PROJECT CHARTER

Device Remanufacturing

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Executive Sponsor:

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Please contact CASCADES@utoronto.ca if you have any questions.

NAVIGATION

Goal & Scope

1 What do you want to achieve?

Address waste from single-use devices by:
a) submitting eligible single-use devices for reprocessing ("collecting"), and/or
b) purchasing reprocessed devices instead of new devices ("purchasing")

2 Define the limits of what you want to be included in the project and consider the environmental impacts you are targeting for change.

Project Scope: All eligible disposable devices used for surgical procedures. The stakeholders include operating room (OR) staff that use the devices, the procurement department for the OR, suppliers that provide device remanufacturing services, and the hospital's environmental services department.

Emission scope: Scope 3; these emissions arise from activities or products that are related to health sector activities, but not owned or controlled by the organization, such as pharmaceuticals and other medical products and devices.

Problem/Opportunity Statement

3 Briefly state the problem you want to solve or the opportunity you want to realize.

Although many medical devices were once made of stainless steel and sterilized for reuse in-house, concerns around convenience, cost, infection prevention, and the efficacy of in-house processing prompted a shift to single-use devices (SUDs) (1–3), such that in the past thirty years, the healthcare sector has become reliant on single-use materials (4) – a practice further exacerbated by the COVID-19 pandemic. By recent estimates, the disposable medical device industry has an approximate value of $50 billion, which is increasing at a rate of 4% annually (5).

SUDs represent a linear supply chain in which products are manufactured, used once, then discarded (4). This type of arrangement is unsustainable on a number of fronts. Not only are single-use devices vulnerable to supply chain disruptions; they also contribute to environmental degradation by depleting natural resources and generating solid waste, greenhouse gases, and other harmful emissions (4). In an attempt to disrupt this linear model, efforts have been made to increase the number of times a single-use device can be used, thereby keeping products in circulation for as long as possible (in accordance with a "circular economy" model). Through a highly regulated process called device reprocessing (or "remanufacturing"), single-use devices that have been used are taken apart, rebuilt, then used again. As of September 2017, Health Canada approves commercially remanufactured devices according to the same standards by which it assesses virgin devices (6).

Sites can participate in device reprocessing in multiple ways. They can collect used single-use devices in specially designated bins; these are collected without charge by commercial device reprocessors, thereby lowering waste hauling fees, and diverting waste from landfill. Sites can also elect to purchase remanufactured devices; these are less expensive than virgin devices, and likely have a smaller environmental footprint.

Problem/Opportunity Statement

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A growing number of studies have conducted life cycle assessments (LCAs) comparing the environmental impacts of remanufactured devices to virgin devices. The impact of the manufacturing, transportation, and disposal of the virgin device must be weighed against the impact of the water, sterilization gasses, detergents and disinfectants, packaging materials, and energy use involved in creating the remanufactured device. These studies indicate remanufactured devices offer environmental and cost benefits.

For example, for electrophysiological diagnostic catheters used in cardiac ablation procedures, device remanufacturing is a well-established process that guarantees equivalent or better quality than virgin devices. Compared to a virgin device, the remanufactured device was superior in 13 of 16 environmental categories evaluated, including a 50.4% reduction in global warming impact, 90% reduction in ozone depletion, 66.8% reduction in disease incidents from respiratory inorganics, and 60.9% reduction in cancer causing human health effects (7). A follow-up effort to validate the results of this study determined long-term emission reductions of up to 48% per remanufactured catheter life compared to virgin devices. The authors also note that remanufactured catheters have the potential to produce significant financial savings on a large scale (up to £1.7 m annually in the UK) (8).

It is important to note that the sustainability of the remanufacturing process factors heavily into the environmental superiority of a remanufactured device. An LCA of seven remanufactured devices used in Phoenix hospital (deep vein thrombosis (DVT) compression sleeve, pulse oximeter, ligasure, harmonic scalpel, endoscopic trocar, arthroscopic shaver, and scissor tip) found that "if reprocessing inputs are minimized, then employing reprocessing is favorable from both a global warming and human health perspective." (9) Notably, this study assumed packaging was the same for remanufactured and virgin devices; statistics offered by Stryker Sustainability indicate their remanufactured devices have 13–41% less packaging than virgin devices (depending on the device in question).

Problem/Opportunity Statement

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Major impediments to device remanufacturing in healthcare relate to concerns about infection risk and cost. Despite the commonality of single-use devices, there is no compelling evidence that they reduce infection risk (4). Many studies support a multifactorial model for infection, and most decreases in surgical site infection rates can be attributed to evidence-based medicine protocols such as glycemic control and normothermia (10,11,12). In addition, medical device reprocessing offers significant savings via the elimination of waste hauling fees for collected single-use items, and reduced costs for reprocessed items. (9) Estimates have placed the average cost of SUDs at 40–60% lower than new products (13,14)

Current State of the System/Process

4 What do things look like today?

Disposable devices

1. Vendor provides medical devices to the hospital
2. Device is used during a surgical procedure
3. Device is placed in waste bin to be picked up by the custodial staff
4. The bins are collected by the waste haulers to go to the landfill or incinerator

Remanufactured devices

1. Vendor provides medical devices to the hospital
2. Commercial device reprocessor identifies the devices that can be returned to be remanufactured
3. Commercial device reprocessor provides bins for the collection of devices that can be remanufactured
4. Device is used during a surgical procedure
5. Device is placed in special bin to be picked up by the custodial staff
6. Commercial device reprocessor arranges transport of the bins (the hospital does not need to make arrangements)
7. Device undergoes the remanufacturing process (non-eligible devices are sent for recycling)
8. Remanufactured device is packaged, labeled and sold at a reduced cost or using credits earned from collected devices.
9. Device can only be reprocessed a certain number of times, and must pass a quality check before being delivered to a hospital for use
10. At end-of-life, device is landfilled or autoclaved and then landfilled.

Root Cause Analysis

5 What gets in your way?

Education & Awareness
- Lack of knowledge surrounding the incentives for participating in a device remanufacturing program.
- Misconceptions that it is costly to send items to be remanufactured.
- Lack of awareness that remanufactured devices are Health Canada approved and meet quality standards.
- Misconceptions from uninformed vendors who are not reliable sources of information on device remanufacturing.
- Lack of awareness of legal liability and warranty of the remanufactured devices.

Clinical Workflow
- Concerns about the safety and efficacy of remanufactured devices.
- Concerns that there may not be enough devices on site to carry out surgical procedures.
- Concerns that a new waste stream will require extra staffing and physical space that may not be available.

Finance & Procurement
- Some hospitals have both options available to staff, which does not maximize cost savings and environmental impact.
- Some hospitals do not have a contract with a vendor that remanufactures devices (for pick up or purchasing).
- Concerns that there may not be enough remanufactured devices available to meet hospital demand (supply chain shortages).
- Poor experiences with vendors in the past lead to avoidance of remanufactured devices.

Design the Improvement & Define Change Ideas

6 What are your ideas to achieve your goals, address your root causes and close the gap from your problem statement?

Education & Awareness

- Create educational materials (posters, rounds, letters, memos) on:
  - the environmental impacts of single-use devices, and
  - the cost savings and environmental benefits of remanufactured devices (be sure to address concerns and misconceptions about device remanufacturing)
  - Devices eligible for remanufacturing **(Resource: Stryker Guide)**
- Share education materials with department managers with decision-making power over device procurement (e.g., Procurement, Medical Device Reprocessing Department, Surgical Division, Operating Room Manager, etc.)
- Ensure staff know how to correctly dispose of devices to be remanufactured (e.g., put the device in correct bin, do not cut cord on energy devices, etc.)

Finance & Procurement

- Create a business case that indicates long term cost-savings or neutrality
- Transition to 100% purchasing of remanufactured items to optimize costs, incentives and environmental impact
- Connect with a representative from a vendor that has a request for proposal (RFP) with your hospital's existing surgical device provider to support the transition to procuring remanufactured devices
- If your hospital's medical device supplier does not have an RFP with a vendor that remanufactures disposable devices, the hospital will need to renegotiate the contract or change to a supplier that has an RFP with the vendor.

Measure & Test Impact

7 How will you estimate the environmental impact of your changes?

Activity/Outcome Metric

1. Collection: Number of bins full of single-use devices collected per month
2A. Purchase: # remanufactured devices purchased
2B: Purchase: # virgin devices purchased

Source(s):
- Vendor data
- Procurement data
- Self-audit

Considerations:
- For 1: weight diverted from landfill/treatment can be converted into waste disposal cost savings, and added to the cost savings from purchasing remanufactured devices
- Monthly counts are recommended to observe progress, but data can be processed for any given time frame.

Related Environmental Metric

1. **5kg (average weight of waste diverted from landfill)**
2. **A&B: Available metrics:**
   - **Electrophysiology Catheters:**

Remanufactured (kg CO2e)	OEM * (kg CO2e)	Source
0.61	1.53	Meister
0.87	1.75	Schulte

   - **Other metrics of interest:**
     - **Per Stryker (15), packaging for remanufactured devices is 13–41% less than for virgin devices, depending on the device**
     - **Per Eze (13) the energy required for remanufacturing is 15% of the energy required to manufacture equivalent new products**

**Original Equipment Manufacturer*

Sources:
- Meister, 2023 (8); Schulte et al. 2021 (7); Stryker (15); Eze et al. 2020 (13)

Considerations:
- For 1: Note that only a small portion of what is collected in each bin is actually eligible for reprocessing. The rest is sent for recycling, which has associated emissions.
- For 2: Given the variability of devices that can be remanufactured, there is no one comparison that can be made between remanufactured vs. virgin devices. Keep collecting activity metrics so they can be put into conversation with environmental data as these become available.

Environmental Impact

#1 and #2 are separate calculations.

For #2, you can:
- *Tally your 2A and 2B metrics; the resulting figure will be the total emissions associated with your devices*
- *Run a calculation assuming ALL devices are virgin, then subtract the figure you obtained from adding the 2A and 2B metrics together; the result will be your emissions savings*

Considerations:
- There should be a REDUCTION in this number over time as the proportion of remanufactured devices rises relative to the proportion of virgin devices.
- Use the Natural Resources Canada Greenhouse Gas Equivalencies Calculator to translate your results to stakeholders.

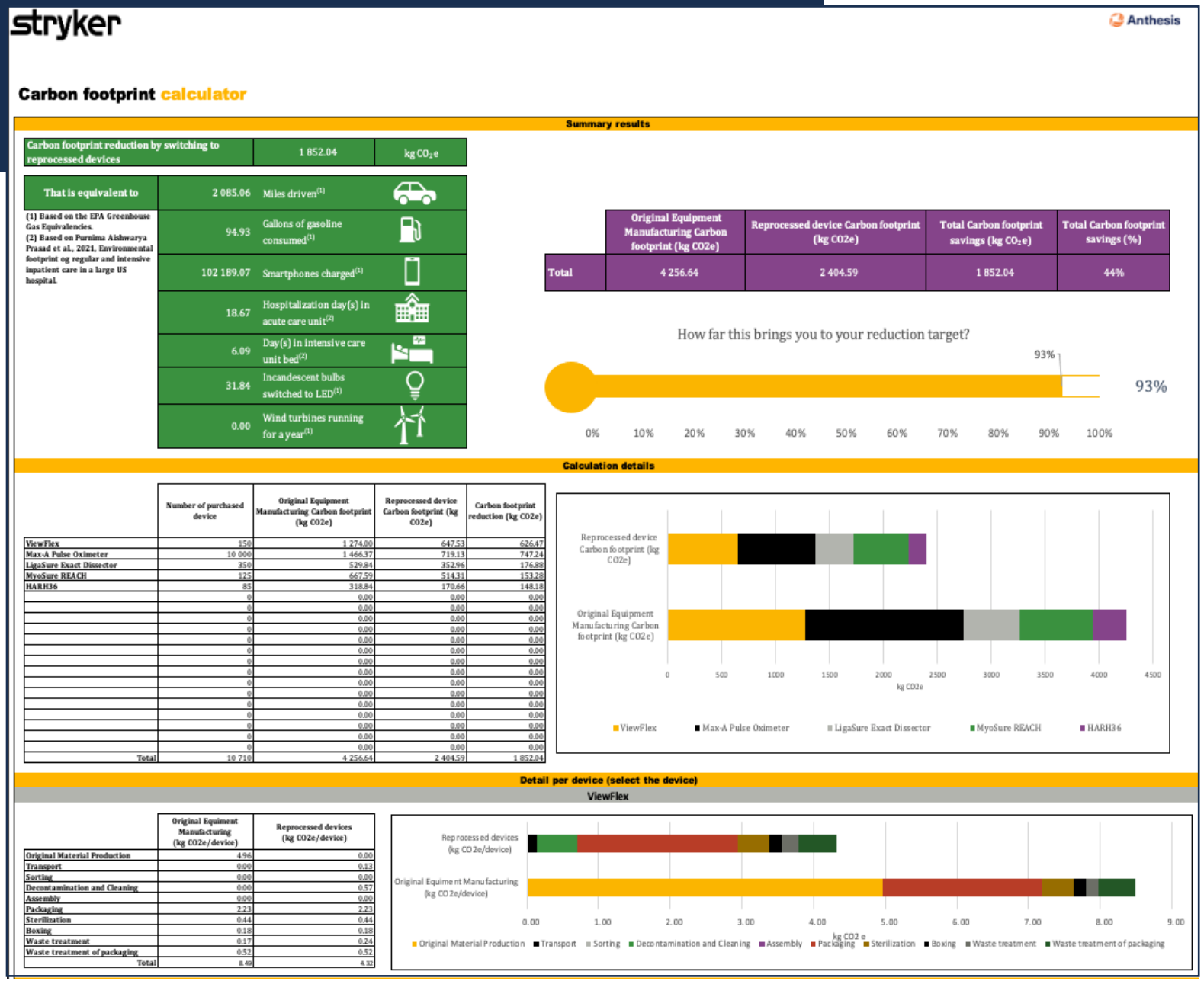
Measure & Test Impact

The Stryker 2022 Comprehensive Report (pg. 52) offers LCA data for five of its most popular remanufactured devices; the reduced carbon footprint of reprocessed devices is largely attributable to their not requiring the production and manufacturing of new virgin plastic and metal material.

Device	Original Device kg CO2 eq/device	Remanufactured Device kg CO2 eq/device	Reduction in carbon footprint from original to remanufactured device
ViewFlex (Catheter)	8.49	4.32	49%
HARH36 (Ultrasonic shears)	3.75	2.01	46%
Ligasure Exact Dissector	1.51	1.01	33%
MyoSure REACH (Tissue removal device)	5.34	4.11	23%
Max-A Pulse Oximeter	0.15	0.07	53%

Measure & Test Impact

The Stryker Carbon Footprint Calculator allows sites to work with their Stryker rep to calculate the carbon savings associated with the use of its most popular remanufactured devices. (*Tool accessible only via site Stryker Rep*)



stryker

Anthesis

Carbon footprint calculator

Summary results

Carbon footprint reduction by switching to reprocessed devices	1 852.04	kg CO_2e

That is equivalent to		
2 085.06	Miles driven(1)	
94.93	Gallons of gasoline consumed(1)	
102 189.07	Smartphones charged(1)	
18.67	Hospitalization day(s) in acute care unit(2)	
6.09	Day(s) in intensive care unit bed(2)	
31.84	Incandescent bulbs switched to LED(1)	
0.00	Wind turbines running for a year(1)	

(1) Based on the EPA Greenhouse Gas Equivalencies.
(2) Based on Purnima Aishwarya Prasad et al., 2021, Environmental footprint og regular and intensive inpatient care in a large US hospital.

	Original Equipment Manufacturing Carbon footprint (kg CO2e)	Reprocessed device Carbon footprint (kg CO2e)	Total Carbon footprint savings (kg CO_2e)	Total Carbon footprint savings (%)
Total	4 256.64	2 404.59	1 852.04	44%

How far this brings you to your reduction target?

Calculation details

	Number of purchased device	Original Equipment Manufacturing Carbon footprint (kg CO2e)	Reprocessed device Carbon footprint (kg CO2e)	Carbon footprint reduction (kg CO2e)
ViewFlex	150	1 274.00	647.53	626.47
Max-A Pulse Oximeter	10 000	1 466.37	719.13	747.24
LigaSure Exact Dissector	350	529.84	352.96	176.88
MyoSure REACH	125	667.59	514.31	153.28
HARH36	85	318.84	170.66	148.18
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
	0	0.00	0.00	0.00
Total	10 710	4 256.64	2 404.59	1 852.04

Detail per device (select the device)

ViewFlex

	Original Equipment Manufacturing (kg CO2e/device)	Reprocessed devices (kg CO2e/device)
Original Material Production	4.96	0.00
Transport	0.00	0.13
Sorting	0.00	0.00
Decontamination and Cleaning	0.00	0.57
Assembly	0.00	0.00
Packaging	2.23	2.23
Sterilization	0.44	0.44
Boxing	0.18	0.18
Waste treatment	0.17	0.24
Waste treatment of packaging	0.52	0.52
Total	8.49	4.32

Embed & Spread

8 What steps have been taken to ensure lasting change? How could it be spread to other contexts?

Micro (What can you do?)
- Choose to use devices that can be remanufactured if both types are available.
- Identify an internal champion for device remanufacturing who will engage with leaders and green teams.
- Share information with green teams and champions at other hospitals about the benefits of purchasing remanufactured devices.
- Publish your results so others can reference your work when building a case for change.

Meso (What can you do within your organization?)
- Build instructional content on device remanufacturing process into staff onboarding and training.
- Ensure policies are in place to purchase remanufactured devices.
- Ensure the hospital utilizes any existing RFP with a vendor that remanufactures devices.
- Highlight positive change with awards or public acknowledgements.

Macro (What can your organization do?)
- Lobby governments and corporations to make it easier to find companies that will sell remanufactured devices.

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