plant readiness including cleanroom was evaluated. Another criteria was the size of the cleanroom opening through which the corrugated containers currently are conveyed from the cleanroom to the shipping area. The cleanroom opening size is fixed therefore the returnable crate dimensions had to be within these values of 19"x 12" x 35" (LxWxD). Other material handling concerns were associated with the investments in workstations, the loading dock changes for smoother and faster returnable crate loading as well as a labor increase of one person due to increased material handling. It was found that the current space and material handling equipment is available to manage returnable crates.

The next step was to evaluate cleanliness requirements to determine the need for sophisticated cleaning equipment, and where the cleaning should take place. It was decided to perform the cleaning of the returnable trays at K&W. Since the empty trays must be returned to K&W, the trays could be contaminated during transportation if cleaned at the manufacturer. Several cleaning equipment suppliers were researched based on the following criteria: Cleaning mechanism, cleanliness requirement cleanroom class 10,000, automated continuous flow to reduce labor and handling, and price. Two systems were found: NEY Ultrasonics ($325K) and S&K Products ($125K). These systems work with ultrasonic waves, NEY with a cleaning solution that is water based and S&K with a chemical solution. The latter can be operated automatically, the former only as batch cleaning which would increase labor.

In conclusion of the cleaning aspect, it was decided that Medrad would develop its own in-house cleaning system that will basically consist of a particulate blow off and an alcohol wipe down. This system meets the class 10,000 cleanroom requirements. The advantage of this system: Medrad already has a system in place so development costs as well as other investments will be saved, and furthermore, it is already validated. The cleaning machine investments of suppliers were not feasible (see purchasing analysis).

To evaluate labor due to a higher level of material handling, time studies were performed during the second walk-through demonstration after the first prototype of the new thermoform tray was done. A walk-though demonstration plan guided the plant trip. The time to finish each step was taken from the current packaging process, and also in the cleanroom. The time studies were performed by an individual who was currently working on the molding machine and packaged the syringe barrels. There were no time studies performed at Medrad yet, since the automation system for barrel loading is not in place yet. As a result of the time studies at K&W, it was found that the worker will not have enough time to accommodate more material handling. One solution was suggested to employ a new person per shift which increases labor by approximately $30,000 to $60,000. The company is now looking for an advanced automation system at the molding machine which includes inspection, packaging, and labeling.

To comply with the GMPs, traceability of containers and trays was very important. Each set of trays has to be marked individually to show from which molding machine the barrels were made. It was decided to label each stack of trays, and to place a (self-adhesive or pocket) label on the shipping crate. Labeling was found to be a cost driver. Automating the barrel loading process inside K&W's cleanroom was not possible because quality assurance required 100 percent visual inspection by inspectors.

4.4 Inventory and Warehouse Management

Inventory was another issue which was not considered to be risky. The company tries to maintain enough inventory to satisfy its customers without an out-of-stock situation for at least 15 to 21 days. The company does not have an electronic or computer based tracking system in place nor a warehouse management system for returnable containers. It was recommended to look into third-party tracking programs to reduce manual labor costs and to make the system more reliable in terms of keeping records.

Container tracking was not an issue since the company currently has a sophisticated incoming computer system which is appropriate for inventory and warehouse management, i.e. as introduced as SAP system.

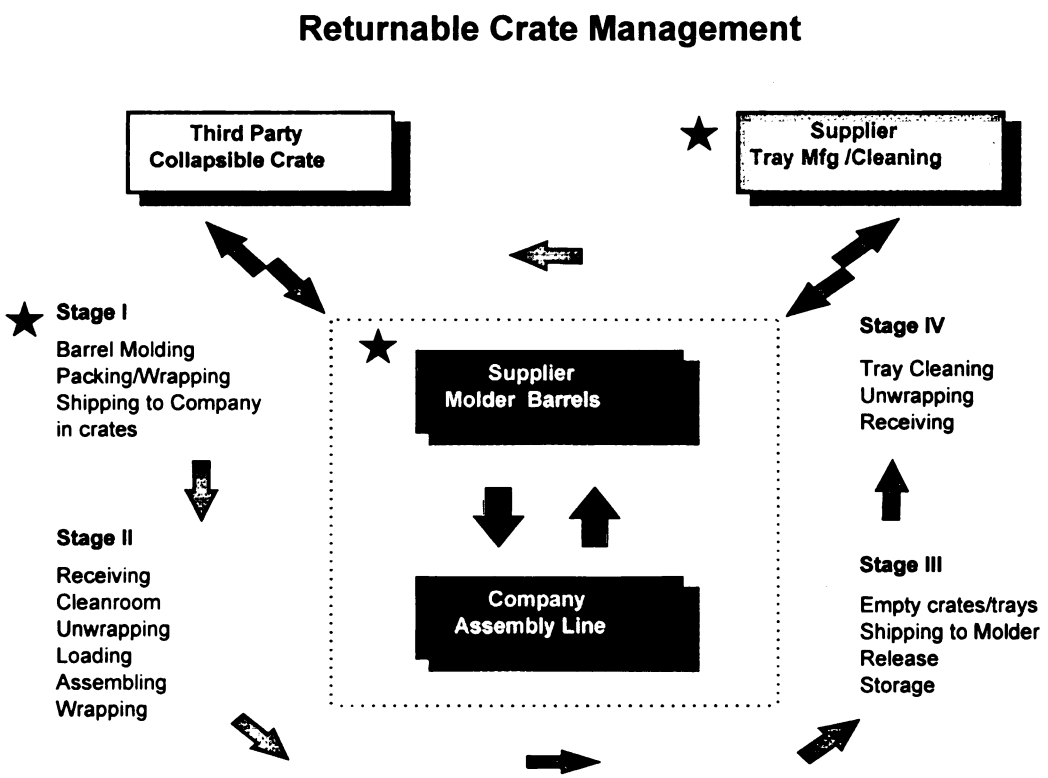
4.5 Transportation System

Figure 7 shows the suggested material handling and transportation route model. The stars in this figure mean that a supplier will provide the thermoformed trays who also could provide cleaning as a third-party service. This would be integrated in stage I at the facility of Medrad's syringe molding supplier K&W.

Barrel molding and loading in returnable trays will be done at K&W. The trays will be manually double bagged, labeled with a tamper evident label and closed with a twist tie. The packaged trays will be loaded into returnable containers outside the cleanroom. The full crates are loaded onto a trailer with a capacity of 44 crates per truckload and shipped to Medrad by truckload. A critical factor within the transportation characteristics is the distance between Medrad and K&W. A truck must drive about 4 to 5 hours between Medrad and K&W. Medrad pays for each truck shipment (one way only; from K&W to Medrad) the price for a full round trip. Since empty returnable containers must

be shipped back to K&W, the costs for shipments in return to K&W are already considered. To keep the empty shipped crate and tray volume low, the crates must be collapsible and the trays nestable.

Figure 7 Flowchart Returnable Crate Handling



4.6 Distribution Environment, Product Protection, and Efficiency

For the analysis of the distribution and environmental hazards, it is recommended to monitor vibration, drop impacts and compression characteristics during a one-way trip. As described, triaxial accelerometers to measure vibration, compression testers to simulate a constant load, and drop tester are used to test the damage characteristics of the individual package system in a stack of two crates. These tests can only be conducted when the container prototype is ready for testing. It is recommended to write a test plan which indicates assurance levels, tests performed,

standards used, etc. A possible information source for test a test center is the International Safe and Transit organization (ISTA). Usually, performance tests in the normal shipping environment are performed by using ASTM 4169 or ISTA 1 and 2A.

The lifespan of a crate or the tray is greatly influenced by the material used, mode of transportation, and manual handling by individuals. Ergonomics of the tray and crate play an enormous role to reduce employee injuries and faster handling. The crate should be lightweight, able to be handled by only one individual, stackable and collapsible with the lowest return ratio possible. The container design requirements were already discussed earlier. However, it is important to mention that a universal crate is required in order to reduce initial investment and so is a thermoformed tray.

The tray is preferably made from high impact polystyrene (HIPS) which is 35% rubber modified to be more flexible to withstand temperature changes and impact resistant. A non-modified polystyrene tray would be more brittle, less resistant to temperature changes and less impact resistant during handling. Rubber integrated in the styrene matrix gives more flexibility in the polymer chains.

4.7 Third-Party Container Management vs Ownership

The returnable system can consist of the following three options: a) Full-service by the third party for bulk containers, trays, and cleaning of trays. CHEP and Perstorp are returnable crate leasing companies, and Re-source America is offering third-party cleaning; b) Third-party management of bulk container, and Medrad owns the trays including cleaning; and, c) Medrad owns the whole system including container, trays, and cleaning equipment (see Figure 8).

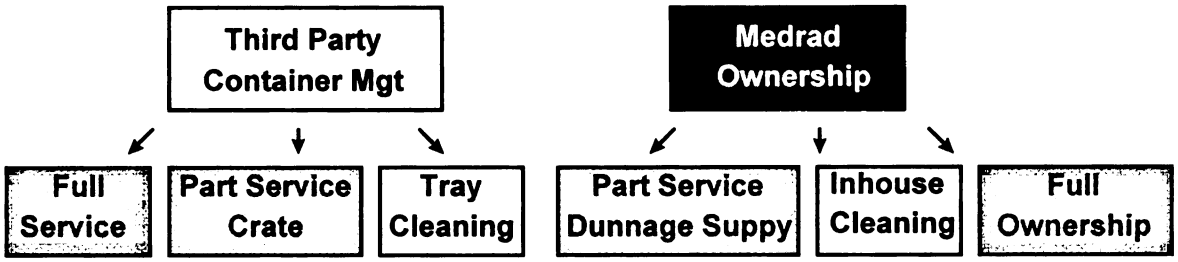
The returnable cycle between the tray supplier, K&W (barrel molder), Medrad, and the third-party company is shown in Figure 7. It was found that full ownership by

Medrad would be the most beneficial solution since it is a closed loop system with low container tracking requirements, the number of containers needed per year is continuously increasing, and the cost of a third-party management would increase the systems' overall cost. Various options of returnable container systems and suppliers, as well third-party service companies were researched as stated in Table 8 and Table 11. Regarding cleaning service provided by a third party company, several companies were evaluated to provide cleaned trays. It was found that the cost of cleaning by using an outside supplier would drastically increase the operational costs. Under consideration of labor, shipping, and availability of cleaning service, the price for one cleaned tray would be approximately $1 (Re-Source America). Due to these additional costs, it was decided that third-party cleaning is not feasible when considering 500,000 trays per year. The investment in an in-house blow and wipe down cleaning system would be much lower ($75K) and considered to be feasible for the whole project.

Since the supply chain between Medrad and K&W is not very complex, both parties can closely cooperate and use a contract carrier to ship returnables between Medrad and K&W. The container and trays will circulate in a closed loop system. The containers will be controlled by both partners. Records will be kept during incoming inspection. Since Medrad would own the whole container system, the company has better control over container use, availability, cleanliness, and flexible manufacturing.

Figure 8 Container Management

Ownership vs Third Party Container Management



4.8 Supplier Evaluation

A vendor analysis was performed to understand the current available returnable container systems in the automotive industry, medical packaging, grocery, and beverage industries. The following areas were investigated: Returnable bulk containers, thermoformed trays, polymer films/bags as wrapping materials, cleaning equipment suppliers, and third-party container management, tray suppliers, and cleaning services.

The following tables include all supplier evaluation results based on the criteria: Price, quality, lifespan, services, and flexibility. Further information is provided in APPENDIX D. In Table 8, all investigated container suppliers are listed, as are price and performance criteria such as lifespan, and service information. It is a collection of data provided by each company's representatives which are not based on literature and laboratory performance testing. Currently, there are no performance based test methods to test and evaluate returnable intermediate bulk container (IBC) available (Singh 1999). However, The School of Packaging at Michigan State University has been extensively involved in the development of test methods that can be used to provide a uniform basis to compare the performance of returnable containers. Singh has developed several methods to test the performance of reusable plastic containers (Singh 1999). The first method developed was for closed reusable containers for loads up to 150 lb. This

method was recently adopted by the International Safe Transit Association as Project 1F (ISTA 1998). Two new methods are currently being proposed. The first is for open reusable containers, and the second for reusable IBC's.

Buckhorn, Ropak and Perstorp offered very durable container solutions. However, these containers are heavy, cannot be handled by one person and are mostly used for heavy parts in the automotive industry. Compared to the aforementioned suppliers, TriEnda manufactures a light weight container that was considered a better solution for medical device components because it was easy to handle and load by one person and withstands sufficient compressive load.

Table 8 Returnable Container Evaluation (Supplier Information)

Company	Price	Quality/Life Time	Service/Flexibility
Ropak Corp., Canada	$140/ collapsible	best in class, ISO 9002 certified quality tests in laboratory life time: 7 years, easy to handle supplies automotive industry	Best customer support, fast quotation, cost/ performance comparison over expected life time gave best results
Buckhorn Inc., OH	$140/ collapsible	life time: 5 years, supplies automotive industry	Good customer support
TriEnda, Inc.	$80, collapsible	sleeve system is less durable, life time: 5-7 years, very good space utilization, light weight	Good customer support and fast quotation, lowest price
Perstorp Plastic System	$140/ collapsible	life time: 4 years	Good customer support third party management
Orbis	$140/collapsible	life time: 3 years	Poor customer service

In the following table, supplier information regarding thermoforming companies are listed. It was found that UFP Technologies was the most sophisticated and knowledgeable company in the area of medical packaging and provided the fastest quoting, designing and prototyping services.

Table 9 Thermoformed Trays Evaluation (Supplier Information)

Company	Price	Quality	Service/Flexibility
UFP Technologies NJ	$1.74/ tray for 30,000 trays; $6,000 tooling	high quality trays exhibited at PackExpo, ISO 9001, references in various industries, experience in medical device industry, Medrad is already customer for cushioning supplies, FDA approved, HIPS white thermoformed trays, 50 mil, with 35% rubber modified, withstands cleaning and high cycle time if proper handled	Best customer service most information supplied fast quotation cost/performance comparison gave best results
Tuscarora	$652 for 25000 trays	lower life time due to thinner tray thickness, quality work, less expensive but more repairs needed, light weight, less protection	Good customer support long customer consultation fast quotation
Plastech	$ not available	good quality	Good service/no quotation

Table 10 Polymer Bag Evaluation (Supplier Information)

Company	Price	Quality	Service/Flexibility
Polydynamic	$??? no quote yet	LDPE polybags, 1.5 mil thickness	No further information yet
Duratech	$0.08 per 3 pack tray	LDPE polybags, 3 mil thickness	Only cost information from UFP, company must be contacted to get quotation
Crystal X	$0.62/bag	LDPE polybags, 2 mil thickness	Currently used by Medrad

Table 11 Cleaning Equipment Evaluation (Supplier Information)

Company	Price	Quality	Service/Flexibility
S&K Products NY	$325,000 $40,000 maintenance	chemical solvent cleaning, applicable for class 10,000 clean room requirements, EPA approved, no toxicity, non flammable solvent from DuPont, sonic system, drying, batch process, automated, quality tests international references	Best support most information supplied fast quotation cost/performance comparison analysis over expected life time gave best results
NEY Ultrasonics	$125,000	water based ultrasonic, continuous process	Good customer support, less motivated
Re-Source America	$1/ tray cleaning	recommended by UFP	Third party cleaning, fast service
Hague America	>$1/tray cleaning	recommended by UFP	Good customer service, fast service

Evaluation results for wrapping and the cleaning system are provided in Table 10 and Table 11. Medrad and K&W would continue to purchase polymer bags from their current supplier Crystal X because of low prices of existing standard bags. None of the cleaning systems offered by NEY Ultrasonics and S&K products would be considered due to the high investments needed which would not justify a positive NPV.

4.9 Quality Function Deployment (QFD)

Three different crate suppliers and one thermoforming company were identified to conduct the selection process. A QFD analysis and supplier performance evaluation (Figure 9, APPENDIX D) was done to find the best crate solution. The QFD matrix was built by listing the customer demands as Medrad's "wish list" (performance criteria) such as puncture resistant crate walls, optimal containment of trays, cleanliness, reduction in particulates, and low investment. Each criterium was rated. A supplier performance assessment was done by comparing the crate performance of each supplier (Ropak, Buckhorn, Trienda) with Medrad's wish list. For each customer demand, the individual crates were evaluated. The absolute scores were summarized and a relative score was calculated in percent. From the matrix, it was found that the most important factors were stackability, collapsible, light weight container with drop doors, less than 1.5 inch wall thickness, made of a friction resistant material, i.e. HDPE, to reduce particulates and guarantee cleanliness. The ideal package was found to be the TriEnda crate with 91% customer satisfaction over all customer demands (Figure 9).

The outcome of the QFD analysis is that TriEnda delivers the best crate solutions with respect to 91% customer satisfaction over all customer demands, i.e. light weight, easy tray loading, easy crate handling, and lowest investment.

Figure 9 QFD Matrix

Package Function	Customer Demands \ Quality Characteristic	"What" Importance	Stackable/Collapsible	Interlock pallets/Four-way ent	Drop doors	Label holder	Flexible dimensions	Wall thickness (< 1.5 inch)	Total weight (light weight)	Friction resistent material	Compression strength	Fork lift resistance	Supplier: ROPAK	Supplier: TriEnda	Supplier: Buckhorn
Protection	Puncture resistant	9						9				9	5	4	4
	Compressive load resistant	3	3					3	1		9		5	5	5
	Cleanliness/no particulate	9								9			3	3	3
Utility/ Containment	Containment of trays	3					9						3	5	3
	Easy to move	9	9	9					9				2	5	2
	Easy to open	3	3		3				3				3	5	2
	Easy to load trays	9			9		3						4	4	4
Communication	Easy to label/to print	3				9				3			3	5	3
Cost	Low investment	9	3	1	1	1	3	1	1	1	3	1	2	5	2
	Absolute Score		**126**	90	99	36	81	99	**102**	99	54	90	30	**41**	28
	Relative Score (%)		**14%**	10%	11%	4%	9%	11%	**12%**	11%	6%	10%	67%	**91%**	62%

"What" Importance
1 = very low
3 = Low
9 = High

Matrix Relationship
1 = Weak relationship
2 = Medium relationship
3 = Strong relationship

Supplier Performance Assessment
0 = N/A
1 = Poor
3 = Good
5 = Excellent

Ideal Package
TriEnda Crate
91% Customer Satisfaction

4.10 Financial Analysis

The financial analysis is designed as a spreadsheet in Excel format which allows to be adjusted for various sale forecasts, inventory levels, float days and container amounts. The analysis is divided in three different levels of evaluation:

- Inventory level (100%, 60%, and 40%);
- Returnable system float (four and two days); and
- Savings received (starting in year zero or year one).

In Table 12, sales forecast determines the number of containers needed. Annual sales increase is included in percentage. All numbers have been modified and do not represent Medrad's syringe sale forecast. Two different returnable system floats are used: Four and two days. By reducing the float from four to two days, the containers are returned to the manufacturer in only two days (instead of four) and are used twice as much as with a float of four days. Therefore, the amount of containers floating in the system can be reduced by 50 percent. This lowers the initial investment in containers.

The current expendable cost of $56,352 (Table 13) is compared to the proposed returnable container investment considering three different inventory levels (100%, 60%, 40%). These new investments represent the new package costs for each inventory level. 100% inventory level represents the company's current amount of containers needed to accommodate a production quote of 304,800 barrels for 24 days inventory. 60% and 40% inventory levels were chosen as opportunities for reduction of initial investments. The total savings or expenses associated with wrapping, labeling, freight, disposal, labor cost at Medrad and K&W as well as quality savings due to less contaminated barrels are listed in Table 15 through Table 22. In these tables, the current system (expendables) is always shown on the left and the proposed system on

the right side. Savings or expenses are indicated as "New" which are integrated in the total cost analysis to evaluate the profitability. The total savings or expense numbers in these tables are summarized in the NPV tables for different inventory levels to identify the NPV difference and payback period due to lower investments in returnable crates if a lower inventory level or floating time is considered.

Beside inventory levels and floating time, it was investigated the influence of savings received in year zero and year one. The calculations for year zero are shown in table 23 through 34, and for year one in tables 35 through 46.

The NPV is calculated under consideration of an internal rate of return of 30%. For the analysis, only the best suppliers TriEnda and UFP Technologies were chosen. NPV and payback period were evaluated. It was found that the NPV continuously increases and the payback period decreases the lower the inventory level.

Table 12 Cost Analysis - Returnable Container System

Company: Medrad, Inc.	**Returnable System Float: 4, and 2 days**				
Sales Forecast	2000	2001	2002	2003	2004
Annual volume:	**3,004,568**	**3,305,025**	**3,602,477**	**3,890,675**	**4,201,929**
Annual increase:		**10%**	**9%**	**8%**	**8%**
Barrels/day (*)	**304,800**				
Total Crates/day (**)	300	303	306	308	310
100% Inventory, 4 days	**300**	**303**	**306**	**308**	**310**
60% Inventory	**180**	**182**	**184**	**185**	**186**
40% Inventory	**120**	**121**	**122**	**123**	**124**
100% Inventory, 2 days	**150**	**152**	**153**	**154**	**155**
60% Inventory	**90**	**91**	**92**	**92**	**93**
40% Inventory	**60**	**61**	**61**	**62**	**62**
(*Barrels/day, barrel in stock, no inventory reduced)					
(**Crates/day for 24 days inventory)					

Table 13 Cost Comparison Current System (Expendable) and Proposed System (Returnables) for Float 4 Days

Current System			Proposed System (Float 4 days)			
Packaging Cost			**Crate and Tray Investment**			
Parts/Ctn:	150		Parts/Crate:	**1,008** 41" OD/38"ID		
Ctns/Plt:	24		Crate/Plt:	1 Crate:14 layers x 6 trays/layer x 12 barrels/tray		
Parts/Plt:	3,600		Parts/Plt:	1,008		
Exp Mtl Wt (lbs):	90		**Inventory (%)**	**100%**	**60%**	**40%**
Ctn.cost ($):	$1.38		Tray	$1.67	$1.71	$1.78
Ctn.cost/plt ($):	$33.12		Crate:	$80	$80	$80
Plt cost ($):	$0.00		Tray/crate: 84	$140	$144	$150
Shrink Wrap/plt ($):	$2.00		**Crate + Tray Cost**	**$220**	**$224**	**$230**
			Tray Req.	**25,200**	**15,120**	**10,080**
Unit cost ($):	35.12		Ret Crate Req:	**300**	**180**	**120**
Expendable cost:	**29,311**		**Investm Returnable:**	**$66,084**	**$40,255**	**$27,542**
Barrel Sleeves	**27,041**		**Tooling:**	$6,000	$6,000	$6,000
Sleeve cost/barrel	$0.009		**Cleaning:**	$50,000	$50,000	$50,000
			Automation:	$100,000	$100,000	$100,000
Current Packaging Cost:		**$56,352**	**New Investment (year 0):**	**$222,084**	**$196,255**	**$183,542**

Table 14 Cost Comparison Current System (Expendable) and Proposed System (Returnables) for Float 2 Days

Proposed System (Float 2 days)				
Crate and Tray Investment				
Parts/Crate:		**1,008** 41" OD/38"ID		
Crate/Plt:		1 Crate:14 layers x 6 trays/layer x 12 barrels/tray		
Parts/Plt:		1,008		
Inventory (%)		**100%**	**60%**	**40%**
Tray		$1.82	$1.83	$1.84
Crate:		$80	$80	$80
Tray/crate:	84	$153	$154	$155
Crate + Tray Cost		**$233**	**$234**	**$235**
Tray Req.		**12,600**	**7,560**	**5,040**
Ret Crate Req:		**150**	**90**	**60**
Investm Returnable:		**$34,932**	**$21,035**	**$14,074**
Tooling:		$6,000	$6,000	$6,000
Cleaning:		$50,000	$50,000	$50,000
Automation:		$100,000	$100,000	$100,000
New Investment (year 0):		**$190,932**	**$177,035**	**$170,074**

Table 15 Wrapping Cost

Wrapping Cost		**Wrapping New**		
Bags/Ctn:	2 ($0.26/bag)	Bags/7Trays	2	
Ctn/year	20,030	Bags/year	71,537	Barrels per crate * 24bags/crate
		Bag cost/year	$18,600	2 tray stacks*2bags/stack)
Bag cost/year	**$10,416**	**New (Increase) Wrapping:**	**($8,184)**	

Table 16 Development Cost

Development	$0	New Development:	($18,500)

Table 17 Labeling Cost

Labeling Cost			**Labeling New**	
Label/Ctn	1		7Trays = 1 Label →	**7 trays = 1 stack = 7 trays * 12 barrels = 84 barrels**
1000 Labels:	$23.75		Stack/year	**35,769**
Label cost/ctn	0.02375		Labels/year	35,769
Ctn/year	20,030	(150 barrel/ct	Label cost/year	**$850**
Label cost/barrel	0.000158			
Label cost/year	**$476**		**New (Increase) Labeling:**	**($374)**

Table 18 Freight Cost

Freight Cost			**Freight New**	
Distance (Round trip)	400	miles	Cost/TL Rd Trip ($)	$580 Time: 5 hrs/trip
Cost/TL one/way:	$580		Plt/TL:	44
Plt/TL:	22		Part/TL:	44,352
Part/TL:	79,200		Freight Cost:	**$39,291**
Freight Cost:	**$22,003**		**New Freight Cost Impact:**	**($17,288)**

Table 19 Quality Improvement (Reduced Particulate)

Reduced Particulate		0.5%	**New Particulate**	
Handling (labor)	5%	$1,000	Material	$0
Scrap(0.62/barrel)	0.5% scra	$9,314		
Reduced Particulate/Quality		**$10,314**	**New: Labor Cost Savings**	**$10,314**

Table 20 Disposal Cost

Disposal cost (End-Item-User)		**New Disposal**	$100
Disposal Savings:	$500	**Disposal Savings:**	**$400**

Table 21 Labor Cost (Medrad)

Labor Cost (Medrad)		**New Labor Cost (Medrad)**	
Assembly Line:	$85,000	Labor Cost (Assembly)	$0
Material Disposal/Maint:	$5,000		
Annual Labor (End-Item User)	$90,000	**New: Labor Cost Savings**	**$90,000**

Table 22 Labor Cost (K&W)

Labor Cost (K&W)		**New Labor (Manufacturer):**		
Labor/hr:	$16	Plts/hr	44	1 hour loading/1 hour unloading (maximum)
Ctn making/hr	250	Plts/annual:	2,981	
Plt wrap/hr (5min/plt)	10.42	**Labor loadi**	**$1,084**	
Opt plt/hr	12.00	Rotations	9.94	
Labor Wrapp/250 ctn	14	Tray/Clean	125,190	(cleaning after each cycle, devided by 2)
Labor Wrapp/plt:	1.33	Tray/Clean/h	100.0	(1 person)
Labor Wrapp/ctn	0.06	**Labor**	**$20,030**	
Wrapping:	*$1,113*			
Box making:	*$1,282*	**Annual Labor cost:**	**$21,114**	
Pallets/annual:	835	**Additional Labor cost:**	**$60,000**	Projected by Medrad
Load Time: 0.5hr/TL	417 Hours			
Labor Loading:	*$6,677*			
Labor Cost:	**$9,072**	**New Labor Cost (Manufacturer):**	**($12,043)**	(1 employee/shift)

In Tables 15 through 22, all total savings or expenses of the current and proposed system are listed. These savings and expenses represent only year zero and will not be discounted. The total savings or expense numbers are summarized in the NPV calculations in Tables 23 through 46.

Table 23 NPV (100% Inventory, Float 4 days, Savings in Year 0)

NPV Analysis (100% Inv., 4 days float)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$222,084				
Total Investment Required		(222,084)	0	0	0	0
10 year Depreciation	$22,208	22,208	22,208	22,208	22,208	22,208
Cash Flow from Depriciation (35%)			7,773	7,773	7,773	7,773
Total Cash Flow from Investment		**($222,084)**	**$7,773**	**$7,773**	**$7,773**	**$7,773**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		400	441	477	510	548
Total Savings		119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$18,000	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0
Tray Prototype		2,000	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0
Total Start-Up		18,500	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($163,118)	$93,235	$100,189	$106,479	$113,908
Internal Rate of Return	30%	**($163,118)**	**$71,719**	**$59,283**	**$48,466**	**$39,882**
Net Present Value (NPV)		**$56,232**	**NPV if inventory levels not reduced!**			
Payback (years, months)		**2.66 Years**	**32 Months**			

Table 24 Payback (100% Inventory, Float 4 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months) **32**	(Years) **2.66**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($163,118)	($163,118)	
Year (Months)	**1 (12)**	71,719	(91,399)	
Year (Months)	**2 (24)**	59,283	(32,116)	
Year (Months)	**3 (36)**	48,466	16,350	
Year (Months)	**4 (48)**	$39,882	$56,232	

Table 25 NPV (100% Inventory, Float 2 days, Savings in Year 0)

NPV Analysis (100% Inv., 2 days float)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$190,932				
Total Investment Required		(190,932)	0	0	0	0
10 year Depreciation	$19,093	19,093	19,093	19,093	19,093	19,093
Cash Flow from Depriciation (35%)			6,683	6,683	6,683	6,683
Total Cash Flow from Investment		**($190,932)**	**$6,683**	**$6,683**	**$6,683**	**$6,683**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		400	441	477	510	548
Total Savings		119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$18,000	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0
Tray Prototype		2,000	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0
Total Start-Up		18,500	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($131,966)	$92,145	$99,098	$105,389	$112,818
Internal Rate of Return	30%	**($131,966)**	**$70,881**	**$58,638**	**$47,970**	**$39,501**
Net Present Value (NPV)		**$85,022**	**NPV if inventory levels not reduced!**			
Payback (years, months)		2.05 Years		25 Months		

Table 26 Payback (100% Inventory, Float 2 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months) **25**	(Years) **2.05**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($131,966)	($131,966)	
Year (Months)	**1 (12)**	70,881	(61,086)	
Year (Months)	**2 (24)**	58,638	(2,448)	
Year (Months)	**3 (36)**	47,970	45,522	
Year (Months)	**4 (48)**	$39,501	$85,022	

Table 27 NPV (60% Inventory, Float 4 days, Savings in Year 0)

NPV Analysis (60% Inv., 4 days float)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$196,255	$0	$0	$0	$0
Total Investment Required		(196,255)				
10 year Depreciation	$19,626	19,626	19,626	19,626	19,626	19,626
Cash Flow from Depriciation (35%)			*6,869*	*6,869*	*6,869*	*6,869*
Total Cash Flow from Investment		**($196,255)**	**$6,869**	**$6,869**	**$6,869**	**$6,869**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		400	441	477	510	548
Total Savings		*119,178*	*131,480*	*142,178*	*151,856*	*163,284*
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$18,000	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0
Tray Prototype		2,000	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0
Total Start-Up		18,500	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($137,290)	$92,331	$99,285	$105,575	$113,004
Internal Rate of Retur	30%	**($137,290)**	**$71,024**	**$58,748**	**$48,054**	**$39,566**
Net Present Value (NPV)		**$80,103**	**60% Inventory**			
Payback (years, months)		**2.16 Years**		**26 Months**		

Table 28 Payback (60% Inventory, Float 4 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months) **26**	(Years) **2.16**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($137,290)	($137,290)	
Year (Months)	**1 (12)**	71,024	(66,266)	
Year (Months)	**2 (24)**	58,748	(7,517)	
Year (Months)	**3 (36)**	48,054	40,537	
Year (Months)	**4 (48)**	$39,566	$80,103	

Table 29 NPV (60% Inventory, Float 2 days, Savings in Year 0)

NPV Analysis (60% Inv., 2 days float)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$177,035	$0	$0	$0	$0
Total Investment Required		(177,035)				
10 year Depreciation	$17,703	17,703	17,703	17,703	17,703	17,703
Cash Flow from Depriciation (35%)			*6,196*	*6,196*	*6,196*	*6,196*
Total Cash Flow from Investment		**($177,035)**	**$6,196**	**$6,196**	**$6,196**	**$6,196**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		400	441	477	510	548
Total Savings		*119,178*	*131,480*	*142,178*	*151,856*	*163,284*
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$18,000	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0
Tray Prototype		2,000	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0
Total Start-Up		18,500	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($118,069)	$91,658	$98,612	$104,903	$112,331
Internal Rate of Retur	30%	**($118,069)**	**$70,506**	**$58,350**	**$47,748**	**$39,330**
Net Present Value (NPV)		**$97,866**	**60% Inventory**			
Payback (years, months)		**1.82 Years**		**22 Months**		

Table 30 Payback (60% Inventory, Float 2 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months) **22**	(Years) **1.82**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($118,069)	($118,069)	
Year (Months)	**1 (12)**	70,506	(47,563)	
Year (Months)	**2 (24)**	58,350	10,788	
Year (Months)	**3 (36)**	47,748	58,536	
Year (Months)	**4 (48)**	$39,330	$97,866	

Table 31 NPV (40% Inventory, Float 4 days, Savings in Year 0)

NPV Analysis (40% Inv., 4 days)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$183,542	$0	$0	$0	$0
Total Investment Required		(183,542)				
10 year Depreciation	$18,354	18,354	18,354	18,354	18,354	18,354
Cash Flow from Depriciation (35%)			*6,424*	*6,424*	*6,424*	*6,424*
Total Cash Flow from Investment		**$183,542**	**$6,424**	**$6,424**	**$6,424**	**$6,424**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		10,314	11,379	12,305	13,142	14,131
Reduced Particulate/Quality		(374)	(412)	(446)	(476)	(512)
Savings Disposal Cost		400	441	477	510	548
Total Savings		*119,178*	*131,480*	*142,178*	*151,856*	*163,284*
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$18,000	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0
Tray Prototype		2,000	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0
Total Start-Up		**18,500**	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($124,577)	$91,886	$98,840	$105,130	$112,559
Internal Rate of Retur	30%	**($124,577)**	**$70,682**	**$58,485**	**$47,852**	**$39,410**
Net Present Value (NPV)		**$91,852**	**40% Inventory**			
Payback (years, months)		**1.92 Years**		**23 Months**		

Table 32 Payback (40% Inventory, Float 4 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months)	(Years)
			23	**1.92**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($124,577)	($124,577)	
Year (Months)	**1 (12)**	70,682	(53,895)	
Year (Months)	**2 (24)**	58,485	4,590	
Year (Months)	**3 (36)**	47,852	52,442	
Year (Months)	**4 (48)**	$39,410	$91,852	

Table 33 NPV (40% Inventory, Float 2 days, Savings in Year 0)

NPV Analysis (40% Inv., 2 days)		Year 0	Year 1	Year 2	Year 3	Year 4
Investment Capital		$170,074	$0	$0	$0	$0
Total Investment Required		(170,074)				
10 year Depreciation	$17,007	17,007	17,007	17,007	17,007	17,007
Cash Flow from Depriciation (35%)			*5,953*	*5,953*	*5,953*	*5,953*
Total Cash Flow from Investment		**$170,074**	**$5,953**	**$5,953**	**$5,953**	**$5,953**
Savings/Expense						
Reduction current pkg cost		$56,352	$62,169	$67,228	$71,804	77,208
Increase Freight/Shipping		(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		10,314	11,379	12,305	13,142	14,131
Reduced Particulate/Quality		(374)	(412)	(446)	(476)	(512)
Savings Disposal Cost		400	441	477	510	*548*
Total Savings		*119,178*	*131,480*	*142,178*	*151,856*	*163,284*
Total Cash Flow Savings		**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development						
MSU, Labor		$0	$0	$0	$0	$0
Lab Testing		0	0	0	0	0
Tray Prototype		0	0	0	0	0
Testing/Validation Cleaning		0	0	0	0	0
Total Start-Up		**0**	0	0	0	0
Total Cash Flow Development		**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($92,608)	$91,415	$98,368	$104,659	$112,087
Internal Rate of Retur	30%	**($92,608)**	**$70,319**	**$58,206**	**$47,637**	**$39,245**
Net Present Value (NPV)		**$122,799**	**40% Inventory**			
Payback (years, months)		**1.38 Years**			**17 Months**	

Table 34 Payback (40% Inventory, Float 2 days, Savings in Year 0)

Returnable Container Investment Payback Period:			(Months)	(Years)
			17	**1.38**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($92,608)	($92,608)	
Year (Months)	**1 (12)**	70,319	(22,289)	
Year (Months)	**2 (24)**	58,206	35,917	
Year (Months)	**3 (36)**	47,637	83,554	
Year (Months)	**4 (48)**	$39,245	$122,799	

Table 35 NPV (100% Inventory, Float 4 days, Savings in Year 1)

NPV Analysis (100% Inv., 4 days float)		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$222,084					
Total Investment Required		(222,084)	0	0	0	0	0
10 year Depreciation	$22,208	22,208	22,208	22,208	22,208	22,208	22,208
Cash Flow from Depriciation (35%)			7,773	7,773	7,773	7,773	7,773
Total Cash Flow from Investment		**($222,084)**	**$7,773**	**$7,773**	**$7,773**	**$7,773**	**$7,773**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		0	10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		$0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($240,584)	$85,239	$93,235	$100,189	$106,479	$113,908
Internal Rate of Return	30%	**($240,584)**	**$65,568**	**$55,169**	**$45,603**	**$37,281**	**$39,882**
Net Present Value (NPV)		**$2,919**	**NPV if inventory levels not reduced!**				
Payback (years, months)		4.93 Years		59 Months			

Table 36 Payback (100% Inventory, Float 4 days, Savings in Year 1)

Returnable Container Investment Payback Period:			(Months) **59**	(Years) **4.93**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($240,584)	($240,584)	
Year (Months)	**1 (12)**	65,568	(175,016)	
Year (Months)	**2 (24)**	55,169	(119,847)	
Year (Months)	**3 (36)**	45,603	(74,245)	
Year (Months)	**4 (48)**	37,281	(36,963)	
Year (Months)	**5 (60)**	$39,882	$2,919	

Table 37 NPV (100% Inventory, Float 2 days, Savings in Year 1)

NPV Analysis (100% Inv., 2 days float)		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$190,932					
Total Investment Required		(190,932)	0	0	0	0	0
10 year Depreciation	$19,093	19,093	19,093	19,093	19,093	19,093	19,093
Cash Flow from Depriciation (35%)			6,683	6,683	6,683	6,683	6,683
Total Cash Flow from Investment		**($190,932)**	**$6,683**	**$6,683**	**$6,683**	**$6,683**	**$6,683**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		0	10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	$106,135
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($209,432)	$84,148	$92,145	$99,098	$105,389	$112,818
Internal Rate of Return	30%	**($209,432)**	**$64,729**	**$54,524**	**$45,106**	**$36,900**	**$39,501**
Net Present Value (NPV)		**$31,327**	**NPV if inventory levels not reduced!**				
Payback (years, months)		**4.21 Years**			**50 Months**		

Table 38 Payback (100% Inventory, Float 2 days, Savings in Year 1)

Returnable Container Investment Payback Period:			(Months)	(Years)
			50	**4.21**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($209,432)	($209,432)	
Year (Months)	**1 (12)**	64,729	(144,703)	
Year (Months)	**2 (24)**	54,524	(90,179)	
Year (Months)	**3 (36)**	45,106	(45,073)	
Year (Months)	**4 (48)**	36,900	(8,173)	
Year (Months)	**5 (60)**	$39,501	$31,327	

Table 39 NPV (60% Inventory, Float 4 days, Savings in Year 1)

NPV Analysis (60% Inv., 4 days float)		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$196,255					
Total Investment Required		(196,255)	0	0	0	0	0
10 year Depreciation	$19,626	19,626	19,626	19,626	19,626	19,626	19,626
Cash Flow from Depriciation (35%)			6,869	6,869	6,869	6,869	6,869
Total Cash Flow from Investment		**($196,255)**	**$6,869**	**$6,869**	**$6,869**	**$6,869**	**$6,869**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		0	10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($214,755)	$84,335	$92,331	$99,285	$105,575	$113,004
Internal Rate of Retur	30%	**($214,755)**	**$64,873**	**$54,634**	**$45,191**	**$36,965**	**$39,566**
Net Present Value (NPV)		**$26,473**	**NPV if inventory levels not reduced!**				
Payback (years, months)		**4.33 Years**			**52 Months**		

Table 40 Payback (60% Inventory, Float 4 days, Savings in Year 1)

Returnable Container Investment Payback Period:			(Months) **52**	(Years) **4.33**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($214,755)	($214,755)	
Year (Months)	**1 (12)**	64,873	(149,882)	
Year (Months)	**2 (24)**	54,634	(95,249)	
Year (Months)	**3 (36)**	45,191	(50,058)	
Year (Months)	**4 (48)**	36,965	(13,093)	
Year (Months)	**5 (60)**	$39,566	$26,473	

Table 41 NPV (60% Inventory, Float 2 days, Savings in Year 1)

NPV Analysis (60% Inv., 2 days float)		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$177,035					
Total Investment Required		(177,035)	0	0	0	0	0
10 year Depreciation	$17,703	17,703	17,703	17,703	17,703	17,703	17,703
Cash Flow from Depriciation (35%)			6,196	6,196	6,196	6,196	6,196
Total Cash Flow from Investment		**($177,035)**	**$6,196**	**$6,196**	**$6,196**	**$6,196**	**$6,196**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	(374)	(412)	(446)	(476)	(512)
Reduced Particulate/Quality		0	10,314	11,379	12,305	13,142	14,131
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	$106,135
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($195,535)	$83,662	$91,658	$98,612	$104,903	$112,331
Internal Rate of Return	30%	**($195,535)**	**$64,355**	**$54,236**	**$44,885**	**$36,729**	**$39,330**
Net Present Value (NPV)		**$44,001**	**NPV if inventory levels not reduced!**				
Payback (years, months)		3.87 Years		46 Months			

Table 42 Payback (60% Inventory, Float 2 days, Savings in Year 1)

Returnable Container Investment Payback Period:		(Months)	(Years)
		46	**3.87**
	Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($195,535)	($195,535)
Year (Months)	**1 (12)**	64,355	(131,180)
Year (Months)	**2 (24)**	54,236	(76,944)
Year (Months)	**3 (36)**	44,885	(32,059)
Year (Months)	**4 (48)**	36,729	4,670
Year (Months)	**5 (60)**	$39,330	$44,001

Table 43 NPV (40% Inventory, Float 4 days, Savings in Year 1)

NPV Analysis (40% Inv., 4 days float)		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$183,542					
Total Investment Required		(183,542)	0	0	0	0	0
10 year Depreciation	$18,354	18,354	18,354	18,354	18,354	18,354	18,354
Cash Flow from Depriciation (35%)			6,424	6,424	6,424	6,424	6,424
Total Cash Flow from Investment		**($183,542)**	**$6,424**	**$6,424**	**$6,424**	**$6,424**	**$6,424**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	10,314	11,379	12,305	13,142	14,131
Reduced Particulate/Quality		0	(374)	(412)	(446)	(476)	(512)
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	**$106,135**
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($202,042)	$83,890	$91,886	$98,840	$105,130	$112,559
Internal Rate of Retur	30%	**($202,042)**	**$64,530**	**$54,370**	**$44,989**	**$36,809**	**$39,410**
Net Present Value (NPV)		**$38,066**	**NPV if inventory levels not reduced!**				
Payback (years, months)		4.03 Years		48 Months			

Table 44 Payback (40% Inventory, Float 4 days, Savings in Year 1)

Returnable Container Investment Payback Period:			(Months) **48**	(Years) **4.03**
		Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($202,042)	($202,042)	
Year (Months)	**1 (12)**	64,530	(137,512)	
Year (Months)	**2 (24)**	54,370	(83,141)	
Year (Months)	**3 (36)**	44,989	(38,153)	
Year (Months)	**4 (48)**	36,809	(1,344)	
Year (Months)	**5 (60)**	$39,410	$38,066	

Table 45 NPV (40% Inventory, Float 2 days, Savings in Year 1)

NPV Analysis (40% Inv., 2 days flo		Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Investment Capital		$170,074					
Total Investment Required		(170,074)	0	0	0	0	0
10 year Depreciation	$17,007	17,007	17,007	17,007	17,007	17,007	17,007
Cash Flow from Depriciation (35%)			5,953	5,953	5,953	5,953	5,953
Total Cash Flow from Investment		**($170,074)**	**$5,953**	**$5,953**	**$5,953**	**$5,953**	**$5,953**
Savings/Expense							
Reduction current pkg cost		$0	$56,352	$62,169	$67,228	$71,804	$77,208
Increase Freight/Shipping		0	(17,288)	(19,073)	(20,625)	(22,029)	(23,686)
Savings Labor Cost (Medrad)		0	90,000	99,290	107,369	114,678	123,308
Increase Labor Manufacturer		0	(12,043)	(13,286)	(14,367)	(15,345)	(16,500)
Increase Wrapping		0	(8,184)	(9,029)	(9,763)	(10,428)	(11,213)
Increase Labeling Cost		0	10,314	11,379	12,305	13,142	14,131
Reduced Particulate/Quality		0	(374)	(412)	(446)	(476)	(512)
Savings Disposal Cost		0	400	441	477	510	548
Total Savings		0	119,178	131,480	142,178	151,856	163,284
Total Cash Flow Savings		**$0**	**$77,466**	**$85,462**	**$92,416**	**$98,706**	$106,135
Development							
MSU, Labor		$18,000	$0	$0	$0	$0	$0
Lab Testing		2,000	0	0	0	0	0
Tray Prototype		2,000	0	0	0	0	0
Testing/Validation Cleaning		15,000	0	0	0	0	0
Total Start-Up		18,500	0	0	0	0	0
Total Cash Flow Development		**($18,500)**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flow		($188,574)	$83,418	$91,415	$98,368	$104,659	$112,087
Internal Rate of Return	30%	**($188,574)**	**$64,168**	**$54,092**	**$44,774**	**$36,644**	**$39,245**
Net Present Value (NPV)		**$50,349**	**NPV if inventory levels not reduced!**				
Payback (years, months)		3.70 Years		44 Months			

Table 46 Payback (40% Inventory, Float 2 days, Savings in Year 1)

Returnable Container Investment Payback Period:		(Months)	(Years)
		44	**3.70**
	Gross Savings	**Cummul. Net Savings**	
Year (Months)	**0 (0)**	($188,574)	($188,574)
Year (Months)	**1 (12)**	64,168	(124,406)
Year (Months)	**2 (24)**	54,092	(70,314)
Year (Months)	**3 (36)**	44,774	(25,540)
Year (Months)	**4 (48)**	36,644	11,104
Year (Months)	**5 (60)**	$39,245	$50,349

Figure 10 Cash Flow vs Payback (Float 4 Days)

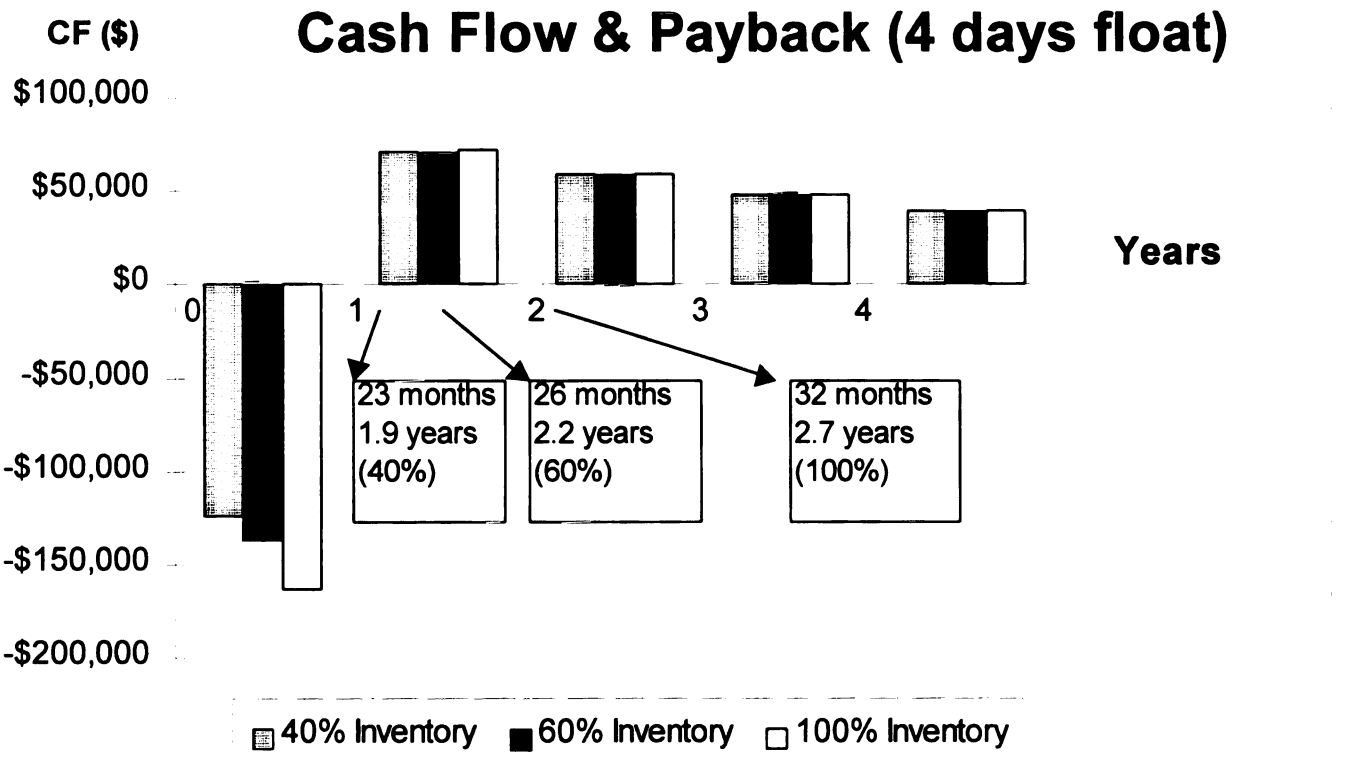


Figure 10 represents the discounted cash flows during the duration of the project for three different inventory levels and a returnable system float of four days. It is shown the initial investment during year 0 and positive cash flows during year 1 to 4. The payback is reached when the project's savings (positive cash flows) cover the initial investments. The lower the inventory level the sooner the payback period is reached.

Figure 11 Cash Flow vs Payback (Float 2 Days)

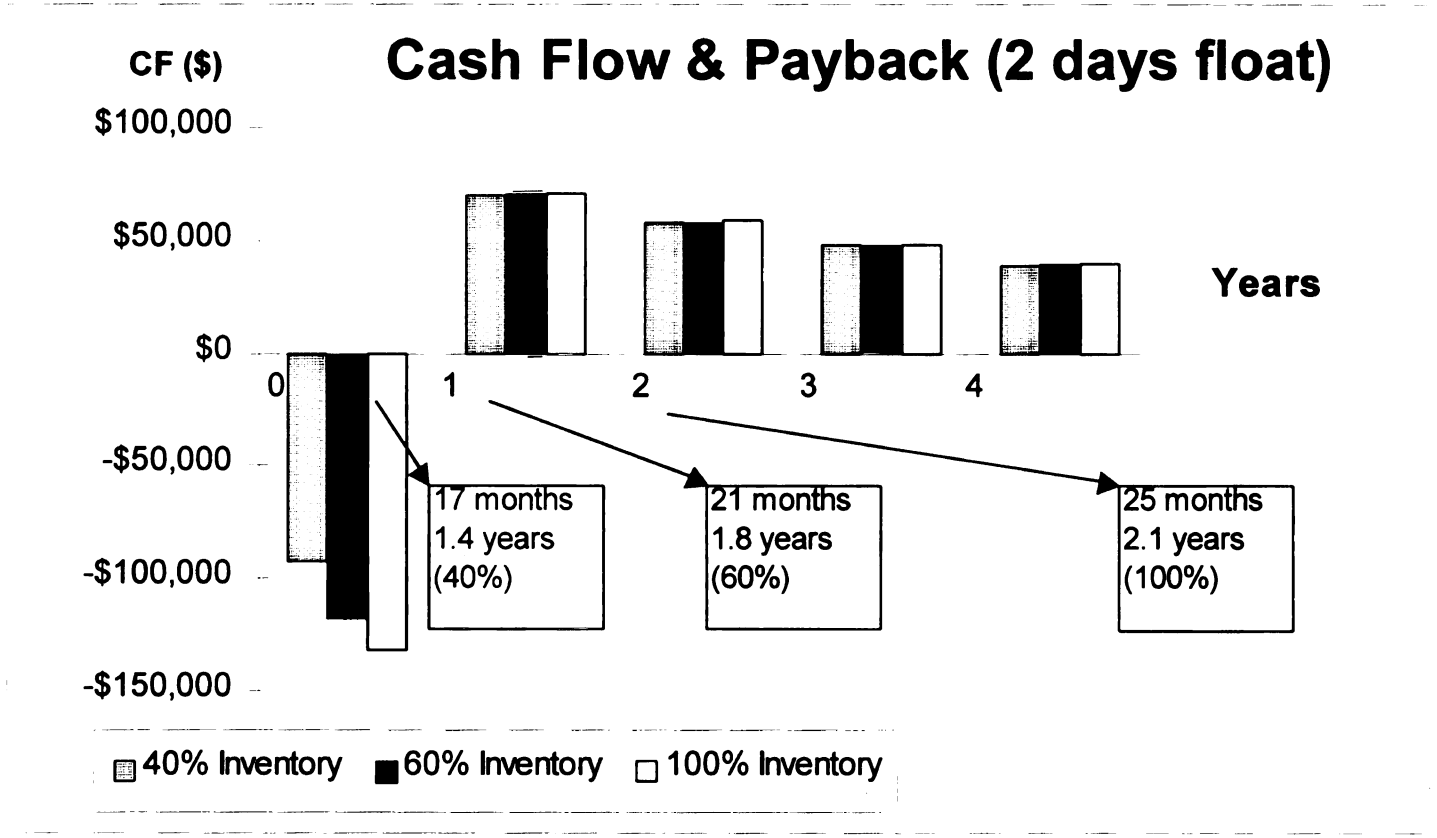


Figure 11 shows the cash flow and payback periods for different inventory levels and a returnable system float of two days. Compared to figure 10, the payback period is decreased for each inventory level due to the shorter floating time of two days instead of four.

In order to justify the financial analysis it should be assured that the data are accurate. The data used in this case study are modified by a multiplication factor. They do not represent the actual costs at Medrad.

However, the benefits, payback and NPV are greatly influenced by the inventory level at K&W and Medrad, the frequency of returnable container use (float or rotation per time), and the time the savings are counted or the investment took place.

Tables 13 through 22 show the cost analysis including the comparison of expendable vs returnable crate investment, the additional packaging cost from wrapping, labeling and cleaning. The cost analysis for the bag closures are not included yet, since data were not available at the time of publication. Activity-based costing is applied to analyze potential savings from operation and investments.

Tables 23 through 46 show the capital budgeting analysis using the NPV method and it also shows the payback based on the calculated values. In all inventory cases (100%, 60%, and 40%), the NPV is positive and will be even increased if the inventory level or the floating time is decreased. It is also important to consider the time when the savings start to return to the project and the time of investment. In this NPV model, the savings are counted in year zero and year 1. If savings return in year zero it becomes a return to the investment and decreases the amount invested and being discounted over the life time of a project. This is positive because a higher NPV will be achieved and the payback period decreases. Figure 10 and Figure 11 show the relationship of accumulated cash flows and payback. More cash flow is generated the more inventory is reduced and the lower the floating time due to lower initial container and tray investments and lower total cost of inventory. Variable costs are constant. It is also shown the relationship if savings are credited already in year zero.

The spreadsheet analysis used during this case study can be used for any further adjustments or new returnable packaging projects. All changes are easy to review since all numbers are programmed based on the annual sales forecast. All charts are linked with the NPV analysis. Even changes of annual production volume, returnable crate/tray amounts and prices, as well as cleaning equipment cost are easy to adjust, since they are the basis for this calculation.

5. Conclusions

5.1 Research Summary

The change to returnable packaging for medical device components is technically feasible with minimal technical risks. The most significant outcome of this research was to show that the new logistical package system will improve product integrity, increase quality due to less particulate from shipping, handling and materials. The thermoformed tray will also facilitate automated barrel loading which increases productivity, machine efficiency, and decreases labor by approximately $90,000 per year. There are other savings in automation and cleaning possible due to the fact of reducing manual handling and particulate in the cleanroom that need to be further investigated.

The compatibility of the package system to comply with device good manufacturing practices is assured due to the use of FDA approved materials from UFP Technologies. The technical design of the thermoformed trays can be improved by designing a tray that accommodates various device components. In this case, the shipped product volume per year can be increased as well as the usage of returnables for other product lines. By using the same amount of returnable containers, the savings would increase depending upon the current cost in expendables and disposal costs. The investments in returnables are also better utilized be expanding the use of the containers to other medical device components manufactured at Medrad.

The new package system is a corporate asset and can generate a positive NPV if the whole system is well adjusted and additional cost from cleaning and increased material handling at the suppliers' base (K&W) will be limited. The payback period varies from 32 months to 17 months depending upon which inventory level, returnable

system float, and savings return (in year zero or year one) is used. The lower the inventory level and the returnable system float, the lower will be the initial investments in returnable containers. Therefore the payback period can be reduced down to 17 months. This period is acceptable for a return on investments considering an internal rate of return of 30%.

5.2 Final Decision and Profitability

The company evaluates returnable packaging for medical device components as a "borderline" financial opportunity. The company will consider implementing this project in the future when all open questions raised during the feasibility and design stage are answered. The project complexity is high due to major process changes at K&W, the need for an automation system for automated barrel loading, and tray cleaning and package development. Engineering capacity (labor) is needed to develop these system components to make the returnable crate solution work. The estimated cost savings are currently not high enough to justify the investments in returnable container if the inventory level as well as floating time are kept at 100 percent and 4 days. Other justifications to find more savings should include the reduction of inventory in stock and inventory in process which is waiting to be assembled at the supplier and the manufacturer. Considering marketing requirements and customer orders, it is suggested to map the whole manufacturing, shipping, and order process to find possible cost savings from reduced inventory levels and shorter float times. Finally, the comparison between returnable and expendable would give a more favorable result if additional investments in cleaning, cleanroom automation, or material handling equipment at K&W were much lower. The investments are necessary due to cleanliness requirements and automation. Under the current circumstances, the least cost were associated with this

project. Further cost savings could come from further in-house developments in cleaning and barrel loading automation, as well as much lower inventory levels (60% or 40%). The current inventory level is considered to be 100%. There is no doubt that the returnable system is a beneficial investment for a long term perspective.

Compared to the automotive, furniture or grocery industry, the medical device industry is much more challenging in terms of regulatory and cleanliness requirements, validation, and quality assurance which is stronger regulated by the FDA. Therefore, as this case study has shown, more investments in cleaning equipment, wrapping, labeling, and automation are needed.

5.3 Strength and Opportunities of Returnable Packaging for Medical Devices

In the long run, returnable packaging is a good opportunity for quality improvement, productivity, and customer satisfaction. It will also contribute to the company's overall financial performance. All benefits, opportunities and risks as well as threats and weaknesses are shown in Figure 12. These are areas for improvements, i.e., the cost driver due to more tray and crate handling could be adjusted by a better material handling system at K&W and Medrad. Transportation is another issue which increases cost tremendously. The opportunity to decrease these costs by using another carrier and negotiate lower shipping costs should be investigated. There are major changes at the supplier necessary which mean barrel inspection and loading inside the cleanroom could be automated if a better visual inspection system were in place. Another issue is the inventory risk when the number of crates in inventory is reduced. A well adjusted IMS can help to reduce this risk.

5.4 Recommendations

Other packaging materials and dunnage forms should be considered that are more standardized to reduce tooling cost. In terms of the crate development, it is necessary to keep the crate clean during life time. It is necessary to investigate a dunnage or container washing system for in-house use that is packaging material and medical device compatible. It can be of benefit if inventory levels are better controlled to lower the total cost of inventory and investments. Since the project is not integrated in Medrad's manufacturing processes yet, it is recommended to monitor the returnable packaging market, new developments of cleaning solutions and better transportation opportunities such as larger truck sizes to reduce the number of trips.

Figure 12 Strengths, Opportunities, Weaknesses, and Threats of Returnable Packaging for Medical Devices

Strengths

- **Feasible? YES**
- **Product quality**
- **Material savings**
- **Stackable/collapsible**

Opportunities

- **Automation labor savings**
- **Inventory management**
- **Lower investment based on lower inventory levels**
- **Easy handling**

Weaknesses

- **Cost driver: More handling & transportation**
- **Investments**

Threats

- **Major changes at supplier**
- **Cleaning investment**
- **Inventory risk**

APPENDICES

APPENDIX A

Packaging Evaluation Criteria

Criteria / Idea	Time	Area	Customer Satisfaction	Investment	Savings	Innovation	Total
1. Boxing							
1.1. Prefilled Syringe	ST	E	5				
1.2. Container Utilization	ST	E	3				
1.3. Dispensing Feature	ST	M	5				
1.4. Printing	ST	M	4				
1.5. Tape	ST	M	3				
2. Tray							
2.1. Easy opening/Label	ST	M	4				
2.2. Recycling number	ST	M/E	2				
3. Distribution Cycle							
3.1. Standard Syringe	ST	E	3				
3.2. Prefilled Syringe	ST	E	5				
4. Automation							
4.1. Loading syringe/tray	LT	A	5				
4.2. Loading tray/box	LT	A	4				
4.3. Pre-steriliz inspection	LT	Q	5				
4.4. Pallet wrapping	LT	T	3				
5. Transportation/Supplier							
5.1. Returnable syr manuf pkg	LT	P	4				
6. Bar Coding							
6.1. Bar Coding System	LT	L	4				
7. Lid							
7.1. Sterilizable Mat. (Paper)	LT	S/E	3				
8. Seal							
8.1. Color safe seal	LT	M/E	2				
9. Sterilization							
9.1. Materials	LT	S/E	3				
9.2. Machinery	LT	S/E	3				
10. Recycling							
10.1. In-house recycle system	LT	Q	2				

1.-10. Areas for Improvements:

A = Advanced Manufacturing Engineering
E = Engineering Disposables
L = Internal Logistics
M = Marketing
P = Purchasing/Supplier Evaluation
Q = Quality / Environment (Recycling)
S = Sterilization
T = Transportation/External Logistics

ST = Short Term Projects
LT = Long Term Projects

APPENDIX B

Packaging Development Guideline

Based on the course Packaging System Development (PKG 485 1997), and the internship at Medrad (Block and Castro 1998), the following document was prepared. The guideline is a checklist to develop new packaging solutions including packaging processes and equipment from the planning stage through implementation/validation. It follows the six phases: planning, feasibility, technical design, implementation, validation, and improvement.

1. Planning

- To focus on a major packaging problem which is a reason for packaging innovation or improvement.
- To describe the packaging idea (project outline).
- To define the goals of the packaging project (time, cost, savings, benefits).
- To guide the activities and coordinate package planning responsibilities.

Procedure

1. Description of the packaging problem (focus).
2. Define the company´s packaging goal (match with other department goals).
3. Setup a project management plan with problem solving steps, schedules, and responsibilities.

2. Feasibility

The feasibility phase is proposed:

- To evaluate the packaging problem.
- To show the feasibility of the packaging project by evaluating internal and external requirements and resources.
- To specify new packaging investment (financial evaluation).
- To describe a packaging concept (packaging alternative spreadsheet) including the pretechnical evaluation (concept testing, prototyping, full screen).

Procedure

1. Define a model for the overall packaging project evaluation (matrix or decision table) and consider following aspects:
    - Customer needs: Internal (other departments), external customer (Hospitals).
    - Investigation of product requirements:
        - Product protection: Packaging material durability; distribution cycle (shock, vibration, stacking, dropping, climate hazards)
        - Utility/function purpose for external/internal customer

- Communication requirements concerning the packaging problem (damage) or external requirement (hospital/marketing need)
- Environmental and legal considerations (regulatory: federal, state, local, international)

- Financial Analysis (financial worksheet, NPV, investment/expenses/cost, labor savings; see appendix 4 and 5)
- Innovation/Starter: Investigate internal technical capabilities, suppliers' capabilities, Benchmark competitors/non-competitors/supplier; visit other benchmark companies

2. Additional Feasibility Aspects
   - Project management: Scheduling (urgent, importance for internal/external customers)
   - Consider lead time for packaging development and testing: Select outsourcing areas (testing at the School of Packaging), in-house resources (packaging dept.)
   - Internal resources: Drawings (Departments participated in testing prototypes)
   - External resources for research & development (investigate new package materials), design, production, supplier (prototypes), machinery (assembly line, forming, printing, sealing, cutting, boxing), market research (size, type, and target share of market, project market success).

A) Conceptual design/prototyping and testing (see appendix 2).
   - Investigate packaging design (tray, pouches, boxing, other types)
   - Prototyping and testing (packaging student, interns, MSU)

B) Conceptual process analysis (flow charts: packaging idea implemented in process)
   - Consider market research aspects (growing into the global market, define business tactics)
   - Technical safety factors
   - Applicable regulations, standards (ASTM, ISTA, ISO), global laws (recycling issues: European Packaging Waste Directive; Japanese packaging standards)
   - Environmental considerations (other markets, domestically)
   - Logistics considerations (shipping, production logistic, materials handling)
   - Final evaluation review: consumer evaluation, competition, conflicts with current processes

3. Conclude decisions
   - Define packaging materials specification (plastic, paper, glass, metal, wood)
   - Define type of packaging (flexible, aerosol/tube, closure, adhesive, medical device, industrial, returnable, distribution package)
   - Define the packaging process (assembly line, packing operations) and internal customer requirements concerning the current production layout
   - Close gaps between packaging and non-packaging machinery, conveyer systems (material handling), supplier, and the package
   - Define packaging machinery
   - Start purchasing equipment, tools, in-house testing equipment as needed (involve internal technical capacities): Consider lead time of supplier.
   - Define shipping requirements (distribution cycle)
   - Outsource tasks (packaging consultants, packaging students at school, interns)

3. Technical design

This phase is considered:

- To develop and design the packaging idea.
- To plan and organize the needed equipment and simulate the packaging process within the whole production layout for the applicable specifications.
- To close gaps between packaging and syringe assembly line (facilitate automation).

Procedure

Define and review packaging design, process, equipment.

- Packaging materials composition.
- Write design verification for QC, testing, prototyping, sterilization.
- Evaluation of the facilities of external resources (universities, consultants).
- Involve other related packaging alternatives (Decision table).
- Rewriting of manufacturing specifications/documentation including flowcharts, drawings, facility changes.
- Review technical design and set further target lines, identify upcoming tasks.

4. Implementation

The implementation phase is following the steps:

- To setup the packaging solution and validate in-process with the current manufacturing line requirements.
- To communicate the product's / package's competitive advantage to internal and external customers.
- To review packaging and other specifications.
- To redesign the package idea.

Procedure

- Establish shipping procedure including contract carrier, logistical channels, distribution modes.
- Define packing and shipping requirements (palletization, stacking, contract carriers, handling)
- Market testing and launch, promotion, advertising (external customer survey)
- Write Medrad´s/supplier packaging specifications and requirements (purchasing agreements)
- Define and perform a protocol, review test results
- Suggest redesign and rewrite specs (also for packaging vendors)
- Implement the solution (updated with drawings, new software written, innovative machinery/equipment).

5. Validation

- Feedback with regulatory testing.
- Review facility changes, safety aspects, and GMPs.
- Integrate maintenance activities.
- Plan for TPM/QC/QA: process control and monitoring the packaging materials, machinery and facility including the sterilization process).

6. Improvement

- Define continuous packaging improvement plan, set new quality targets, starter for new projects. Feedback from other departments.

APPENDIX C

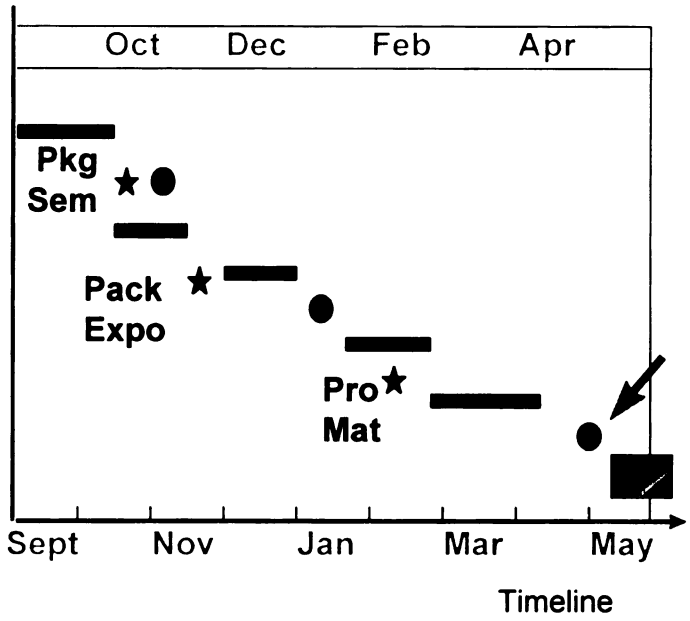
Project Plan

This project plan shows all packing development activities and dead lines for completion of tasks.

	Deliverables	**Time Line**
1	**Basic research/process concept generation** • Flowchart • Returnable Packaging Seminar, MSU • Visit the suppliers' facilities, PA • Benchmarking analysis (crate design, cleaning equipment) • PackExpo, Chicago, IL • Teltech/PIRA/Internet research • Vendor bids/financial evaluation (payback/NPV calculation) • Cost analysis • Outlining various options	6-8 weeks (10/31/98) 9/29-30/98 10/8/98 11/8-11/98
2	**Detailed prototyping/design** • Drawings (AutoCAD, ProEngineer) • **First report to Medrad:** Discuss options • ProMat, Material Handling Show, Chicago, IL • Evaluation/selection of concept	2-3 weeks (12/31/98) **1 day (1/8/99)** 2/8-11/99 3-5 weeks (02/15/98)
3	Prototype fabrication (extern) • Writing packaging specifications for all crate components • Arrangement of prototype schedule with all suppliers • Tooling, prototype sample	7 weeks (3/21/99)
4	Package/product testing/evaluation • Time studies • Meeting to discuss material handling concept • Report test results • Testing: Shock, vibration, compression.	3 weeks (4/15/99) **1 day (3/30/99)**
5	Package/process specifications • Crate cleaning: system/process evaluation • Inventory control/management recommendations • Rewriting specifications (Palletization, Inspection, etc) • Transportation/logistical cost evaluation/recommendations	5-6 weeks (5/31/99) **Final Meeting/Report** **Thesis Defense**

Project Schedule

1. **Basic Research**
2. **Concept**
3. **Detailed Design**
4. **Financial Analysis**
5. **Report Medrad**
6. **Package Specification**
7. **Supplier Scheduling**
8. **Prototype Fabrication**
9. **Walk-Through Demo**
10. **Thesis** MSU **Final Report**



APPENDIX D

Supplier Performance Assessment - ROPAK

MSU Research

Returnable Packaging Development for Medrad, Inc.
Investigator: Christine S. Block

THE SCHOOL OF PACKAGING
MICHIGAN STATE UNIVERSITY

MEDRAD

Date: 11/10/98

Vendor No: 001
Vendor Name: ROPAK
ADDRESS:
Contact Person: Filipe Amorim
Phone#: (_____) **Fax #(**_____)
Critical Supplier ☑ **ISO Certified** **Medical Device Experience** **Audit**
Product(s):

Supplier Performance Evaluation:

Packaging Performance	Score ROPAK	0 = N/A, 1 = Poor, 2 = Good, 3 = Good, 4, 5 = Excellent
Puncture resistant	5	5
Compressive load resistant	5	5
Cleanliness/no particulate	3	3
Containment of trays	3	3
Easy to move	2	2
Easy to open	3	3
Easy to load trays	4	4
Easy to label/to print	3	3
Low investment	2	2
Absolute Survey Score	30	
Relative Survey Score	67%	

General Evaluation	Acceptable	Not Acceptable	N/A
Service & Support	x		
Quality System in Place	x		
Network/Associations	x		
Sampling	x		
Design/Prototyping			x
Meet Specifications	x		
Manufacturing Capability	x		
Meet Delivery Date	x		
Financial Strength	x		

Comments:

Supplier Performance Assessment - TriEnda

MSU Research

Returnable Packaging Development for Medrad, Inc.
Investigator: Christine S. Block

Date: 11/11/98

MEDRAD

Vendor No: 002
Vendor Name: TriEnda
ADDRESS: _____
Contact Person: Rick
Phone#: (_____) _____ **Fax #**(_____) _____
Critical Supplier ☑ **ISO Certified** ☑ **Medical Device Experience** ☑ **Audit** ☑
Product(s): _____

Supplier Performance Evaluation:

Packaging Performance	Score TriEnda	0 = N/A, 1 = Poor, 2 = Good, 3 = Excellent, 4, 5
Puncture resistant	4	x
Compressive load resistant	5	x
Cleanliness/no particulate	3	x
Containment of trays	5	x
Easy to move	5	x
Easy to open	5	x
Easy to load trays	4	x
Easy to label/to print	5	x
Low investment	5	x
Absolute Survey Score	41	
Relative Survey Score	91%	

General Evaluation	Acceptable	Not Acceptable	N/A
Service & Support	x		
Quality System in Place	x		
Network/Associations	x		
Sampling	x		
Design/Prototyping	x		
Meet Specifications	x		
Manufacturing Capability	x		
Meet Delivery Date	x		
Financial Strength	x		

Comments: _____

Supplier Performance Assessment - Buckhorn

MSU Research

Returnable Packaging Development for Medrad, Inc.
Investigator: Christine S. Block

THE SCHOOL OF PACKAGING
MICHIGAN STATE UNIVERSITY

MEDRAD

Date: 11/12/98

Vendor No: 003
Vendor Name: Buckhorn
ADDRESS:
Contact Person:
Phone#: (_____) **Fax #**(_____)
Critical Supplier ☑ **ISO Certified** **Medical Device Experience** **Audit**
Product(s):

Supplier Performance Evaluation:

Packaging Performance	Score Buckhorn	0 = N/A, 1 = Poor, 2, 3 = Good, 4, 5 = Excellent
Puncture resistant	4	x
Compressive load resistant	5	x
Cleanliness/no particulate	3	x
Containment of trays	3	x
Easy to move	2	x
Easy to open	2	x
Easy to load trays	4	x
Easy to label/to print	3	x
Low investment	2	x
Absolute Survey Score	28	
Relative Survey Score	62%	

General Evaluation	Acceptable	Not Acceptable	N/A
Service & Support	x		
Quality System in Place	x		
Network/Associations	x		
Sampling	x		
Design/Prototyping			x
Meet Specifications	x		
Manufacturing Capability	x		
Meet Delivery Date	x		
Financial Strength	x		

Comments:

APPENDIX E

Packaging Specification

Package Specification, Part A: Returnable Tray Design (UFP Technologies)

Purpose:

- To provide the tentative design requirements for prototyping of the returnable tray for the 200mL FLS barrel (and 125mL). Barrel capacity 14 barrels per tray.
- Prototyped trays are used to perform time studies within the returnable cycle Medrad/K&W and to adjust the final tray design.
- To be provided to UFP to deliver tray design (drawings, tooling, prototypes, final tray design).

Design:

- Based on the inside dimensions of the returnable crate (package specification part B: TriEnda pallet and plastic sleeve with Ever-Lok2 system), the tray dimensions are determined as follows: L x W x D = 19" x 15" x 2.683".
- Barrel orientation:
- No clearance is considered to be between the stacks when placed in the pallet.
- Material: High Impact Polystyrene (HIPS), 35% rubber modified virgin, white, FDA approved for use in medical packaging. 50 mil thickness.
- If tray does not need to be FDA approved, recycled material can be used instead of virgin resin if the required performance properties mentioned in this spec such as toughness, lifespan, cleanliness, no migration of resin into product over time are the same. Advantage of recycled resin: Less expensive. Disadvantage: Tray color would have a pink huge, does not look as clean as white looks. Product properties can become more brittle over time and influences lifespan of trays. Medrad needs to decide! It is recommended to use virgin material with no recycled content.
- Final weight of tray: 0.55575 lbs. (needed to determine gauge and compression load requirements of TriEnda pallet (Part B).
- Weight calculation: Length x Width x Gauge of material x "K" Factor[1] = Weight of one tray, in this case the calculation is: 19"x 15" x 0.05" x 0.039" = 0.55575 lbs. per tray.
- The tray is formed to hold the contents securely during shipment and storage without product contact. The tray is neither covered by a lid nor considered a hinged package.
- The tray will be bagged to protect against environmental influences during shipment and storage.
- The tray will neither have undercuts nor sharp edges or corners (It will have round edges/corners that will not puncture plastic bags).
- The tray is used to be part of the assembly process; barrels will be loaded automatically. It will need to fit on Medrad's future assembly line, and must fit on K&W's conveyer system.
- The trays will not be sterilized only cleaned with alcohol wipe down.

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[1] The "K" factor for High Impact Polystyrene is 0.039. Each polymer resin has a different "K" factor based on the specific gravity.

- The tray must pass regulatory requirements for testing and cytotoxicity. It must be resistant to alcohol cleaning solutions (wiping solution used for tray cleaning).
- Stacking characteristics. When tray is filled it should not be supported by product (syringe). It should stack.
- Nesting: When trays are empty trays should nest inside each other and be easily separable by incorporated denesting lugs to facilitate handling and loading.
- Nesting/stacking: Reversable image.
- Return flange: The tray on top of another tray should be considered as a cover for the tray underneath. It is not a separate lid but it functions as a lid. The tray design should incorporate this cover function.
- Stack height: Max 12 trays per stack/crate based on crate size (customized sleeve height up to 38" possible), 4 trays individual bagged to fit K&W conveyor size.
- Universal tray to accommodate (2) product configurations (200ml, 125ml barrels). Desired but not required if tray design is not feasible within dimensions and barrel numbers as specified.[2]
- Desired contact surface between syringe and tray will be shown in sample.
- Tray interior is based on product configurations specified in drawings to be provided to UFP.

Materials provided by Medrad

- Product samples and drawings for two product configurations (200ml, 125ml barrels) will be send by Medrad, EA Gelblum to UFP. Shipping address of UFP is needed.
- The existing final package will be sent to UFP to show the desired contact surface between the syringe and the package.

Thermoformer Requirements:

- Knowledgeable company with competent staff and designer (UFP Technologies).
- Experience in medical packaging.
- Proper facilities to manufacture/thermoform the trays.
- Design assistance by the technical staff to meet the specified design and budget requirements.
- Material inventory provided by thermoformer to meet requested lead times.
- Full service capabilities have to be provided for prototyping, tooling, and production processes. The thermoformer advises Medrad in all design and prototyping stages.
- Quality assurance: Excellent quality standards approved by inspection, SPC, and QA procedures that meet GMP guidelines covering the whole manufacturing process must be guaranteed.
- Overall production cost should be kept to a minimum to increase perceived value.
- Drop, vibration, and compression testing should be provide by thermoformer based on ASTM 4169.

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[2] Note: This will be difficult to design without compromising loading efficiency.

Package Specification, Part B: Returnable Crate Design (TriEnda)[3]

Purpose:

- The inside dimensions (ID) of the returnable crate are the required dimensions to determine the tray outside dimensions (OD).
- To provide dimensional fit to accommodate the returnable trays for maximum loading capacity.
- Barrel capacity per crate: 6 trays/layer x 12 layers x 14 barrels/tray = 1008 barrels per crate. Number can be optimized if truck size would be increased, or last pallet removed and cover used instead (would increase truck capacity by 168 barrels/crate.
- Design is tentative and to be adjusted during time studies.

Design:

- The crate consists of (3) components: (2) Pallet (top, bottom), (1) sleeve with Ever-Lok2 system integrated in sleeve and pallet for safe fit and secured distribution.
- A top, twin sheet layer as cover can be supplied instead of a top pallet only for the top crate. That saves about 3" height used for a higher sleeve and more barrel loading capacity per truck. The cover will be quoted by TriEnda. Final decision if cover needed is done by Medrad. The cover is not necessarily needed. The cover will also be supplied with the sample crate.
- Price/quotation - will be new quoted by TriEnda. Sample crates: No cost! Crates based on 1400 pallets, 700 sleeves: $24.13/pallet, $30/sleeve = $78.26/crate (tentative, new quote will follow). Total crate cost < $80.
- The sample crate will have standard dimensions: 40" x 48" x 36" sleeve height.
- Light weight single sheet thermoformed plastic pallet construction guarantees durability and lifespan (estimated trips/lifespan: 400 trips/lifespan depends on how the crates are handled during distribution and warehousing at Medrad, K&W and by the trucking company. It is recommended to educate people how to use these crates to assure proper handling and to reduce damage. Lifespan is considered for NPV/financial analysis.
- TriEnda will provide benchmarks of other medical device companies, addresses will be provided by TriEnda.
- Universal crate design with standard US pallet configurations (40" x 48").
- The weight of pallet is 19 lbs. Weight of sleeve to be determined when compression load is known. To be determined by TriEnda.
- Based on truck height (height is not determined yet, must be provided by K&W, Medrad), the crate dimensions are determined as follows: L x W x D = 40" x 48" x D" (sleeve height as specified by TriEnda depends on truck height).
- Sleeve ID: 38.25" x 45.875" x sleeve height (check ID after truck height is known).
- Sleeve height: Up to 38" ID, total 41" (sleeve stack in pallet 3" deep in total).
- Materials: High Density Polyethylene (HDPE) for the pallet, for the sleeve: PP.
- All components are weather resistant, resists UV light.
- Materials can be FDA approved but is not a requirement.
- Pallet: black as standard color. Four-way entry for quicker more efficient handling.
- Interlocking pallet legs for secure stacking. Create safer and stable stacks.

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[3] A second, more severe crate solution has been suggested during the feasibility study. The package specification has to be revised if Medrad decides to use ROPAK container as presented during meeting 1/8.

- Light weight system to reduce shipping cost, labor, and manual material handling. Advantage against heavy bulk container from Ropak.
- Pallet thickness/gauge: 0.250 in. The gauge of the pallet depends on the compressive load on top of the bottom pallet (load/weight of trays, product, bags, pallets, and sleeves). Based on a stack height of two crates high, the following weights are expected on top of the bottom pallet. The total weight on top of the bottom pallet is about 464 lb. The gauge of 0.250 in is sufficient to carry the load without product or packaging damage.

Parts	Number	Weight	Total Weight (lb.)
Barrels	1008/crate	0.1564	315.28
Trays	72/crate	0.55575	80.03
Bags	18/crate	0.025	3
Pallets	2/crate	19	57
Sleeves	1/crate	4 lb.	8
			463.31

- Reinforced fork entry resists damage and helps to guide fork tines into proper position.
- Top an bottom pallet are interchangeable - less inventory.
- Sleeve: Corrugated plastic (single wall, 10mm and 8mm are offered) - to be specified when product/tray weight is known.
- The corrugated flutes should be sealed to prevent contamination.
- Sleeve color and printing can be customized for Medrad CI.
- The sleeve or pallet must contain a proper place for labeling (label pocket to insert labels, flexible/interchangeable solution). Labels must be a clean solution, easy to place and remove, no residuals when removed, and should not involve additional labor or equipment.
- The crate does not need to pass regulatory requirements for testing and cytotoxicity since it is not in direct contact with product. It must be resistant to any type of cleaning method to be specified by Medrad.
- Stacking characteristics. When the crate is filled with trays the crates should stack. The stack should not be supported by product (syringe).
- Pallets are fully nestable to save space on return shipping and while stored.
- Pallets are partly used to ship empty trays back to K&W.
- The pallet have a mirror image design.
- Collapsible characteristics: The sleeves should Z-fold to minimize return ratio and storage space requirements.
- Stack height of crates/pallet in truck: (2) crates high to utilize truck height of 96".
- Max stack height in warehouse depends on gauge size, Medrad's requirements to utilize warehouse space and TriEnda's recommendations. 2 crates per stack to be shipped from K&W to Medrad based on container height and storage space at K&W.
- Performance: Floor 3,500 lbs., Fork 400 lbs. Sleeve 1,500 lbs.
- Barrel capacity per crate: To be determined.
- Pallets per truck (truck dimensions: 90" x 48' x 96" (height)). Check dimensions.
- Pallet and sleeve design to be provided by TriEnda.
- Performance/lifespan data will be provided from TriEnda and other returnable crate user within medical device/cleanroom related industries.

Materials provided by Medrad

- Sample crates will be delivered within two weeks.
- Sample crates are provided by TriEnda free of charge, and consist of 2 crates (4 pallets, 2 sleeves with Ever-Lok2 system, twin-sheet cover, diverse opening designs—no opening, two drop doors).

Information provided by TriEnda

- Based on compressive load, TriEnda will calculate starting gauge.
- Performance testing information will be provided by TriEnda.
- List of customers within the pharmaceutical and medical device industry, or similar industry applications to be used within cleanrooms (e.g. computer and appliances industry).
- Cost quotation for final order.
- Lifespan and number of trips to be checked.
- Return ratio of pallets, sleeves, and trays.

Material Handling

- The crate can be carried by one person.
- Lifespan: Up to 6-8 years if treated properly.
- Predicted number of trips: 400.
- Custom printing on sleeves: possible, $ will be quoted. It depends on design wishes. Provide printing for bar code or Medrad ID (if needed).
- Covers needed for top cover. Crate quote should include covers.
- Test data for compression, puncture resistance, drop, vibration and shock, as well as ease of cleaning etc. to be provided by TriEnda.
- How will the pallet and sleeve be cleaned? Some cleaning solutions will be suggested by TriEnda.
- What is the return ratio on all components.
- Fork lift truck height to lift one stack of (2) crates? To be specified by K&W or TriEnda. Must be approved during time studies at Medrad/K&W.

Package Specification, Part C: Disposable Plastic Bag (Crystal X)[4]

Purpose:

- The new bag will provide containment and protection for the tray (Part A).
- Current bag spec: L x W x D = 23" x 17" x 48". 2mil. Polyethylene.
- The current bag is used to bulk package the barrels in the currently used corrugated shipper.
- K&W wants to get the new bags supplied by its current supplier since K&W receives the best quality and particulate free bags from Crystal X. Contact at Crystal X: Joe Burman, (800) 255-1160. Price/bag: $0.26. K&W uses Medrad's specification to determine the bag needed.

[4] It is suggested to use the previous K&W bag supplier, Crystal X.

Design:

- The bag specifications depend on stack height of (4) trays per bag.
- The returnable tray is double bagged for shipment from K&W to Medrad, and back.
- The plastic bag is designed to accommodate the returnable trays and to protect the trays from dust and particulate.
- Before the empty tray is leaving the cleanroom, the tray will be put back in its clean bag.
- Approx. dimensions: L x W = 48" x 51" = ((19"+2*12") + 10%) x (((15"+2*12") + 10%) + 8" to fold over the inner bag, and twist twice the outer bag).
- Bag dimensions should be approved for dimensional fit by the bag supplier and Medrad when time studies are performed. Bags need to be ordered by Medrad prior on tray arrival!
- Bag closing: Folding over the inner bag and twist twice the outer bag is recommended to close[5] the bags tightly and prevent trays from contamination.
- Folding should not prevent nesting of the (4) tray stack on another stack. Thickness: 2 mil.
- Design: A stock item provided in regard to the tray stack size should be ordered. In general, Medrad should purchase a stock item, since a specific designed bag cost much more, or, Medrad has to consider trade-offs, such as higher cost but material savings and better product protection. It is recommended to use a standard bag size and material specified as a stock bag offered by a supplier.
- Material: LLDPE or LDPE. (LLDPE recommended because tougher and better clarity).
- Material should be FDA approved for medical device use.

Materials provided by K&W and Medrad:

- Sample bag. Bag specification.

Package Specification, Part D: Crate and Bag Labeling (Label Supplier, not selected yet)[6]

Purpose:

- The bags and crates have to be labeled to meet traceability requirements of Medrad and K&W.

Design:

- The labels will be placed on each crate and each stack of (4) trays on the outer bag.
- Labeling should not involve additional labor.
- Labels must be compatible to the crate and bag material.
- Pressure sensitive adhesive is used to provide permanent adherence of labels to bags.
- The labels placed on crates should provide a good adherence, ease/clean label removal.
- Requirements: The label must include the following information—part name, tool number/molding machine, date, container number (sequential), control# and operator name.

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[5] A zip lock could be another (better) bag closing device. It will associate higher cost.

[6] It is suggested to use the previous K&W bag supplier, Crystal X.

- Current label set up: L x W = 6" x 4", place manually by hand on the outside of the box in an area visible when the boxes are palletized.
- The current label used by K&W includes additional information requested by Medrad. These issues must be addressed in future labeling application.
- The following issues are recommended: For the bag labeling, it is suggested to use a permanent adhesive label that is tamper evident. It should not be easy to remove that tamper evidence is seen if manipulations are done. Tracebility will be maintained.
- For the crates, a non-permanent adhesive label is suggested that is easy to remove, it is a clean solution and no further investments for label holder are needed. For both applications-tray stacks packaged in bags (stack of four trays) and the crate, you may need two different labeling machines. The letter can be manually done ($1,200), the former should be in-line labeling ($8,000).
- K&W has different molding machines. Each label needs to show the molding machine or tool number. There are several machines that mold the barrels at a time, and each label must include the machine number, operator name, etc.
- Labels need to be applied on each stack of trays for all molding machines.

Materials provided by K&W and Medrad:
- Label specification. Name of supplier, contact address and phone number.
- Sample label (done).
- Medrad's and K&W's labeling requirements and description of current labeling process (as specified in memo CB-1-98; done, see enclosure).
- A material handling layout including the material handling of barrels and labeling is needed.
- A material handling study should be performed by K&W/Medrad, how labeling can be integrated and controlled in-line at K&W.

Additionals

Testing:
- The returnable container system will be tested at the School of Packaging. A test plan will be provided.
- The Guide for the Testing of Returnable or Reusable Transport Containers is used to outline the test plan. This guide is not an ASTM standard. It is under consideration within an ASTM Technical Committee but has not received the approvals required to make it an ASTM standard. It is not considered to be published without ASTM approval.

Cleaning:

The cleaning system will be designed and evaluated by Medrad.

Figure 13 Returnable Crate with Drop Door from TriEnda

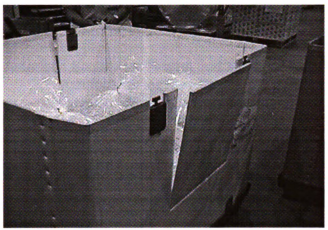

Figure 14 Returnable Tray with Syringes designed by UFP Technologies

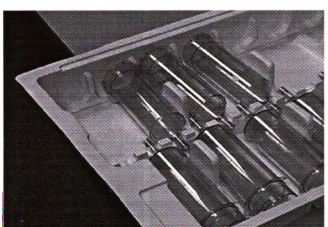

Figure 15 Returnable Trays packaged in Bags and Stacked in Returnable Crate

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