Developing a packaging solution for GI endoscopes

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MASTER THESIS

Ambu

Developing a packaging solution for GI endoscopes

An exploration of how waste management will come to define future challenges of SUD packaging

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Abstract

Nurses are in need of effective sterile packaging for transporting, storing, handling, preparing and disposing of single use medical devices. At the same time, requirements surrounding sustainability are mounting both from a regulatory and user perspective. Producers need to develop more sustainable options for hospitals with a great variation in waste management practices while not impeding on the nurses' procedures. This thesis evaluated the usability of sterile barrier systems and found one that supported the way in which nurses wanted to work. This was then turned into a completely mechanically recyclable packaging concept by examining existing market solutions. Another inquiry was made into how signifiers could potentially make packaging that are known to be hard to recycle less prone to user error during waste sorting. However, it did not seem to help although more research should be done on the topic. Branding touchpoints were added to aid the adoption of Ambu's take-back program, this seems to be an acceptable addition and should be considered.

Keywords: Packaging Design, Sustainable Design, Single Use Devices, Medical Waste Management, Desing for Recyclability

Sammanfattning

Sjuksköterskor är i stort behov av sterila förpackningslösningar för att transportera, förvara, hantera, förbereda och göra sig av med medicinska engångsprodukter. Samtidigt blir kraven om hållbarhet allt strängare både från regulationer och användare. Producenter behöver ta fram hållbara alternativ för sjukhus vars avfallshantering kan se väldigt olika ut i praktiken utan att påverka sjuksköterskors arbetssätt. Detta examensarbete har utvärderat sterila barriärsystem och har funnit ett som stöttade sjuksköterskor i det sätt som de vill jobba på. Detta var sedan utvecklat till ett förpackningskoncept genom att utforska kommersiella lösningar. En undersökning som utfördes var ifall symboler potentiellt kan göra det lättare att återvinna förpackning som tidigare varit känd för att vara svår genom att minimera användarefel vid sortering. Det verkar dock som att det inte hjälper, men att mer forskning borde utföras. Varumärkesupplevelser tillades för att öka värvandet till Ambus take-back-program vilket verkar vara acceptabelt enligt användare och borde övervägas.

Nyckelord: Förpackningsdesign, Hållbar Design, Engångsaparater, Medicinsk Avfallshantering, Design för Återvinning

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Lund, May 2026

Erik Henriksson and Gustav Liljegren

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Glossary

	Definition	*Source*
Aseptic presentation	Transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination	ISO 11139:2018, 3.13
Life Cycle Assessment	Compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system	ISO 14040:2006, 3.4
Sterile	Free from viable microorganisms	ISO 11139:2018, 3.271
Sterile barrier system	Minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use	ISO 11139:2018, 3.272
Terminal sterilization	Process whereby a product is sterilized within its sterile barrier system	ISO 11139:2018, 3.295

List of acronyms and abbreviations

CEPI	confederation of European paper industries
CFR	code of federal regulations
CMR	carcinogenic, mutagenic, reprotoxic
DfE	design for environment
DfM	design for manufacturing
EoL	end-of-life
EU	European union
FDA	food and drug administration
GI	gastrointestinal
ICU	intensive care unit
IFU	instructions for use
ISO	International Organization for Standardization
LCA	life cycle assessment
MDR	medical device regulation
OR	operating room
PCR	postconsumer recycling
PET	polyethylene terephthalate
PMA	premarket approval
RQ	research question
SBS	sterile barrier system
SDG	sustainable development goals
SUD	single-use device
UN	United Nations

1 Introduction

This chapter will introduce the area of gastrointestinal endoscopy, the design of single-use medical devices in general, and medical waste management. It will also formulate the purpose of this thesis and its relevance in the field of sustainable packaging design.

1.1 Background

A gastrointestinal (GI) endoscope is a medical device that uses a long flexible tube with a camera on the end to view the digestive tract to identify conditions such as tumors, ulcers and bleeding. GI endoscopes are primarily used in clinical settings like operating rooms and dedicated endoscopy suits. The digital endoscopy has not changed in its core function since its inception in 1984. The digital signal is sent to a video processing unit that then displays the image on a screen (Ginsberg, Kochman, Norton, & Gostout, 2012).

1.1.1 Medical device regulation and Code of Federal Regulations

Medical device regulation (MDR 2017/745) is a regulatory document that governs the certification and monitoring of medical products inside of the European Union (EU). It ensures that appropriate risk management efforts have been made, safe transport and storage, the product having been labeled correctly, instructions for use (IFU) or electronic instructions for use (eIFU) are included, among other criteria (European Union, 2017). The equivalent regulations in the United States lay under subchapter H of Chapter I of Title 21 of the Code of Federal Regulations (CFR) mandated by the Food and Drug administration (FDA). It is based on a risk assessment system where Class I devices considered low risk and therefore do not require Premarket Notification 510(k), Class II are considered moderate risk and require a 510(k), and Class III are assessed as high risk and requires rigorous Premarket Approval (PMA). Under 21 CFR 876.1500, it classifies endoscopes as a Class II device. After a 510(k) the device is subject to audit against Part 820 – Quality System Regulation (Food and Drug Administration, 2025).

1.1.2 Single-use devices

Single-use devices (SUDs) are medical devices that are meant to be used on one patient to then be discarded and have been heavily favored in surgical departments for their convenience, sterility, and quality assurance compared to their multi-use counterparts. These SUDs contribute to a major amount of plastic waste coming from operating theaters. Up to 50% of total plastic waste from operating rooms (ORs) originates from plastic packaging, and an average of 30 composite packages are used per operation (Ramos, Christensen, Oturai, & Syberg, 2023).

1.1.3 Medical waste management

A study done in Italy found that 14% of all waste in hospitals comes from surgeries, third most overall. Another study in Taiwan found that as much as 17% comes from the intensive care unit (ICU). There are major inefficiencies in medical waste management all around the world. One of the identified causes is the lack of guidance for clinicians as to what objects should be categorized as hazardous waste which leads to the unnecessary classification of waste as infectious. Around 70 to 80 percent of waste that leaves the hospital as infectious waste is non-infectious and got mixed in erroneously. These waste streams often require incineration. Due to the need for decontamination and specialized handling, these treatments incur a 560% cost premium (Windfeld & Brooks, 2015). This is not only a question about cost. A life cycle assessment (LCA) was performed comparing if 1 kg of plastic were to be either incinerated as hazardous waste, put in a landfill as general waste, or recycled. The study found a reduction of 20.3% in global warming impact when switching from a hazardous waste stream to landfill and 88.2% when the plastic was recycled (Yoora, et al., 2024). It should be noted that the LCA was performed in South Korea.

The current practice of waste management can be divided into three phases: collection, transport, treatment & disposal. In the hospitals, waste is typically sorted into colored bins dependent on the waste streams. This system is not standardized and varies between hospitals. The waste is then transported to treatment sites, either external or internal to the hospital. The last step is commonly done by a third party. There is a clear need for standardization and implementation of practices like waste sorting at the “point-of-disposal” within healthcare facilities. (Windfeld & Brooks, 2015). Waste management regulations in the EU have become increasingly stringent as producers are now financially responsible for waste prevention and treatment operations under the Extended Producer Responsibility (EPR) framework (Jackman, o.a., 2025).

1.2 Purpose

Ambu is a multinational MedTech company that was founded in 1937. In 2009 they launched the world's first single-use flexible bronchoscope (Ambu A/S, 2026). Ambu's stated ambition is to achieve global endoscopy leadership. They have penetrated the market in respiratory and urology endoscopy but have less than one percent of the market share in GI which they aim to expand. Ambu states that 91% of their emissions are considered Scope 3, meaning they come upstream from raw material extraction, material formulation and material transportation, but also downstream from distribution, use of products sold, and waste management (Fauldi, 2025, p. 127). Ambu is addressing waste management by being the first to implement a take-back system for their endoscopy product lines called the Recircle program (Ambu A/S, 2025). Ambu has achieved an incineration rate for hazardous waste of less than 5.6% and an overall recycling rate of 46%. However there has been little focus on the user experience of the Recircle program or waste management overall. This project is motivated by the possible sustainability improvements that can be made to GI endoscope packaging, affordances that alleviate the cognitive burden connected to medical waste management, and branding touchpoints that promote take-back systems for medical device packaging. Other factors are also at play, the overall ease of use which could result in reduced handling-time and fewer mistakes by doctors using the endoscope, and a lower cost will make Ambu's solution more competitive on the market.

Ambu's current primary packaging solution can be viewed in the picture below. It consists of a pouch, mounting card, and two trays. The pouch is made of two materials that are sealed together, one permeable and the other not. The mounting card keeps the product from deforming before use and the two trays encapsulate the handle, connector and insertion tube, protecting them from mechanical shock.

Figure 1.1 Nurse opening the Ambu GI endoscope (Ambu, 2023)

1.3 Problem description and research questions

Ambu's current packaging solution makes up a large part of the Scope 3 emissions tied to the endoscope and at a steep manufacturing cost. It also doesn't support the workflow of nurses in terms of logistics and waste separation.

This will be an empirical study on the redesign of sustainable, accessible, and cost-effective single use packaging for GI gastroscopes. We have identified a research gap in the field of Medical Waste Management. Packaging from SUDs and other medical consumables is contributing to strained waste management in ICUs and Operating Theaters. The underlying contributing factors have been identified, but the human factors surrounding the packaging have yet to be understood. We need to know how different packaging solutions impact the environment so that we can make informed design decisions in terms of ease of recyclability. The following research questions (RQs) will be answered.

RQ1: How can medical device packaging be designed for recyclability and sustainability, while maintaining sterility, resulting in decreased waste and carbon dioxide equivalent?

RQ2: How can packaging affordances and signifiers increase sorting accuracy in high-stress clinical environments, e.g. the OR resulting in increased recycling?

RQ3: How can packaging design support take-back systems in hospital settings making it easier to separate waste streams?

The research questions will be the academic basis for the thesis project and be used to inform the redesign of the current packaging solution. However, Design for Manufacturing and more general usability and UX will also be important aspects during the development of the new packaging.

1.4 Related works

There is an increasing interest in the development of more sustainable packaging both in medical devices and pharmaceuticals. The article called *Global Innovations in Sustainable Pharmaceutical Packaging in the Last 25 Years: A Scoping Review* summarizes the developments done in the last quarter-century (Jackman, et al., 2025). Although the criteria for packaging intended for medical devices and pharmaceuticals differ, both packaging solutions rely heavily on plastic blisters and are terminally sterilized. Therefore, the developments done in either field have relevance for the other. The article identifies four categories when it comes to sustainable innovation. Developments in Material Innovations have extensively looked at plastics and alternatives such as plant-based, protein-based, and synthetic biodegradable polymers. Design Innovations tackle standardization of the eco-

design process, material and manufacturing efficiency, user-centered sustainability, and packaging reduction. Smart Technology Innovations have looked at technology such as QR codes, 3D printing, and Computer-Based Design tools. Waste Management Innovations have looked at processes such as Electrohydraulic Fragmentation, Green Solvents, Hydrometallurgical methods, and Thermal Degradation.

The article also mentions the new Packaging and Packaging Waste Regulation 2025/40 (PPWR), a European legislation that states that all packaging must be recyclable and that plastic packaging must contain certain required amounts of recycled content. Primary packaging for medical devices is however exempt until 2035. This puts less strain on medical device manufacturers now but the authors stress that the developments done in the coming decade are just as important.

As previously detailed, medical waste management is a huge problem in large part to the amount of waste that is produced in the OR and ICU. The report *Reducing plastic in the operating theatre: Towards a more circular economy for medical products and packaging* (Ramos, Christensen, Oturai, & Syberg, 2023) takes a critical look at waste management in Denmark and makes a couple of recommendations regarding the development of more sustainable medical products. Their first suggestion is for the design and procurement of more sustainable medical products by ending the use of composite materials that cannot be mechanically recycled, using alternative materials to plastic or at least making onsite sorting possible, and keeping the products in the value chain as long as possible. Their second suggestion is to help healthcare workers separate and sort plastics. Thirdly, any plastic that does not get in contact with the patient should get recycled. Lastly, there should be consideration regarding switching from SUDs to multi-use devices, although that is outside of our scope.

The priorities surrounding patient safety should not be lost for the sake of sustainability. In the report *Evaluating Aseptic Presentation of Different Medical Device Packaging Configurations* (Qin, Li, Yin, & Fang, 2023) five groups of packaging solutions were evaluated in terms of their SBS's ability to prevent contamination. They found that vent bags performed the worst, followed by header bags, form-fill seal, trays, and lastly pouches.

Table 1.1 SBS Configuration, failure, reason for failure, and possible advantages (Source: Qin, Li, Yin, & Fang, 2023)

SBS Config-uration	*Failure Rate (%)*	*Observations and reasons for Failure*	*Advantages*
Header Bag	78	Device may pop out upon opening, leading to contamination. High risk of touching the inner surface or sterile package interior during opening. The opening area is often too narrow or small relative to the device size. The package cannot be completely torn, and the sterile multilayer cannot be easily recognized.	n/a
Tray	33	Difficult to hold due to a lack of "pinch" parts found in similar products. Removing the device is inconvenient as there is no reserved space within the tray.	The rigid structure is easier to hold. Opening is more predictable, fluid, rugged, and durable.
Vent	85	Tear openings are irregular, roll inward, and can easily contaminate the device. Opening position is easily confused with the middle seal or is hard to identify. Large devices block the line of sight, making it impossible to confirm aseptic removal. Material is weak, prone to breaking, and difficult to tear to the end in one motion. Exposed area of contents is small, making them difficult to reach.	n/a
Pouch	26	Package size is excessively long. Curling often occurs after tearing; a second layer of packaging is recommended. Seal strength is too high, and the label position is too low.	The opening area is large and easy to recognize.
Form-Fill Seal	45	Paper is prone to "tearing up," which releases fiber and dust onto the device and into the air. Seal strength is too high, making the package hard to open.	Effective for holding devices securely.

Even if the pouch performed better, the tray was heavily favored over the pouch. Furthermore, there seemed to be a positive correlation between the size of the packaging and the risk of contamination, something that is very relevant in the case of the GI endoscope.

There has also been a previous thesis done on this packaging solution called *Degree project in Product Development of packaging concepts for single-use endoscopes* (Bota & Kasama, 2025). They deployed product development

methodology to gather concepts for the packaging solution. Their result was a blister tray made from 100% recycled PET sealed with a 30% recycled HDPE sheet. The report highlighted improper sorting of endoscopic accessories by medical staff which led us to explore the field further. They gathered that the paper label renders the plastic film of the pouch unrecyclable, although the heat-sealing also does so the pouch cannot be recycled. Other key insights were the bulkiness of the current packaging solution making handling difficult, the number of different components and steps to retrieve the endoscope increasing handling-time, and the need for a hanging device so that the nurses are able to carry everything they need for the procedure.

1.5 Limitations

The thesis limited its scope to the packaging design development of the Ambu® aScope™ Gastro. This was due to the needs of Ambu and how challenging it has been to find design compromises at its size. The scope of the thesis rules out a lot of decisions having to do with the product itself, e.g. the method of sterilization and if the product even has to be sterilized, which could have a significant impact on sustainability.

Limiting the analysis of affordances to the efficiency of signifiers was done as it would be a very simple addition with large sustainability gains to be realized. Other affordances like the interaction between bin and waste could be explored as it has been done with public bins, but any kind of friction-based nudging was rejected because of the high stress clinical environment.

As medical waste management is burdened with the separation of infectious and non-infectious waste, clear and effective use of take-back systems could make both the endoscope and packaging more sustainable. As the packaging has little to do with the program itself, branding touchpoints were thought of as a supporting role for the packaging in the adoption and use of such a program. Although other functions could be thought of, this is an initial exploration of how packaging could interact without being a part of it.

1.6 Relevance for sustainable development

The sustainable development goals (SDG):s are goals set by the United Nations (UN) to foster ecological, social, and economic sustainability by 2030. There are two goals that are particularly relevant for this thesis. The first is Goal 12 – Responsible Consumption and Production, where 2023 the reduction of domestic material consumption was considered moderately distant to the target which is

related to the reduction of material usage in packaging design. The second is Goal 13 – Climate Action, where 2023 reduction of global greenhouse gas emissions was considered far from the target and could be improved by general eco-design principles which this thesis aim to add knowledge for (Independent Group of Scientists appointed by the Secretery-General, 2023).

1.7 Ethical considerations

The primary ethical consideration for this project is the same as in the medical profession, the Hippocratic Oath of "Do no harm". This was critical during the material selection process due to the potential harm to clinicians, patients, and the environment. The project also considers how sex and gender play a role into the ergonomics and other aspects of product development which might make certain products only adjusted for normative males due to overrepresentation in studies. Ensuring voluntary and risk-free participation during the thesis was also crucial. This included clear explanation of its purpose, the handling of any personal information and the use of informed consent forms.

1.8 Outline of the thesis

The thesis was divided into phases although multiple activities were happening concurrently. For the sake of readability, the thesis was documented following the structure shown below.

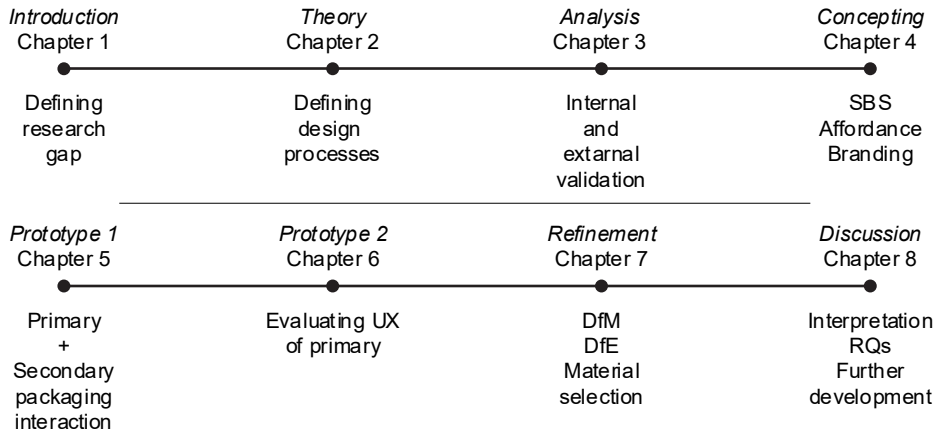

Figure 1.2 Outline of thesis

1.9 Resources

The following is a table detailing the resources used to complete the thesis.

Table 1.2 Resources

Resource Category	***Item***	***Purpose in research***
Data	Stakeholder interviews	Validating research gap and putting it into context for generation of brief
Data	Ethnographic observations at Hvidovre hospital	Validating user journey
Data	User testing at Kungälv Hospital	Validating primary packaging concepts
Data	User testing at EGSE	Validating packaging solution
Data	Ecoinvent database	Producing LCA
Data	Researchrabbit database	Gathering relevant literature
Data	User testing at ESGE Milano	Usability evaluation
Software	Excel	Conducting multiple analysis
Software	Creo Parametric	Drawing concepts
Software	Rhinoceros 3D	Drawing concepts
Software	Blender	Visualizing concepts
Software	Adobe Illustrator	Illustrations
Software	Adobe Photoshop	Photo editing
Access	Ingvard Kamprad Design Centrum (IKDC)	Prototyping and offices

2 Theory

This chapter will present the relevant theory behind the product development processes that occurred during the thesis.

2.1 Design for the sterility of medical products

2.1.1 Sterile barrier systems

Sterility is the absence of viable microorganisms (ISO, 2019). To ensure sterility you must take three things into consideration and their relation to one another. Firstly, there is the type of medical device, its intended use, expiry date, transport, and storage. Secondly, it is the intended sterilization method which can affect certain design decisions. Lastly, it is the packaging system design which includes the sterile barrier system (SBS) and the physical protection against mechanical shock. There are four sterile barrier systems that are recognized by ISO 15223 and are shown in Figure 1.1 (ISO, 2021).

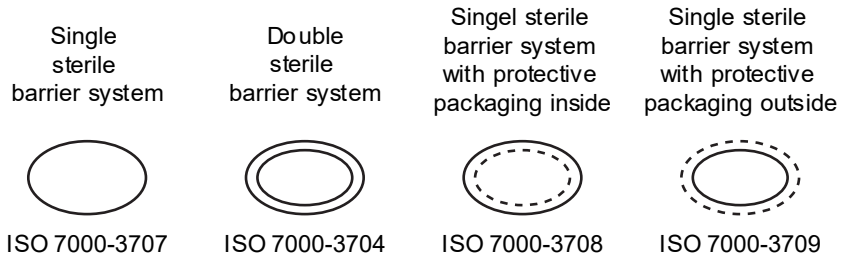

Figure 2.1 The four SBS symbols and their ISO numbers

2.1.2 Ethylene oxide sterilization

Ethylene oxide (EO) sterilization is a widely used sterilization method for medical devices. The low cost, high material compatibility and low operating temperature make it especially suitable for single-use devices containing polymers and electronics. The high process flexibility in terms of moisture and heat control also

contributes to its popularity. EO sterilization works by exposing the packaged device to ethylene oxide gas under pressure which diffuses through the porous material of the packaging and kills bacteria, spores and viruses. The effectiveness of EO sterilization depends on the EO concentration, exposure time, temperature and humidity. An increase in EO concentration results in increased microbial inactivation and decreases the required exposure time. However, an increased EO concentration elevates the health risks because EO is highly toxic. Both the workplace toxicity for personnel working with the sterilization and the residual toxicity that medical professionals are exposed to need to be taken into consideration. Different aeration techniques are used to flush out the EO, thereby reducing the health risks. EO sterilization is most effective at humidity around 60% and the temperature normally doesn't exceed 60°C, making it suitable for heat- and moisture sensitive devices. (Mendes, Brandão, & Silva, 2007).

2.2 Design for the environment

2.2.1 Design for recycling

When designing for recycling there are many considerations. To support the sorting and disposal of waste, materials should be easily identifiable, and the user should be given sufficient infrastructure to sort waste themselves or give back the responsibility to the company through a take-back program. When choosing material, consider using common materials with established recycling streams, minimizing the number of materials, avoiding materials that are difficult to separate, avoiding surface treatments and avoiding hazardous substances. For assemblies, any fixed connections should be avoided. Material enclosures like glue and coatings make parts unrecyclable while form closures e.g. friction fits and force closures e.g. screws keep the assemblies from being incinerated.

To analyze the recyclability of a design, all parts of the assembly are listed, what material they are, how they are connected in the assembly, and what they are mounted to. Then the recycling processes are considered for each part and the potential losses are recorded. (Fauldi, 2025, pp. 244-255)

2.2.2 Plastic recycling

When plastic waste has been transported to the recycling facility it will most likely be recycled in one of three ways and it all depends on the level of contamination. The primary and secondary way of recycling is mechanical recycling. What separates the two is whether it is industry waste such as plastic scrap during manufacturing, or postconsumer recycling (PCR), items that are discarded after use

by the consumer. The latter has no traceability and is considered highly contaminated waste that requires cleaning. In either case, after pretreatment the plastic gets shredded, floated, sorted and remelted which doesn't majorly alter the molecules but does degrade the polymer chain and limits the process to thermoplastics, plastics that melt rather than burn. Another issue during mechanical recycling is contaminants. Any material present during the reprocessing of a plastic that is not that plastic can lead to worsened esthetic and material characteristics which spoils the recyclate. Composite and mixed plastic waste are also affected as they are very hard to separate through shredding and floating. The tertiary way of recycling is chemical recycling, which also makes it possible to recycle composite materials. This process reverts polymer chains back to lighter compounds. It is a process that consumes a lot of energy and chemicals, which is why it is only economically and ecologically viable for a very few expensive polymers like PEEK, although others are technically possible (Rudolph, Kiesel, & Aumnate, 2017).

2.2.3 Paper recycling

The confederation of European Paper Industries (Cepi) has developed guidelines for paper-based packaging recycling. Paper that reaches the recycling mills first gets screened to separate residue, paper, and board products. After the screening process, the recyclate goes through pulping, cleaning, and final screening, before being remanufactured. According to the guidelines, there is an amount of plastic or metallic laminate that is allowed although it should be minimized. Adhesives should also be minimized and preferably easily separable at typical recycling mill temperature and environment. Separation between paper and residues should be easily done during the recycling processes. Fiber alternatives should be prepared for papermaking. If inks are applied, the area should be minimized and the inks mineral oil-free, heavy metal free, and preferably deinkable (Confederation of European Paper Industries, 2020).

2.2.4 Fast-track life cycle assessment

Evaluating the embodied carbon dioxide of concepts required Life-cycle-assessments (LCA). For the sake of feasibility, the Fast-track LCA procedure was followed as outlined by Faludi. The first thing to do is to determine the scope of the LCA, what it sets out to answer. Then the boundaries are set. The Scope 1 boundary only considers the impact of manufacturing and on-site energy, Scope 2 considers the purchased energy, and Scope 3 or "Cradle-to-Grave" considers everything from material extraction to end-of-life (EoL). As the thesis heavily concerns itself with the EoL of packaging, Scope 3 was used throughout the thesis. Then the functional unit is chosen, the unit through which comparison is fair. In this case embodied carbon dioxide per single packaging was chosen as the functional unit. Then

everything is inventoried, calculated, and analyzed often using material databases such as Idemat, and approximations when no direct equivalent can be found. This in turn creates uncertainty that is factored into the answer. The goal is to find outliers that are a factor better or worse than the rest and continue to develop anything that seems promising (2025, ss. 125-140).

The sustainability and recycling were analyzed through a systemic approach and design principles that enable the product to be recycled were applied according to Faludi (2025, ss. 233-260). The applied design principles and material selection led to design concepts.

2.2.5 Affordances in recyclability

Affordances are all the possible interactions between people and their environment. They are determined by an object's physical properties and the capability of the agent. Signifiers signal possible actions and how they should be done (Norman, 2013). Existing signifiers include the Resin Identification Codes. These codes were never meant to be recycle codes and does not imply that you can recycle an item that has it (Advancing Standards Transforming Markets, 2022). The Nordics have implemented a standardized waste sorting system where pictograms on products correspond to the correct bins. The program has been very well received when it was implemented (Nordic Council of Ministers, 2021).

2.2.6 Branding touch points for take-back systems

Brand touch points are the ways in which people can interact with your brand. This can be in the form of products, environments, communication and behavior. It is important to be consistent in messaging and maximizing brand value (Best, 2017). In terms of take-back systems this would be tying it closer to the core of Ambu's sustainability efforts by increasing its salience, adoption and perception as a responsible producer. This can be done in a multitude of ways, but as the endoscope itself is the only thing that goes through the Recircle system, the focus here will lie around the interaction between the packaging and the program when very little can be communicated through the product alone. Packaging could also help reinforce the memory structure for the specialized instructions that need to be followed for successful use of the program.

2.3 Design for manufacturing

2.3.1 Fabricius Seven Step Procedure

The manufacturability of the designs was analyzed from Fabricius Seven Step Procedure for Design for Manufacture (1994). The first step is to determine the manufacturability of products on the market. Second is to set objectives for the new development. Third is to clarify the function of the product. Fourth is to clarify the evaluation parameters and design ideas. Fifth is to generate conceptual designs. Sixth is to evaluate the designs. Lastly, seventh is to transition to production. The main objective was set as minimizing production costs so that sustainability gains could be realized while being economically sustainable.

2.3.2 Feedstock availability

The feedstock availability analysis will look at raw materials produced in Malaysia that can be used for the packaging. The data for virgin plastic materials is taken from the report Market Study for Malaysia: Plastics Circularity Opportunities and Barriers (World Bank Group, 2021). The data for woody biomass comes from National Biomass Action Plan 2023-2030 (Ministry of Plantation and Commodities, 2023).

Innovation Ambition Matrix

The Innovation Ambition Matrix developed by Bansi Nagji and Geoff Tuff (Pichler, 2025) is a template used to categorize concepts and products based on their novelty and degree of innovation. Increased innovation also comes with increased risk which is something that has to be taken into consideration when developing new products. There are three categories, from least to most innovative.

1. Core Innovations

Small scale innovation focusing on improving existing products. Industry standard changes. Lowest risk.

2. Adjacent Innovations

Usually builds on existing products found on the market, but new to the own business. Medium risk.

3. Transformational Innovations

Transformative to the business or the market at large. Great potential, but also highest risk.

2.4 Packaging design

The function of packaging can be broken down at two different levels. At the first level there is the overall functioning of the packaging system which is containing, protecting, preserving, transporting, informing about, and selling the product. When you start to break down the packaging system, first you have the packaging in immediate contact with the product known as the primary packaging, then there is the secondary packaging that contains the primary packaging, and last is the tertiary packaging or distribution package that allows for safe and efficient handling during distribution. A unit load is the number of bound tertiary packages recognized as one unit during shipping and storage (Soroka, 1999).

So, in order to have a complete packaging solution you must consider the dimensional constraints during logistics which include palletization and storage solutions at hospitals. ISO 3394 Packaging — Complete, filled transport packages and unit loads — Dimensions of rigid rectangular packages (ISO, 2012) defined a submultiple system for adapting rectangular packaging for standard sized pallets. The international standard for pallets is 1200x1000 mm, while the European standard is 1200x800 mm. A number of manufacturers of hospital furniture like e.g. Hygenius (Hygenius, 2025) have designed their shelving systems after the 600x400 mm submultiple. This is due to an English standard called HTM71 that is no longer accessible, nor enforced according to a text file on NHS's website (NHS, 2026). However, it defined a modular storage system for hospital logistics based on an international standard that is still in use today, and the HTM71 furniture is still available for purchase. Therefore, it will be used for the dimensional constraint in lack of anything more recent.

2.5 User research

2.5.1 Ethnographic observation

The ethnographic studies were done in accordance with chapter five of Just enough research by Hall (2019). The goal of ethnographic studies is to understand a certain cultural group through their ordinary activities and habitual environment. This is done by following individuals that are deeply involved rather than focusing on a large quantity of subjects. To gain ecologically valid insights, control over the participants' environment was limited by conducting the observation at their workplace. Observations of the studied individuals were gathered continuously throughout the day and subsequently analyzed to establish a common workflow and identify annoyances and opportunities.

2.5.2 Journey mapping

Journey mapping is done to understand the experience of the user, make informed decisions and ideation. The type of user or users are determined, along the horizontal axis, the stages that the users go through are recorded. On the vertical axis, aims, activities, barriers, opportunities and emotions are recorded (van Boeijen & Daalhizen, 2020).

2.5.3 Product usability evaluation

Validation of assumptions made during the product development process is done through product usability evaluation. Creating a representation of the design letting the intended user interact with it in a realistic environment doing specific tasks. Assumptions about the user journey and designs can be tested. The tests should be setup up with relevant tasks and participants for ecological validity. One to four participants are required for a simple qualitative evaluation (van Boeijen & Daalhizen, 2020).

2.6 Product development

2.6.1 Stakeholder analysis

The organizational research methodology was taken from Chapter 4 of Just Enough Research by Hall (2019). It says to identify and interview leaders, managers, and subject matter experts related to the project. The goal is to neutralize politics, gather requirements, understand priorities, tailor the design process, make sure everyone has been heard and to understand how the project impacts the organization.

2.6.2 Function analysis

The function analysis is taking a product and recognizing it as a technical system comprised of main function and sub-functions. This way alternative solutions to functions can be realized (van Boeijen & Daalhizen, 2020).

2.6.3 List of requirements

A list of requirements is created at an early stage of product development. The requirements can be categorized using the following set of categories:

- Performance
- Environment
- Life in service
- Maintenance
- Target product cost
- Transport
- Packaging
- Quantity
- Production facilities
- Size and weight
- Aesthetics
- Materials
- Product life span
- Standards rules and regulations
- Ergonomics
- Reliability
- Storage
- Testing
- Safety
- Product policy
- Societal and political implications
- Product liability
- Installation and initiation of use
- Reuse and recycling

The goal should be to identify as many requirements as possible within these categories, identify knowledge gaps, and ensure the requirements are valid, operational, non-redundant, concise and practicable. Distinctions should be made between demands and wishes through prioritizing musts, should-haves, could-haves, and must-nots (van Boeijen & Daalhizen, 2020).

3 Analysis

The entire thesis was initialized with an internal review with the various stakeholders at Ambu that related to the development of the GI endoscopes and a review of the state of the art for Ambu and its competitors when it comes to medical device packaging. This was done to be able to formulate an actionable brief with quantifiable criteria.

3.1 Stakeholder analysis

3.1.1 Methodology

Nine interviews were held with various internal stakeholders at Ambu. These interviews touched upon the development of the endoscopes, the persisting issues with the packaging, and specific questions about the interviewee's role. The interviews were coded with a hybrid approach of á priori categories that were extracted from an internal analysis approach from Just Enough Research by Erika Hall (Hall, 2019) and secondly an inductive thematic analysis. Later these statements were turned into requirements for the development of the new packaging concept as seen by the internal stakeholders.

3.1.2 Result

Table 2.1 shows the predetermined themes, their recurrence during all the interviews, and lastly the inductive themes, and the thematic analysis was translated into a list of requirements that can be viewed in Table 2.2 List of requirements.

Table 3.1 Gathered statements from interviews

Á priori themes	*Recurrence*	*Inductive themes*
Expectations	38	Outcome, priorities, requirements
Assumptions and working knowledge	21	The market, Ambu's market position, the customer, the product
Problems	35	Packaging, Protection, Cost, Interdependencies, Sustainability, Material, Usability
Unanswered questions	6	n/a

3.1.3 Discussion

The goal was to gain insight into:

- Expectations surrounding the new development
- Assumptions and working knowledge that drive current development
- Problems that have occurred during development
- Catch any unanswered questions

The general sentiment surrounding each topic is captured here.

3.1.3.1 Expectations

The dream scenario is if Ambu's GI endoscopes gain market share compared to reusable endoscopes. They would also like to provide a more complete endoscopy offering. This will enable risk reduction regarding usability for the end user as well as the ability to realize features that might only be possible with the Ambu ecosystem and single-use approach, giving them an edge in the market. Another outcome that they would like to see is a more sustainable packaging solution that is more inclusive for female and smaller-bodied physicians, especially in regard to hand size.

The number one priority when revising the endoscope is keeping in line with the clinical needs of actual users. These users are quite varied, but the primary user archetype for Ambu's GI endoscopes is a bariatric surgeon in an operating room or a gastro enterologist working in the ICU. For the packaging, however, the thesis should diverge from this archetype and consider the perspective of nurses who will interact with the packaging most. A key selling point of the endoscope is its availability in hospitals, and the packaging needs to reflect this. Following this we should prioritize the remaining functions of the packaging, like protecting the product during transport and ensuring that it functions as expected when it is taken out of the packaging. Any packaging concept also needs to improve on three main areas which are cost, sustainability and ease of use. All of these goals are

synergetic in their reduction of the total weight of the packaging but might diverge in other factors. A majority of Ambu favors a numerical and data-driven approach.

3.1.3.2 Assumptions and working knowledge

Ambu is not bound by expectations in the field of GI endoscopes like reusable competitors might be. Ambu is also expected to produce objective data to support marketing claims. Ambu must produce a product that is a tiny fraction of the cost of the reusable endoscopes due to the single use solution.

Hospitals with reusable endoscope solutions are unlikely to completely replace it with a single use solution. Specialty use cases that favor or necessitate single use solutions would make them more inclined to stash them. Strained working conditions like cramped workspaces or ambulatory settings might point to this as well as the lack of access to cleaning personnel. Cleaning reusable endoscopes also requires coordination between departments at hospitals, which is viewed as quite cumbersome. US customers often have to pay for certain procedures that they want to perform which could speak to the accessibility of an Ambu solution. Clinicians are not shy to point out products that don't work to procurement which makes their preference favor the end goal even in a purely economic sense. They will also compare Ambu's GI endoscopes to endoscopes they have used in the past, even unconsciously. Products that cause occupational injuries and bad ergonomics will become increasingly scrutinized in the medical community. The challenge will be to balance the innovative solutions that might give Ambu an edge and the overall conservative customer who prefers things to remain as they were when they were taught how to do the procedure. It is also assumed that nurses are thought to viewing the experience of throwing away the endoscopes as overall negative.

For the case of sterility there doesn't seem to be an explicit need when performing an endoscopy because the area where the procedure is performed is not considered sterile. There does however seem to be an appreciation for the fact that Ambu's products are sterile and that the case for sterility has to do with the maintainability of sterility inside of e.g. an OR. The current sterilization method ETO is therefore considered the method for sterilizing the future GI endoscopes although alternatives could be considered.

3.1.3.3 Problems

There are too many materials used in the packaging making it overly complex and expensive to manufacture. In the current packaging, the Tyvek pouch and the mounting card are the most expensive parts, and they are made of different materials. The mounting card in particular makes up a substantial amount of the total cost of the packaging, while not providing much in terms of functionality. The environmental impact of the packaging compared to the endoscope itself is also problematic.

It is important to find a balance between innovation and familiarity, especially for the endoscope but also for the packaging. Changing it too much may cause steep learning curves and increase hesitancy for product adoption. The users of the GI endoscope feel uncomfortable throwing away the endoscope and the packaging because of the amount of waste it produces. Some of the users are unsure of how to recycle or dispose of the different components of the packaging, and whether the packaging should be considered hazardous waste or not. Another issue is the storage of the product. In the current version, the packaging is not stackable, but users have expressed a desire to be able to stack the product. Retrieving and opening the right product is also an issue with the current version. It is difficult to properly evaluate the individual products within the project in terms of UX and usability when it is not part of the complete solution. Storytelling about ergonomics is difficult and lacking in the current version.

3.2 Competitive analysis

3.2.1 Method

Due to Ambu's immense market share of SUD GI endoscopes, the quantity of complete packaging solutions is rather limited. Therefore, the current packaging was broken down using a functional analysis, as outlined in Delft's Design guide (van Boeijen & Daalhizen, 2020), so that sub-solutions could be explored. The external search was loosely based on the aseptic presentation evaluation presented in Table 1.1 SBS Configuration, failure, reason for failure, and possible advantages (Source: Qin, Li, Yin, & Fang, 2023). As the pouch and tray were found to be the most effective with the fewest drawbacks, the others were disregarded with the exception of the header pouch. The header pouch was included to see if the minimization of the permeable sheet had effect on DfE and DfM, although the performance was terrible with a failure rate of 78%. Different variations in the pouch were found with protective barriers inside and outside of the sterile barrier and made from different materials. The different market solutions were found by using commercial search engines for SUDs and adapting their packaging to potential packaging solutions that were scaled so that they could potentially house Ambu's GI endoscope. This made them approximately comparable through the metrics recorded below.

The sustainability of the current packaging solution compared to the other options was evaluated with the LCA fast-track method as mentioned in chapter 2.2.4. Then their eco-intensity was summarized and normalized.

The manufacturability of the solutions was analyzed from six different evaluation parameters that were gathered from Fabricius Seven Step Procedure for Design for

Manufacture (1994). The six parameters were material cost, weight, number of components, number of assembly steps, and the match between required and current process capabilities. These specific ones were chosen because according to Fabricius these are ones that are associated with higher direct cost, supporting the most prioritized DfM objective discovered during stakeholder interview; lowering the cost of the packaging while keeping complexity low.

3.2.2 Result

From the functional analysis the following requirements were gathered for each of the parts.

Table 2.2 Functional requirements for each part of the current packaging solution

Parts	***Functional Requirements***
Tray	Protect wheels and valves, protect distal end
Pouch	At least one permeable material, communicate expiration, communicate variant of endoscope, communicate use, tactile irreversible opening, strong sterile barrier, labeling, traceability
Mounting card	Prevent memory effect, keep product centered

The external search for packaging solution gave rise to the following solutions.

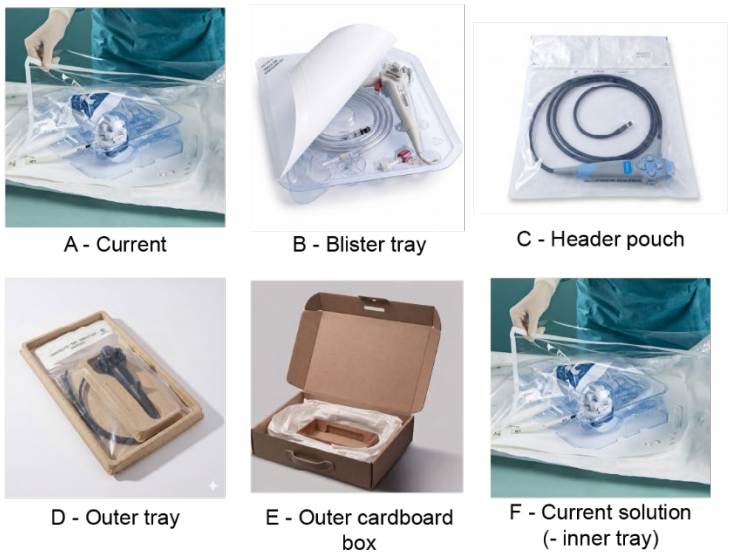

Figure 3.1 External solutions for competitive analysis

Table 3.3 Functional analysis of each solution

Solution	*SBS-system*	*Sterile barrier*	*Physical protection*
A	Single sterile barrier system with protective packaging inside	Outer permeable pouch	Inner tray, Mounting card
B	Single sterile barrier system	Permeable sheet	Outer tray
C	Single sterile barrier system with protective packaging inside	Outer permeable sheet	Inner tray, Mounting card
D	Single sterile barrier system with protective packaging outside	Inner permeable pouch	Outer tray
E	Single sterile barrier system with protective packaging outside	Inner permeable pouch	Outer cardboard box
F	Single sterile barrier system with protective packaging inside	Outer permeable sheet	Mounting card

The following figure shows the normalized environmental impact.

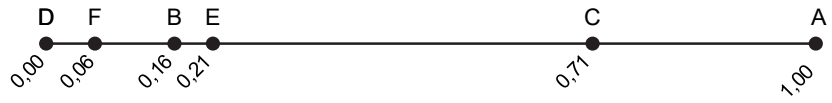

Figure 3.2 The normalized carbon dioxide equivalent produced by each solution

The following table shows the five key parameters for each solution.

Table 3.4 Summary of DfM parameters for each solution

Solution	*Normalized Material Cost*	*Weight (g)*	*Number of Components*	*Number of Assembly Steps*	*Current process capability (%)*
A	1	729	9	12	100
B	0,40	548	7	8	87,5
C	0,37	724	7	9	100
D	0,18	950	6	8	100
E	0	550	6	8	100
F	0,56	149	7	12	100

3.2.3 Discussion

There is a real need to cut down on the number of components in the packaging. When you analyze each solution broken down into its components, it's clear that the mounting card has an extreme impact on every solution that it is a part of. It is possible to cut down on other components as seen in solution F to achieve

sustainability gains. However, you do lose important functionality when removing the tray. End of life is mostly proportional to the ingoing material. It is important to note that Figure 3.2 does not try to imply that solution D is climate neutral, it has simply the least climate impact. Chemical recycling such as pyrolysis has been considered because of the reliance of heat-sealing which often requires a surface treatment making it unrecyclable through mechanical recycling. A recycling analysis can be seen in Appendix B but as chemical recycling is not a widely used recycling method, the LCA considered it as general waste and got incinerated. The IFU was a constant that could be replaced with a eIFU which would reduce emissions.

The most effective way to improve the DfM objectives is to reduce the number of components, which in turn reduces the number of assembly steps and material cost. The mounting card constitutes a majority of the price and weight of the primary packaging, while performing few functions. Redesigning the packaging to exclude the mounting card would result in large DfM benefits. Changing the SBS system could eliminate the need for a mounting card but would necessitate large overhead costs in the form of a new sealing machine. Further DfM analysis is needed to determine the possible profitability of changing the SBS system.

3.3 The User

3.3.1 Method

The user journey is based on the user journey done by Ambu for the GI endoscope but adapted to the OR nurse and their interaction with the packaging from the moment they retrieve the endoscope to when they discard the packaging. Annoyances and opportunities were recorded under each activity.

A hospital in Hvidovre was visited where an ethnographic study of the endoscopy suite and interview with the nurses in the OR were done in order to confirm the user journey where certain aspects needed correction.

3.3.2 Result

The user journey provided by Ambu was updated using the results from the ethnographic study at Hvidovre hospital resulting in a new user journey that highlights several key annoyances and opportunities during the pre- and post-procedure phases.

3.3.2.1 Key annoyances identified

Storage and Transport: The current packaging takes up too much space in storage and does not stack well. Furthermore, there is no intuitive way to transport the endoscope with a cart, and the way to grab and carry it is ambiguous.

Preparation: Nurses find it difficult to open the "fiddly" tabs on the packaging, especially in the occasional low-light conditions of the operating room or ICU. Additionally, the nurse must pick up the endoscope before gaining access to the connector.

Waste Management: Time pressure and a lack of physical proximity to sorting bins hinder the correct separation of waste. As a result, non-hazardous waste is frequently treated as hazardous, and composite packaging is incorrectly sorted as plastic, which ruins the quality of the recycled yield. After the procedure, the endoscope is generally put directly into the general waste bin.

3.3.2.2 Key opportunities identified

Usability: Nurses prefer packaging that can be opened with one hand, and they favor color-coding over text to distinguish between different products. Trays and pouches also offer the lowest failure rate during aseptic presentation.

Additional uses of the packaging: The packaging could potentially serve as a reservoir for water and lubrication during the preparation phase.

Sustainability: There is an opportunity to use clear signifiers on the packaging to instruct correct waste sorting and to actively nudge the nurse to use the ReCircle program.

3.3.2.3 Complete user journey

The following three pages show the complete user journey map in sequential order.

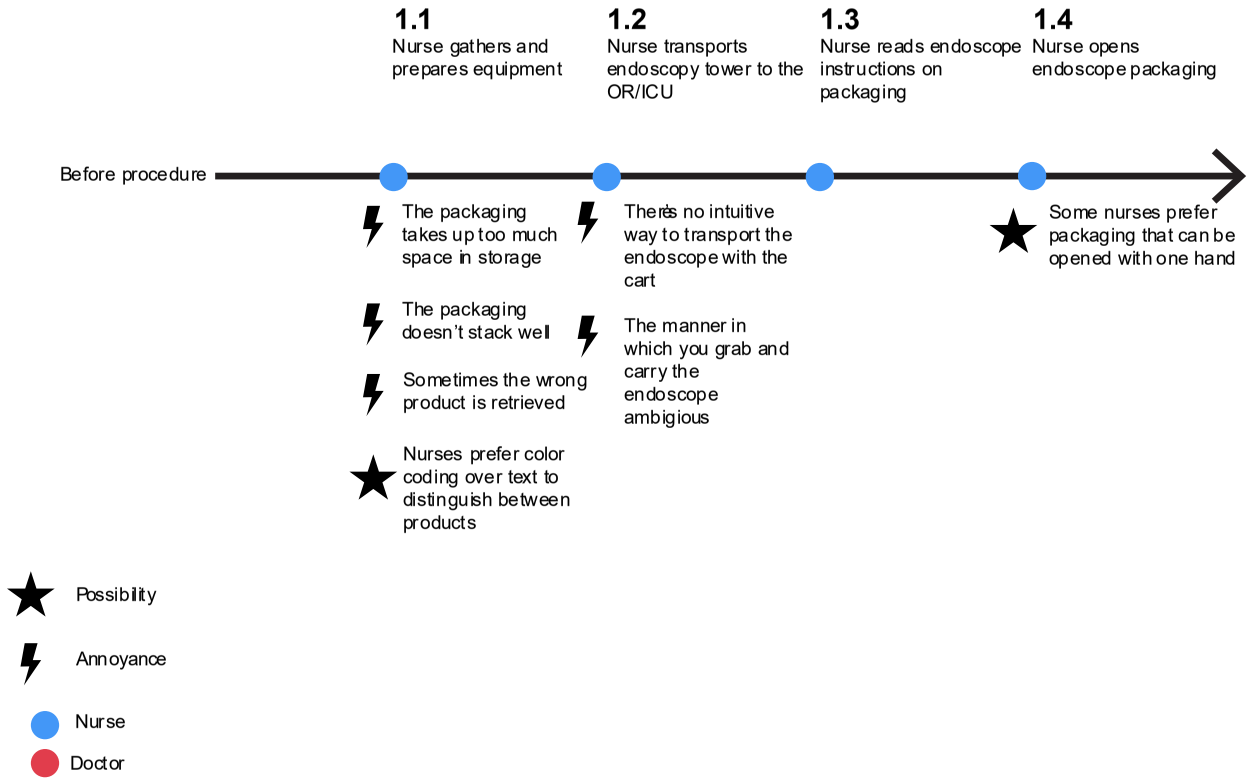

Figure 3.3 User journey before procedure

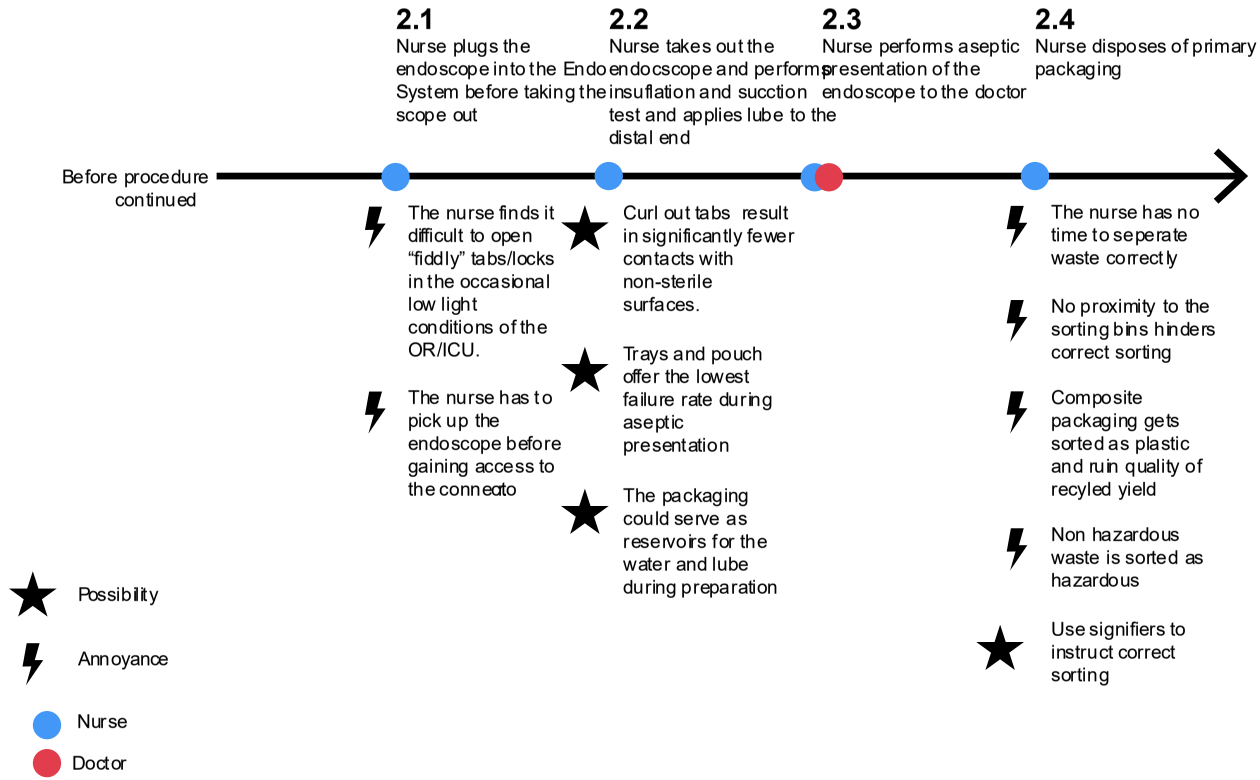

Figure 3.4 User journey before procedure continued

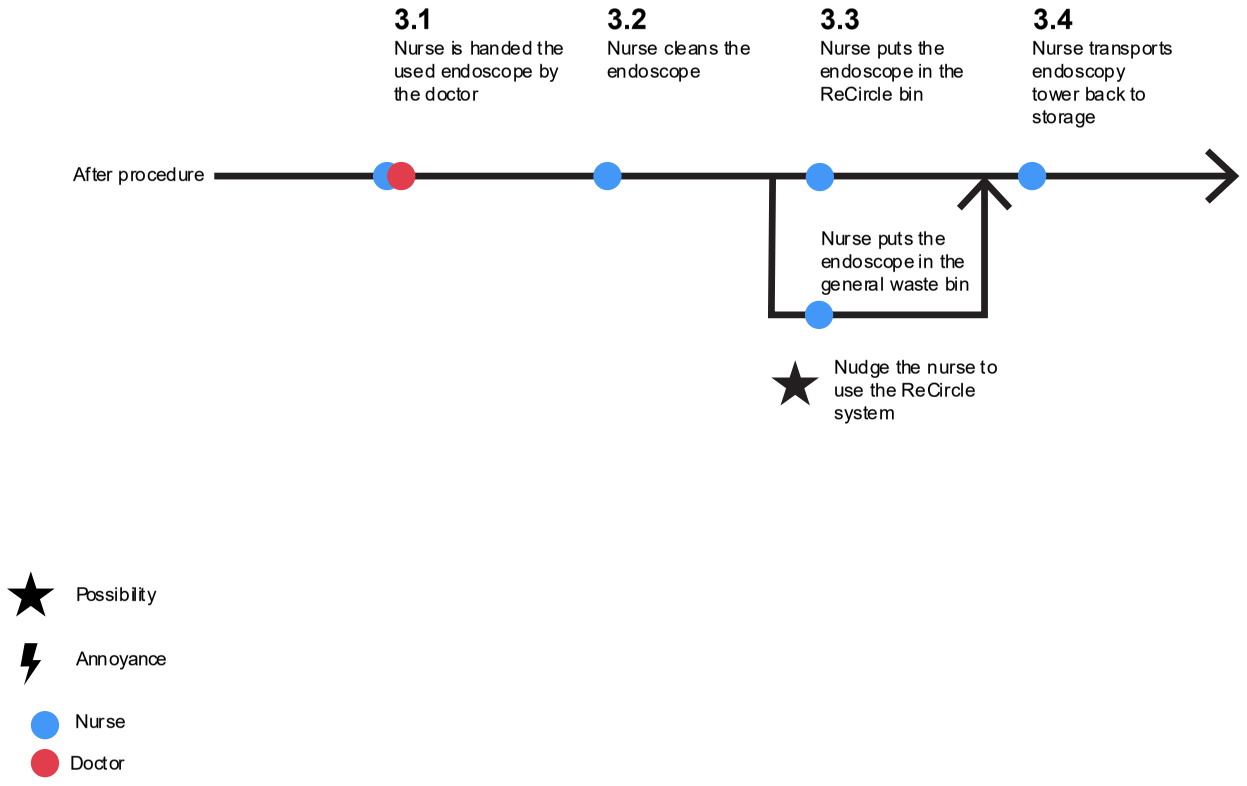

Figure 3.5 User journey after procedure

3.3.3 Discussion

In Hvidovre, the main reason for not sorting at the point of disposal in OR was time pressure and physical proximity. They are also rethinking the use of separate bins. The abundance of composite items is polluting the plastic recycling yield which renders the sorting effort not as impactful. This might be the reasoning of the hospital, and it does reflect the previous research into user errors during waste sorting.

3.4 List of requirements

3.4.1 Method

The list of requirements was constructed using data from four distinct sources stemming from preceding phases of the project. Requirements from internal stakeholders were extracted from nine semi-structured interviews through the previously mentioned a priori and inductive thematic analysis. Secondly, user requirements were derived by translating the specific annoyances and opportunities identified during the ethnographic user journey mapping into actionable design criteria. Thirdly, technical and environmental baseline requirements were formulated based on the functional and life-cycle analyses (LCA) of existing competitive solutions. Finally, external regulatory requirements were gathered by reviewing applicable medical device frameworks, specifically the MDR and CFR. When all the requirements had been gathered, they were categorized according to the framework proposed by van Boeijen & Daalhuizen (2020) to ensure that no design aspects were overlooked. The requirements were then prioritized according to their importance and impact on patient safety, regulatory compliance and user need, using the categories Must, Should and Could. By deriving the requirements directly from a combination of empirical observations, expert interviews, and standardized regulations, the validity and traceability of the final list are ensured.

3.4.2 Result

Table 3.5 List of requirements

Requirement	*ID*	*Source*	*Priority*
Allow for EtO sterilization	1	Stakeholder	Must
Show clearly if packaging has been opened	2	MDR, CFR	Must
Tactile feel when opening the product	3	Stakeholder	Should
Minimize space during storage	4	Stakeholder, User Journey	Should
Ship maximum number of products	5	Stakeholder	Should
Communicate expiration	6	Stakeholder, MDR	Must
Protect handle	7	Stakeholder	Must
Protect distal end	8	Stakeholder	Must
Prevent memory effect of insertion tube	9	Stakeholder	Must
Allow quick retrieval	10	Stakeholder, User Journey	Should
Follow brand profile	11	Stakeholder	Must
Integrate with the endoscopy suite	12	Stakeholder	Should
Be cheap	13	Stakeholder	Must
Consist of few materials	14	Stakeholder	Should
Prevent punctures	15	Stakeholder, MDR	Must
Communicate variant of endoscope	16	Stakeholder, MDR, CFR	Must
Balance innovation and familiarity	17 18	Stakeholder	Should
Instruct recycling	19	Stakeholder, User Journey	Must
Be stackable	20	Stakeholder, User Journey	Must
Facilitate adoption of the Recircle program	21	Stakeholder	Could
Explain pretreatment for Recircle program	22	Stakeholder	Could
Match clinical workflow	23	Stakeholder, User testing	Should
Allow storage inside of Ors	24	Stakeholder	Should
Allow hanging	25	Stakeholder	Should
Make it possible to keep secondary packaging in storage after opening it	26	User journey	Could

Table 3.6 List of requirements continued

Requirement	*ID*	*Source*	*Priority*
Include recycled material where it is allowed	27	Stakeholder	Should
Consider bioplastic alternatives when possible	28	Stakeholder, DfE	Should
Use colors indications when applicable	29	User testing	Should
Be intuitive to sort (waste)	30	User Journey	Should
Be intuitive to hold	31	User Journey	Should
Compromise the safety of the patient	32	MDR	Must not
Reduce use error and risks related to ergonomics	33	MDR	Should
Environmental factors such as temperature and humidity will not affect intended use	34	MDR	Must
Reduce as far as possible any residue that may come in contact with the body as a result of the use of the device	35	MDR	Must
Avoid phthalates	36	Stakeholder, MDR	Should
Allow safe handling	37	MDR	Must
Instruct intended use with drawings and diagrams in a human readable format	38	MDR	Must
Supplement instructions with e.g. RFID, QR.	39	MDR	Could
Replace IFU with eIFU in accordance with Regulation (EU) No 207/2012	40	MDR	Could
Remove the risk of accidental ingress of substances	41	MDR	Must
Avoid carcinogenic, mutagenic or reprotoxic (CMR) materials	42	Stakeholder, MDR	Must
Stop the use of composite packaging	43	DfE	Could
Find alternatives to plastic wherever possible	44	DfE	Should
Ensure recyclability of all plastics not in contact with the patient	45	DfE	Could

3.4.3 Discussion

This list is not exhaustive when it comes to MDR or CFR but the selection of what criteria to include was made based on what was believed to be relevant specifically for the development of packaging. Requirements 1, 2, 7, 8, 15, 32, 34, 35 and 41 could be tested with the tests provided in Table B.1 in ISO 11607-1. The testing of unvalidated materials for terminally sterilized packaging is outside of the scope of this thesis. However, the price of research and development of low impact materials that has seen previous adoption in other medical fields could be seen as a strategic goal so they will not be disqualified, but they will have an asterisk attached (*) (ISO, 2019). Other requirements such as 3, 10, 12, 17, 23, 26, 30, 31, 33 and 37 were qualitatively validated and will be mentioned only when relevant to the RQs.

4 Concept generation

After the competitive analysis it was quite clear that fragmenting the problem into partial ones was an effective approach. The concept generation can be broken down into Primary and Secondary packaging, Waste management affordance, and Branding touchpoints for Recircle.

4.1 Brief

The proposed outcome are concepts that have been tested in a simulated environment with a lower environmental impact. The product development target audience is medical professionals and more specifically ICU and OR nurses. The primary need of the user is packaging that supports effective procedures with collaboration between themselves, other nurses, the doctor, and the patient. Their endoscopy activities include bariatric surgery and GI bleeds. Their current frustrations are sorting waste at work, not having enough space, and producing a lot of waste during procedures. Components have been identified as impacting cost and sustainability unproportionally and must be reconsidered.

4.2 Primary and Secondary packaging

The competitive analysis revealed that there was about as much variation between different SBS as there were within the same SBS when it comes to sustainability and recyclability. Due to the heavy focus on usability, it is therefore interesting to isolate the observed SBSs, trying to minimize the overall footprint and embody them in packaging solutions to determine which one is most suitable for the nurse's workflow. Once this was determined, more concepts were developed based on material.

4.2.1 Method

To create a packaging experience that supports the whole user journey, concepting was done for both the primary and secondary packaging following the individual

steps of the user journey. The first step consisted of exploring pallet sizes and standard shelving systems used in hospital environments to create sizing constraints for the primary and secondary packaging.

This was followed by an analysis of the possible footprints allowed for the primary packaging by coiling the endoscopes in different configurations that adhered to the constraints discovered through the stakeholder analysis. Those constraints exist to keep the insertion tube from being damaged during storage and state that the insertion tube can have a maximum bending diameter of 200 mm and the last 300 mm of the insertion tube must be straight. Furthermore, the insertion tube can only have one 180-degree bend. These are constraints are visualized in Figure 4.1

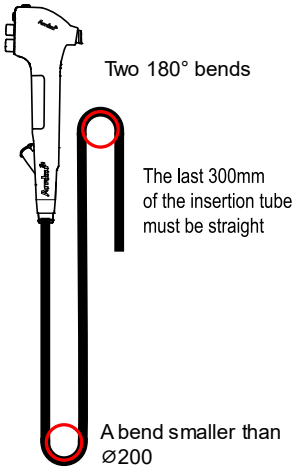

Figure 4.1 Showing incorrect layout of insertion tube

Step 1.1 in the user journey is the retrieval of the primary packaging from storage. To allow for the primary packaging to be stored inside the secondary packaging, a brainstorming session focusing on secondary packaging size and primary packaging retrieval from the secondary packaging was done. The footprints discovered were used as a starting point, but the concepts were also constrained by shelving and pallet size and took into consideration the ergonomics of carrying the secondary packaging. Brainstorming on the retrieval of the primary packaging also included orientation inside the secondary packaging and handle placement. The orientation of the packaging and handle placement are dependent on each other if the handle is to be easily accessible to the user.

Step 1.2 in the user journey involves taking the primary packaging from storage to where the endoscope will be used, usually in an OR or a patient room in the ICU. Through another brainstorming session, different solutions for the transport of the primary packaging were explored. This included the handle for carrying the primary

packaging as well as a hang hole which enables the primary packaging to be transported hanging on the endoscopy tower.

Step 1.4 is opening the primary packaging, connecting the endoscope to the equipment on the endoscopy tower, conducting suction and insufflation tests and putting lube on the distal end. So far, the concept generation has been for an arbitrary primary packaging not taking the different SBS into account. For the brainstorming that explored how the primary packaging can support these steps, the concepts were divided into single sterile barrier system and single sterile barrier system with protective packaging outside for them to be compared to the original packaging which is a single sterile barrier system with protective packaging inside. Concepts were generated with the primary packaging either lying flat on a utility cart or hanging on the endoscopy tower.

4.2.2 Result

By making the cable of the endoscope have either one or two 180-degree bends, two layouts of the endoscope that meet the criteria for not damaging the insertion tube were found. This generated two footprints, one long and narrow with dimensions 800 mm x 250 mm and one short and wide with dimensions 600 mm x 400 mm. The long and narrow will be referred to as the narrow footprint and the short and wide will be referred to as the wide footprint. The picture below shows the two allowed footprints. The area of the narrow footprint is 0.2 m^2 and the area of the wide footprint is 0.24 m^2. This means that the area of the wide footprint is 20% larger and would require about 20% more material compared to the narrow footprint.

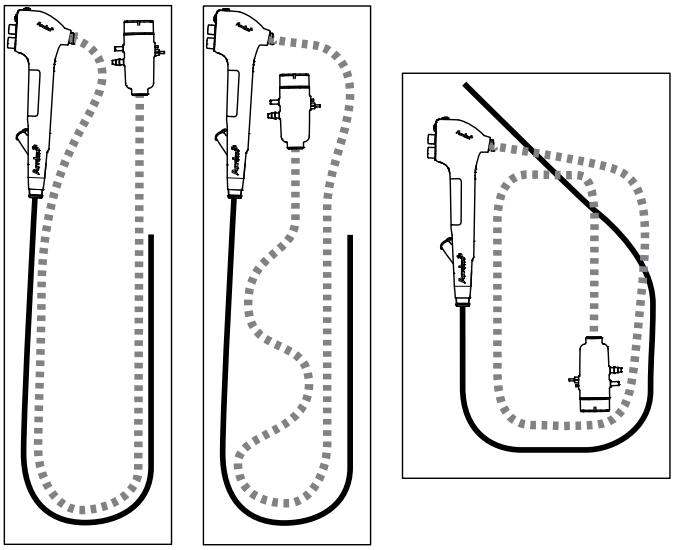

Figure 4.2 (Left) 800x250 layout suitable for long pouch, (Middle) 800x250 layout suitable for tray, (Right) 600x400 layout suitable for tray and fitted for ISO-standard and EU pallets

The ISO standard for pallet size is 1200 mm x 1000 mm. The standard size in the EU is 1200 x 800 mm. The sketches below show the palletization for the two allowed footprints found. Both footprints fit the same number of times, 6 times for the ISO standard pallet and 5 times for the EU pallet. There is no extra space on the pallets for the wide footprint, in contrast to the narrow footprint where there is extra space on both pallets.

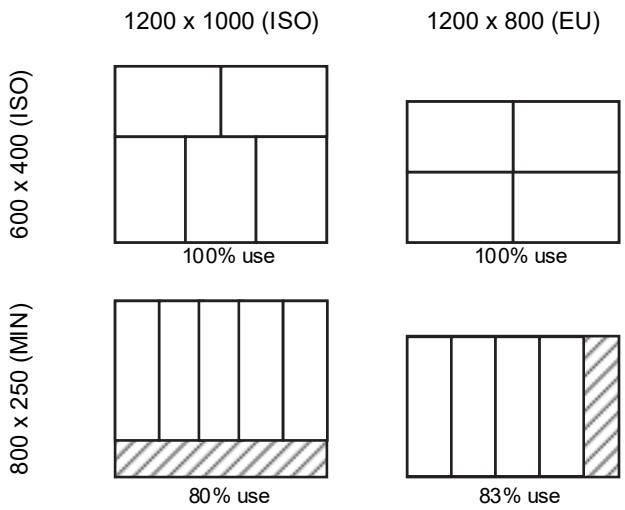

Figure 4.3 Palletization of the wide and narrow footprint

Most cabinet systems for hospital environments are based on the ISO 3394 standard dimension of 600 x 400 mm. The wide footprint fits perfectly into the standardized shelving, while narrow would stick out as it is too long. Open shelving systems used for storing bulkier items in hospital environments come in larger variety of sizes, but in most cases the depths of the shelves are at least 400 mm, meaning that the depth is normally sufficient to store both configurations if the long side of the packaging is placed along the front of the shelf. Shelf length also varies, from 600 mm to 1800 mm.

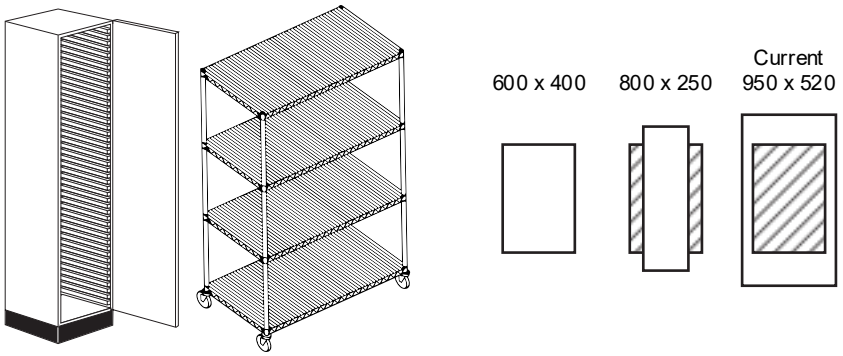

Figure 4.4 Hospital storage unit size compared to packaging footprint (Solid for packaging, striped for shelf)

Palletization and compatibility with standardized hospital storage were primary considerations when choosing which footprint to use. Both footprints allow for the same number of units to be transported on ISO and EU pallets, but the wide footprint (600 x 400 mm) fits perfectly with the widely adopted HTM71 hospital shelving and cabinet standard. In contrast, the narrow footprint would require more shelf space and would not fit inside standard hospital cabinets. For this reason, the wide footprint was chosen over the narrow one, even though it has a 20% smaller area.

The footprint was not the only thing to be explored when it came to the layout of the packaging. You need three levels of support, firstly there is the plane parallel to the connector cord, secondly is the plane parallel to the insertion tube, and lastly is the bottom extremity which in this case are the valves. Because the handle of the endoscope is a lot thicker compared to the cable and insertion tube, it was apparent that the shape of the primary shape of the packaging didn't have to be a cuboid. When coiled in the two footprint configurations, the height of the endoscope at the handle end was 130 mm while the opposite end measured 30 mm. By placing the two endoscopes facing each other with the handle in opposite directions, they create a cuboid with a height of 160 mm. Three different variations of this configuration were explored, as seen in the picture below. The benefit of A is that there is not a diagonal stacking-surface, but it does force a more complex top-down coiling because both cords run in the same plane. The benefit of B is that you have two planes for the cords allowing you to cross them like in the wide footprint. The benefit of C is that if you were to add a handle along the long side of the packaging, stacking them in this manner would ensure that all handles are facing the same direction, but the stacking is more irregular and awkward.

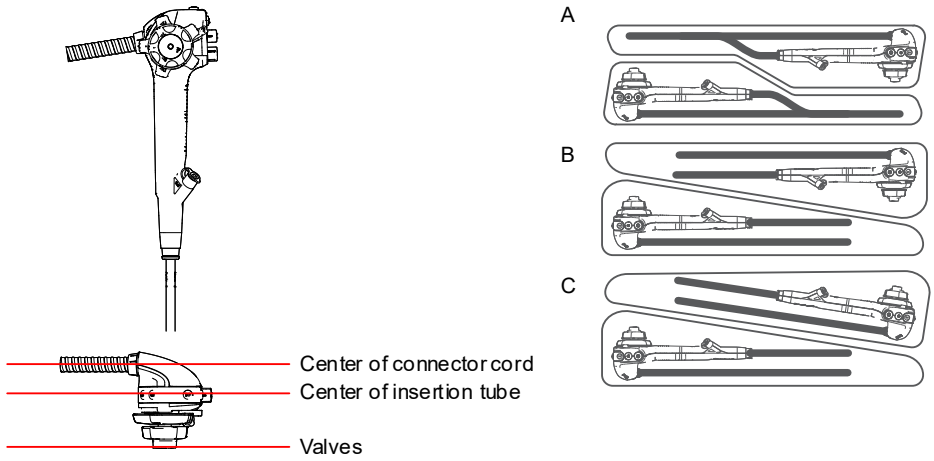

Figure 4.5 Stacking primary shapes

Secondary: Realistically, if the primary packaging is kept in the secondary packaging during storage, it would be placed in an open shelving system. The shelf height is normally adjustable, but for standard 4 level shelving systems the distance between shelves is between 500 mm and 600 mm. When stacking two of the primary packaging on top of each other, as shown above, the resulting height is 160 mm. This means that most open shelving systems can comfortably store a secondary packaging containing 6 endoscopes with a height of 480 mm.

The dimensions of the secondary packaging are primarily determined by the chosen footprint, the number of units to ship in one secondary packaging, and the manner in which you stack them. The orientation in which you store them during distribution should look like Figure 4.3 but the way in which you open the secondary packaging is still undetermined at this point.

4.2.3 Discussion

This ideation laid the foundation for how each packaging concept was built around going forward. It leaves out detailed features as they could be added at a later stage. When it comes to the footprint analysis, it really comes down to if storage and palletization is worth the extra material and cost. Endoscopes with the longer footprint will have to be stored in a vertical orientation with a lot of headroom otherwise the packaging must be allowed to hang out over the edge of the open shelving and the cabinets will not close.

4.3 Waste management affordance

4.3.1 Method

There are no internationally recognized way of labeling or coloring waste. However, the Nordics share a system that originated from Denmark. It shows that there is potential for such a system to be implemented across larger economic zones such as the EU. If such a system would be set in place and utilized in a high-stress clinical setting and it showed promise, it could incentivize its adoption. The symbols used in the Nordic system are somewhat generic and could be understood or learned quite easily, therefore the use of color is put into question. This is because the colors are very much not standardized and meaning not derived innately. The use of generic symbols might be acceptable in countries that have not adopted the system. Two variants of the same diagram were developed in order to instruct waste sorting and were added at the end of the current instructions that are printed on the outer pouch.

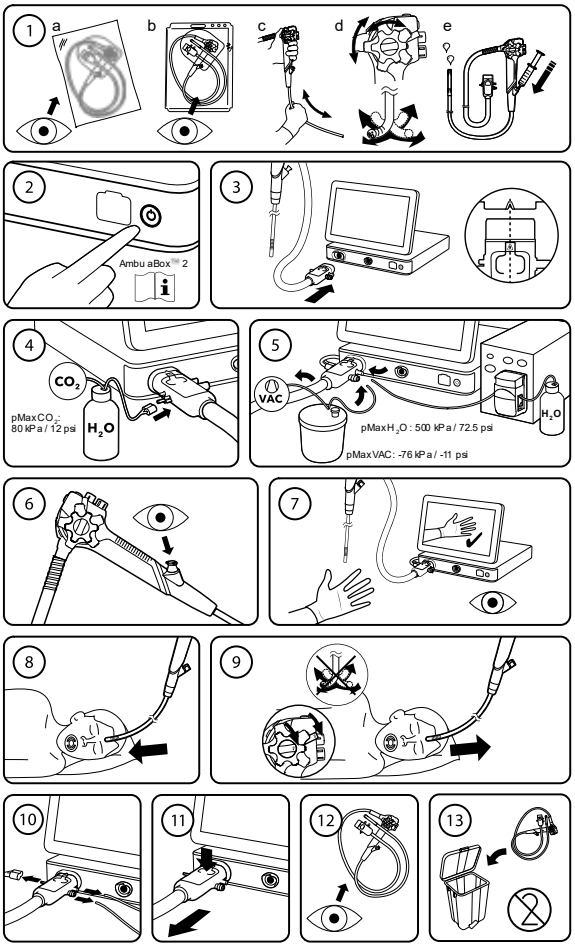

Figure 4.6 Current instructions printed on the packaging

4.3.2 Result

Figure 4.7 and Figure 4.8 show diagrams that were developed to instruct recycling by visually mapping each packaging component to its correct waste stream. Both diagrams explicitly break down the packaging into its individual components and show that the endoscope, the tray, the mounting card and the pouch require different disposal methods. The diagrams use standardized pictograms used in the Nordics for waste sorting, which enables the nurse to sort the packaging without any text instructions. Two variants were created to test whether the addition of color-coding serves as an effective signifier that improves sorting accuracy, or if monochromatic pictograms are sufficient.

Currently, nurses experience time pressure and lack intuitive guidance at the point of disposal, which frequently leads to sorting errors, such as placing composite packaging into plastic recycling streams. By providing clear, visual signifiers directly on the packaging, these diagrams are designed to reduce the cognitive burden of waste separation in high-stress clinical environments. Rather than relying on the nurse's prior knowledge, the diagrams aim to improve sorting accuracy by using well established signifiers already known by the nurses.

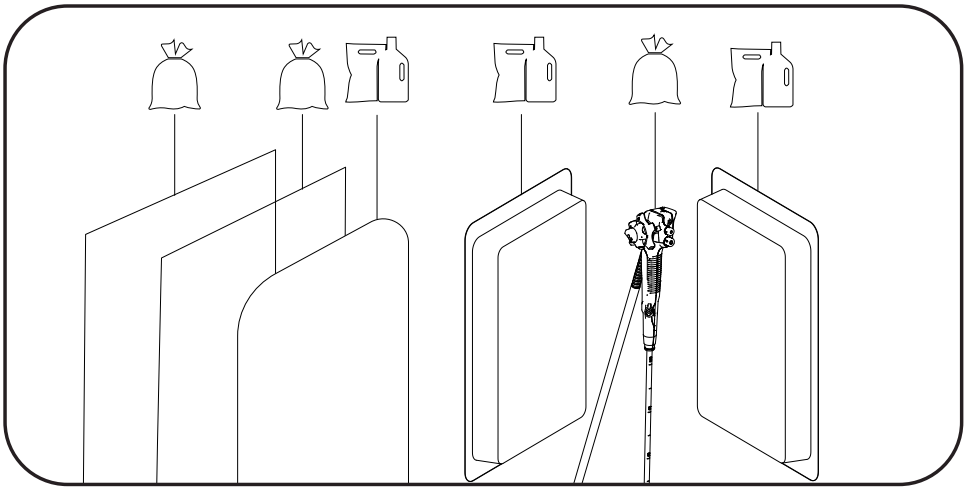

Figure 4.7 Diagram with symbols and no color

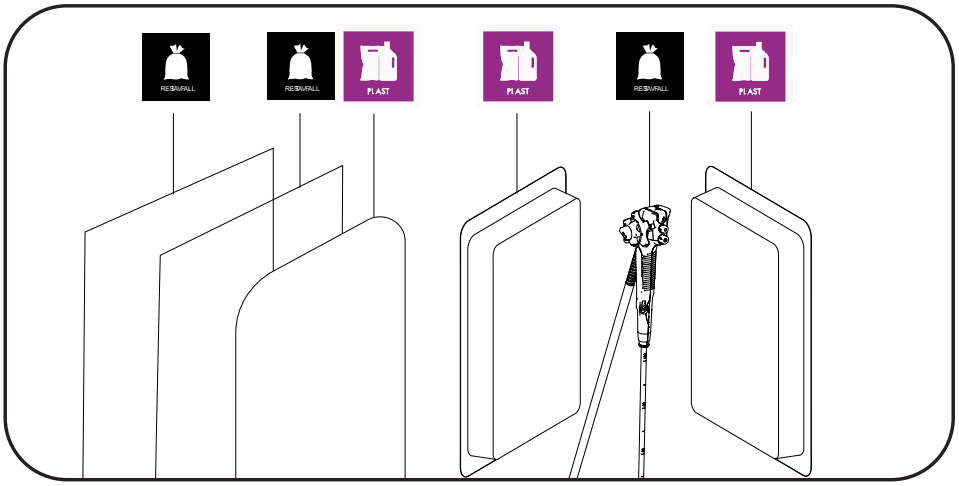

Figure 4.8 Diagram with symbols and color

4.3.3 Discussion

Most of Ambu's customers are outside of the Nordics. This is a clear drawback to what is trying to be achieved here. The resin-based numbering system that is present on each of the parts today should still be supported by some kind of diagram for instructing waste sorting even if international customers are averse to this solution.

4.4 Branding touchpoints for Recircle

4.4.1 Method

It was found out through interviews at Ambu that the Recircle program had certain pain points that might hinder its adoption by more hospitals. Hospitals are under immense pressure, often with other initiatives, there is often little time for the pretreatment that is required for the endoscope to be recycled through the program, there is often a need for ambassadors to motivate the adoption, and implementing new workflows is hard to motivate.

This motivated the development of branding touchpoints that could firstly improve the salience of the program for nurses so that the instigation to join might come from them and their desire to improve sustainability in the workplace and secondly instructing the required pretreatment. This started with a brainstorming session trying to examine the possibilities within the secondary and primary packaging. Then variants of the secondary packaging were designed to better understand what sort of response we could get and implement the possibility for the use of QR codes.

4.4.2 Result

The following are the secondary packaging concepts aimed at improving the program's salience and potentially informing the nurses about the program.

Figure 4.9 Secondary packaging designs

Figure 4.10 Visualization of how the packaging could potentially look

The second exploration was if primary packaging should include instructions for the Recircle program which has a secondary effect of promoting it.

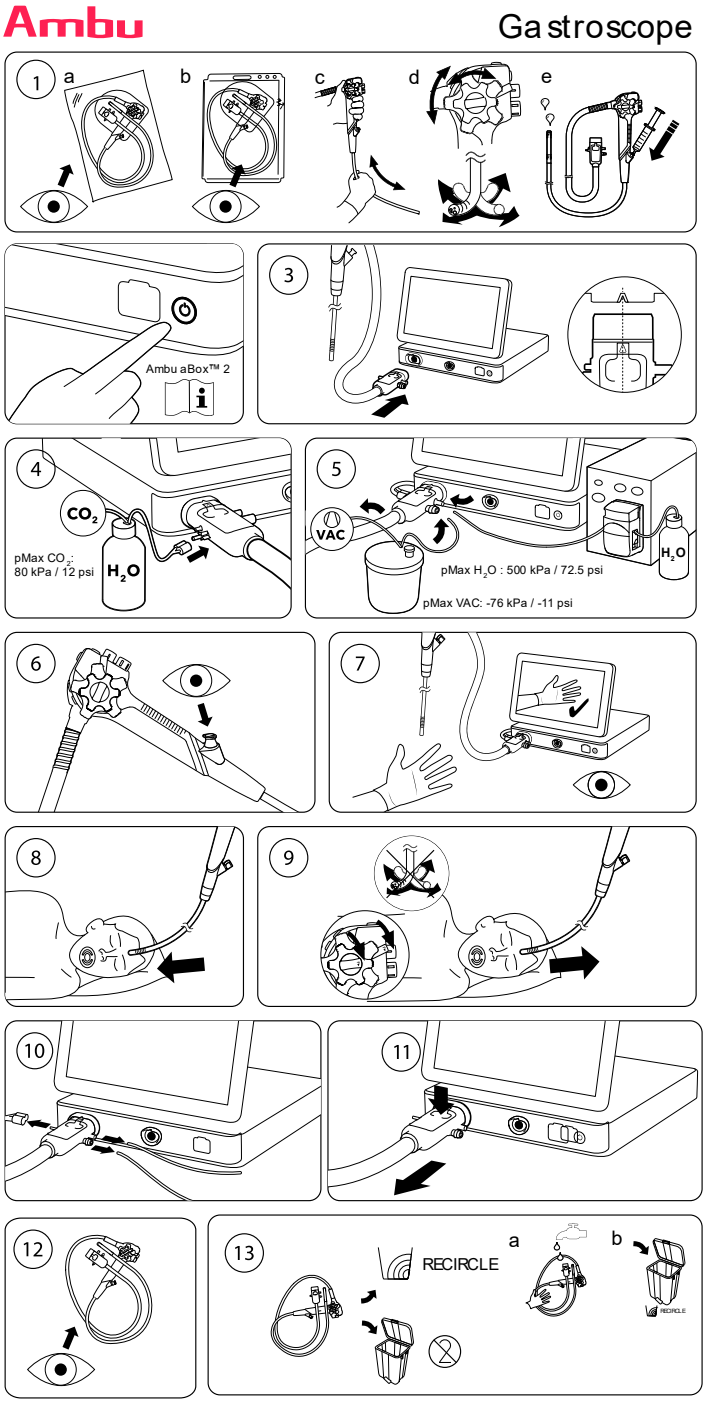

Figure 4.11 Modified instructions for the Recircle program – variation 1

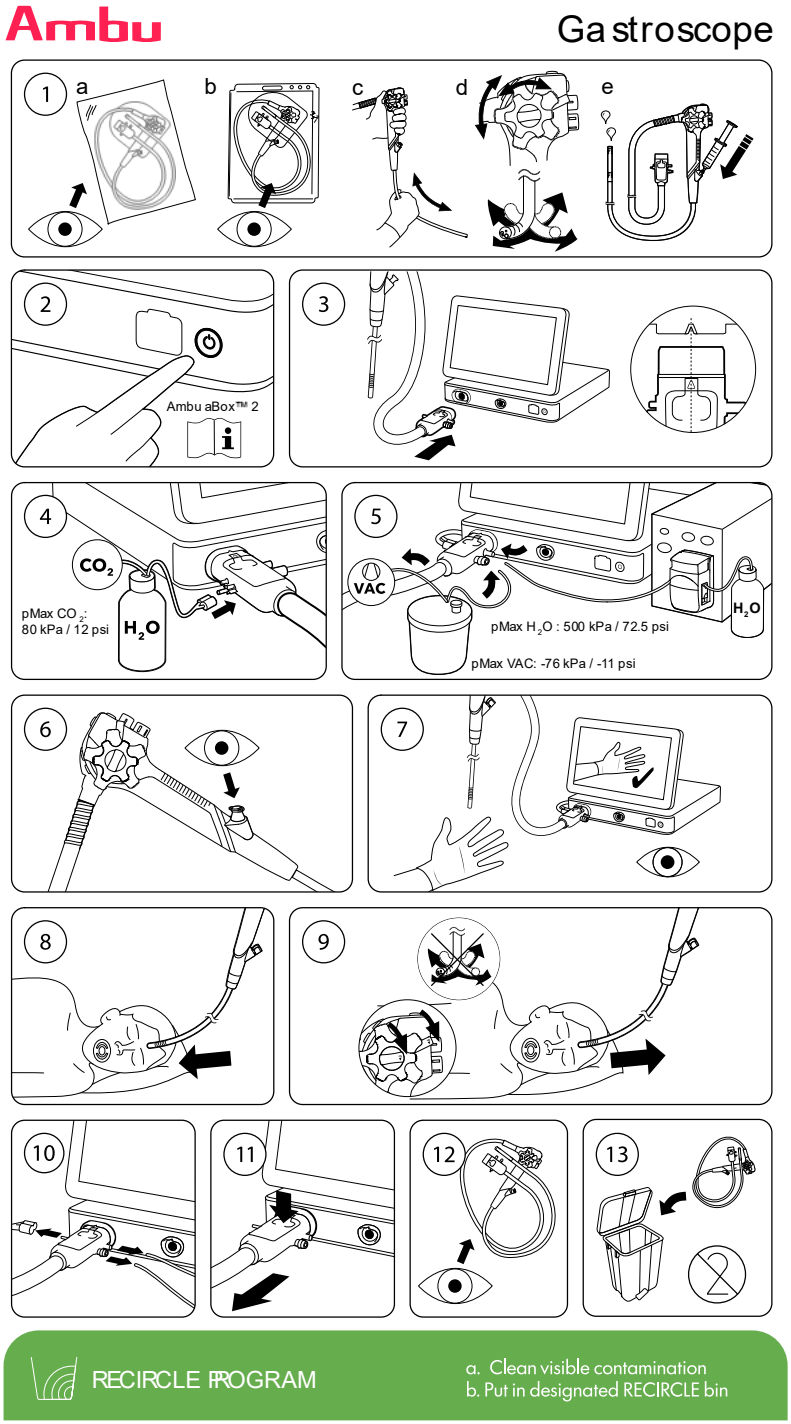

Figure 4.12 Modified instructions for the Recircle program – variation 2

4.4.3 Discussion

Using green for sustainability has a lot of cultural connections but could be considered a quite global phenomenon. Other branding touchpoints could have been explored, but as they did not concern the design of the packaging it was considered out of scope. The reason why ‘descriptive’ was put up against ‘Call-to-action’ was an interest in if the nurses are more intrinsically or extrinsically motivated to pursue a take-back program. The two variations of the IFUs were created to see how they would respond if a take-back program could be instructed in the normal procedures or if it was viewed as invasive.

5 First prototype

This chapter details the first prototyping stage. Evaluating the general shape of the primary packaging with its smaller footprint and its interaction with the secondary packaging was the major focus.

5.1.1 Method

Multiple miniature scale primary packaging prototypes were made from PU foam and cardboard with width and length determined by the footprint analysis and the side profile. The miniatures can be seen in Figure 5.1. Two prototypes of the secondary packaging were made from cardboard. One opened along the length and the other at the end. The height of the secondary packaging was chosen to be able to house six endoscopes stacked on top of each other, as determined in the concepting phase.

Figure 5.1 Miniature packaging concept

Following the small-scale prototypes, full-scale lo-fi prototypes were constructed out of cardboard, and a 3D-printed handle was added along the length of the primary packaging as seen in Figure 5.2.

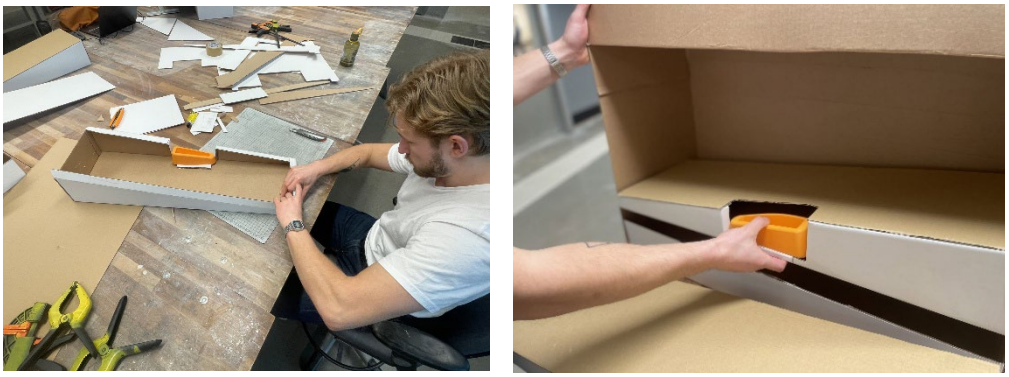

Figure 5.2 Making of full-scale packaging prototype

The lo-fi prototypes were evaluated through an early-stage usability test using the method Thinking Aloud (Nielsen, 1993). The objective was to gather initial impressions of the packaging's general shape and identify fundamental geometric or ergonomic design flaws before moving into higher-fidelity prototyping. The evaluation involved 10 employees recruited from the Ambu office. These employees all had prior knowledge of the current packaging and were aware of its existing shortcomings. While they are not the end-users, this internal group is familiar with the specific problems that nurses experience with the current solution. Therefore, they were well-suited to act as a proxy user group to evaluate the physical interactions of these early-stage concepts. During the interactions, the participants were prompted to continuously verbalize their thought processes regarding the handling, and any perceived points of friction that might arise. The test can be seen in Figure 5.3.

Figure 5.3 Informal user testing in Ambu's office

5.1.2 Result

The feedback gathered was quite varied but still gave a lot of insight into the continued development so the quotes are paraphrased below.

Paraphrased quotes regarding secondary packaging:

- "I would just throw that away and stack them" – talking about the cardboard box
- "It looks nice but a bit clumsy" – talking about the box with a larger opening
- "It is not hygienic to have the box standing on the floor of the storage room, this would not be allowed" – about the box with the opening at the top
- "I prefer this one because the other one is hard to remove" – about the one with the opening at the top, there was some friction between the primary and secondary when removing it from the other
- "I think removing the primary packaging from the secondary is more worrisome than the primary in itself" – about if they had any worries about the primary packaging
- "Not too large – not at all from what I have seen" – about the size of the boxes
- "It's much cleaner" – about the prototype compared to the current box

Paraphrased quotes regarding the primary packaging:

- “I like that you can grab it with one hand” – about the handle
- “The handle is really easy to grab” – about the handle
- “I prefer the new concept, it’s nice because there are fewer parts so it’s easier to throw away” – about the concept compared to the current packaging
- “The current packaging looks old” – about the current primary packaging
- “The rigidity makes it feel more compact” about the concept

5.1.3 Discussion

Although some preferred the box with the opening at the top, it was clear that we would not be able to continue with its development as it was deemed unhygienic as everything needs to be off the floor so that it could be cleaned. This decision was also strengthened during our visit to Kungälv where they had modified Ambu packaging for hanging on the wall, something that would not be possible due to the size of the GI endoscope. During the testing there was a lot of friction when trying to get out the primary packaging from the secondary with the sideways opening. This was something that we realized while making the prototype and had to be addressed by having more forgiving tolerances. The formfactor of the wedge was largely accepted, described as feeling compact and modern compared to the current solution. The wedge as a primary shape was adopted for both later prototypes as it fits the geometry of the endoscope quite well, but more primary shapes could possibly have been tried. The handle was also a welcome addition.

6 Second prototype

This chapter details the second prototyping stage. Evaluating the SBS of primary packaging in terms of usability, testing recycling signifiers and evaluating branding touchpoints was the primary focus.

6.1.1 Method

The first goal of the second generation of prototypes was to evaluate the nurse's experience of utilizing packaging with different SBS in a simulated clinical environment. The three systems to be evaluated were:

- Single sterile barrier (Blister Tray)
- Single sterile barrier with protective packaging inside (Inner tray)
- Single sterile barrier with protective packaging outside (Outer tray)

During the prototyping stage, multiple variants were created at different sizes, with different materials and different methods. The opening mechanism for each sterile barrier was made reversable for the sake of repeatably during the testing. The Product Usability Evaluation from chapter 2.5.3 while repurposing the User Journey from section 3.3. Three hypotheses were developed.

1. The SBS makes a difference in the storage and transport (Based on steps 1.1 to 1.2 in the user journey)
2. The SBS makes a difference in the ease of access to and preparation of the endoscope (Based on steps 1.4 to 2.2 in the user journey)
3. The SBS makes a difference in the ease of recyclability and disposal (Based on step 2.4 in the user journey)

The participants were taken through the entire user journey with the three packages on display on a table for the participant to interact with. The participants were asked to go through steps 1.1 to 2.4 of the user journey, and the researcher would stop them to ask which of the packaging concepts they would prefer and why during each step.

The second goal was to understand step 2.4 in terms of the recyclability of the current packaging and if the signifiers developed in section 4.2 would aid the nurses. This was done by letting the nurses have a look at the packaging and giving them one of the diagrams to describe how they would recycle the packaging. The number

of correctly sorted items and time were recorded. They were told to verbalize their thinking during the task to gain insight into their decisions.

The third goal was to evaluate the branding touchpoints from section 4.3, if they served their intended purpose, if so, how well, and if they were acceptable by the nurses. The secondary packaging was evaluated by showing the original next to one of the Recircle boxes, asking how they differed and what the Recircle box was trying to promote. Then they were asked if they usually reflect on the sustainability of the products they use during work, how it affects them, if the branded box would pique their interest, and if they would use a QR-code to get more information about the program. Lastly, they were shown one of the Recircle versions of the instruction sets to see if they could tell the researchers how to prepare an endoscope for the Recircle program, and their thoughts on its inclusion on the primary packaging.

The testing was conducted in a room at the ICU unit at Kungälv hospital, which ensured the approximate ecological validity. Cameras were stationed for recording the sessions.

6.1.2 Result

Three nurses participated in the usability evaluation and the following were captured.

SBS Usability Evaluation (Hypothesis 1 - The SBS makes a difference in storage and transport)

Participants noted that space is rather limited both in the ICU and OR. They all confirmed the necessity for stacking endoscopes for this reason. During storage stability, sturdiness and compactness were mentioned multiple times as desirable. When all nurses were asked which concept was preferred for overall storage, the blister tray was preferred over the pouch, and pouch over the outer tray due to the size difference they perceived. The outer tray was seen as overly large and the blister as compact. When it came to stacking the outer tray with its simpler geometry was perceived as the best followed by the blister tray and lastly the pouch which was thought to be hard to stack due to the lack of rigid surfaces.

Some nurses noted that they would like to use a cart when transporting the equipment for the procedure when considering the different SBSs. One nurse appreciated the ability to transport similar products by hanging it in a portable IV pole. The outer tray was considered a bit cumbersome to carry by hand, some suggesting that they would prefer a trolley. Another said that they would prefer to transport it in its packaging carrying everything in their hands if they do not carry too many things.

SBS Usability Evaluation (Hypothesis 2 – The SBS makes a difference in the ease of access to and preparation of the endoscope)

One major point of interest was whether the nurses transporting the endoscope by cart would like a solution where they would start to prepare the procedure with the different packaging still hanging on the cart. As it turned out most nurses did not find this useful in any case and would rather prepare the endoscope on a table. The major concern was the uncertainty about if anything would fall out and the possibility of contamination.

There was no concern for aseptic presentation when preparing the GI endoscopy with any packaging. The performance difference seen between the different systems was speed. The blister tray was described with words like “fast”, “frictionless” and “nice” to use by all nurses. Its smaller size made it possible to open it without overextending one’s arms. The rigidity of the tray could support the workflow by replacing other working surfaces. For the pouch it was thought of as alright, the tabs located along the insertion tube and connector were a pain point for most and described as “fiddly”. The overall structure was considered flimsy by some prompting them to remove it from their workstation as fast as possible.

SBS Usability Evaluation (Hypothesis 3 – 3. The SBS makes a difference in the ease of recyclability and disposal)

The participants were not all in agreement about which was the easiest packaging to discard. Nurse 1 thought that the blister tray was the easiest to sort and dispose of because it had the smallest number of parts and that the inner tray is overly complex and has excessive amounts of plastic. Nurse 2 thought that the inner tray was easier to sort and dispose of due to the ease of which they could compress it, although they assumed that Tyvek is paper and would sort it incorrectly. Nurse 3 thought that the blister tray was the easiest to sort and dispose of because of its size as she usually saves all of the trash on a cart and disposes of it afterwards making smaller pieces of trash desirable.

Two nurses participated in the testing of recyclability signifiers and branding touchpoints.

Recyclability signifiers

Neither signifier performed significantly well. The noncolored one got 3/6 items sorted correctly while the colored one got 4/6 with a similar time of around one minute. The nurse who got the uncolored one said that color coding would have helped her.

Recircle branding touchpoints

For the touchpoints of the secondary packaging the intent was to improve the program’s salience and inform about the program. The responses from the nurses about what the packaging was advertising were mixed and met with skepticism about green washing as well as a general understanding that it had to do with recycling and sustainability. The use of more descriptive terms was preferred over an call to action. They described a general frustration with medical products and a

lack of influence in hospitals on systems that are not built for recycling. Everyone said that they often reflect on the sustainability of the products they use during procedures. For the IFU, variation 1 was more effective at describing what the nurses had to do to prepare the endoscope as it is more integrated. This was not something that the nurses found intrusive and wished the regular IFU to also instruct cleaning of the endoscope. Variation 2 was seen as an ad, was overlooked and the steps to prepare the endoscope for takeback was not transferred.

6.1.3 Discussion

The double sterile barrier system was not evaluated as it did not appear during the competitive analysis and only adds complexity and material usage.

The prototypes for the single barrier system and the outer protective barrier system used different materials, vacuum formed PETG for the former and 3D-printed PLA for the latter and may therefore not have been complete representations of their respective SBS. Using the same material for all SBS would have made the comparison fairer. The outer protective barrier system was quite a lot heavier than the single barrier system because of the material choice and might have affected the nurses in their responses about hanging and carrying the packaging. Considering this, it was clear that the nurses preferred the single barrier system for its compactness and lower weight.

When it comes to disposing of the packaging the single barrier system was preferred by two out of three nurses due to having fewer components. In the case where the nurse preferred the inner protective barrier system it was due to the fact that it could be compressed. If the single barrier system could be compressed, for example by folding it along an intentional groove in the packaging, all nurses might have preferred the single barrier system.

A major limitation with the testing was the availability of participants. It is hard to draw any clear conclusions with two participants. One thing you might say is that the signifier's effectiveness did not improve the sorting accuracy for these two nurses. Efforts to improve the sorting accuracy through other affordances like for example making it so that the materiality of a material like Tyvek is not confused as paper by replacing it with paper could be more effective although signifiers should be more thoroughly tested. The same goes for branding touchpoints. Some conclusions you might draw are that some nurses are skeptical about branding touchpoints that try to come off as overly green although it was effective at communicating its intent. It seems like nurses already have intrinsic motivation to work greener which might be why descriptive touchpoints are preferred. The IFU should not come of as an ad, otherwise it loses its purpose.

7 Refinement

This chapter will detail the refinement of single sterile barrier system packaging, from material selection to final usability, environmental, and

7.1 Method

7.1.1 Material selection

As discovered in the competitive analysis, one way to significantly improve the sustainability of the packaging is to reduce the number of components and number of materials used. Another way of potentially improving the sustainability is to change the materials of the packaging. The single barrier system, found to be the superior choice from a UX perspective while also consisting of the fewest number of components, is made out an impermeable blister tray and the permeable blister film. The current packaging uses PET for its tray and Tyvek as the permeable material of the pouch. These materials were used as baseline for DfE and DfM when exploring alternative materials.

Once the material baseline was established, an exploration into materials for the tray and materials for the film was conducted. The following criteria were considered when determining the viability of the materials. The criteria were gathered from chapter 2.4.

Table 7.1 List of criteria for material exploration

Criteria	*Part*
Replace petrol-based plastics	Tray, Film
Be intuitive to sort	Tray, Film
Not compromise the safety of the patient	Tray, Film
Resist environmental factors	Tray, Film
Reduce residue	Tray, Film
No CMR materials	Tray, Film
Remove risk of ingress	Tray, Film
No composites	Tray, Film
Ensure recyclability	Tray, Film
Prevent puncture	Tray, Film
Permeable (EtO)	Film
Suitable for film manufacturing methods	Film
Impermeable (EtO)	Tray
Suitable for tray manufacturing methods	Tray
Compatible with sealing method and second material	Tray, Film
Avoid phthalates	Tray, Film

Another important factor was market availability and feedstock. Therefore, the exploration was conducted through commercial search engines and looking at material options offered by several medical device packaging manufacturers. A consultation on permeable medical paper with a sales representative of a producer of fiber based medical products was held to gain a deeper understanding of the paper's compatibility with different tray materials. Using the identified materials, two different configurations, in addition to baseline, were constructed with appropriate sealing methods. The materials were not chosen in isolation but in relation to the second material, manufacturing method, and sealing method.

7.1.2 DfM

A DfM procedure based on Fabricius Seven Step Procedure for Design for Manufacture (1994) was conducted on the three different variants. The evaluation parameters used for the competitive analysis formed the basis as they support the main DfM objective of lowering the cost of the packaging without making manufacturing more complex. The parameters "Number of components" and "Number of assembly steps" were removed since they are the same across all three

variants. Instead, feedstock availability and innovation were added to reflect the risk for each of the concepts. Below are the evaluation parameters used:

- Material cost (USD)
- Weight (g)
- Current process capability (%)
- Feedstock availability (metric tons per year)
- Innovation (1-3)

7.1.3 DfE

For the evaluation of the environmental impact of the material variants of the blister tray, the Fast-track LCA methodology was applied again. Certain assumptions had to be made about the eco equivalent of the production of the fiber-based products.

After the eco intensity in $kgCO_2e$ was summarized, the resulting comparison between the variants was compiled using a normalized impact unit due to confidentiality.

7.1.4 Product Usability Evaluation

The goal of the final user evaluation was to identify if the concept supported the user journey steps and if not, how it could be optimized to do so. The participants were gathered from the European Society of Gastrointestinal Endoscopy days in Milan 2026. These nurses were considered to be representative of a range of stakeholders from across the world giving an accurate view of how the concept would fare. The test was constructed based on the Product Usability Evaluation from chapter 2.5.3 and consisted of a task and follow-up questions for the steps of the user journey. The responses from the nurses were recorded as audio and their behavior was noted and written down by one of the test facilitators. The test used the final prototype of the primary and secondary packaging, as well as posters showing different material options for the primary packaging. The following topics were tested:

- Storage location of current SUDs
- Reflection on the new packaging in terms of storage/stacking
- Transporting method
- Thoughts on carrying it by hand
- Hook integration in cart/tower
- Unpacking location and reflection
- Preparing procedure – step order
- Additional use of packaging (sterile working area, water, lube)
- Disposal method

- Waste sorting practice
- Reflection on waste production
- Alternative material variants

7.2 Result

7.2.1 Material selection

Material exploration generated the following material variations. The baseline uses PET for the tray and Tyvek for the film. The tray is transparent, allowing the user to see the endoscope without opening the packaging.

The variant A is based on medical grade paper and medical grade paper pulp to eliminate the use of plastic. Through talks with producers, this solution would require a plastic sealing layer. The sealing remains as residue on both the film and tray after opening the packaging, but since the amount of plastic is very small, both the pulp and tray can be recycled as paper in most paper recycling mills. Using molded fiber and medical paper results in opaque packaging, meaning the endoscope would not be visible to the user before opening the packaging.

Variant B also uses medical grade paper for the film. The need for a sealing layer during heat-sealing could be negated when using medical paper by choosing the right thermoplastic tray material. This material has a smaller carbon footprint than PET, is widely recycled and has bioplastic alternatives. This results in packaging with a transparent tray, though the clarity is not as good as for PET, meaning that the user would be able to see the endoscope without opening the packaging.

7.2.2 DfE

The following figure shows the normalized carbon dioxide equivalent.

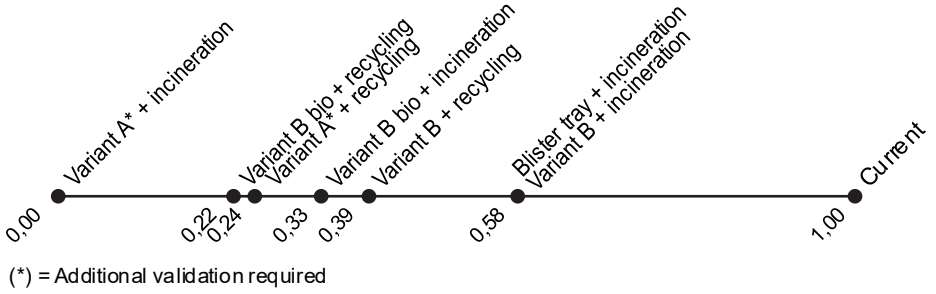

Figure 7.1 Normalized carbon dioxide equivalent

7.2.3 DfM

The values for material cost and weight of the packaging have been normalized due to confidentiality. The feedstock availability refers to the tray material.

Table 7.2 DfM criteria for the different variants

Variant	*Normalized Material Cost*	*Normalized Weight*	*Process capability (%)*	*Feedstock availability (million metric tons/year)*	*Innovation (1-3)*
Baseline	1	1	100	0.58	1
A	0	0.44	0	1.94	3
B	0.79	0	50	0.59	2

7.2.4 Usability evaluation

The usability evaluation done at ESGE in Milano confirmed that the user journey presented earlier in this report is mostly correct. Some of the variations in how the nurses solved the tasks were probably due to the different types of nurses taking part in the testing; endoscopy nurses, OR nurses and ICU nurses. A total of 18 nurses conducted the test.

Table 7.3 Usability evaluation results

Topic	*Result*
Storage of current SUD and comparison with new packaging	Almost no nurses see any issues in storing the new packaging in their existing storage systems. All nurses thought that the new packaging was a big improvement in terms of storage. Nearly all nurses would feel comfortable stacking the packaging without fear of damaging the endoscope.
Transporting method	The nurses use different modes of transportation when bringing the endoscope from storage to its point of use which the new packaging allowed for.
Carrying by hand	The nurses prioritize ergonomics over established methods of carrying by hand, as long as the safety of the endoscope is not jeopardized.
Hook integration in cart/tower	The possibility of hanging the packaging was appreciated by the nurses, giving them an alternative way of transporting the packaging.
Unpacking location	The unpackaging location of the endoscope for all nurses is at the location of the procedure.
Preparing procedure	All nurses thought that it was easy to open the packaging. Some nurses wanted more distinctive signifiers. Most nurses thought that the layout of the endoscope in the packaging supported their workflow.
Additional use of packaging	About two thirds of nurses would use the packaging for additional purposes if it supports their current workflow.
Disposal method	The size of the packaging is an obstacle for most nurses when it comes to disposal. A portion of nurses work at hospitals were recycling is not standard practice.
Reflection on waste production	Most nurses thought that the packaging generates a large amount of waste, but only a few thought that it was an unnecessary amount.
Alternative materials	The highest priority for almost all nurses when considering material options was sustainability and recyclability. Very few nurses had a problem even with opaque packaging if it meant that it was more sustainable.

7.3 Discussion

7.3.1 Material selection

The lack of more rigorous literature study into materials makes the representation of solutions limited to more commercial ones rather than ones found in research contexts. In the list of requirements, there are certain requirements that are conflicting. The inclusion of recycled material in primary packaging and the exclusion of CMR materials is a contradiction when it comes to PCR streams. The lack of traceability in PCR stocks makes it hard for the producer to ensure that no CMR materials are included. Other recycling streams like chemical recycling could potentially close this gap in the future.

Using the same materials as in the current packaging guarantees 100% process capability. The possibility to change from PET to bioplastic in the form of 30% MEG or PEF would not affect the process capability as the characteristics and manufacturing methods as they are essentially the same as for PET. However, at this moment the material stocks for both types are based on first generation sources like sugar cane and have a larger impact on the environment than petrol-based alternatives (Nessi, et al., 2022). The use of Bio-Pet incurs a premium of about 10-15% compared to traditional PET used in the current packaging. As the continued development of bioplastics will potentially unlock commercially viable second-generation bio-PET, Ambu might need to monitor when it is viable to do the change. Because a sealing layer is needed to adhere the Tyvek to the PET, the tray can't be mechanically recycled as it contains two different plastics bonded together.

Variant A

Not seeing the endoscope without opening the packaging puts a greater emphasis on clear labeling that makes it easier to identify the type of endoscope. The use of molded pulp fiber for such a large tray might result in problems with structural integrity, as it is normally used for smaller sized containers. Adding structural elements such as ribs and increasing the thickness of the tray is likely to decrease this problem, but would also increase the cost of manufacturing, material cost and environmental footprint.

There are currently no companies that offer a medical molded fiber tray with a medical paper film for EtO sterilized devices. The individual components and techniques to produce such packaging exist, but a proof-of-concept in the form of an actual prototype remains to be produced and tested for shelf life and stability.

Variant B

Using this thermoplastic material instead of traditional PET for the blister tray incurs a small premium. It in combination with medical paper means that no additional sealing layer is needed, which makes the tray recyclable, greatly reducing the carbon footprint. The medical paper, even though it contains small amounts of plastic, can be recycled through hydrolyzation, making the whole packaging recyclable.

7.3.2 DfE

The fast-track LCA shows that Variant A, by using low impact materials, comes out as the sustainable alternative. A reason why incineration is less impactful in this case could be that it replaces the fossil fuels that would have been used during the firing to generate electricity and that paper recycling is a more energy intensive procedure. It is also clear that Variant B should be used if it is possible to ensure recycling, otherwise it is just as impactful as a standard blister tray because of its relatively high EoL emissions. If it is possible to source second-generation bioplastic thermoformable films for Variant B for a reasonable price, it should be

implemented. There are large assumptions and uncertainties with this analysis, and it should be viewed as an initial look into the sustainability of material variations.

7.3.3 DfM

The material costs are very rough estimates as the information on these subjects is mostly proprietary and handled B2B. The costs for the different thermoplastic materials were estimated using the price of the thermoplastic materials in the current packaging and comparing their raw material price to the raw material price of plastic materials used in packaging variants. The cost of the biobased materials was estimated using the raw material price of virgin wooden fibers, which is why variant A has a significantly lower cost. This is, however, a very rough estimate and therefore it should be seen as an option with potential in terms of cost, rather than a definitive truth. The costs are also very dependent on location, as is the availability of feedstock. The information about feedstock availability in Malaysia, where the packaging is produced, was taken from credible sources such as the World Bank and the Malaysian government. It only considers the tray material as this makes up an overwhelming majority of the product and because Tyvek is a proprietary product that must be imported, making feedstock availability irrelevant.

The DfM analysis shows that variant B is the better choice compared to baseline. It is, however, more difficult to determine how variant A compares to B and baseline. It could be significantly cheaper, though that is uncertain, but it is much heavier and requires a lot of new machinery to be produced. It is also a novel concept that hasn't been tested before, making it a big risk. To determine a possible economic advantage to variant A, producers would have to be consulted.

7.3.4 Usability evaluation

Most nurses have sustainability as their top priority when using SUDs. They were willing to sacrifice some UX and usability gains if it reduced the environmental impact, but they were not willing to accept a performance decrease in terms of protection of the endoscope and patient safety. A lot of nurses were, for example, willing to accept opaque packaging, which is uncommon in the field of SUD, if it meant that the packaging could be made from more sustainable materials.

The design features implemented that didn't fundamentally change the nurse's current workflow were highly appreciated. Some features, like using the packaging for additional purposes and hanging the packaging on a cart, received positive feedback when it could be easily integrated into the existing workflow. In the other cases, the nurses were not willing to change their workflow to make use of the new features. This highlights the importance of balancing innovation and familiarity and designing packaging that doesn't require the nurses to make big changes to their

workflow. However, the design features implemented didn't prevent any of the nurses from following their current workflow, they just choose not to make use of the features in some cases.

One thing that was made even more clear during the testing is the big impact that the footprint of the packaging has. The dimensions chosen for the final prototype is optimized for palletization and compatibility with shelving and cabinets. It was also discovered during testing that a shorter and wider footprint is superior from a UX perspective, specifically regarding ease of carrying and opening. However, many nurses thought that the packaging wouldn't fit in their waste bins due to it being too wide, and it also uses more material compared to a longer and narrower footprint, which was discovered during concepting. One way of solving the disposal issue could be to include a folding mechanism, enabling the user to easily fold the packaging before putting it in the bin. That might decrease the structural integrity of the packaging tough. Further research is required to find out if that is a viable solution. Some nurses were afraid that plastic packaging would not get recycled even if it was recyclable.

8 Discussion

This chapter will interpret the results from previous chapters and bring some insights into each research question.

8.1 Results

8.1.1 RQ1

How can medical device packaging be designed for recyclability and sustainability, while maintaining sterility, resulting in decreased waste and carbon dioxide equivalent?

Conventional manufacturing methods are currently able to produce packaging that is entirely mechanically recyclable, sterile, while not needing excessively carbon intensive processes. Throughout the results of the thesis the main concern of the user is sustainability. The working assumption that familiarity and innovation in SUD packaging are factors to be balanced in terms of sustainability does not align with the results but could still hold true for other aspects of the packaging and the device itself. As patient safety and protection of the device were non-negotiable to the user, limiting the competitive analysis to proven SBSs seemed to be the right decision. However, as the user does not seem to concern themselves with performing aseptic presentation it is possible that future works will reconsider patient safety and protection of the device by not sterilizing the device and finding alternative ways of ensuring safe procedures. The nurses' concern for the EoL scenarios is not unfounded. As is seen in the last DfE analysis, recycling has a major effect on the environmental impact. If the medical waste management infrastructure does not allow nurses to recycle then it might be worth investing in packaging that is incinerable without a large climate impact. If the use of plastic is the only viable option, second generation bioplastic alternatives should be considered as first generation bioplastics like PET does not see the same sustainability gains.

8.1.2 RQ2

How can packaging affordances and signifiers increase sorting accuracy in high-stress clinical environments, e.g. the OR resulting in increased recycling?

The current packaging is very complex, and nurses felt like signifiers did not help with sorting accuracy. This should be studied quantitatively to gain more certainty about signifiers' usefulness. However, it is possible to avoid confusing materials that consistently get sorted incorrectly and overall simplify the packaging by using a single sterile barrier with no additional protective layers. Composite plastic packaging should never be sorted as plastic as it ruins the possibility of effective plastic recycling in hospitals as it worsens the quality of the recyclate. If this cannot be communicated through signifiers then the use of composite plastics should be avoided to help bring forth the second scenario in Figure 8.1.

8.1.3 RQ3

How can packaging design support take-back systems in hospital settings making it easier to separate waste streams?

Branding touchpoints on primary and secondary packaging was an overall neutral addition to the packaging concept. Nurses care a lot about sustainability and supplying them with actionable information about take-back programs that do not overpromise its effectiveness could be implemented without much objection. If the end-goal for both Ambu and nurses is to create a closed system, then user centric marketing could create grassroots pressure at hospitals to adopt the program without the use of ambassadors. One caveat is if nurses enquire about the program and there is no possibility of enrolling. There should always be some sort of possibility to show interest in the program.

8.2 Limitations

During the analysis phase, one major limitation was the solution space that was explored as well as the depth of each analysis. Briefer analyses were required to be able to iterate more on the solution. It is important to be thorough in the analysis of each of the possible solutions, but a compromise had to be made balancing the depth of the analyses and achieving a moderately high-fidelity prototype.

During the project we had limited access to the primary user, which was a major limitation during early development. This led to very late discoveries that could have informed earlier concept development. The project was also limited in terms of access to prototyping capabilities which led to design decisions that were based

on the available tools and manufacturing methods which had a definite impact on the result.

8.3 Relevance for sustainable development goals

The most evident stride this thesis has made towards SDG 12 is the optimization of material use that does not negatively impact the user's workflow. For SDG 13, considering low impact materials as a new direction for SUD packaging has a lot of potential for decoupling Ambu's possibility of climate action from the development and adoption of waste management regulation and recycling technologies.

8.4 Ethical considerations

The size of the 600 x 400 mm footprint was inclusive enough to the degree that during the user evaluation, the size of the person did not indicate whether or not they would have a positive experience opening the packaging. This could indicate that the development overcame the physical biases present during the development of the packaging. There is no indication that anyone has been or will be harmed by the development of the packaging concepts laid forward. Consent forms and proper documentation have been used, and participants have been informed of the purpose of the study beforehand.

8.5 Further development

In the figure below three different scenarios are presented. With the current state of medical waste management there is no clear path towards standardization of practice that ensures that the ~30 composite packages per procedure gets recycled. In the most pessimistic scenario where medical waste management does not improve and chemical recycling does not see worldwide adoption with ecological and economic viability, the development of low impact incinerable packaging could be a way of circumventing external factors of which Ambu has little control. This would entail making a more exhaustive LCA that confirms the sustainability gains of such packaging, producing a prototype, and performing testing to ensure MDR/CFR conformity and stable shelf life. Else, if companies like Ambu are at the forefront of completely recyclable packaging with no composites, this would ease hospitals' burden when managing waste. There is still a need to fix the proximity and time pressure issue that OR nurses experience which makes them inclined to dispose of packaging as general hazardous waste. Preemptively switching to a mechanically

recyclable packaging could be a worthy investment as it is synergetic with the adoption of better waste management practices.

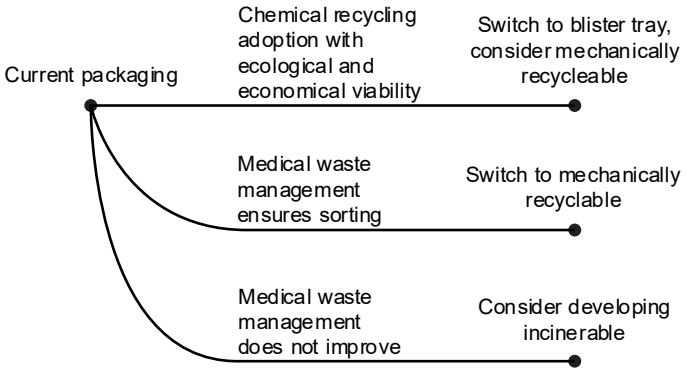

Figure 8.1 Development scenarios

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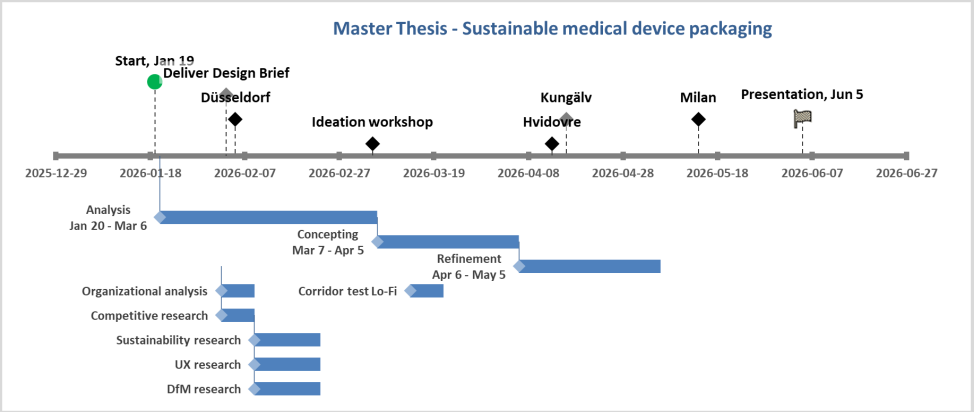
Appendix A Work distribution and time plan

A.1 Work distribution

The work distribution was as evenly as possible with all external factors considered. Most activities were done together the only deviations were the following. During each evaluation, Henriksson was responsible for the DfM analysis and Liljegren performed the DfE. During the prototyping stage Henriksson was responsible for the external protective barrier while Liljegren was responsible for the blister tray.

A.2 Project plan and outcome

The following is the project plan; it is somewhat representative of the real product development course although some alterations have been made. If the development had been faster there were hopes of being more in contact with manufacturers, but then the foundation for the concept would have been lacking.



Appendix B Recycling analysis

This is the analysis performed for 2.2 Competitive analysis

Solution A

Part	***Material***	***Connection method***	***Mounted to***	***Recyclability***
Tyvek film	Plastic	Heat sealed with surface treatment	Plastic film	Chemical
Plastic film	Plastic	Heat sealed with surface treatment	Tyvek film	Chemical
Mounting card	Plastic	(None)	(None)	Mechanical
Tray lower	Plastic	Friction fit	Mounting card	Mechanical
Upper tray	Plastic	Friction fit	Lower tray	Mechanical
Endoscope	Composite plastic	Friction fit, Hook	Trays, Mounting card	Hazardous waste

Solution B

Part	***Material***	***Connection method***	***Mounted to***	***Recyclability***
Tyvek film	Plastic	Heat sealed with surface treatment	Lower tray	Chemical
Lower tray	Plastic	Heat sealed with surface treatment	Tyvek film	Chemical
Endoscope	Composite	Friction fit	Lower tray	Hazardous waste

Solution C

Part	*Material*	*Connection method*	*Mounted to*	*Recyclability*
Tyvek film	Plastic	Heat sealed with surface treatment	Plastic film	Chemical
Plastic film	Plastic	Heat sealed with surface treatment	Tyvek film	Chemical
Mounting card	Plastic	(None)	(None)	Mechanical
Tray lower	Plastic	Friction fit	Mounting card	Mechanical
Upper tray	Plastic	Friction fit	Lower tray	Mechanical
Endoscope	Composite	Friction fit, Hook	Trays, Mounting card	Hazardous waste

Solution D

Part	*Material*	*Connection method*	*Mounted to*	*Recyclability*
Tray	Molded Paper	(None)	(None)	Paper recycling
Lid	Molded Paper	Friction fit	Tray	Paper recycling
Tyvek film	Plastic	Heat sealed with surface treatment, Friction fit	Plastic film, Molded pulp	Chemical
Plastic film	Plastic	Heat sealed with surface treatment, Friction fit	Tyvek film, Molded pulp	Chemical
Endoscope	Composite	Friction fit	Tray	Hazardous waste

Solution E

Part	*Material*	*Connection method*	*Mounted to*	*Recyclability*
Case	Cardboard	(None)	(None)	Paper recycling
Tyvek film	Plastic	Heat sealed with surface treatment	Plastic film, Molded pulp	Chemical
Plastic film	Plastic	Heat sealed with surface treatment	Tyvek film, Molded pulp	Chemical
Endoscope	Composite	Friction fit	Tray	Hazardous waste

Solution F

Part	*Material*	*Connection method*	*Mounted to*	*Recyclability*
Tyvek film	Plastic	Heat sealed with surface treatment	Plastic film	Chemical
Plastic film	Plastic	Heat sealed with surface treatment	Tyvek film	Chemical
Mounting card	Plastic	(None)	(None)	Mechanical
Endoscope	Composite	Friction fit, Hook	Mounting card	Hazardous waste