Economia Circular
al sector Sanitari
Estudi Sectorial

7/10/2025

“Reprocessament de catéters d’un sol ús” a una Unitat d’Arrítmies

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Servei de Cardiologia
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Un projecte de:

ClubEMAS
associació d’organitzacions registrades EMAS a Catalunya

Amb el suport de:

Generalitat de Catalunya

Agència de Residus de Catalunya

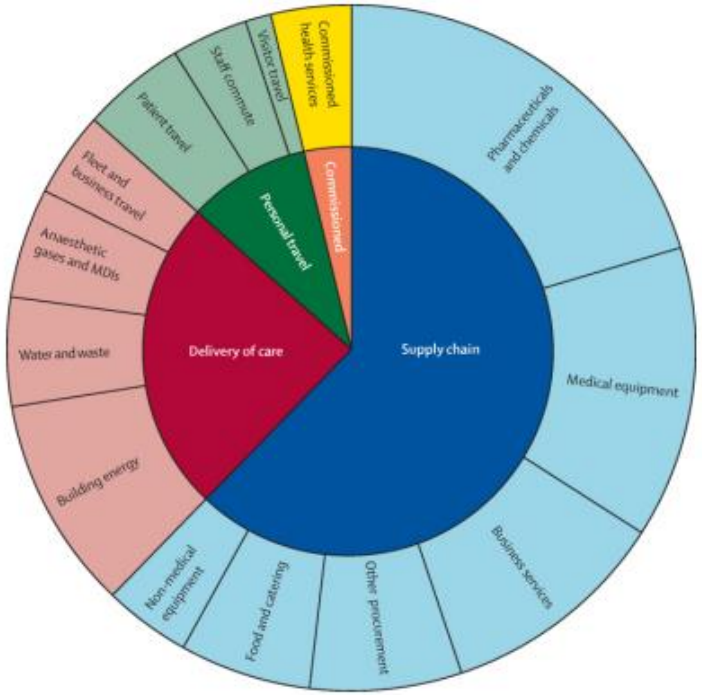
Healthcare: Improving human health while causing environmental damages

- **4.4 %** of **global GHG emissions** *(2Gt CO_2)*
- **5th largest emitter** on planet
- **62** à **82%** from the **supply chain** *(scope 3)*
- **56%** from **US, China & Europe**

Complex sustainability challenge:

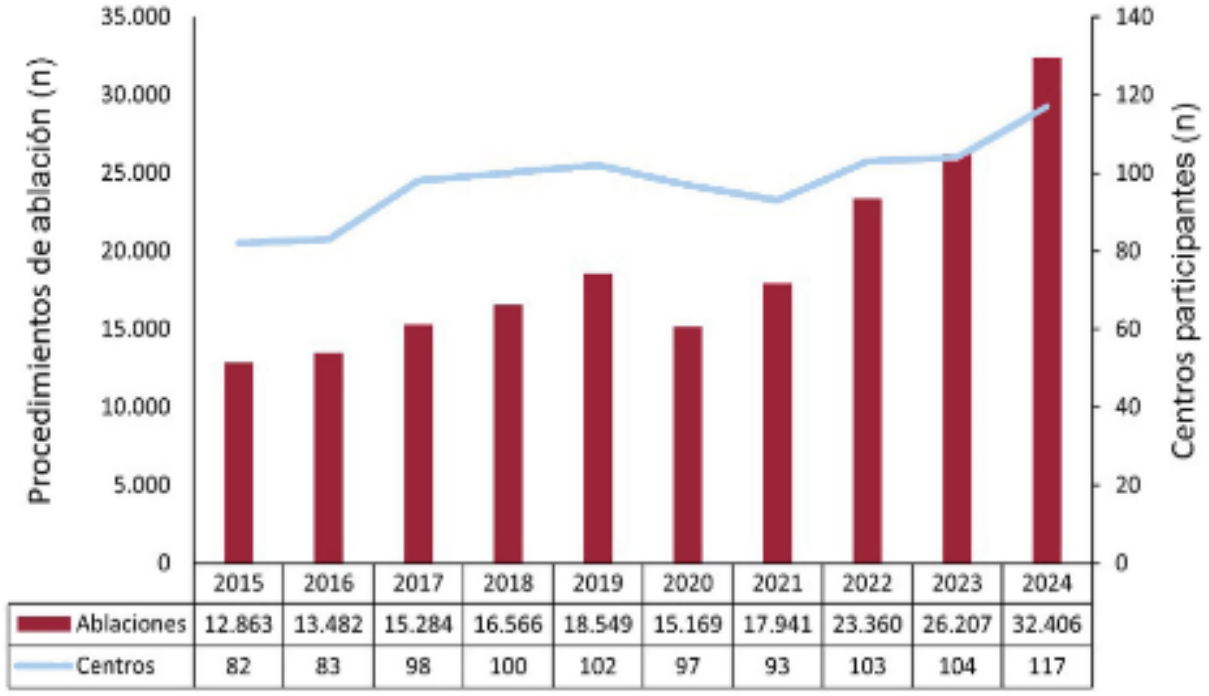
> **Need to reduce the footprint**

> **Need of high performance & safety for patients**

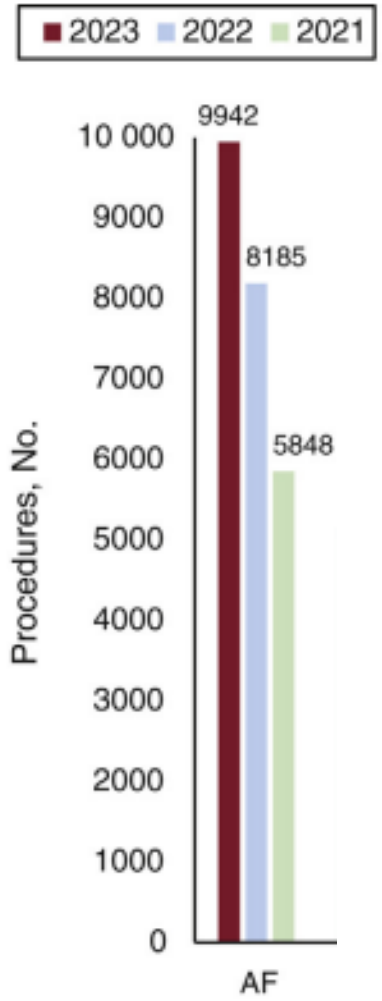


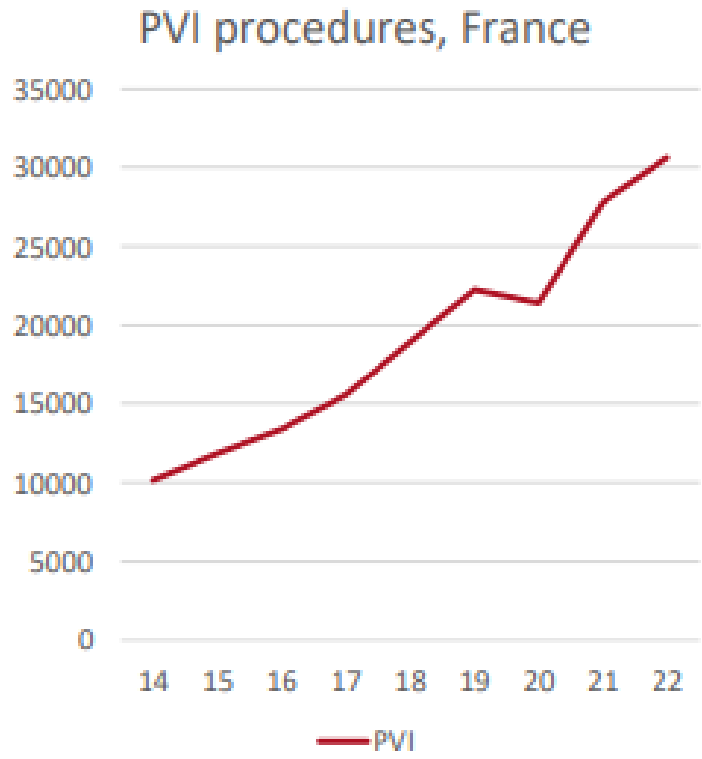
Contribution of different sectors to the GHG emissions of the NHS England, 2019
Tennison et al, The Lancet, 2021

Augment d'activitat a les Unitats d'Arrítmies



	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Ablaciones	12.863	13.482	15.284	16.566	18.549	15.169	17.941	23.360	26.207	32.406
Centros	82	83	98	100	102	97	93	103	104	117

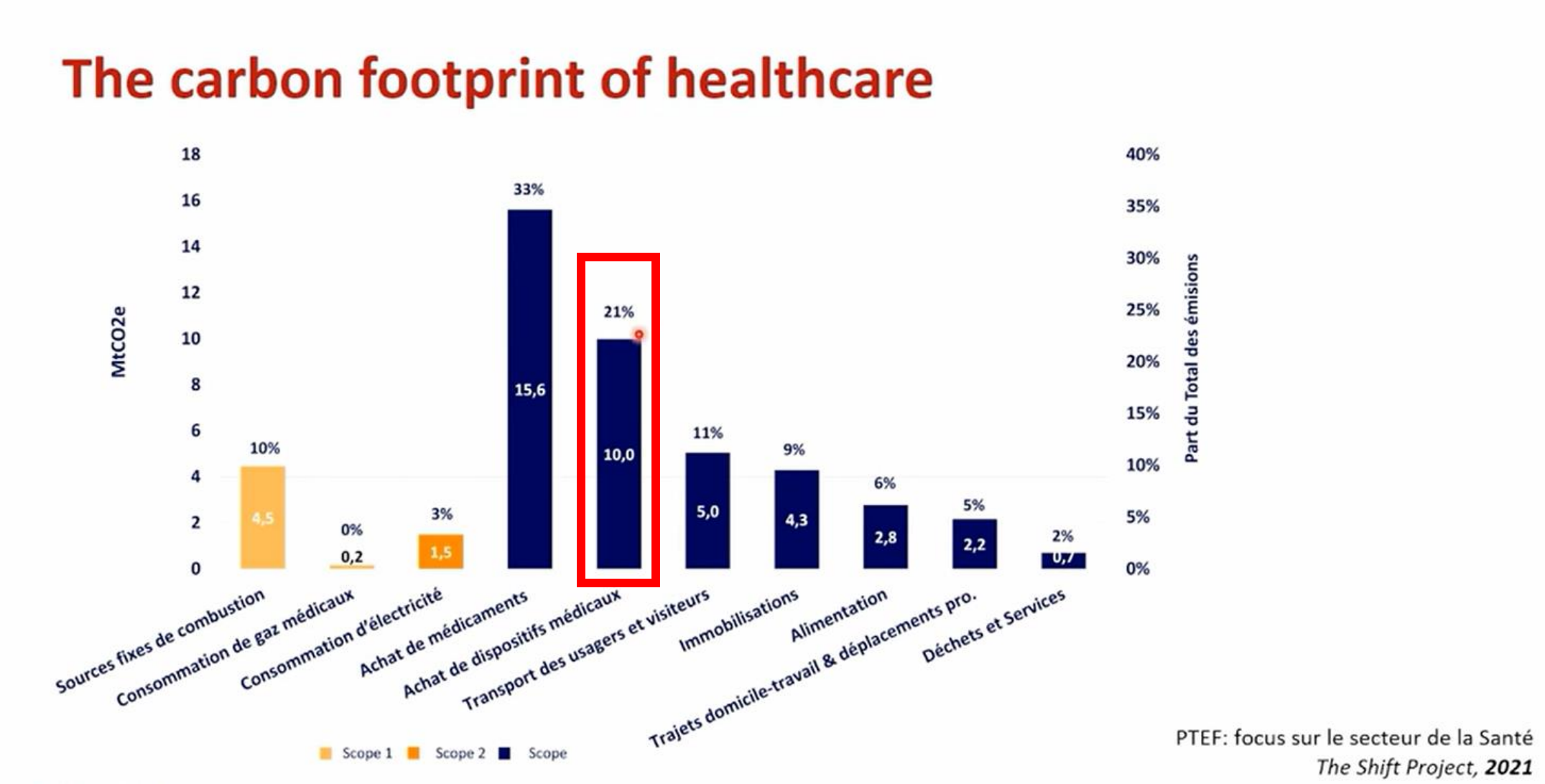




EHRA 2023

Arana E, et al. Rev Esp Cardiol 2025

Petjada de carboni: compra de dispositius mèdics

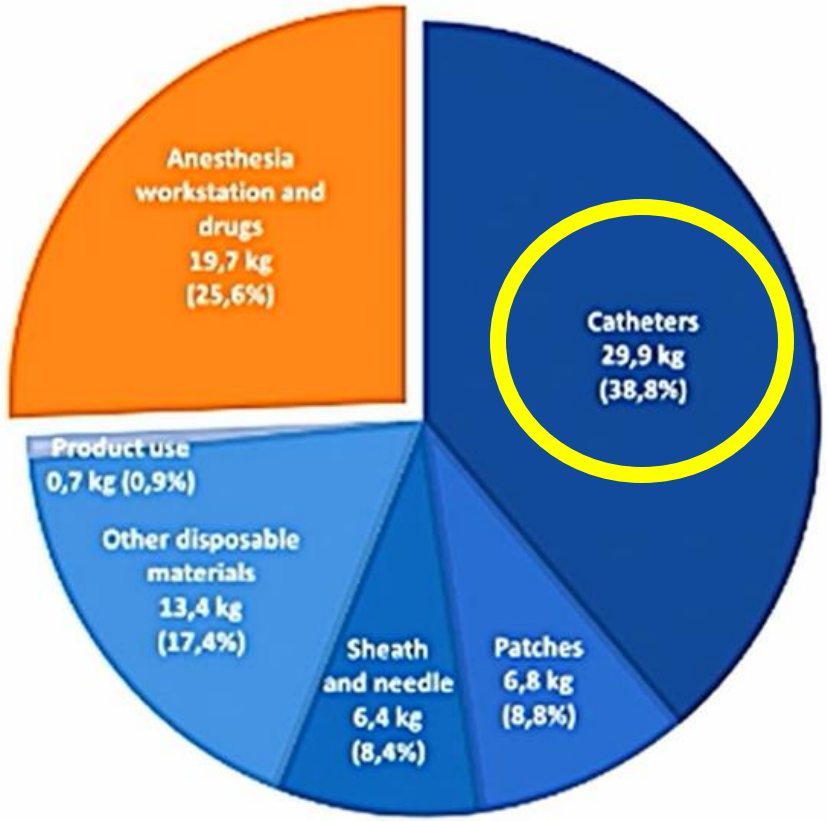


PTEF: focus sur le secteur de la Santé
The Shift Project, ***2021***

La petjada de carboni de l'Ablació de Fibrilació Auricular

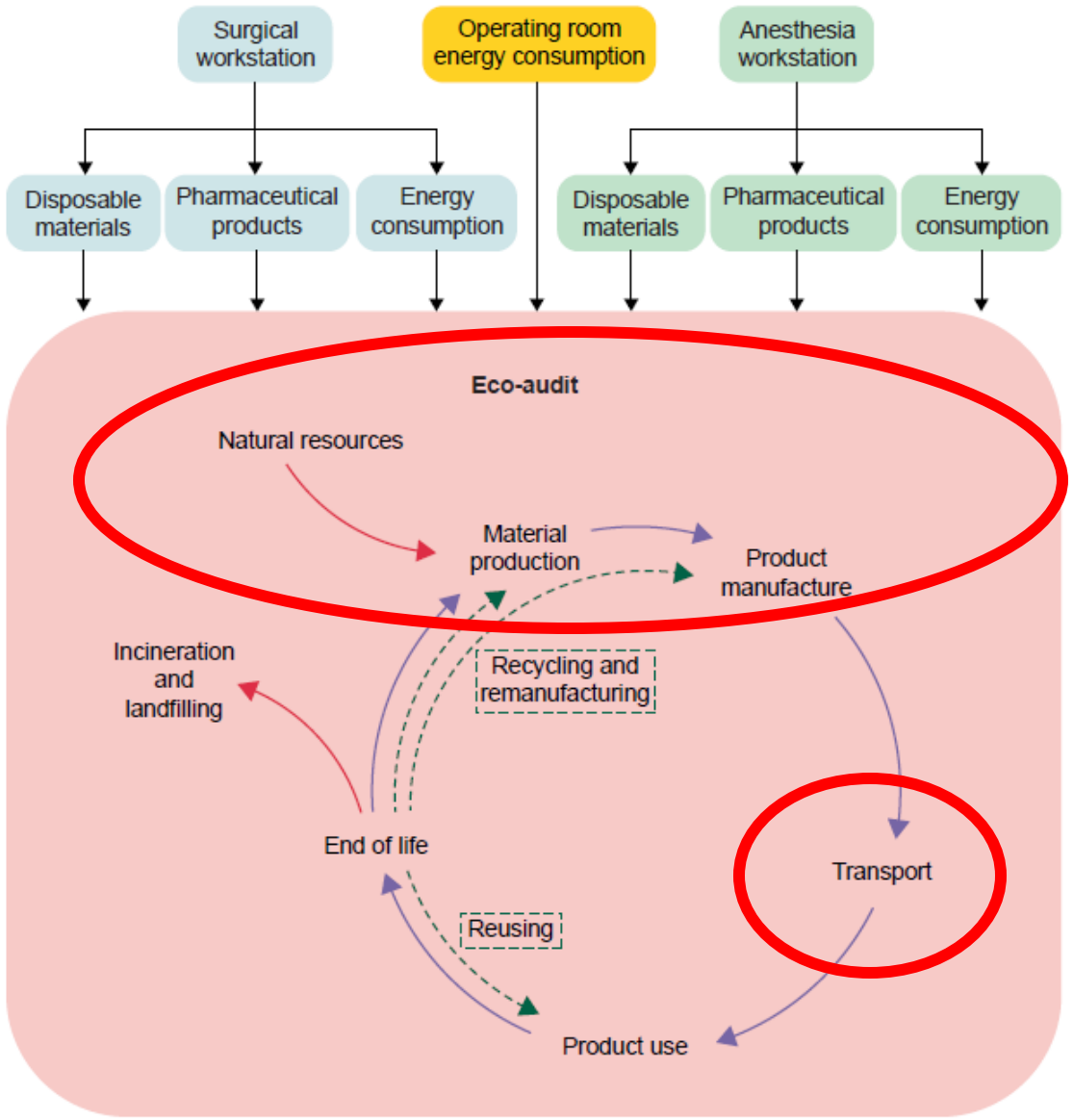
Carbon footprint of atrial fibrillation catheter ablation

- **Carbon footprint due to**
  - Single use medical devices (device, packaging, shipping)
  - Amplifiers, Workstations, Pumps, etc.
  - Maintenance, delivery
- **Medical waste (landfill)**
- **Plastic pollution**
- **Depletion of rare resources (Platinum)**



Ditac *et al.*, Europace **2023**
10.1093/europace/euac160

La petjada de carboni de l'Ablació de Fibrilació Auricular



88%

10%

Canvi en la normativa legal

BOLETÍN OFICIAL DEL ESTADO
Núm. 69 Miércoles 22 de marzo de 2023 Sec. I. Pág. 42678

I. DISPOSICIONES GENERALES

MINISTERIO DE SANIDAD

7416 *Real Decreto 192/2023, de 21 de marzo, por el que se regulan los productos sanitarios.*

CAPÍTULO III

Reprocesamiento y nueva utilización de productos de un solo uso

Artículo 11. *Reprocesamiento de productos de un solo uso.*

1. El reprocesamiento y la nueva utilización de productos de un solo uso regulados en el artículo 17 del Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo, de 5 de abril de 2017, podrán llevarse a cabo siempre y cuando se cumplan los requisitos del presente real decreto.

Les estratègies d'economia circular

Rethink towards sustainability: Circular strategies

Recycling

- Keeping the **material value**
- **Ability to disassemble** products
- Knowledge of **product's composition**

Reprocessing

- **Single-use MD**
- Cleaning, disinfection, sterilisation**, testing, restoring technical & functional safety**
- Reprocessor assume obligation of original manufacturer
- "Remanufacturing" when conducted by commercial entities
- Possible **if permitted by national law**

Resterilisation

- **Reusable MD**
- cleaning, disinfection, packaging, sterilisation
- Original manufacturer assume responsibilities for reused MD
- Usually done **on-site by health institutions**

EHRA2024

Regulation (EU) 2017/745 on medical devices

¿Qui pot reprocesar?

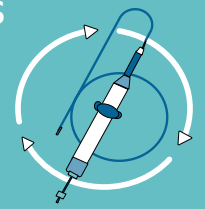
VANGUARD
MEDICAL REMANUFACTURING

Over 25 years of experience in remanufacturing

Three production sites in Germany, coupled with a 100% subsidiary in the UK

approx. 1.200 customers (university clinics, hospitals and medical practices) in Germany and Europe

> 3.0 Mio. Remanufactured Devices



~ 200 Employees

Vanguard AG is a subsidiary of Santo Holding GmbH (Can be attributed to the founders of Hexal, the Strüngmanns)

Only European member of the Association of Medical Device Reprocessors

AMDR
ResponsibleReuse.org

Own microbiological L2 hygiene laboratory and R&D, as well as an established and certified QM system.

VANGUARD
MEDICAL REMANUFACTURING

OPT IN legal regulated

(UK)

Netherland

Belgium

Germany

Ireland

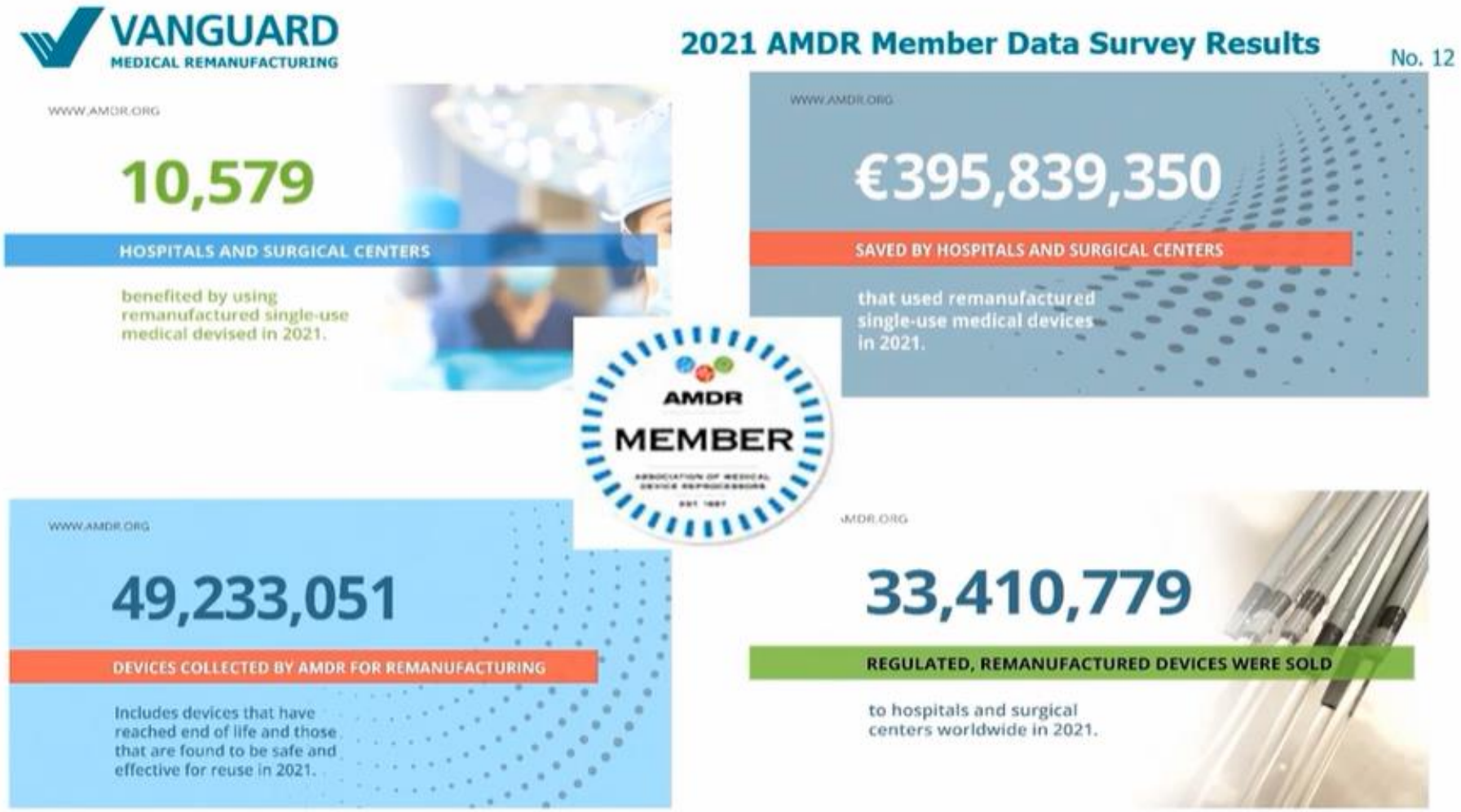
Croatia

Sweden

Spain

Iceland

Dades de l'AMDR al 2021 (associació de Reprocessadors de Dispositius Mèdics)



Economia Circular al sector Sanitari

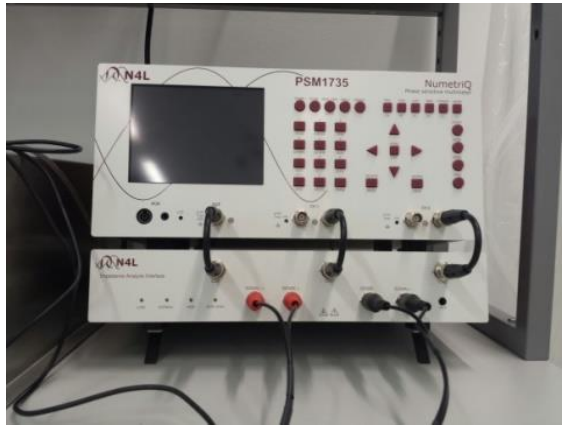
Estudi Sectorial

Commercial Reprocessing

Tests for product specification and verification of technical / functional safety

Microbiological Testing
To confirm the effectiveness of the cleaning process, each catheter is checked for possible protein residues in our L2-hygiene Vanguard laboratory using the modified OPA method (in accordance with ISO 15883).

chemical compatibility

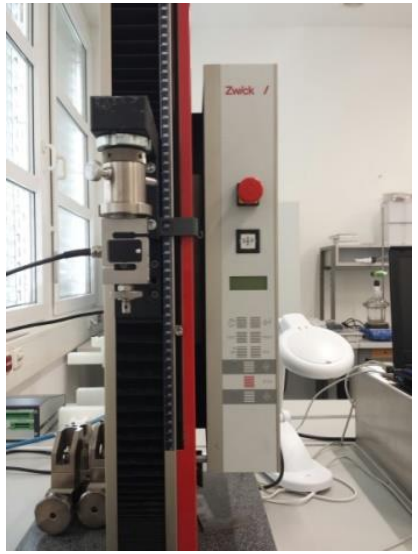


electrical impedance

Unique rinsing concept
Potential residue is flushed from the lumen using a specially-developed cleaning system. Cleaning media that flow through the lumen are subject to continuous volumetric monitoring.

material analysis

Visual inspection
We inspect the device at up to 40x magnification, checking for any changes in its curvature shape or damage along the full length of the catheter from the electrical connection to the tip.



material and functional testing

Mechanical function test
We test the performance of each component.
In the case of force-sensing catheters, our processes ensure full functionality.

Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters

Figure 1. Electrophysiological diagnostic catheter [34].

Assessing Long-Term Medical Remanufacturing Emissions with Life Cycle Analysis

Julia A. Meister, Jack Sharp, Yan Wang * and Khuong An Nguyen

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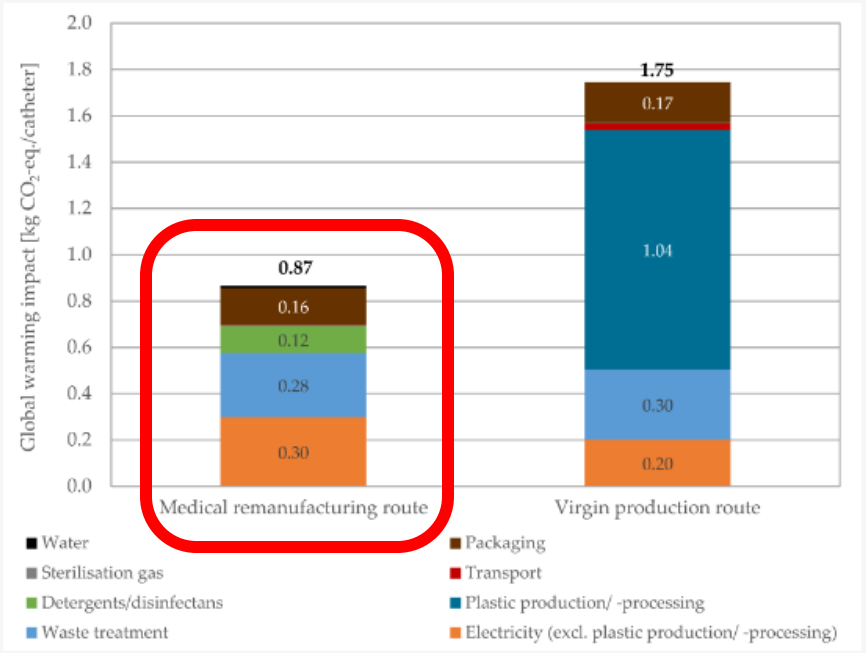
* Correspondence: y.wang5@brighton.ac.uk

Abstract: The unsustainable take-make-dispose linear economy prevalent in healthcare contributes 4.4% to global Greenhouse Gas emissions. A popular but not yet widely-embraced solution is to remanufacture common single-use medical devices like electrophysiology catheters, significantly extending their lifetimes by enabling a circular life cycle. To support the adoption of catheter remanufacturing, we propose a comprehensive emission framework and carry out a holistic evaluation of virgin manufactured and remanufactured carbon emissions with Life Cycle Analysis (LCA). We followed ISO modelling standards and NHS reporting guidelines to ensure industry relevance. We conclude that remanufacturing may lead to a reduction of up to 60% per turn (−1.92 kg CO_2eq, burden-free) and 57% per life (−1.87 kg CO_2eq, burdened). Our extensive sensitivity analysis and industry-informed buy-back scheme simulation revealed long-term emission reductions of up to 48% per remanufactured catheter life (−1.73 kg CO_2eq). Our comprehensive results encourage the adoption of electrophysiology catheter remanufacturing, and highlight the importance of estimating long-term emissions in addition to traditional emission metrics.

Figure 5. Results of the GWI for using a remanufactured medical catheter and using a catheter from virgin production disposed after single-use.



Schulte A, et al. Sustainability 2021

global warming impact is reduced by 50.4%

Bellvitge
Hospital Universitari

Unitat d’Electrofisiologia i Arrítmies

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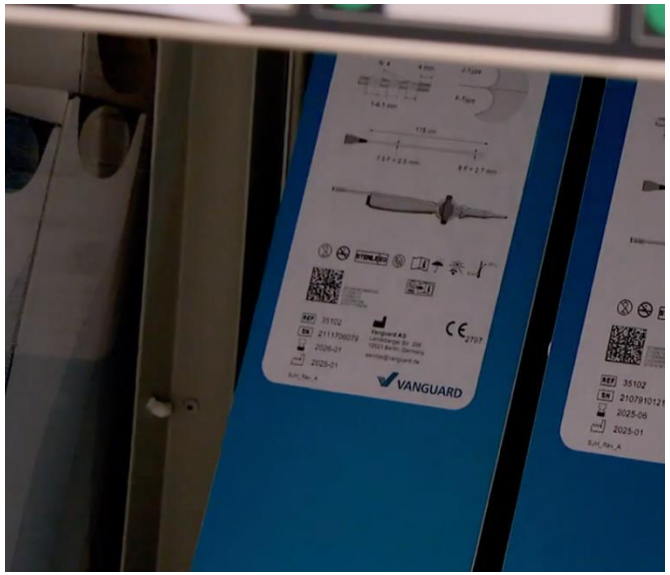
Unitat d'Electrofisiologia i Arrítmies

L'hospital consumeix **1.500-2.000/any catèters** en diferents procediments electrofisiològics (estudis diagnòstics i ablacions per tractar les arrítmies).
Fins a un 30% d'aquests dispositius poden entrar al circuit (recollida, devolució i compra de catèters reprocessats)

RESULTATS



559 catèters

346 catèters

L'AMDR estima que produir un nou catèter genera aproximadament 3.92 Kg CO2e durant el procés de fabricació, mentre que reprocessar-ho genera 1.93 kg CO2 (**reducció del 49% de les emissions**).

Per la qual cosa, els **559 catèters** que s'han subministrat a Vanguard per reprocessar ha contribuït a una reducció de 1112 kg d'emissions de CO2 (més d'1 tona), que és el que contamina un cotxe al conduir-lo durant 4557 km.

BARRERES

- Aliniament amb els objectius de sostenibilitat de l'Hospital
- Dificultats a nivell de Gerència/Direcció de Centre (Convèncer a l'hospital que era factible i segur)
- Dificultats a nivell de Direcció d'Unitats d'Arrítmies
- Model de compra basat en concurs públic
- Revisió del canvi normatiu (department Legal)
- Presència i força (incentius) dels competidors (fabricants primaris)
- Gestió del canvi de l'equip assistencial (gestió del material per a la correcta devolució dels catéters)
- Integrar amb circuits de recollida de residus

PERSONAL IMPLICAT

- Direcció centre
- Infermer gestor
- Cardiòlegs (Electrofisiòlegs)
- Infermeria
- Neteja
- Direcció infrastructures i serveis generals
- Unitat de Compres

Conclusions

- El nostre sistema sanitari és insostenible i incompatible amb els objectius climàtics. Tenim el deure de reduir les emissions de C02 i de contribuir a la sostenibilitat del sistema participant en un projecte d' economia circular.
- Posar en marxa projectes d'economia circular més sostenibles és complicat, amb moltes barreres.
- El reprocessat de catèters disminueix de forma molt important les emissions de CO2 i ens permet:
    - disminuir les emissions i el cost de la nostra activitat
    - afrontar l'augmentar de l'activitat sense augmentar les emissions

Moltes gràcies

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