Stryker Sustainability Solutions

Comparative Carbon Footprint of Reprocessed Single Use Medical Devices

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Date: May 26, 2023

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We exist to shape a more productive and resilient world by helping organizations transition to new models of sustainable performance.

Our team combines broad and deep sustainability expertise with the commercial and operational capabilities it takes to conceive and deliver real change.

Comparative Carbon Footprint of Single Use Medical Devices.

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Analysts:	**Report version:**
Joris Deschamps, Senior LCA Consultant	V2.1 – Response to critical review V2.2 – Naming convention for devices was adjusted post-review V2.3 – Editorial review, re-approval from the critical review committee.
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Abbreviations and acronyms

CFP	Carbon footprint of a product system
CO_2	Carbon dioxide
FDA	U.S. Food & Drug Administration
D&C	Decontamination and Cleaning
GHG	Greenhouse Gas
GWP	Global Warming Potential (in general in g or kg of CO_2 eq)
IPCC	Intergovernmental Panel on Climate Change
ISO	International Organization for Standardization
I&P	Inspection and Packaging
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
MJ	Mega Joules
PCB	Printed Circuit Board
PCR	Product Category Rules
PFD	Process Flow Diagram
SUD	Single-Used Device
US	United States of America

1 Goal and scope definition

1.1 Background

Stryker Corporation is a publicly traded American multinational medical technologies and medical device manufacturer. It is one of the world's leading companies in this sector with a presence in over 75 countries, 46,000 employees, and impacting more than 100 million patients annually. Within the company, Stryker's Sustainability Solutions division is responsible for the collection, inspection, cleaning, testing, sterilization, and packaging of over 21 types of medical devices for repeated, safe clinical use. It is currently the leading provider of reprocessing and remanufacturing services for single-use medical devices (SUDs).

Recognizing that their products, even reprocessed, have an environmental footprint, Stryker Sustainability Solutions has commissioned Anthesis LLC to conduct a comparative carbon footprint (CFP) of five reprocessed SUDs and their original manufacturing SUDs scenarios.

This study was performed following the principles described in the ISO 14067 standard for a publicly disclosed comparative assertion.

The following LCA practitioners from Anthesis were involved in this project:

- Joris Deschamps – Joris has been researching, and applying LCA to various products, sectors, and industries for the past five years. He is an engineer by training with an Applied Research Master's in environmental engineering.
- Caroline Gaudreault – With technical expertise in both LCA, and in the treatment of biomass in carbon accounting and goal setting, Caroline is the LCA Lead for North America. Prior to Anthesis, Caroline has more than 15 years' experience in LCA, GHG inventory, and forest/biomass carbon-related projects.

A product CFP is the sum of greenhouse gas (GHG) emissions and GHG removals in a product system, expressed as CO_2 equivalents and based on a life cycle assessment (LCA) using the single impact category of climate change. ISO 14067 defines the principles, requirements, and guidelines for the quantification of product CFPs. ISO 14067 is based on principles, requirements and guidelines identified in existing international standards on life cycle assessment (LCA), ISO 14040 and ISO 14044, and aims to set specific requirements for the quantification of a CFP. The principles, requirements, and guidance on communication of the product CFP are covered in ISO 14026. This report has been written to be consistent with the international standards for LCA and CFP notably ISO 14040:2006 and ISO 14044:2006, ISO 14067:2018 and ISO 14026:2017. ISO 14067 requires that where relevant Product Category Rules (PCR) or CFP–PCR exist, they shall be adopted. No relevant PCR is found that would apply to the products under study.

The report follows the required four-stage iterative LCA process below (and represented in Figure 1).

1. Goal and scope definition: The first stage of LCA is to define the goal and scope of the study, to understand the objectives and intended applications, the boundaries of what is being assessed and the performance requirement of the products.

2. **Inventory analysis:** The second stage is inventory analysis, where an inventory of flows to and from nature is created, usually using a combination of primary and secondary data collected for each unit process of the product systems.

3. **Impact assessment:** The third stage is impact assessment, which is where inventory data are applied to characterization factors to generate the main results and determine the environmental impacts.

4. **Interpretation:** The final stage is interpretation, which is where conclusions are drawn, sensitivity and uncertainty analyses are performed, and recommendations made.

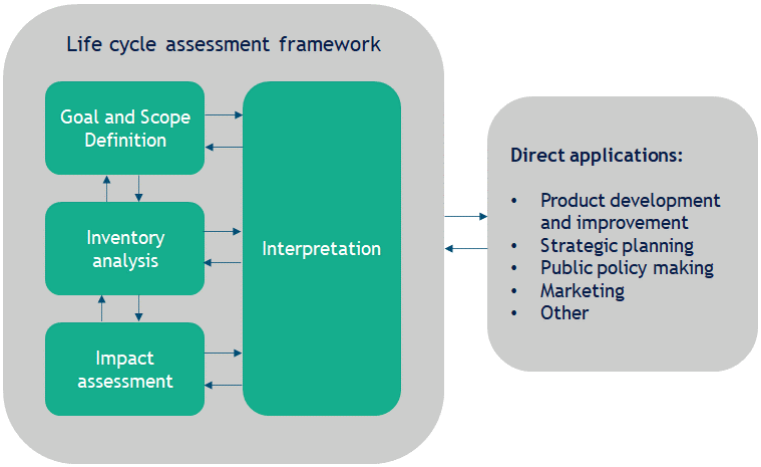

Figure 1 – The four stages of LCA as defined by ISO 14040

The LCA (and CFP) process is iterative, with feedback loops between the interpretation and all other stages of the LCA, as is the case in this study. Following the definition of the goal and scope in this LCA project, the project involves the development of Process Flow Diagrams (PFD) by Anthesis and Stryker jointly, in an iterative process. Then appropriate inventory data are gathered from Stryker and secondary sources to cover all unit processes within each product system. These inventory data are used to create a model, characterization factors are applied, and results are subsequently generated and interpreted.

1.2 Goals of the study

For each of the five devices under study, the goals of this study are to:

- Calculate the CFP of the reprocessed SUDs,
- Identify the life cycle carbon hotspots of a reprocessed SUDs,
- Calculate the CFP of the original manufacturing process for SUDs, and
- Compare the CFP of reprocessed and original SUDs.

The intended applications are to:

- Understand the carbon benefits and trade-offs of Stryker reprocessed SUDs and original manufacturing SUDs, and
- Help inform opportunities for environmental impact reduction for Stryker.

The intended audiences include a range of internal and external stakeholders, such as production engineers, development scientists, sales and marketing teams, and health care practitioners. The results are intended to support comparative assertions and may be disclosed to the public. Note that when communicated publicly, this report (or a version of this report) should be available as supporting information. A CFP is one of many environmental indicators and does not reflect overall environmental preferability.

1.3 Functional unit

In this study, reprocessed medical devices for single-use are compared with original single-use devices. The function of the product systems is, in each case, to provide the function of a single-use medical device, compliant to the relevant Food & Drug Administration (FDA) standard.

The functional unit quantifies the function provided by the product system and serves as a basis of comparison between systems, it is therefore an important factor. The functional unit for this study is defined as:

"Provide 1 medical device for single use, compliant to the relevant FDA standard, in the US."

The reference flow is one SUD (reprocessed or original).

In this study, reprocessed SUDs are considered functionally equivalent to original SUDs. This is supported by the 510(k) submission that has been validated by the FDA, which deemed the reprocessed SUDs under study as substantially equivalent to their original counterpart. [1]

1.4 Product systems descriptions

The five products under study (in their original and reprocessed version) are described in the following sections. They are the ViewFlex (D087031) originally manufactured by Abbott, the HARMONIC ACE +7 shears with advanced hemostasis (HARH36) originally manufactured by Ethicon, the LigaSure Exact Dissector (LF2019) originally manufactured by Medtronic, the MyoSure REACH (10-401FC) originally manufactured by Hologic, and the Max-A Pulse Oximeter (Max-A) originally manufactured by Nellcor.

[1] ViewFlex 510(k) submission: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K182238

HARH36 510(k) submission: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K202554

LF2019 510(k) submission: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220481

MyoSure 510(k) submission: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K201756

Max-A 510(k) submission: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K211138

1.4.1 ViewFlex

The ViewFlex catheter is a temporary intracardiac ultrasound catheter intended for use in patients to accurately visualize cardiac structures, blood flow and other devices within the heart when connected to compatible intracardiac ultrasound console. A picture of the device can be seen in Figure 2.

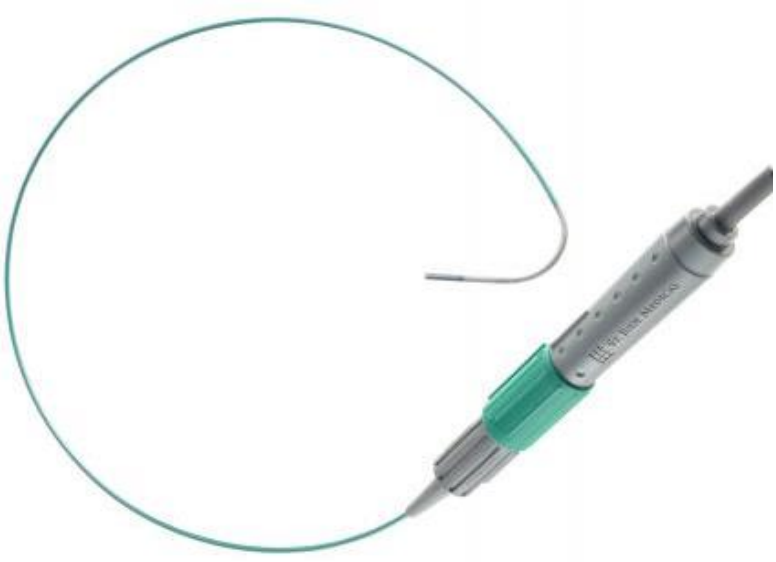

Figure 2 – Picture of the ViewFlex device

1.4.2 HARH36

The HARH36 is an ultrasonic shears. It is used for coagulation and transection of vessels up to 5 mm, and can handle multiple surgical jobs such as dissection, sealing, transection and otomy creation. A picture of the device can be seen on Figure 3.

Figure 3 – Picture of the HARH36 device

1.4.3 LF2019

The LF2019 is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics in desired. The device can be used on vessels (arteries and veins) up to 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic and reconstructive. A picture of the device can be seen on Figure 4.

Figure 4 – Picture of the LF2019 device

1.4.4 MyoSure REACH

The MyoSure Tissue Removal Device is a hand-held unit which is intended for hyteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue, including submucous myomas, endometrial polyps and retained products of conception. It connects to a control unit via a 6-foot flexible cable. There are different models of the device depending on the characteristics of the treated pathology, from the smallest to the largest, the MyoSure LITE, the MyoSure REACH and the MyoSure XL. This LCA is based on the MyoSure REACH, as it is the most reprocessed model. A picture of the device can be seen in Figure 5.

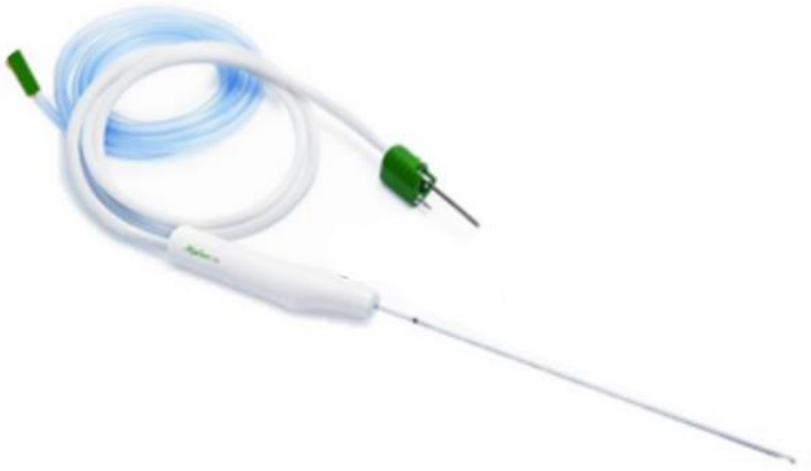

Figure 5 – Picture of the MyoSure Tissue Removal Device

1.4.5 Max-A

The Max-A in a pulse oximeter sensor intended to perform a non-invasive continuous monitoring of arterial blood oxygen saturation and heartbeat. A picture of the device can be seen on Figure 6.

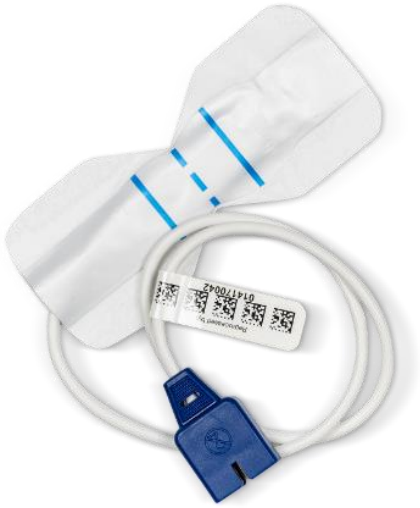

Figure 6 – Picture of the Max-A device

1.5 System boundaries

The system boundary of this LCA study is "cradle-to-grave". This includes the extraction and production of raw materials, manufacturing processes, packaging, main transportation stages, and final disposal of the products, equipment, packaging, and waste. The system boundaries of both original manufacturing SUDs and reprocessed SUDs are presented in the Figure 7 and further explained in the next section. Note that raw material extraction and processing for the manufacturing of the parts is included within "Component manufacturing" for original devices and within "Assembly/inspection" in the case of replacement parts of reprocessed devices.

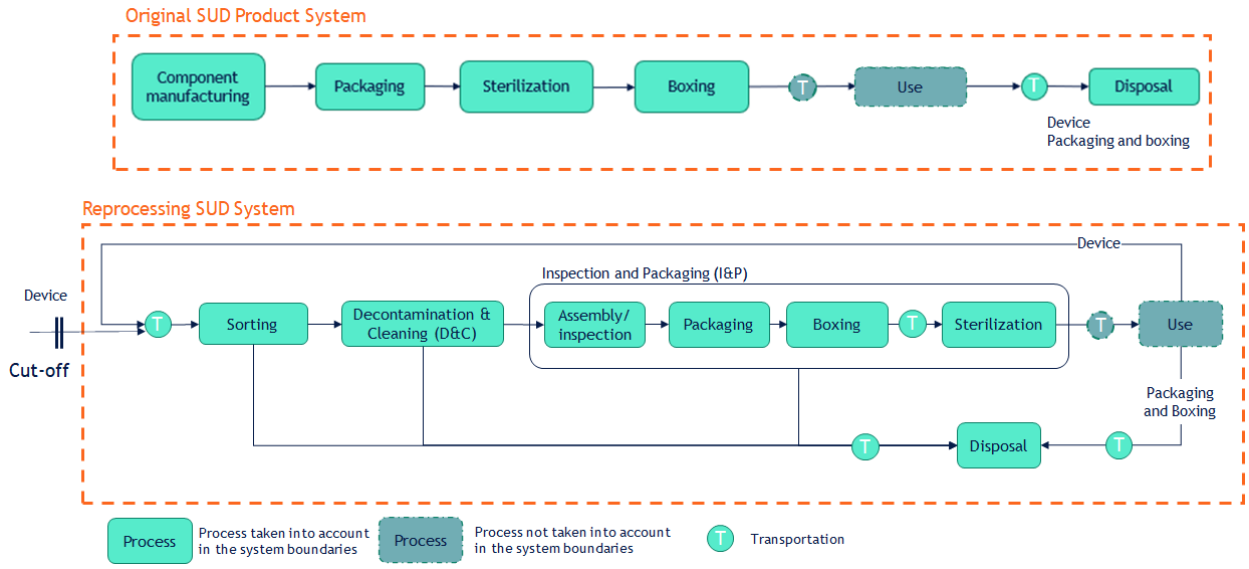

Figure 7 – System boundaries of the SUDs original product system and reprocessing system

A full description of all LCI data used for each unit process of each product system is provided in a supplementary spreadsheet (A2_Stryker_Life Cycle Inventory Data). These comprised all elementary flows to and from nature associated with each product system.

1.5.1 Original Product System

The original product system consists of manufacturing the medical devices from raw materials. The component manufacturing includes the raw material production, as well as processing to shape the different components of the SUDs. Production of raw material and processing were modeled using data from the ecoinvent database either by choosing an already manufactured part or by choosing the material and a processing process (e.g., injection molding + plastic). To be conservative in comparing with reprocessed devices, assembly of components are assumed to be the same location as their manufacturing and additional energy for assembly has been neglected. The material type and mass of each device's component was collected via a teardown analysis.

Packaging and boxing represent the production of the primary and secondary packaging used to protect the SUDs during transportation. Sterile medical devices are placed in primary packaging that protects the device and is sterilized. This packaging is then placed in secondary packaging (like cardboard boxes or cartons) for shipping. Primary data was collected on packaging.

Sterilization is a process to render a product free of all forms of viable microorganisms. As no information was collected on the original sterilization process, it was assumed that this step was made in-house, via the same process that Stryker uses to sterilize the reprocessed SUDs. Ethylene oxide gas is assumed for the ViewFlex, HARH36, LF2019 and MyoSure. Vaporized hydrogen peroxide is assumed for the Max-A.

The exclusion of transportion to hospital, and the use phase is explained in section 1.6. Transportation of various consumable is based on ecoinvent markets.

The disposal represents the end-of-life treatment of the SUDs as well as their primary and secondary packaging. Because of the biohazard nature of SUDs, their end-of-life treatment is assumed to be autoclaving followed by landfilling. End-of-life treatment of other materials has been modeled as follows:

- Paper: 68% recycled, 26% landfilled, 6% incinerated based on US average statistics (EPA 2020);
- Plastics: 9% recycled, 75% landfilled, 16% incinerated based on US average statistics (EPA 2020); and
- Metals: 100% landfilled as, when applying a cut-off approach, the disposal of metal will have very little contribution to the footprint, irrespective of the management type.

We assumed autoclaving would require 1.9 kWh of electricity by kg (Mc Gain et al. 2017). Transportation distances and modes were based on ecoinvent markets.

The location of production of original devices is unknown. For this reason, we applied global averages for data where possible.

1.5.2 Reprocessing System

The reprocessing system boundaries start with the collection of the used medical device at the hospitals (use phase). Allocation method for recycling is described in section 1.11. The transportation from the hospitals to the reprocessing facilities is estimated based on the weighted average of distances for volumes of collected device during the year 2021 in US-based hospitals (see appendix A2). The transportation mode is assumed to be exclusively by trucks.

The sorting step represents the manual disassembly and sorting of the SUDs arriving at the reprocessing facilities. It usually consists of consumable items in very small amounts. We assumed any erroneous items would be captured by the yield of sorting and would have the same weight of the studied device.

The decontamination and cleaning phase (D&C) consists of a series of enzymatic and/or ultrasonic soak and rinse, followed by a heated or vacuum drying phase.

The assembly and inspection phase consist of the production of the replacement parts for the device, and the reassembly of the device. The tables presented in the appendix A1 and appendix A2 describe the replacement part for each SUDs under study. Manufacturing of replacement parts was modeled assuming the same as the original part.

Packaging and boxing represent the production of the primary and secondary packaging used to protect the SUDs during the transportation. It is the same as the original packaging and boxing, except for the reprocessed LF2019 and MyoSure.

The sterilization phase is modeled based on Stryker's data. For the HARH36, LF2019 and MyoSure, it happens at a different location from other reprocessing activities. Transportation was assumed to occur by truck and distances between reprocessing facilities are shown in appendix A2.

Quantities of consumables in each reprocessing steps were typically known on a per "lot" basis. Quantities per device were calculated by dividing by the number of devices in each lot. Consumables used in each of the reprocessing steps are listed in Table 1. Quantities of each of these consumables are available in appendix A2.

The electricity requirements for each of the reprocessing steps were provided by Stryker. The values were taken either through direct measurement during manufacturing or from labels on the equipment in conjunction with process parameters.

The disposal is assumed to be the same as the original devices. Rejected devices from the various reprocessing steps are also assumed to be disposed of in the same way. Transportation distances and modes are based on ecoinvent markets.

Transportation of various consumable is based on ecoinvent markets.

Data collected was representative of 2021.

Table 1 – Summary of consumables used in reprocessing

Reprocessing Step	ViewFlex	HARH36	LF2019	MyoSure REACH	Max-A
Sorting	N/A	N/A	Isopropanol, cleaning swabs, zip tie, nylon brush	Plastic bag, zip tie, cleaning swab, Isopropanol, stainless steel brush,	Label
Decontamination and cleaning	Isopropanol, nylon brush, cleaning swabs, detergent, water	Detergent, steel brush, plastic bag, cleaning swabs, zip tie, nylon brush, isopropanol, water	Cleaning swabs, nylon brush, isopropanol, water	Isopropanol, cleaning swabs, stainless steel brush, nylon brush, water	Scrub wipes
Inspection & assembly	Sealbag	Isopropanol, printed paper cup, plastic bag, cleaning wipes	Cleaning swabs, zip tie	Cleaning swabs, corrugated box, plastic bag	Taper, paper tape
Replacement/ additional parts	N/A	Shaft rotation knob pin, jaw tissue pad, trigger return, spring, torque wrench, torque wrench spring	Plug housings, plug housing circuit board	End cap, handle screws, drive cable, suction tube, distal hand piece screws, handle shaft, handle shroud	N/A
Packaging and boxing	Handle tray, tip tray, tube, nylon pouch, bubble wrap, corrugated box	Tyvek lid, thermoformed tray, retainer, folding carton	Mountain card, peel puch, printed paper, corrugated box	Chipboard box, thermoformed tray, Tyvek lid, corrugated box	Plastic pouch, label, corrugated box
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide	Hydrogen peroxide

1.6 Exclusions and cut-off criteria

In the process of building a life cycle inventory (LCI), it is typical to exclude items considered to have a negligible contribution to results. To do this in a consistent and robust manner, there must be confidence that the exclusion is fair and reasonable. To this end, cut-off criteria can be defined based on mass, energy

or environmental significance. In this study, no flow was cut-off, but the following processes were omitted for the product systems.

- *Transportation from the manufacturing location to the hospitals:* Transportation from manufacturing to hospital is assumed to be similar between in the original and reprocessed systems mainly due to lack of data for the original devices. This exclusion is tested in sensitivity analysis below.
- *Use phase:* The reprocessed and original manufacturing SUDs consume a small amount of energy during their utilization. However, because of the exact same functionality delivered by the reprocessed SUD and the original manufactured SUD, this energy consumption between the two compared systems process is strictly equivalent. Because the main objective of this study is the comparison between the two product systems, the use phase was excluded from the analysis.
- *Minor packaging*: This includes packaging of the raw materials used during the original manufacturing of the SUDs and the consumable used during the reprocessing process. Environmental significance of minor packaging is assumed to be minimal but greater for original devices than for reprocessed due to the multiple parts that need to be assembled.
- *Human inputs to processes:* Some operations need human input. No environmental load was associated with this.
- *Production and disposal of the infrastructure (machines, transport vehicles, roads, etc.) and their maintenance*: It is standard practice to exclude them and the differences between the two systems is assumed to be minimal.
- *Environmental impacts associated with support functions* (e.g., R&D, marketing, finance, management etc.).

1.7 Data collection procedures

Quantitative and qualitative foreground data and background data are collected for all processes within the system boundary and these data are used to compile the LCI.

In this study, whenever possible, primary data are used to quantify foreground data. Primary data are values obtained from a direct measurement or a calculation based on direct measurements at its original source. When primary data are not available, secondary data are used. Secondary data are values obtained from generic LCA database, literature, or expert assumptions. Table 2 present the type of data used depending on the stage of the life cycle. The manufacturing of the various consumables was modeled using the ecoinvent database.

Table 2 – Type of data collected (foreground)

System	Item	Primary Data	Secondary data
Original Product System	Devices component mass	X	
Original Product System	Devices component material type	X	
Original Product System	Original manufacturing of devices components		X (ecoinvent 3.8)
Both	Packaging	X	
Reprocessing System	Transportation from hospital to the reprocessing facility	X	
Reprocessing System	Consumable used during sorting	X	
Reprocessing System	Consumable, water and energy used during D&C	X	
Reprocessing System	Consumable used during I&P	X	
Reprocessing System	Yields during sorting, D&C and I&P	X	
Reprocessing System	Transportation to the sterilization center	X	
Both	End-of-life scenarios		X (assumptions)
Both	Background data		X (ecoinvent 3.8)

1.8 Data quality requirements

The main data quality requirements are presented in Table 3. These are based on the pedigree matrix approach. The correlation of these quality indicators with ISO requirements is shown in the table. In addition, in alignment with the ISO standard, consistency and reproducibility will be discussed, data sources will be reported, and uncertainty will be addressed. While for non-comparative assessment, ISO does not specify which data quality indicators should be included for stand-alone LCAs, the study included an evaluation of all data quality indicators to facilitate future comparative assessment as this is required for that type of LCA.

Table 3 – Data quality requirements

Data Quality Indicator	Corresponding ISO requirement	Score				
		1	2	3	4	5
Reliability	Precision Completeness	Verified data based on measurements	Verified data partly based on assumptions OR non-verified data based on measurement	Non-verified data partly based on qualified estimates	Qualified estimates; data derived from theoretical information	Non-qualified estimates
Completeness	Completeness Representativeness	Representative data from all sites relevant for the market considered over an adequate period to even out normal fluctuations	Representative data from > 50% of the sites relevant for the market considered over an adequate period to even out normal fluctuations	Representative data from only some sites (<< 50%) relevant for the market considered OR > 50% of sites but for shorter periods	Representative data from only one site relevant for the market considered OR some sites but for shorter period	Representativeness unknown or data from a smaller number of sites AND from shorter period
Temporal correlation	Time related coverage Representativeness	< 3 years difference to the reference year*	< 6 years difference to the reference year*	< 10 years difference to the reference year*	< 15 years difference to the reference year*	Age of data unknown OR > 15 years difference to the reference year
Geographical correlation	Geographical coverage Representativeness	Data from the area under study**	Average data for larger area in which the area under study is included	Data from smaller area than area under study		Data from unknown OR distinctly different area (e.g., Europe)
Technological correlation	Technology coverage Representativeness	Data from enterprises, processes and material under study (i.e., identical technology)		Data on related processes or material but same technology OR Data from processes and materials under study but from different technology	Data on related processes or materials but different technology OR data on laboratory scale processes and same technology	Data on related processes or materials but on laboratory scale of different technology

*Reference year is 2021. **Area under study is US for reprocessing and global for original devices.

1.9 Temporal boundary

The temporal boundary is the time period for which the quantified figure for the CFP is representative. The CFP developed in this study is representative of the year 2021. Some activities related to the product system might have occurred in the past (e.g., manufacturing of consumables, growing of the trees needed to manufacture paper packaging) and some other in the future (e.g., emissions associated with disposal). As required by ISO 14067, the GHG emissions and removals arising from the life cycle of a product are calculated over the entire lifetime of the product, including its end-of-life operations and tree growing. Removal and emissions associated with wood will occur over more than 10 years. However, these are not significant for the results, and hence are not presented year by year. Similarly, most of landfilling, which would result in emissions over more than 10 years, happen in the background and are not very significant either.

1.10 Assumptions regarding electricity production

Electricity production for reprocessing was modeled using the ecoinvent processes that include the US states in which the facilities are located (WECC for ViewFlex and SERC for others). Grid mixes for these are presented in Table 4. These processes include the full life cycle of producing the electricity including transmission and distribution losses. According to ISO 14067, *"the relevant grid shall reflect the electricity consumption of the related region, excluding any previously claimed attributed electricity.*" This is difficult to apply in practice since these grid mixes are not readily available in existing databases. However, ISO 14067 also specifies that "[i*]n case no electricity tracking system is in place, the selected grid shall reflect the electricity consumption of the region."* The ecoinvent processes represent consumption and not production of electricity. That said, ViewFlex is more likely to be affected by not taking a grid mix that excludes any previously claimed attributed electricity because of a higher proportion of its regional mix from renewable. The implications are tested in a sensitivity analysis.

Table 4 – Grid mixes used for reprocessing

	SERC	WECC
Coal and lignite	23.1%	21.3%
Hydro	3.4%	23.5%
Natural gas	46.3%	33.2%
Nuclear	24.4%	8.0%
Oil	0.2%	0.0%
Wind	0.4%	7.6%
Other biofuels	2.2%	1.3%
Geothermal	0%	2.2%
Solar	0%	0.5%
Import from Canada	0%	1.7%
Import from Mexico	0%	0.8%

1.11 Life cycle impact assessment (LCIA) methods

In LCA, the life cycle impact assessment (LCIA) stage is where characterization factors are applied to data to generate environmental impact results. LCIA methods consist of a series of indicators to express the relative severity on an environmental impact category and can either be represented at the 'midpoint' or 'endpoint' level. At the 'midpoint' stage, individual impact categories are shown, whereby a score is given for each in the appropriate reference unit, whereas at the endpoint level, the potential damage to the environment is shown.

To provide an example of the difference, at the midpoint level the contribution to global warming can be measured in kg CO_2 eq, which represents the amount of greenhouse gas equivalents that are released into the environment. To estimate the potential environmental damage caused by an amount of CO_2 eq released into the environment, endpoint characterization factors can be applied, and results expressed in terms of damage to ecosystems (e.g., species loss), human health (e.g., disability adjusted life years, DALY) or resources (e.g., MJ). Endpoint results are far more uncertain than midpoint results because the model needs to estimate the environmental damage, rather than just the amount of environmental substances released into the environment and their relative severity to an environmental issue.

There are several LCIA methods that can be chosen, all with slightly different characterization factors (both in terms of coverage and values) and different underlying characterization models used to generate these factors. In this study a single environmental attribute was studied: the carbon footprint (CFP). A CFP, according to ISO 14067 uses an indicator of global warming. Global warming potential is a measure for the adverse environmental effect caused by man-made emissions of greenhouse gases that cause heat to be trapped in the atmosphere and so result in a temperature rise of the Earth's surface. The Intergovernmental Panel on Climate Change (IPCC) has developed a characterization model to quantify the climate change impact of emissions released to the atmosphere. Emissions of different gases are given characterization factors, expressing the release of a gas in terms of its carbon dioxide equivalent (CO_2 eq.), depending upon its radiating force in relation to that of CO_2.

On calculating CO_2 equivalents, the residence time of the gases in the troposphere is considered and models for time periods of 20, 50 and 100 years have been developed. ISO 14067 requires that the 100-year temporal horizon is used, and that the IPPC values for 2021 are used. All GHGs listed by IPPC are included in this study. All GHG emissions and removals are calculated as if released or removed at the beginning of the assessment period without considering an effect of delayed GHG emissions and removals.

ISO 14067 requires that various components of a CFP are reported differently. This is summarized in Table 5 and Figure 8. Fossil GHG emissions refer to GHG emissions from fossilized material. Biogenic GHG emissions refer to GHG emissions from biomass. Land use change (LUC) is a conversion of one land use type to another as a result of human activity. LUC has impacts on soil properties (e.g., carbon content or compaction), nutrients leaching, N_2O emissions, biodiversity, biotic production and on other environmental aspects such as landscape, albedo and evapotranspiration. There are direct and indirect LUC: Direct LUC (dLUC) is a direct change in the piece of land occupied by the human activity. Indirect LUC (iLUC) is a change that appears in a different area than the direct land use as an indirect consequence (e.g., increase of soybean production in Brazil forces cattle production to deforest).

Table 5 – CFP calculation and documentation requirements according to ISO 14067

Specific GHG emissions and removal	Treatment in the calculated CFP			Documentation in the CFP report	
	Shall be included	Should be included	Should be considered for inclusion	Shall be documented separately	Shall be documented separately if calculated
Fossil and biogenic GHG emissions and removals	X			X	
GHG emissions and removals occurring as a result of dLUC	X			X	
GHG emissions and removals occurring as a result of iLUC			X Not relevant to study		X
GHG emissions and removals from land use		X Included to extent in ecoinvent			X
Biogenic carbon in products					X
Aircraft GHG emissions	X			X	

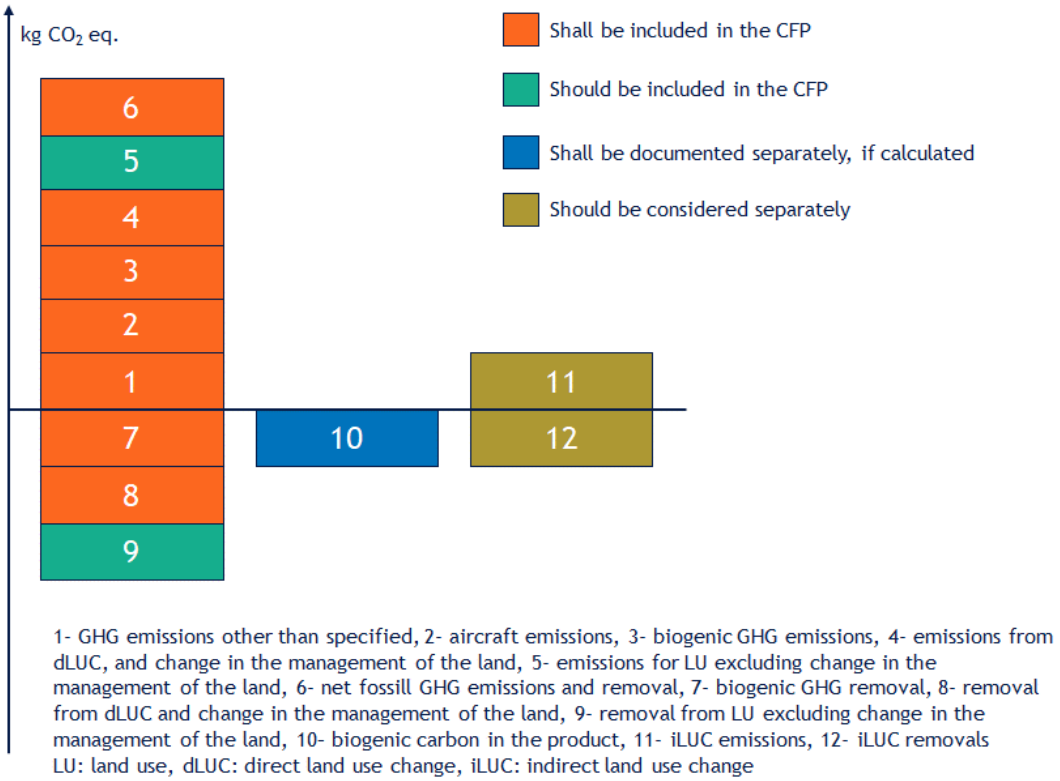

Figure 8 – Specific components of a CFP and how they need to be reported according to ISO 14067

The LCIA method entitled "IPCC 2021 GWP100 (incl. CO2 uptake)" is used in this study. This LCIA method includes four categories:

- Fossil: Includes all emissions of fossil GHGs.
- Biogenic: Includes emissions of biogenic CO_2 and biogenic CH_4.
- CO_2 uptake: Includes the carbon removed from the atmosphere.
- Land transformation: Accounts for the emissions or removals that arise from land use changes. For example, when land is transformed from high carbon state, such as a forest, to a lower carbon state, such as a corn crop, the difference in carbon is assumed to be released to the atmosphere. This category refers to the GHG emissions and removals occurring as a result of dLUC.

In this method, CO_2 into biomass characterized in the LCIA as −1 kg CO_2e/kg CO_2 and the emissions of biogenic CO_2 characterized as +1 kg CO_2e/kg CO_2 of biogenic carbon in the calculation of the CFP.

It is important to note that there is no category associated with aircraft GHG emissions. In this study, aircraft GHG emissions are expected to be negligible. To be aligned with ISO 14067, the contribution of air transport is shown in the results. However, this contribution only refers to the transport activities included in the foreground processes and do not account for the background processes (i.e., air transport of the background ecoinvent processes used). Direct land use change was included to the extent it is in the ecoinvent database, but was not relevant for any of the foreground processes. Similarly, indirect land use change is not expected to be significant for this study and hence is not included.

1.12 General allocation procedures

For cases where there is more than one product in the system being studied, ISO 14040/44 recommends the following procedure for the allocation of material and energy flows and environmental emissions:

- First, allocation should be avoided, by process subdivision.
- If process subdivision is not possible, the product system should be expanded to include the additional functions related to the co-products.
- If the system expansion is not applicable, the allocation should reflect the physical relationships of the different products or functions.
- Finally, for some processes, allocation based on underlying physical relationship is not considered appropriate and, in these cases, simple physical or economic allocation can be used.

In this study, allocation procedures for multi-product processes followed the ISO approach above.

Ecoinvent v3.8 defaults to an economic allocation for most processes. However, in some cases a mass-based allocation is used, where there is a direct physical relationship. The allocation approach of specific ecoinvent modules is documented on their website and method reports (see www.ecoinvent.org).

No additional allocation procedures are applied to the data collected as there are no multifunctional processes in the foreground data.

1.13 Allocation for recycling

Reprocessing is a form of recycling, which means that, in comparing original and reprocessed SUDs, a decision needs to be made with regards to how to allocate the inputs and outputs associated with unit processes for extraction and processing of raw materials, recycling itself and final disposal between the original and reprocessed SUDs. Several approaches can be applied for this. It this study, we applied the "supporter perspective" used by Schulte et al. (2021)[2] where the reprocessed devices are essentially considered in a closed loop in which any extra devices needed to compensate for yield loss come in the system burden free. This approach is reasonable in the short-term for encouraging the development of a circular system. This approach is also equivalent to an approach in which we assume the reprocessing system serves two functions: that of generating the device and that of waste management; and in which system boundaries are expanded to include the avoided waste management. A more neutral approach is presented in sensitivity analysis. For simplicity, a cut-off was applied to recycling of packaging because the environmental impact of disposing of packaging was already minimal.

1.14 Life cycle assessment software

The software SimaPro v9.3.0.2 is used to conduct the LCA. The foreground processes of the product systems are constructed in the software and connected to background processes from the LCI databases selected (i.e., ecoinvent v3.8). When original datasets from the LCI databases need to be adjusted, the processes are duplicated, adjusted, and connected to the appropriate foreground processes.

[2] Shulte, A. Maga, D. and Thonemann, Nils. 2021. Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters. Sustainability. 13 (2). pp. 2021: 13. 898.

1.15 Critical review

A critical review by panel of interested parties is carried out in this study. Critical reviewers are:

- Terrie Boguski (chair), president of Harmony Environmental,
- Yan Wang (member), principal lecturer at the University of Brighton, and
- Cassandra Thiel (member), assistant professor at New York University Langone Health.

Critical review statement is provided in appendix A3.

2 Life cycle inventory (LCI)

2.1 Summary of LCI

A full description of all LCI data used for each unit process of each product system is provided in a supplementary spreadsheet (A2_Stryker_Life Cycle Inventory Data). These comprised all elementary flows to and from nature associated with each product system.

The Table 6 shows a summary of the material composition for each product, and the main parameters of their life cycle assessment. Yields represent the percent of devices that are lost in each step and were used to calculate the number of original devices needed as inputs to the reprocessing process to lead to a single reprocessed device. For instance, for a total reprocessing yield of 41% (ViewFlex), 2.42 (1/0.41) original devices needed to be collected to lead to a single reprocessed device. Devices discarded along the process were assumed to be sent to disposal.

Table 6 – Summary of the five devices inventory

Device	ViewFlex	HARH36	LF2019	MyoSure REACH	Max-A
Mass of the device (g)	164	180	126	427	17.7
Material Composition	Plastic : 89.4% Printed board : 8.1% Metal : 2.5%	Plastic : 65.4% Metal : 34.6%	Electric cable : 35.2% Plastic : 34.3% Metal : 30.5%	Plastic : 72.4% Metal : 26.1% Electric cable : 1.5%	Plastic : 72.4% Metal : 26.1% Electric cable : 1.5%
Original packaging and boxing detail	991 g (58% cardboard, 42% plastic)	274 g (53% plastic, 47% cardboard)	103 g (50% cardboard, 33% plastic, 17% paper)	831 g (57% cardboard, 32% plastic, 11% paper)	3.41 g (98% plastic, 2% paper)
Reprocessed packaging and boxing detail	Same as original	Same as original	89 g (50% cardboard, 40% plastic, 10% paper)	547 g (63% cardboard, 37% plastic)	Same as original
Location of reprocessing site	Phoenix (USA)	Lakeland, FL (USA)	Lakeland, FL (USA)	Lakeland, FL (USA)	Tijuana (Mexico)
Sorting yield (%)	97%	90%	75%	83%	
D&C yield (%)	63%	69%	100%	90%	85%
I&P yield (%)	67%	84%	87%	81%	
Total reprocessing yield (%)	41%	53%	65%	61%	85%
# of device needed as input of the reprocess system	2.44	1.92	1.53	1.65	1.18
Sterilization location	Same as reprocessing	Minneapolis, MN (USA)	Minneapolis, MN (USA)	Minneapolis, MN (USA)	Same as reprocessing

2.2 Data quality assessment

Table 7 presents a qualitative assessment of the quality of the data used in this study (see Table 3 for a description of data quality requirements). As shown, most of the data used for the reprocessed system was of relatively high quality. With regards to the original system, more assumptions needed to be made because, beyond the bill of materials, no primary data was available.

Consistency check: This study applied consistent assumptions to original and reprocessed devices. However, data quality was higher for the reprocessed devices. In general, given that one of the objectives of this study

was to determine whether there were environmental benefits associated with reprocessing, we used conservative assumptions around the original devices i.e., assumptions that would lower their environmental footprint. Where certain data of lesser quality were found to be significant to the results, they have been tested in sensitivity analyses.

Reproducibility: While it is generally difficult to ensure an independent practitioner would be able to reproduce the results, we provided detailed assumptions and data (in appendix A2).

Table 7 – Data quality assessment

Data required	Reliability	Completeness	Temporal correlation	Geographical correlation	Technological correlation
	Score				
REPROCESSED SYSTEM					
Sorting	1-2	1	1	1	1
D&C	1-2	1	1	1	1
Sterilization	1-2	1	1	1	1
Boxing	1-2	1	1	1	1
Disposal	3	5	3[3]	5	1
Manufacturing of consumables	2-3	3	3	3	3-5
Transportation distances and modes	1-2	1-5	1-3	1-3	1-3
Transportation processes	1-2	5	3	2	1
ORIGINAL SYSTEM					
Component manufacturing	1-2	1-3	3	3	3-5
Assembly	5	5	3	3	5
Packaging	1	1	1	1	1
Sterilization	1-2	5	1	3	3
Boxing	1	1	1	1	1
Disposal	3	5	3	5	1
Manufacturing of consumables	2-3	3	3	3	3-5
Transportation distances and modes	3	1-5	3	3	3
Transportation processes	3	5	3	2	1

[3] Everything that is modeled with ecoinvent was assigned a "3" for temporal correlation. Ecoinvent is updated periodically but some of the data is still quite dated.

3 Life Cycle Impact Assessment results and interpretation

The only impact category considered in this study is the global warming potential quantified according to ISO 14067.

All results are presented in terms of the functional unit, which is defined as "*Provide one medical device for single use, compliant to the relevant FDA standard, in the US.*" and covers all processes included within the system boundary.

3.1 Comparative assessment

Table 8 shows the cradle-to-grave CFP of the five SUDs, for both original manufacturing and reprocessing, on four types of GHG emissions and removals, and the total, as required by ISO 14067 and described in section 1.9.

Table 8 – Comparison of the CFPs of Original and Reprocessed SUDs

		ViewFlex		HARH36		LF2019		MyoSure REACH		Max-A	
Type of emissions and removals	Unit	Original SUD	Reprocessed SUD	Original SUD	Reprocessed SUD	Original SUD	Reprocessed SUD	Original SUD	Reprocessed SUD	Original SUD	Reprocessed SUD
GWP100 - fossil	kg CO_2 eq.	8.23	4.04	3.84	2.10	1.51	0.99	5.27	4.02	0.15	0.07
GWP100 - biogenic	kg CO_2 eq.	0.89	0.81	0.42	0.34	0.13	0.10	0.76	0.52	0.01	0.00
GWP100 - land transformation	kg CO_2 eq.	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.00	0.00
GWP100 - CO2 uptake	kg CO_2 eq.	-0.65	-0.54	-0.51	-0.44	-0.13	-0.08	-0.71	-0.43	-0.01	-0.01
Total	kg CO_2 eq.	8.49	4.32	3.75	2.01	1.51	1.01	5.34	4.11	0.15	0.07

The following points can be made from Table 8:

- All reprocessed SUDs have a better CFP than original SUDs, with emissions ranging from 23% to 51% lower than manufacturing the original device. The specific CFP reductions for each device are as follows:
  - Max-A: 51% lower
  - ViewFlex: 49% lower
  - HARH36: 46% lower
  - LF2019: 33% lower
  - MyoSure REACH: 23% lower.
- The main factor contributing to the reduction of GHG emissions when reprocessing medical devices for single use is the fact that reprocessing doesn't require the production and manufacturing of new virgin plastic and metal material (see section 3.2).
- On all product systems, most of the GHG emissions comes from fossil sources rather than from biogenic or dLUC sources.
- For all systems, the biogenic carbon is captured and emitted when biobased materials (in this study, mainly cardboard from packaging and boxing) are made (from pulp material) and then burned. Net biogenic emissions only represent a small part of the overall CFP.

3.2 Environmental hotspots of SUDs

In the following section, the environmental hotspots of both original manufacturing and reprocessing systems are identified for each SUD. Hotspots for ViewFlex, HARH36, LF2019, MyoSure REACH and Max-A follow similar patterns.

Figure 9 shows the contribution analysis by life cycle stage of the ViewFlex device, and Table S1 (cf. appendix A1) briefly describes the processes and assumptions associated with the different stages presented.

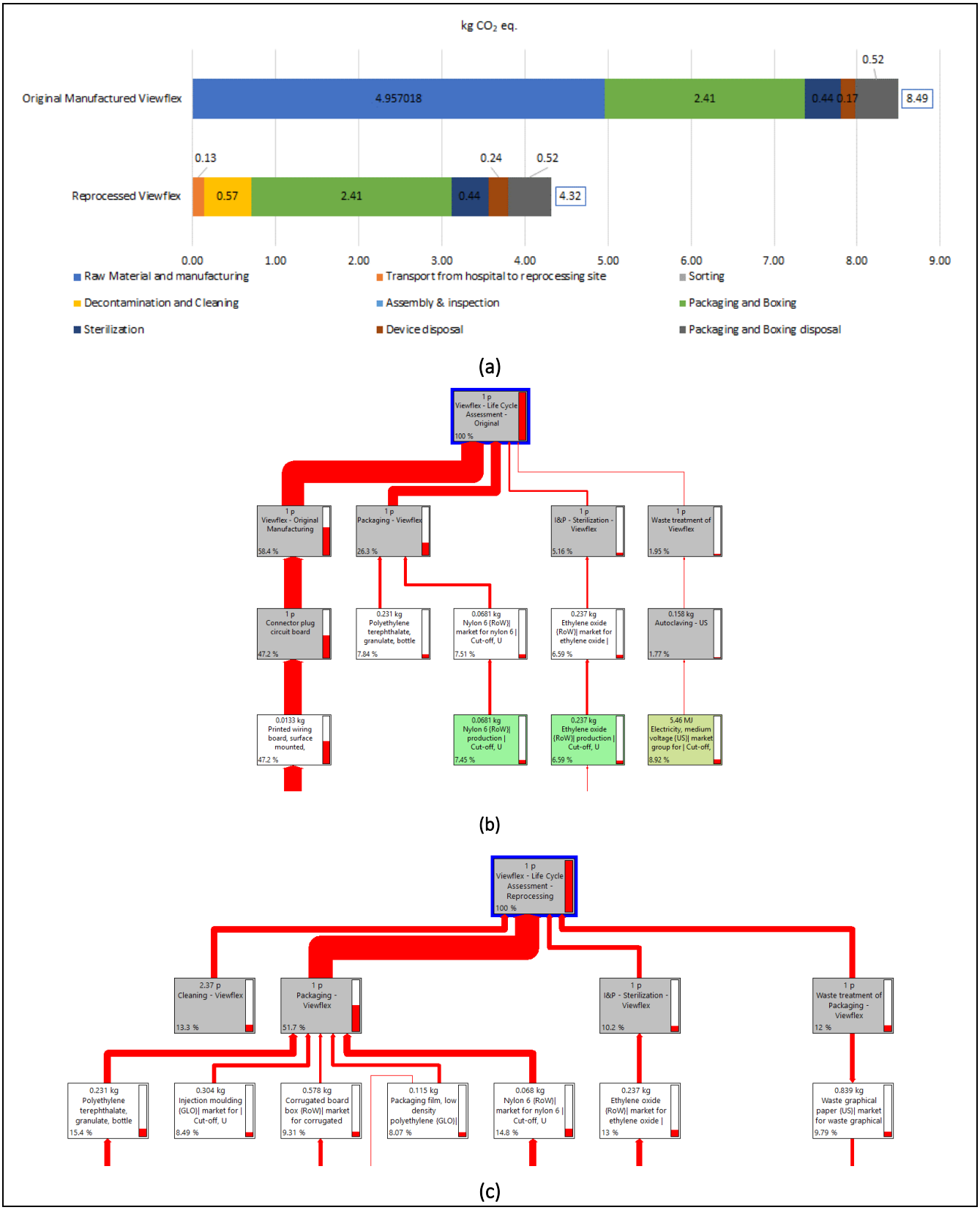

Figure 9 – a) Carbon footprint hotspots for the original and reprocessed ViewFlex by life cycle stage, b) Deep dive in carbon hotspots for original devices, c) Deep dive in carbon hotspots for reprocessed devices

Figure 10 shows the contribution analysis by life cycle stage of the HARH36 device and Table S2 (cf. appendix A1) briefly describes the processes and assumptions associated with the different stages presented.

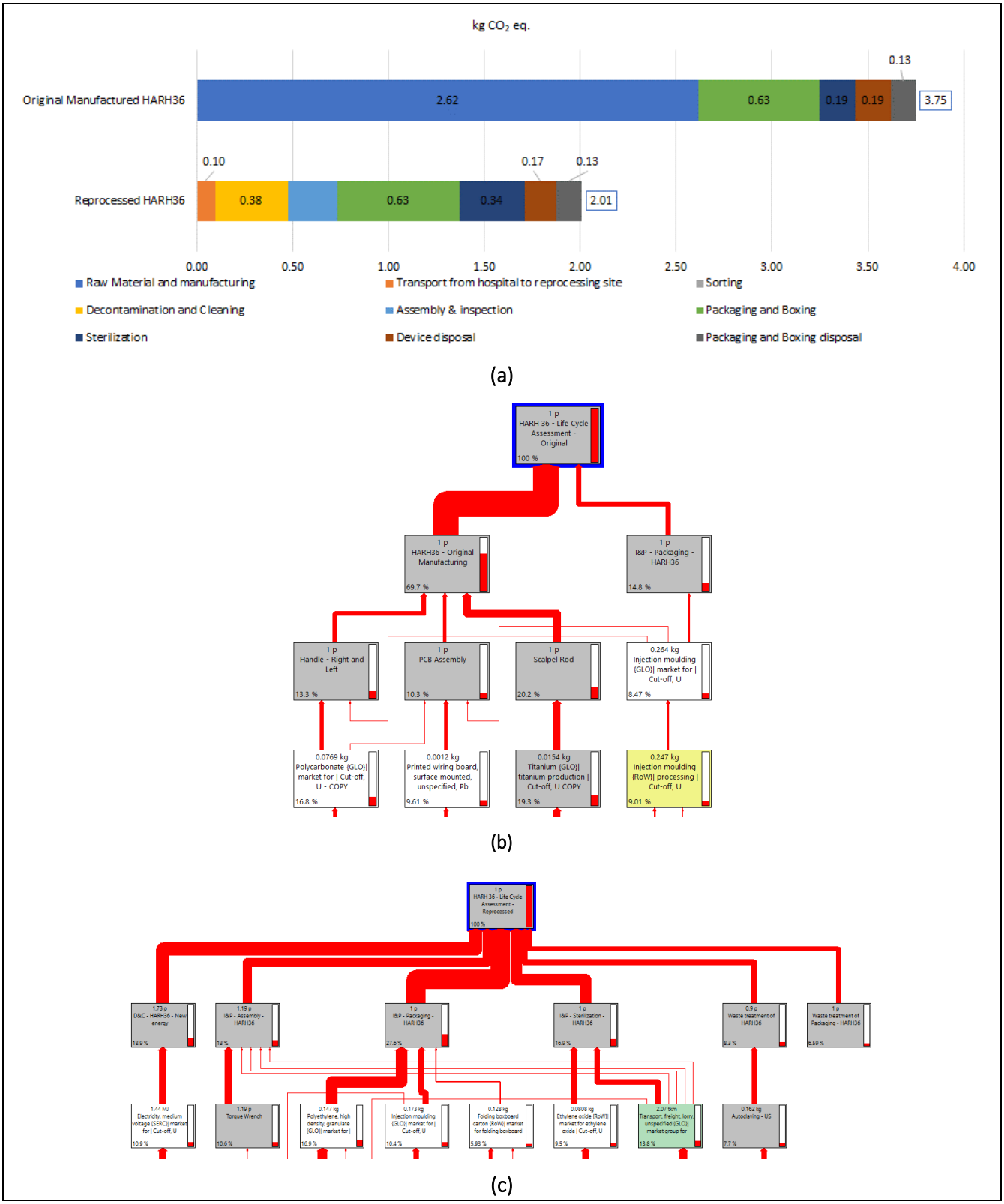

Figure 10 – a) Carbon footprint hotspots for the original and reprocessed HARH36 by life cycle stage, b) Deep dive in carbon hotspots for original devices, c) Deep dive in carbon hotspots for reprocessed devices

Figure 11 shows the contribution analysis by life cycle stage of the LF2019 device. and Table S3 (cf. appendix A1) briefly describes the processes and assumptions associated with the different stages presented.

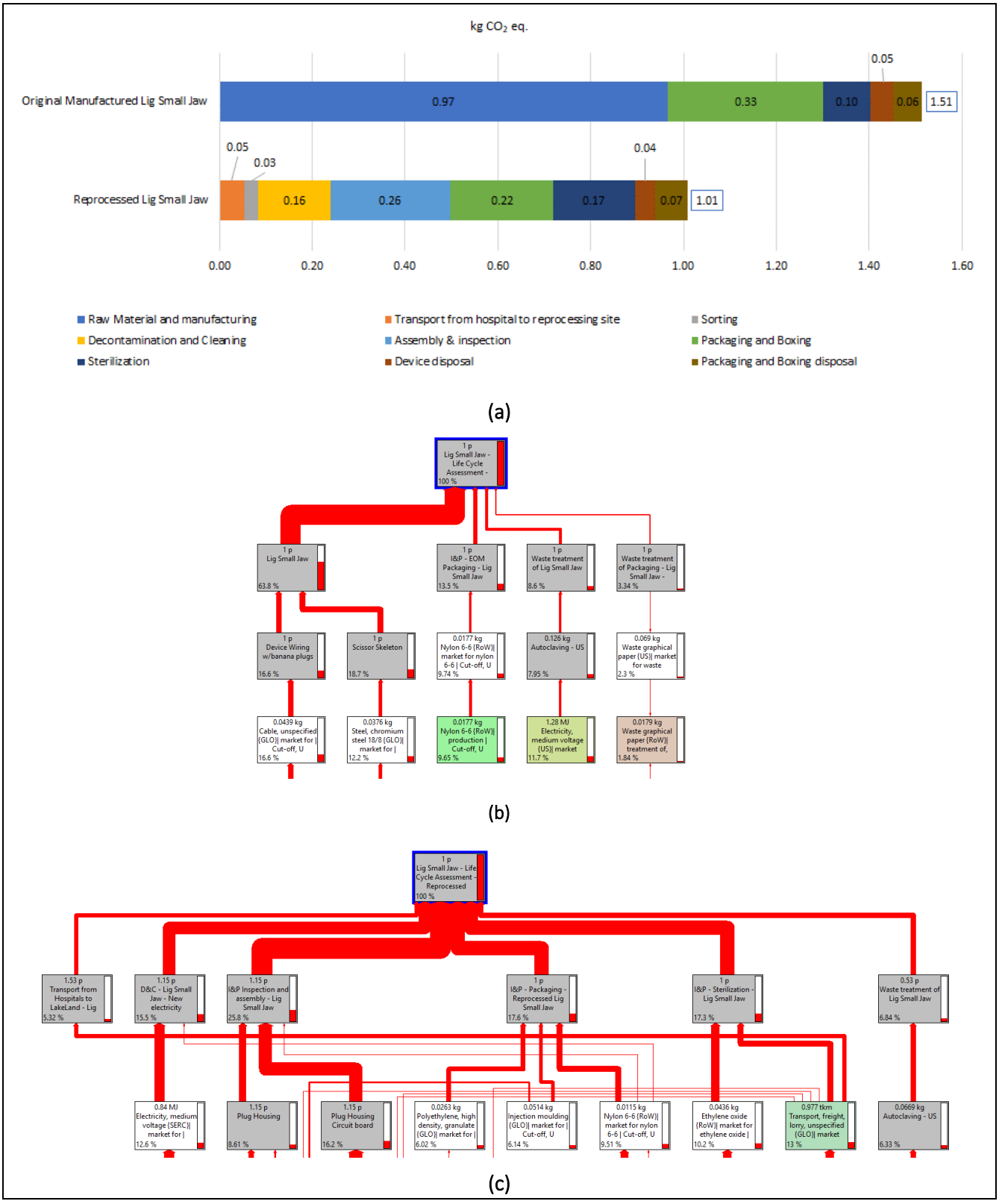

Figure 11 – a) Carbon footprint hotspots for the original and reprocessed LF2019 by life cycle stage, b) Deep dive in carbon hotspots for original devices, c) Deep dive in carbon hotspots for reprocessed devices

Figure 12 shows the contribution analysis by life cycle stage of the MyoSure REACH device and Table S4 (cf. appendix A1) briefly describes the processes and assumptions associated with the different stages presented.

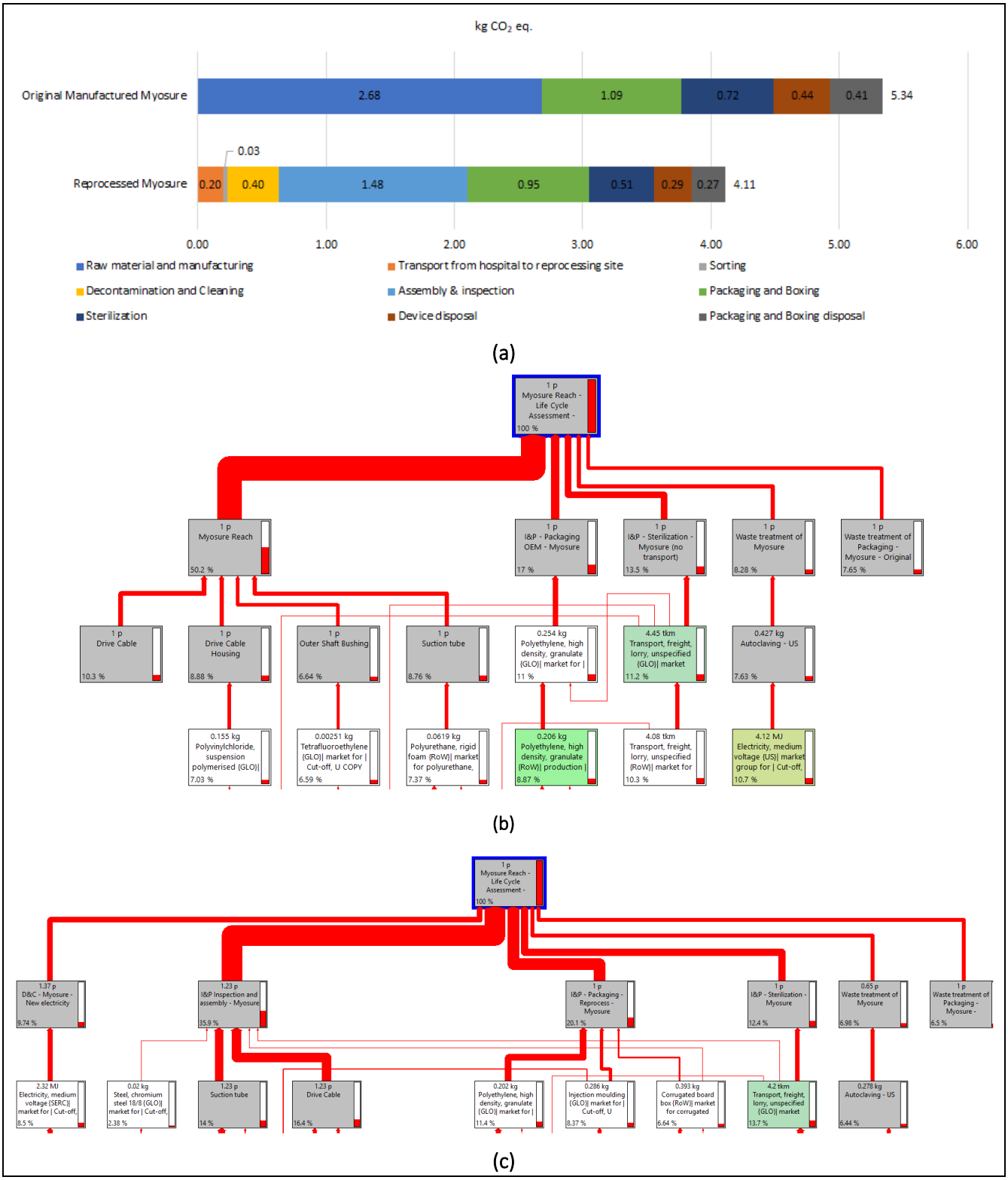

Figure 12 – a) Carbon footprint hotspots for the original and reprocessed MyoSure by life cycle stage, b) Deep dive in carbon hotspots for original devices, c) Deep dive in carbon hotspots for reprocessed devices

Figure 13 shows the contribution analysis by life cycle stage of the Max-A device and Table S5 (cf. appendix A1) briefly describes the processes and assumptions associated with the different stages presented.

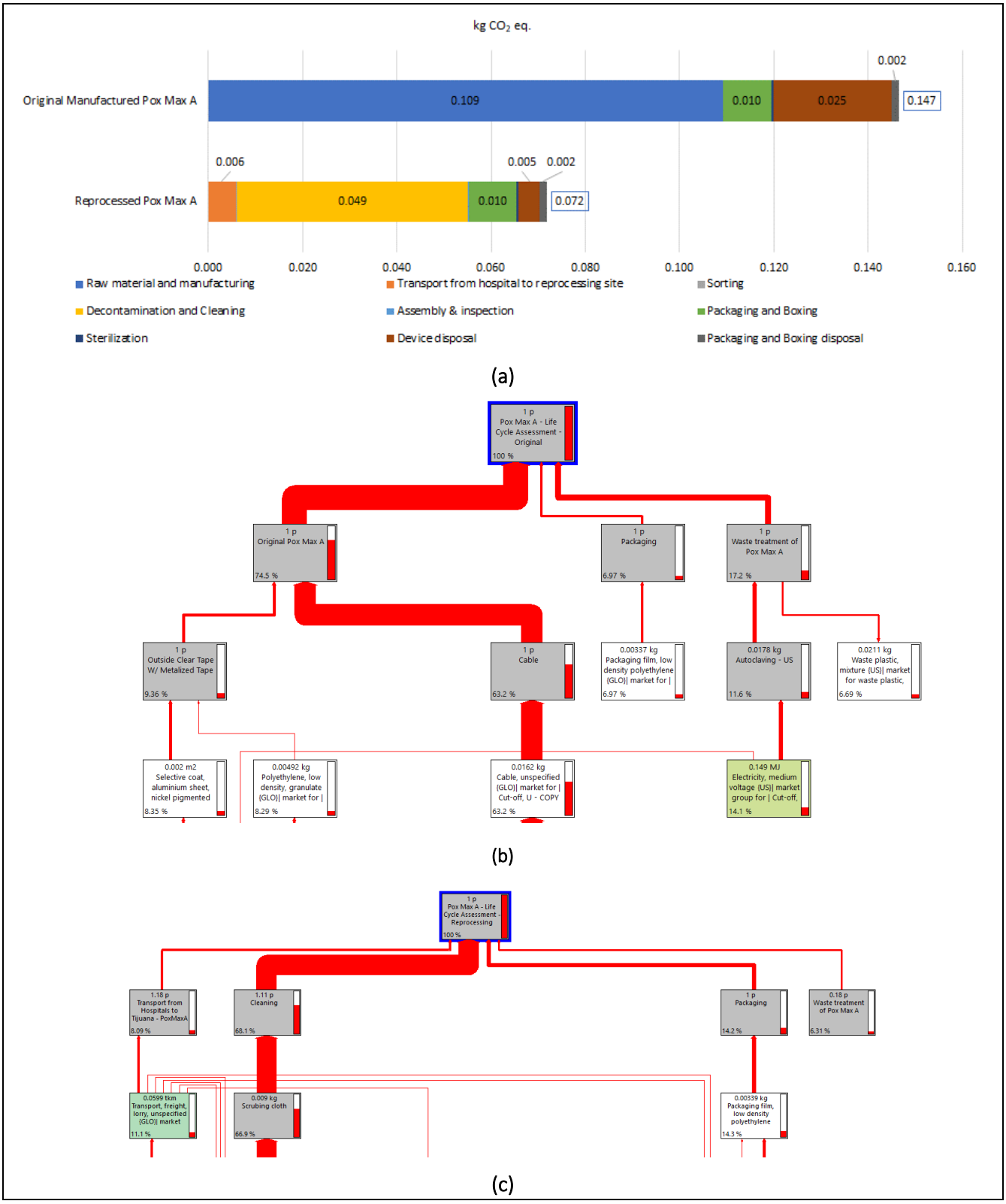

Figure 13 – a) Carbon footprint hotspots for the original and reprocessed Max-A by life cycle stage, b) Deep dive in carbon hotspots for original devices, c) Deep dive in carbon hotspots for reprocessed devices

The following points can be made from the previous figures:

- The production of components and raw materials is the main hotspot for the CFP of the original manufactured SUDs. For each device, the components and raw materials that contribute most to this impact are as follows:
    - ViewFlex: Circuit board (47.2%)
    - HARH36: Titanium scalpel rod (20.2%), left and right polycarbonate plastic handles (13.3%), and PCB assembly (10.2%)
    - LF2019: Stainless-steel scissors skeleton (18.7%) and electric banana plugs cables (16.6%)
    - MyoSure REACH: Zinc drive cable (10.3%), PVC housing (8.9%), plastic suction tube (8.8%), and Teflon outer shaft bushing (6.6%)
    - In general, the processing of raw material is less significant than the production of the raw material itself.
    - Max-A: Electric cable (63.2%)
- The main contributor to the CFP of the reprocessed devices, depends on the device.
    - ViewFlex: Packaging and boxing is the main contributor.
    - HARH36: Packaging and boxing is also the main contributor but decontamination and cleaning (D&C), assembly, and sterilization are also significant contributors. Within D&C, most CFP is due to electricity consumption, the torque wrench contributes to most of assembly, and transport and ethylene oxide contribute the most to sterilization.
    - LF2019: Inspection and assembly, and more specifically replacing the circuit board, is the main contributor. Electricity used in decontamination and cleaning, packaging, and boxing and ethylene oxide and transport to sterilization are other significant contributors.
    - MyoSure REACH: Packaging and boxing is also the main contributor, but electricity used in decontamination and cleaning, replacement parts used in assembly, and transportation to sterilization are also significant contributors.
    - Max-A: The consumable cloth, used during the manual cleaning is the main contributor. Packaging is not significant.
- The transport of the devices to the reprocessing sites has a relatively small contribution on the overall CFP of the reprocessed systems. For the five reprocessed SUDs, it represents no more than 8% of the overall impact.
- For all devices, except the ViewFlex, GHG emissions from disposal are lower in the reprocessed system compared to the original devices because only the equivalent of the reprocessing waste, which is less than one device, is sent to disposal. Producing one ViewFlex reprocessed device requires more than two original devices, hence the emissions from disposal are greater than the original.

3.3 Sensitivity analysis

3.3.1 Raw material production and manufacturing

As the results previously show, the advantage of reprocessed SUDs lies in the fact that it reuses materials, hence saving the environmental impact from their production and manufacturing. However, if the original device manufacturer makes significant improvements regarding the production of the device's parts (with the use of recycled content, alternative materials or other GHG reduction strategies), it may result in a reversal of the results.

This analysis aims to see how significant the CFP reduction of the original device production and manufacturing needs to be to make the original product system less carbon intensive than the reprocessed

device. To achieve the break-even points for each product, the raw material production and manufacturing would need to be reduced by the following percentages:

- ViewFlex: 86%
- HARH36: 67%
- LF2019: 52%
- MyoSure REACH: 46%
- Max-A: 68%

From those result,s we can conclude that reduction of the original SUD's CFP would have to be highly significant in order to reverse the conclusions.

3.3.2 System Boundaries and Allocation

An important limitation of the previous scope of the study is the choice of allocation method for recycling. With the selected approach, the system was credited with avoiding waste management and no environmental burden from manufacturing the original device was considered, which is an approach to incentivize reprocessing. It can be argued that the original production is an unavoidable step that must happen in order for devices to be reprocessed later on, especially that reprocessing cannot sustain itself. In an effort to better consider the full circular economy perspective induced by reprocessing, the system boundaries presented in Figure 14 are considered for this sensitivity analysis. In this analysis, we compared a device made from a completely linear system, with an average device originating from a system where reprocessing is implemented. As such, every use in the cascade, original or reprocessed, receives an equal share of the environmental load associated with raw materials, are equally penalized for low yields, and are equally attributed the benefits associated with reprocessing.

Table 9 presents the parameters to calculate the footprint of the circular system. The total number of uses (u) is from 1 original device and is calculated using the total yield of the different reprocessing steps (x), as well as the number of FDA approved reprocessing cycles (N)[4]:

[4] The number of times a single-use medical device can be reprocessed is determined by a number of factors: materials of construction, design/physical configuration, intended use, and human factors can all contribute to number of reprocessing cycles. For instance, certain directed energy devices contain sacrificial electrodes that slowly degrade (and become shorter) over time during use. Stryker engineers can determine how long a device has been used previously by measuring the electrodes; by measuring large numbers of used electrodes (as well as through procedural observation and interaction with end users), a worst-case surgical procedure usage time can be established, and a minimum electrode length specification can be set. In this specific example, the device electrodes are 10mm in length and degrade during use at a rate of .5mm/minute (so the device could be activated for a total of 20 minutes before ceasing to function). Average actual device usage time during a procedure is less than 2 minutes in total. Therefore, maximum number of reprocessing cycles is set at 3x to account for degradation during original use and provide a wide safety margin during each subsequent use. However, any of these used devices received with electrodes that measure shorter than the minimum length specification must be rejected regardless of cycle count because they are unlikely to remain functional for the duration of a subsequent procedure. External fixation devices (used to set/reset bone and other anatomical structures after trauma) are an excellent example of cycle counts being dictated by human factors. These devices are necessarily composed of extremely strong, durable materials like titanium/vanadium alloys and carbon fiber and have been validated in a laboratory to withstand hundreds of worst-case uses. However, while these devices are applied to patients in a trauma center or acute care facility, they are removed (after the patient has healed for many weeks) in a physician's office, usually nowhere near Stryker's used device collection points. In this case, maximum reprocessing cycles is capped at 3x. While the vast majority of external fixation devices are unfortunately thrown away in the physician's office, those that are collected are only sent to Stryker 1x. We set the maximum cycle count at 3x specifically to accommodate our armed forces/DOD customers that have very high collection compliance rates because external fixation devices are both applied to and removed from armed forces patients in the same military hospital facility.

$$u = 1 + \sum_{i=1}^{N} 1 * x^i$$

To calculate the average footprint of 1 device originating from the circular production system, the total impact of the system is divided by the number of uses.

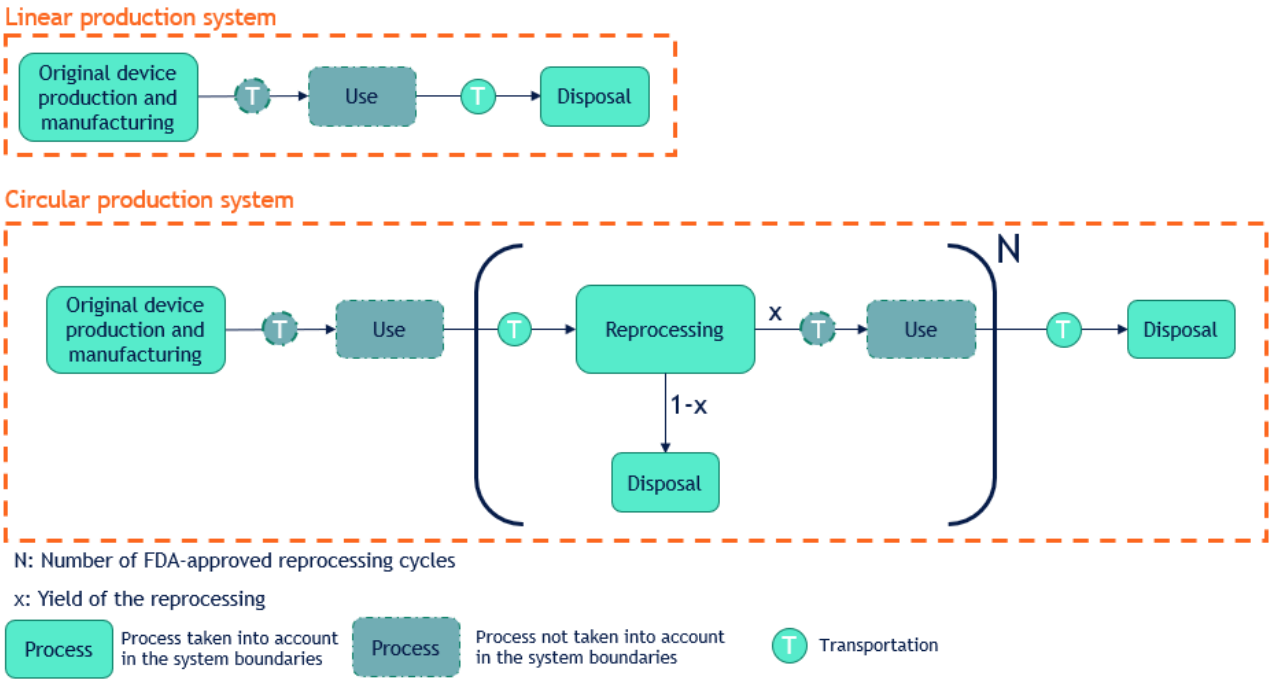

Figure 14 – Updated system boundaries for reprocessed systems and the linear production system in the model sensitivity analysis

Table 9 – Key parameters in the circular reprocessing system

Device	ViewFlex	HARH36	LF2019	MyoSure REACH	Max-A
Sorting yield (%)	97%	90%	75%	83%	
D&C yield (%)	63%	69%	100%	90%	85%
I&P yield (%)	67%	84%	87%	81%	
Total reprocessing yield (%)	41%	53%	65%	61%	85%
FDA approved reprocessing cycles	1	2	1	1	4
Number of uses	1.41	1.79	1.65	1.61	3.71

Results of the comparison of this updated system boundaries can be seen on Figure 15. From this figure, expanding the system boundaries to the full cascades of devices still gives the reprocessed device a lower footprint than the original, but to a lesser extent. This is explained by the fact that the benefits from reduced raw material consumption and disposal are now allocated between the original device and the reprocessed ones rather than solely to the reprocessed ones, recognizing the necessary contribution of both actors in the supply chain to make reprocessing possible. We can also draw the conclusion that the greater the yield and the reprocessing cycles, the lower the footprint of the reprocessed device.

According to Schulte et al., the "supporters perspective" is easier to apply when the focus is on single products and to represent short-terms impacts. The circular approach is more appropriate for making long-term decision on the implementation of circular systems.

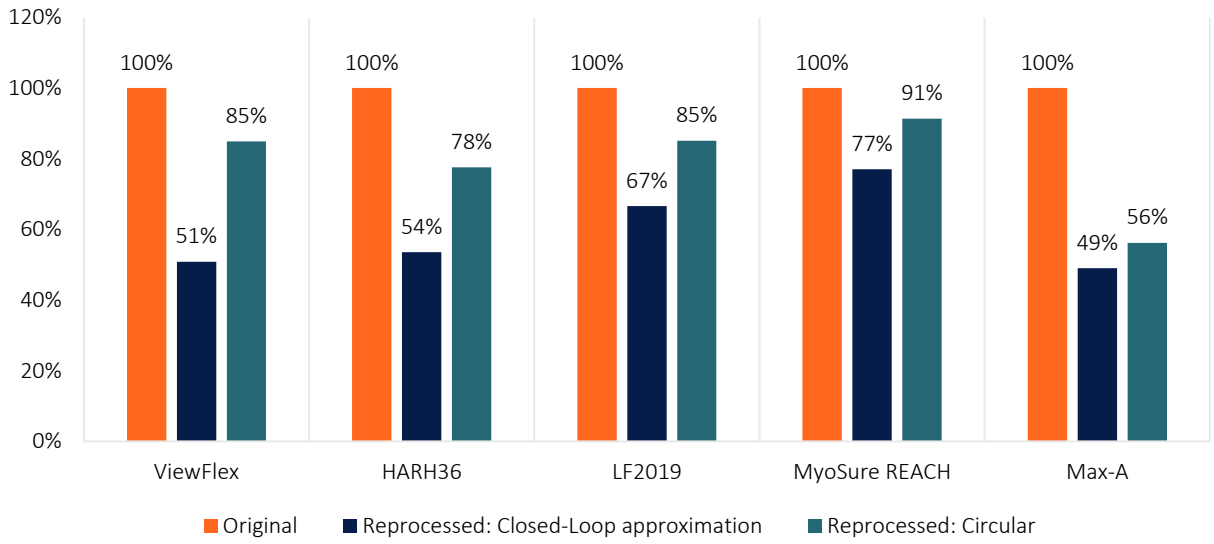

Figure 15 – Results of the carbon footprint of the sensitivity analysis on system boundaries and allocation. [Repro. SUD: Cut-off system boundaries, Circular. Repro. SUD: Updated system boundaries taking into account the production of the original device]

3.3.3 Mode of transportation for the collected devices

The initial assumptions about the mode of transportation of the collected SUDs assumed a truck only logistic. However, because transportation by airplane can still be an accepted logistic choice, and because it emits more than five times what truck emit, this sensitivity analysis aims to assess the sensitivity of our results to a more carbon intensive mode of transportation. Figure 16 shows a difference in the sensitivity when switching to exclusive air freight for the SUD transportation from the hospital to the reprocessing sites. From this result we can point out that switching all the collection mode to airplanes won't change the results of the comparison between original SUDs, and reprocessed SUDs, but it would significantly increase the CFP of reprocessed SUD.

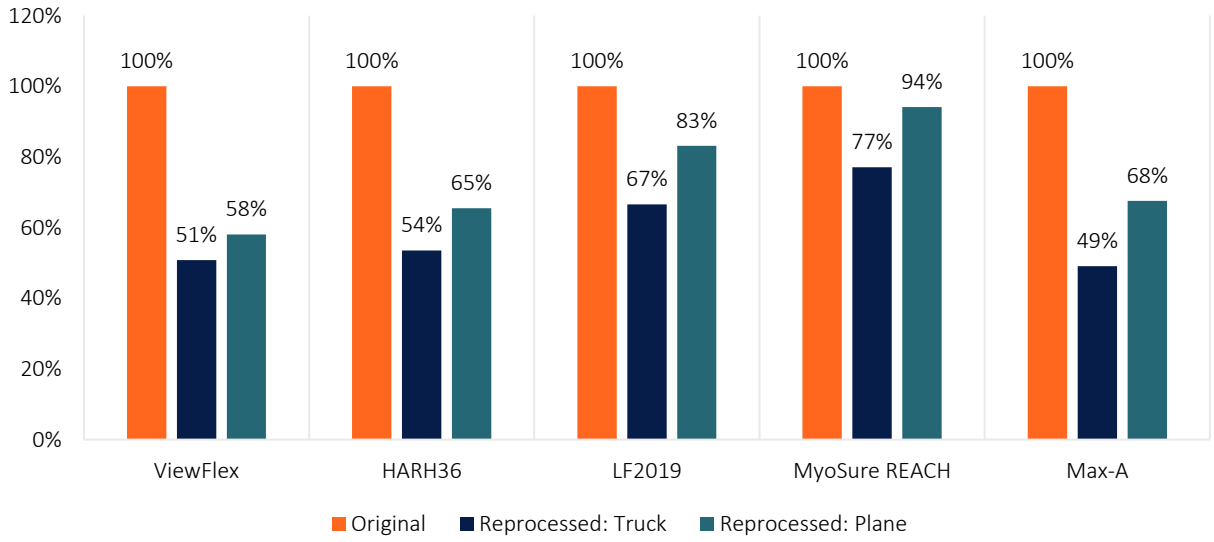

Figure 16 – Sensitivity analysis on transport mode from hospitals for reprocessed SUD scenario

Transportation from manufacturing to hospitals has been excluded from the system boundaries. In this sensitivity analysis (Table 10), we test the amount of additional transportation that would be required for the reprocessed device CFP to be equal to that of the original for both truck and airplane transportation mode. Results generally show that difference in transportation to the hospitals would need to be extremely high to change the conclusions of the study. That said, if devices were transported by airplane much smaller distances would be needed, especially for MyoSure.

Table 10 – Additional transportation needed for the carbon footprint of reprocessed devices to be equivalent to that of original

Device	Breakeven transportation distance	
	Truck	Plane
ViewFlex	>26,000 km	>4,700 km
HARH36	>28,000 km	>5,000 km
LF2019	>16,000 km	>2,900 km
MyoSure	>7,000 km	>1,200 km
Max-A	>26,000 km	>4,600 km

3.3.4 Reprocessing Yield

The lower the reprocessing yield, the higher the CFP of reprocessed devices. ViewFlex has the lowest of the reprocessing yields. This sensitivity analysis assesses the effect of increasing the total reprocessing yield of ViewFlex from 41% to 85% (equal processing losses in each step). Figure 17 show that increasing the yield from 41% to 85% improves the CFP of ViewFlex by 14% with gains observed in each of the reprocessing steps, as well as disposal.

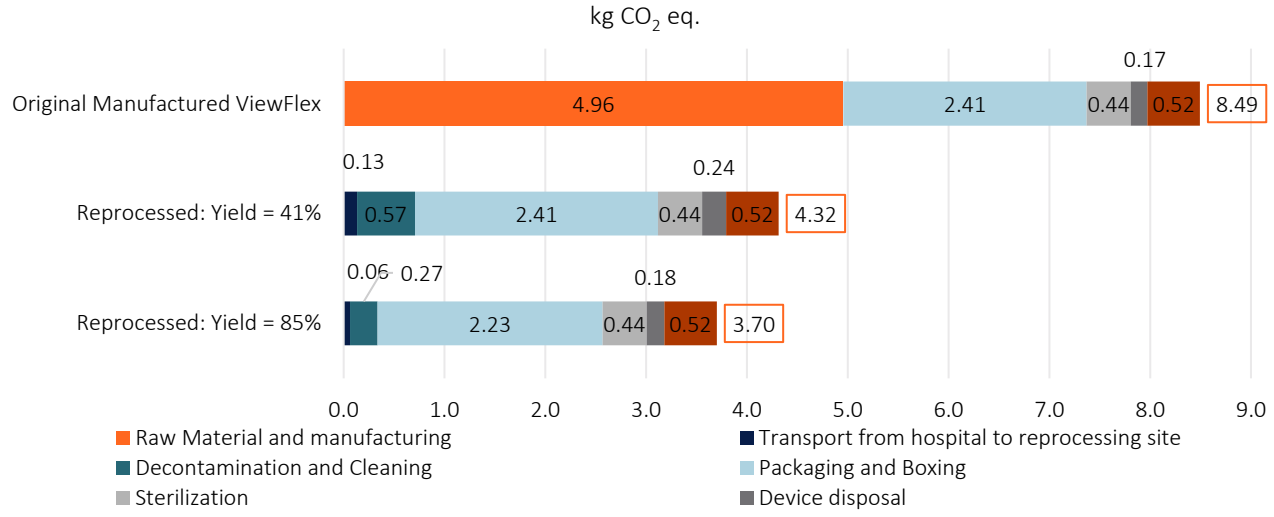

Figure 17 – Sensitivity analysis on reprocessing yield for ViewFlex

3.3.5 Electricity mix for ViewFlex

ISO 14067 requires that when possible the residual electricity mix is used. Reprocessing that uses electricity is from the SERC region is unlikely to be significantly affected by the use of the residual mix instead of the consumption mix because of the low share of renewable energy in this region. Share of renewables in the WECC region, as illustrated in Table 11, is greater. In this sensitivity analysis, we test the effect of using an

approximated residual mix. The residual mix was approximated by assuming 0% electricity from the non-hydropower renewable energy sources (see Table 11, for assumed mix). Results in Figure 18 show that the grid mix has little implications for the CFP of ViewFlex.

Table 11 – Grid mixes used for reprocessing, sensitivity on residual mix

	WECC – Consumption Mix	WECC – Approximated Residual Mix
Coal and lignite	21.3%	24.1%
Hydro	23.5%	26.6%
Natural gas	33.2%	37.6%
Nuclear	8.0%	9.0%
Oil	0.0%	0.0%
Wind	7.6%	0.0%
Other biofuels	1.3%	0.0%
Geothermal	2.2%	0.0%
Solar	0.5%	0.0%
Import from Canada	1.7%	1.9%
Import from Mexico	0.8%	0.9%

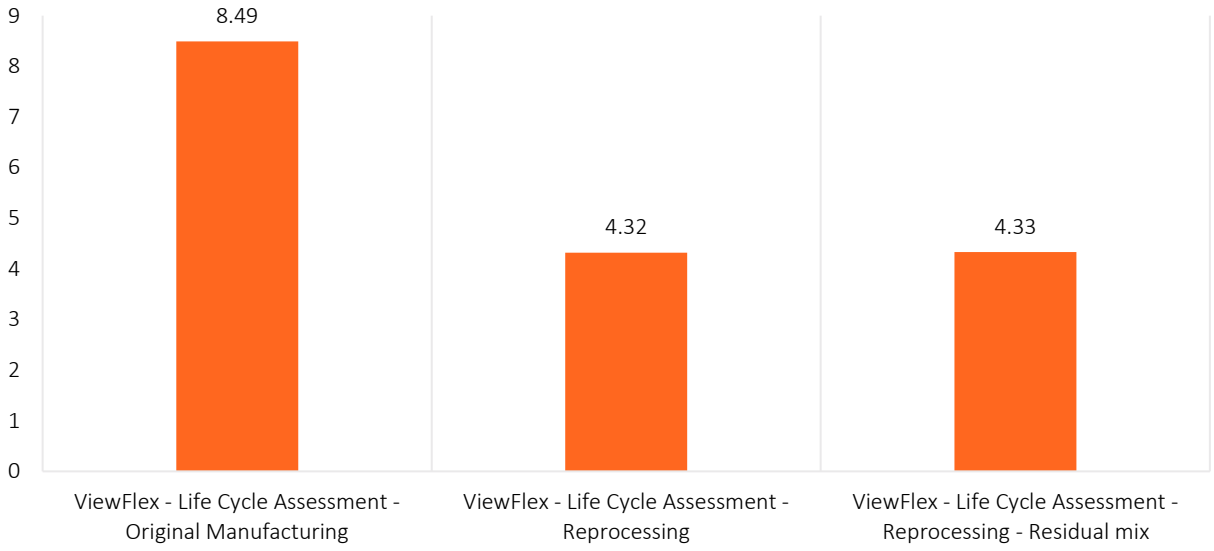

Figure 18 – Sensitivity analysis on grid mix for ViewFlex

3.4 Uncertainty analysis

In this study, no comprehensive quantitative uncertainty analysis is performed. However, uncertainty is important in understanding the significance of the results obtained, especially when comparisons are performed. For this reason, a qualitative analysis is undertaken using significance heuristics. Significance heuristics are pre-defined thresholds of uncertainty such as comparative results are presumed equal unless surpassing the threshold (Matthews 2014). The choice of the threshold is subjective. For example, Matthews et al. (2014) mentioned 20%, as a good practice with no strong justification, and Humbert et al. (2009) mentioned 10% for global warming as a common practice in LCA.

The results of the default scenarios and parameters presented in section 3 show large differences in CFP when comparing both original manufacturing and reprocessed systems. Indeed, this indicates that the differences observed between the two systems always surpass a potential 20% threshold and are considered meaningful. However, the scenario analysis shows that the transportation mode could potentially approach those thresholds if the distance covered was more significant, like a transcontinental logistic model. It therefore means that some specific context and situations could strengthen or weaken the conclusion of this analysis.

In addition, we undertook a limited Monte Carlo analysis (1000 runs) for the original vs. reprocessed Max-A devices for which the difference in CFP was lower than other products (Figure 19). The results show that, when considering only the uncertainty in the ecoinvent data, the probability that the CFP of original devices is greater than that of reprocessed devices is 100%.

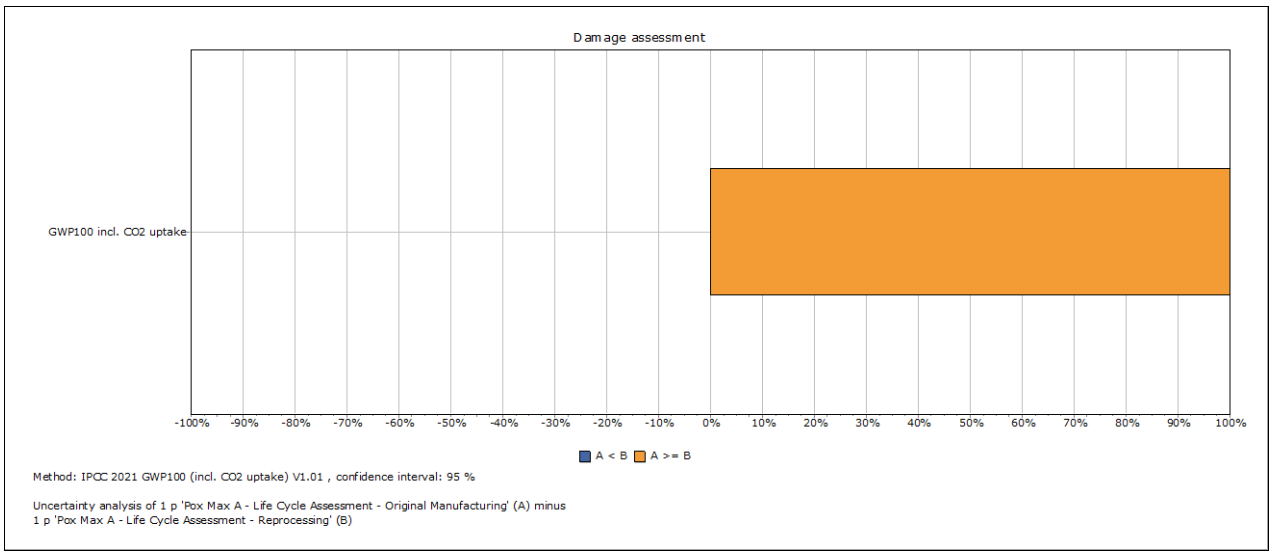

Figure 19 – Limited uncertainty analysis on the original (A) versus reprocessed (B) Max-A devices

4 Conclusions, limitations, and recommendations

The study presented in this report generates CFPs of five single use medical device and compares the CFP of the original manufacturing with the reprocessing of used devices. The functional unit for this study is defined as "*Provide one medical device for single use, compliant to the relevant FDA standard, in the US*". The system boundary is set at cradle-to-grave. A single environmental attribute is studied, the CFP, and uses an indicator of global warming developed by the IPCC. The LCA models are constructed in SimaPro v9.3.0.2, with the ecoinvent 3.8 LCI database. Primary data are collected from Stryker to model the reprocessing systems and secondary data and assumptions to model the manufacturing from the raw material.

4.1.1 Conclusions

The following conclusions can be drawn from the study:

- For all of the devices considered in the study, the reprocessing system shows a better carbon footprint than the original manufacturing.

- For all reprocessed devices except for Max-A, packaging is a significant contributor to the carbon footprint. Other significant contributors to the carbon footprint of reprocessed devices include energy used in

cleaning and decontamination, some replacement parts and transportation to the sterilization facility. For Max-A, the cloth used for cleaning is the main contributor to the carbon footprint.

- The collection of used devices, and their transportation by truck from all over the US to the reprocessing facility doesn't appear as a significant contributor to the carbon footprint.

- The main hotspot of the original SUDs is the production of the material, especially when it represents a significant portion of the mass of the SUD.

4.1.2 Limitations

As the CFPs presented in this report are, in their essence, models, the results are subjects to the following limitations:

- The scope, boundaries and reference period defined within this assessment and to be precise the fact that the study excluded the distribution and the use phase, under the fair argument that the goal of the study is mainly comparative. Those steps could be the main contributor of the absolute CFP of medical devices, and this study doesn't assess their relative importance.
- The presented study only reports one environmental indicator, it doesn't assess the water consumption, or any other environmental indicator that could be relevant to the industry.
- The study doesn't give clear answers regarding more complex, or airborne, or cross continental logistic scenarios. It's limited to collection and reprocessing carried out in the US.
- The original devices are modeled almost exclusively based on the ecoinvent databases and some processes might be relatively dated. Improving data quality for the production of the components in the original footprint is likely to reduce their footprint and disadvantage reprocessing. That said, where possible we made conservative assumptions, which are likely to at least partly compensate for the lack of quality of data of the original devices.
- The results cannot be extrapolated to other SUDs.

4.1.3 Recommendations

This LCA study has highlighted the carbon footprint hotspots of Stryker's reprocessing systems monitoring system and the following recommendations are made:

- Reduce packaging and boxing: This study demonstrated that production and disposal of packaging are major contributors to the CFP of the reprocessed SUDs. Reducing its mass, without compromising its functionality, and finding alternative materials with high recycled content are significant opportunities to improve the CFP of the reprocessed systems even further.

- Improve the yield of the reprocessing steps: Improving the reprocessing yield will reduce the CFP of the reprocessed device due to lower use of energy and consumable and less waste generation. This can be achieved through a more rigorous cleaning and decontamination step. As shown by the application of the circular allocation method, working to move the legislative needle towards more FDA-approved reprocessing cycles for each SUD will also reduce the overall carbon footprint of medical devices.

- Place a greater emphasis on using raw materials with recycled content: Lowering the carbon footprint of raw materials (plastic, metals), for instance through the use of recycled materials has the potential to significantly reduce the CFP of both original and reprocessed devices.

- Limit air transportation: The sensitivity analysis showed that using air transportation significantly increase the CFP of reprocessed SUDs.

- Work with suppliers to reduce the CFP of circuit boards: For some devices, it is necessary to replace the circuit board, which is carbon-intensive. Working with suppliers to reduce the CFP of this is a good opportunity to reduce the broader CFP of reprocessing.

- Quantify and reduce the CFP of consumable cleaning swabs and wipes: Consumable clothes are the main contributor to the CFP of Max-A. The first step would be to collect supplier specific data on the CFP of these clothes. Then, reducing the CFP by finding alternatives (e.g., reusable clothes) or working with the supplier to reduce the CFP of the consumables is a significant opportunity to improve the CFP of reprocessing.

- Improve sterilization: Undertaking sterilization onsite and reducing the amount of ethylene oxide needed would improve the carbon footprint of reprocessed devices.

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Appendices

A1 Additional tables

Table S1 – Life cycle stage description and main assumptions for the ViewFlex systems

	Original manufactured ViewFlex	Reprocessed ViewFlex
Raw material and maufacturing	Represent the production and manufacturing of the different components. Based on tear down analysis and ecoinvent generic manufacturing processes	-
Transport from hospitals to reprocessing site	-	Truck transportation of devices from the hospitals, where they are collected, to the reprocessing site, in Phoenix. Based on the measured collected volume of 2021, in the contiguous USA.
D&C	-	Decontamination and cleaning consist of several bath and heated drying phases. Based on measured data.
Packaging and Boxing	Production of packaging and boxing (secondary packaging)	
Sterilization	Ethylene Oxide sterilization. Based on Stryker data. Assumed the same for both systems.	
SUD waste treatment	End of life scenario of the device at the end of the use phase. Assumed to autoclaved/landfilled.	End-of-life scenario of dicarded device during the reprocessing. Assumed to be autoclaved/landfilled.
Packaging and Boxing waste treatment	End of life scenario of the primary and secondary packaging. Mix of recycling, landfilling and incineration.	

Table S2 – Life cycle stage description and main assumptions for the HARH36 systems

	Original manufactured HARH36	Reprocessed HARH36
Raw material and maufacturing	Represent the production and manufacturing of the different components. Based on tear down analysis and ecoinvent generic manufacturing processes	-
Transport from hospitals to reprocessing site	-	Truck transportation of devices from the hospitals, where they are collected, to the reprocessing site, in Lakeland, FL. Based on the measured collected volume of 2021, in the contiguous USA.
D&C	-	Decontamination and cleaning consist of several bath and heated drying phases. Based on measured data.
Assembly	-	During assembly, the torque wrench assemble, the trigger spring, the teflon pad and the shafct rotation knob pin are replaced.
Packaging and Boxing	Production of packaging and boxing (secondary packaging)	
Sterilization	Ethylene Oxide sterilization. Based on Stryker data.	Ethylene Oxide sterilization. Based on Stryker data. Made outside the facility (Minneapolis, MN)
SUD waste treatment	End of life scenario of the device at the end of the use phase. Assumed to autoclaved/landfilled.	End-of-life scenario of dicarded device during the reprocessing. Assumed to be autoclaved/landfilled.
Packaging and Boxing waste treatment	End of life scenario of the primary and secondary packaging. Mix of recycling, landfilling and incineration.	

Table S3 – Life cycle stage description and main assumptions for the LF2019 systems

	Original manufactured LF2019	Reprocessed LF2019
Raw material and maufacturing	Represent the production and manufacturing of the different components. Based on tear down analysis and ecoinvent generic manufacturing processes	-
Transport from hospitals to reprocessing site	-	Truck transportation of devices from the hospitals, where they are collected, to the reprocessing site, in Lakeland, FL. Based on the measured collected volume of 2021, in the contiguous USA.
Sorting	-	Disassembly and sorting of the SUDs. Inputs are small consumables amounts
D&C	-	Decontamination and cleaning consist of several bath and heated drying phases. Based on measured data.
Inspection and Assembly	-	During assembly, the plug housing and its circuit board are replaced.
Packaging and Boxing	Production of packaging and boxing (secondary packaging)	
Sterilization	Ethylene Oxide sterilization. Based on Stryker data.	Ethylene Oxide sterilization. Based on Stryker data. Made outside the facility (Minneapolis, MN)
SUD waste treatment	End of life scenario of the device at the end of the use phase. Assumed to autoclaved/landfilled.	End-of-life scenario of dicarded device during the reprocessing. Assumed to be autoclaved/landfilled.
Packaging and Boxing waste treatment	End of life scenario of the primary and secondary packaging. Mix of recycling, landfilling and incineration.	

Table S4 – Life cycle stage description and main assumptions for the MyoSure systems.

	Original manufactured MyoSure REACH	Reprocessed MyoSure REACH
Raw material and maufacturing	Represent the production and manufacturing of the different components. Based on tear down analysis and ecoinvent generic manufacturing processes	-
Transport from hospitals to reprocessing site	-	Truck transportation of devices from the hospitals, where they are collected, to the reprocessing site, in Lakeland, FL. Based on the measured collected volume of 2021, in the contiguous USA.
Sorting	-	Disassembly and sorting of the SUDs. Inputs are small consumables amounts
D&C	-	Decontamination and cleaning consist of several bath and heated drying phases. Based on measured data.
Inspection and Assembly	-	During assembly, the handle shroud, outer shaft, suction tube and screws are replaced. The cutting shaft is transported to an external partner to be re-sharpened.
Packaging and Boxing	Production of packaging and boxing (secondary packaging)	
Sterilization	Ethylene Oxide sterilization. Based on Stryker data.	Ethylene Oxide sterilization. Based on Stryker data. Made outside the facility (Minneapolis, MN)
SUD waste treatment	End of life scenario of the device at the end of the use phase. Assumed to autoclaved/landfilled.	End-of-life scenario of dicarded device during the reprocessing. Assumed to be autoclaved/landfilled.
Packaging and Boxing waste treatment	End of life scenario of the primary and secondary packaging. Mix of recycling, landfilling and incineration.	

Table S5 – Life cycle stage description and main assumptions for the Max-A systems

	Original manufactured Max-A	Reprocessed Max-A
Raw material and maufacturing	Represent the production and manufacturing of the different components. Based on tear down analysis and ecoinvent generic manufacturing processes	-
Transport from hospitals to reprocessing site	-	Truck transportation of devices from the hospitals, where they are collected, to the reprocessing site, in Tijuana, Mexico. Based on the measured collected volume of 2021, in the contiguous USA.
Sorting	-	Disassembly and sorting of the SUDs. Inputs are small consumables amounts
D&C	-	Mostly made by hand. Inputs are small consumable amounts. Based on measured data.
Inspection and Assembly	-	Reassembly of the SUD. Inputs are small consumables amounts
Packaging and Boxing	Production of packaging and boxing (secondary packaging)	
Sterilization	Hydrogen peroxide sterilization. Based on Stryker data. Made inhouse.	
SUD waste treatment	End of life scenario of the device at the end of the use phase. Assumed to autoclaved/landfilled.	End-of-life scenario of dicarded device during the reprocessing. Assumed to be autoclaved/landfilled.
Packaging and Boxing waste treatment	End of life scenario of the primary and secondary packaging. Mix of recycling, landfilling and incineration.	

A2 Inventory spreadsheet

Life cycle inventory data is available in a separate spreadsheet (A2_Stryker_Life Cycle Inventory Data.xls).

A3 Critical review statement

The critical review statement is provided on next page.

Critical Review Statement

Date: February 16, 2023

CFP Commissioned by: Stryker Sustainability Solutions

CFP Conducted by: Joris Deschamps and Caroline Gaudreault, Ph.D.
Anthesis LLC
1002 Walnut Street, Suite 202
Boulder, CO 80302

Report Title: Comparative Carbon Footprint of Single Use Medical Devices

Panel Review Conducted by: Terrie K. Boguski, Harmony Environmental, LLC (Chair)
Dr. Cassandra Thiel, NYU Grossman School of Medicine
Dr. Yan Wang, University of Brighton, UK

ISO Referenced Standards: ISO 14067; ISO 14044:2006+Amd1:2017+Amd2:2020;
ISO 14040**:**2006; ISO/TS 14071:2014

Critical Review Process, Scope and Conclusion

In accordance with the international standards, ISO 14067 and ISO 14044:2006, a formal Critical Review was conducted by 3-person review panel of the carbon footprint (CFP) report, Comparative Carbon Footprint of Single Use Medical Devices. The report compared the CFP of 5 reprocessed single-use medical devices (SUDs) and their original manufacturing SUDs scenarios. The review was an end-of-report review, and reviewers received the entire draft report. Review was based on the stipulations in ISO 14067 and ISO 14044. ISO 14044 is a normative reference for 14067. The review followed guidance in ISO 14071:2014.

The reviewers received the draft report on December 7, 2022 and provided initial comments to Anthesis on December 22, 2022. The reviewers received the final revised report on February 9, 2023. The review was conducted by exchanging comments and responses via video conference and email. Comments were recorded in an Excel spreadsheet in tabular format based on Annex A of ISO/TS 14071:2014. All comments were addressed, and all open issues resolved.

The findings of the panel concluded that in addition to conformance with ISO 14067, all required stipulations in ISO 14044:2006 6.3 were met in the revisions to the report (received February 9, 2023). In particular,

- The methods used to carry out the LCA are consistent with this International Standard,
- The methods used to carry out the LCA are scientifically and technically valid,
- The data used are appropriate and reasonable in relation to the goal of the study,
- The interpretations reflect the limitations identified and the goal of the study, and
- The study report is transparent and consistent.

The reviewers did not have access to LCA calculations, underlying data or models. Therefore, the review is primarily limited to the summary data and model results included in the report. Completing the critical review does not mean that the reviewers endorse the results of the LCA study, nor does it mean that they endorse any of the assessed products.

ISO 14044:2006 requires that this critical review statement, as well as the reviewer's comments and any responses to recommendations made by the reviewers be included in the final report.

Submitted on behalf of the Peer Review Panel by

Terrie Boguski

Critical Review Statement ADDENDUM

Date: May 26, 2023

CFP Commissioned by: Stryker Sustainability Solutions

CFP Conducted by: Joris Deschamps and Caroline Gaudreault, Ph.D.
Anthesis LLC
1002 Walnut Street, Suite 202
Boulder, CO 80302

Report Title: *Comparative Carbon Footprint of Single Use Medical Devices*

Panel Review Conducted by: *Terrie K. Boguski, Harmony Environmental, LLC (Chair)*
Dr. Cassandra Thiel, NYU Grossman School of Medicine
Dr. Yan Wang, University of Brighton, UK

ISO Referenced Standards: ISO 14067; ISO 14044:2006+Amd1:2017+Amd2:2020;
ISO 14040**:**2006; ISO/TS 14071:2014

Post-review Summary

After the review panel concluded its work and submitted the Critical Review Report consisting of the critical review statement and final comments log, Stryker adjusted the product naming convention and made minor editorial revisions to the report. The panel chair reviewed the edited report and found that all data, results and conclusions of the report remain the same as in the report version reviewed by the critical review panel.

Terrie K Boguski

Terrie Boguski