EAMDR
European Association for Medical Device Reprocessing

Workshop on the reprocessing of medical devices

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EAMDR
European Association for Medical Device Reprocessing

Established: 2003

Members from science, industry and medical practice

Tasks and Goals:

- Increasing patient safety
- Increasing the quality of medical device reprocessing
- Enhancing quality and economy in health care systems
- Supporting ecological processes

by introducing better and uniform quality standards both on a national and European level

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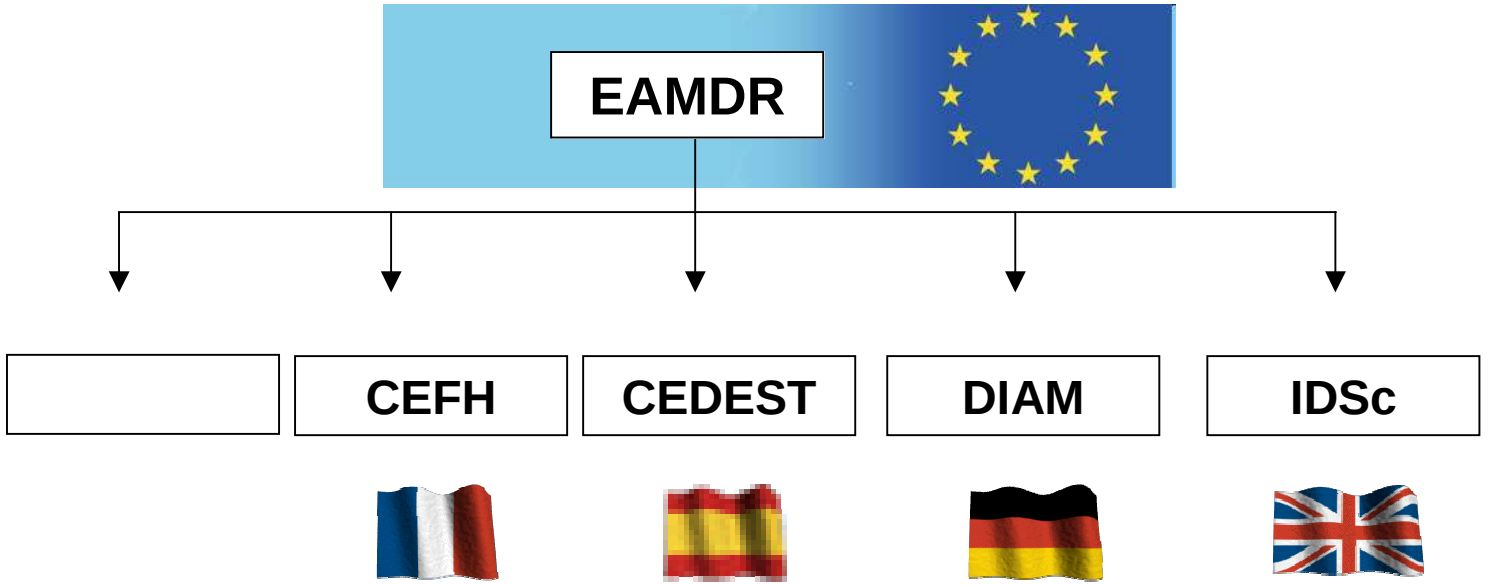
A growing community:

National member organisations of EAMDR



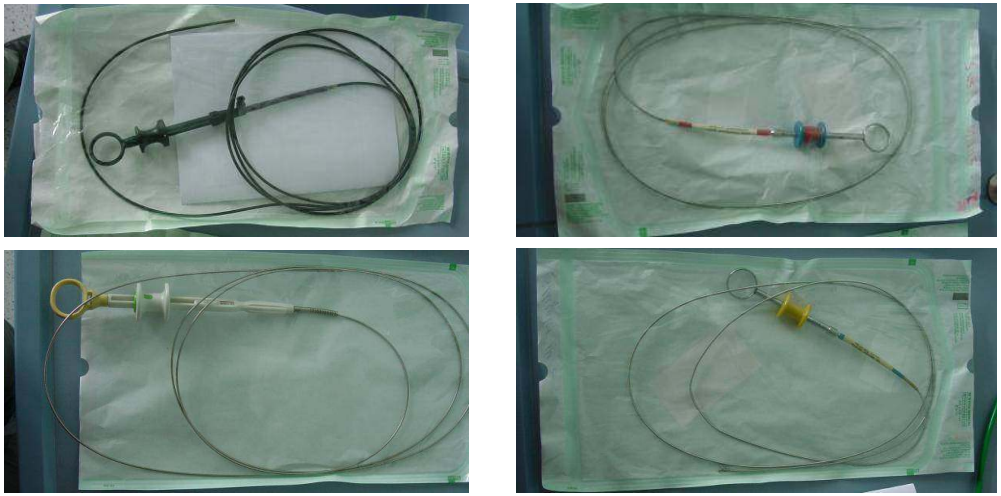
1. What are the public health risks associated with the reprocessing practice of single use medical devices?

The reprocessing of medical device is fundamental concerning the treatment and safety of patients.

Irrespective of the original labelling “single use/ multiple use”

Example: Request from a hospital for examination

Biopsy Forceps (multiple use) / four different manufacturers



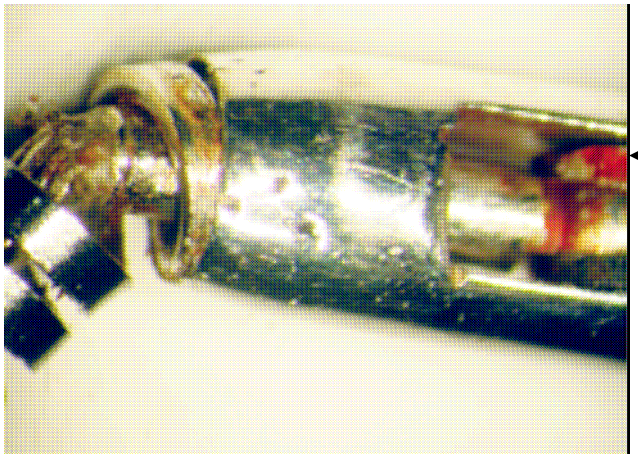
„Multiple-Use“ Medical Devices reprocessed according to Manufacturer Manual

1. What are the public health risks associated with the reprocessing practice of single use medical devices?

Result of Reprocessing „Multiple-Use“ medical devices : according to manufacturer manual

Products delivered from University Hospitals

Biopsy forceps – **contamination and corrosion**



blood leavings

Allgemeine Aufbereitungsanleitung flexibler wiederverwendbarer Endoskopie-Instrumente und Zubehör

Ziel der Maßnahmen ist eine rückstandsfreie Reinigung um anschließende Schritte der Desinfektion und Sterilisation nicht durch z.B. Blut-, Sekret- oder Geweberückstände zu beeinträchtigen.

1. **Vorbereitung der Aufbereitung, Reinigung/ Desinfektion, Spülung und Trocknung**

Die Kette von erforderlichen Maßnahmen muss optimiert sein, da Schwächen in einem Einzelschritt (z.B. der Reinigung) den Gesamterfolg in Frage stellen können. Unzureichende Ergebnisse können durch Mängel bei jedem Schritt der Aufbereitung, z.B. bei Verwendung nicht geeigneter Reinigungs- und Desinfektionsmittel, fehlerhafter Anwendung, kontaminierter Desinfektions- oder Spülflüssigkeiten, unzureichende Trocknung und fehlerhafte Lagerung, auftreten. Zur Gewährleistung einer ordnungsgemäßen Aufbereitung von Medizinprodukten ist daher in der Regel eine Vorbereitung (Vorbehandlung und Sammlung) notwendig.
Grundsätzlich müssen alle äußeren und inneren Oberflächen für die eingesetzten Reinigungs -, Desinfektions- und Sterilisationsmittel zugänglich sein.

1.1. **Vorbereitung der Aufbereitung**

- Prüfen, ob das Instrument zur Reinigung zerlegbar ist. Im Falle der Zerlegbarkeit unbedingt darauf achten, dass es bei den Komponenten zu keinen Verwechslungen kommt.

Achtung: Bei Instrumenten mit Gelenken (Biopsie-, Fremdkörperzangen) müssen während des gesamten Reinigungsprozess die Branchen geöffnet sein.

- Grobe Verschmutzungen des Medizinproduktes sollen unmittelbar nach Anwendung entfernt werden.

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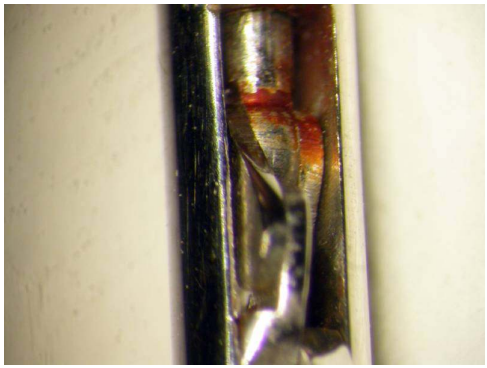
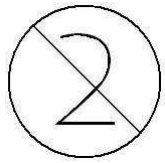


„Single use“ – multiple use



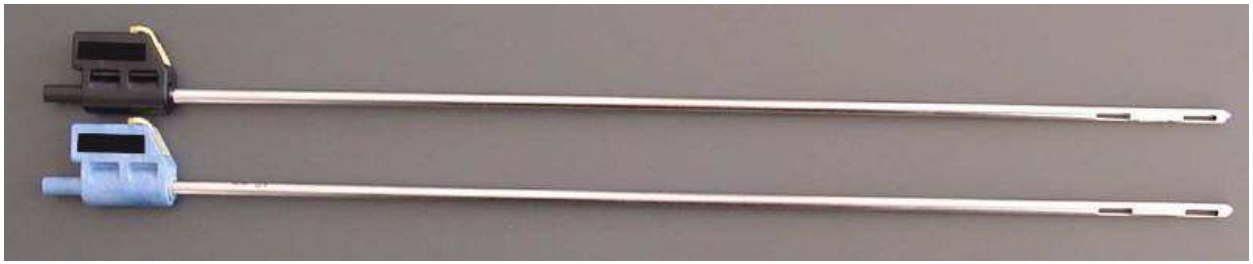
Example 1:

The RadiaXon radiation attenuation glove has been developed for single-use.

Wording on the manufacturer label:
“…There are, however, countries which are, due to reduced purchasing power, not in a position to use these gloves only once. In this case -… - resterilisation or autoclaving at 125ºC for up to a maximum of 30 minutes is recommended.”

Example 2:

Manufacturer of liposuction cannula distributes the same medical device as multiple-use and single-use



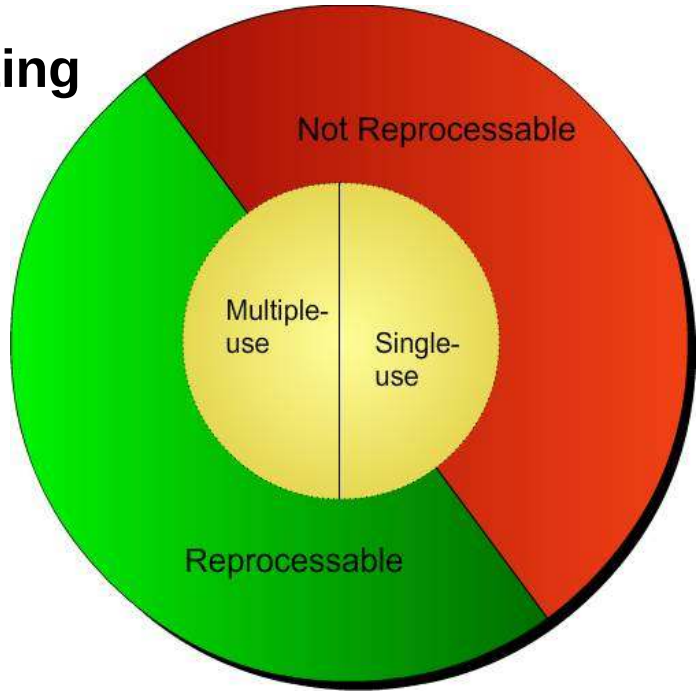
blue „multiple use“
black „single use“

1. What are the public health risks associated with the reprocessing practice of single use medical devices?

The declaration of the manufacturer of the medical device as single use and reusable does not necessarily reflect whether a device really is reprocessable or reusable:

- Some medical device declared "reusable" can in fact not be reused
- Some medical device declared "single use" can be reprocessed

Rather: It depends on careful individual testing



Legal requirements
Council Directive 93/42/EEC, national health & safety regulation, international & national standards, recommendations of scientific societies

Quality Management System
Documented responsibilities, competence for batch release, traceability, e.g. EN ISO 13485

Hygiene concept
Comprehensive hygiene approach for personnel, working environment and adverse events

2. How to assess the level of safety of a reprocessed single use medical device?

Qualified personnel
Trained staff, specific knowledge by education, practical experience, continuous training

Qualified facilities
Working environment (adequate clean rooms, lighting, air conditioning), resources (water supply, sterile air, vacuum) and equipment (WD, sealing device, sterilization devices, visual aids, tools, test equipment)

Risk assessment of medical devices
Classification as non-critical, semi-critical, critical, intended use

2. How to assess the level of safety of a reprocessed single use medical device?

Suitability of reprocessing
Ensuring of safety, performance, and reliability of reprocessed devices, maximum number of reprocessing cycles, functional tests, EN ISO 17664, validation of critical parameters

Effectiveness of processes
Validated processes, approved biocidal and cleaning performance, cleanliness, sterility, freedom from pyrogens and residues of disinfectants and sterilants

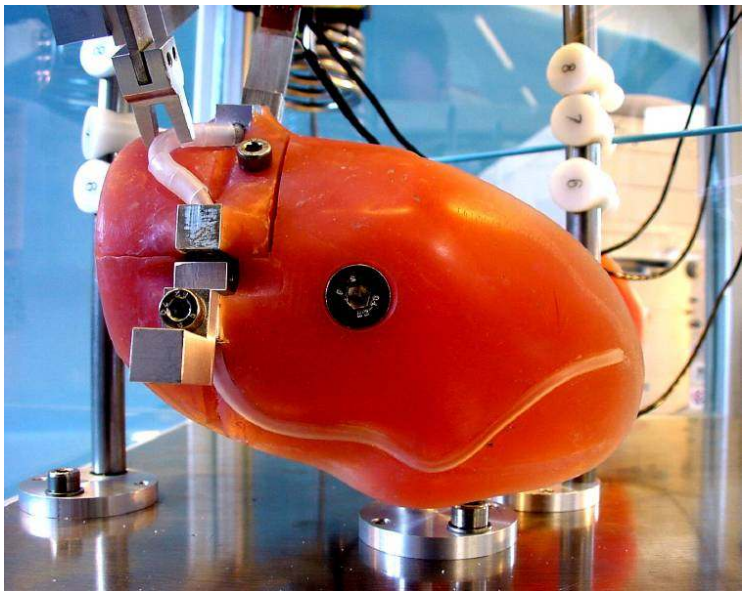
Sustainability of reprocessing
Economic & ecologic assessment, expenses for qualification and validation, assessment of reprocess-ability before invest

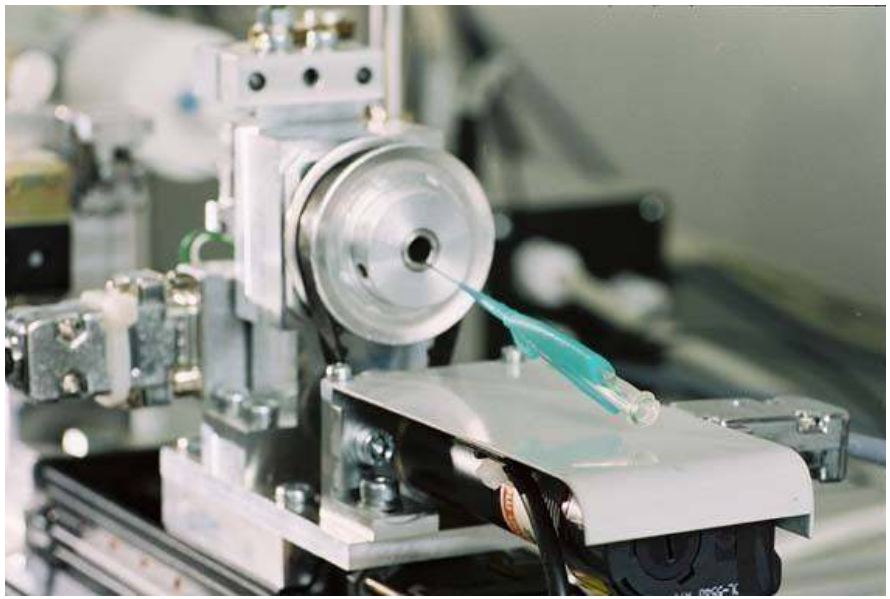
3. How to ensure and assess the performance of a reprocessed single use medical device (*i.e.* functionality)?

Performance ensured by:

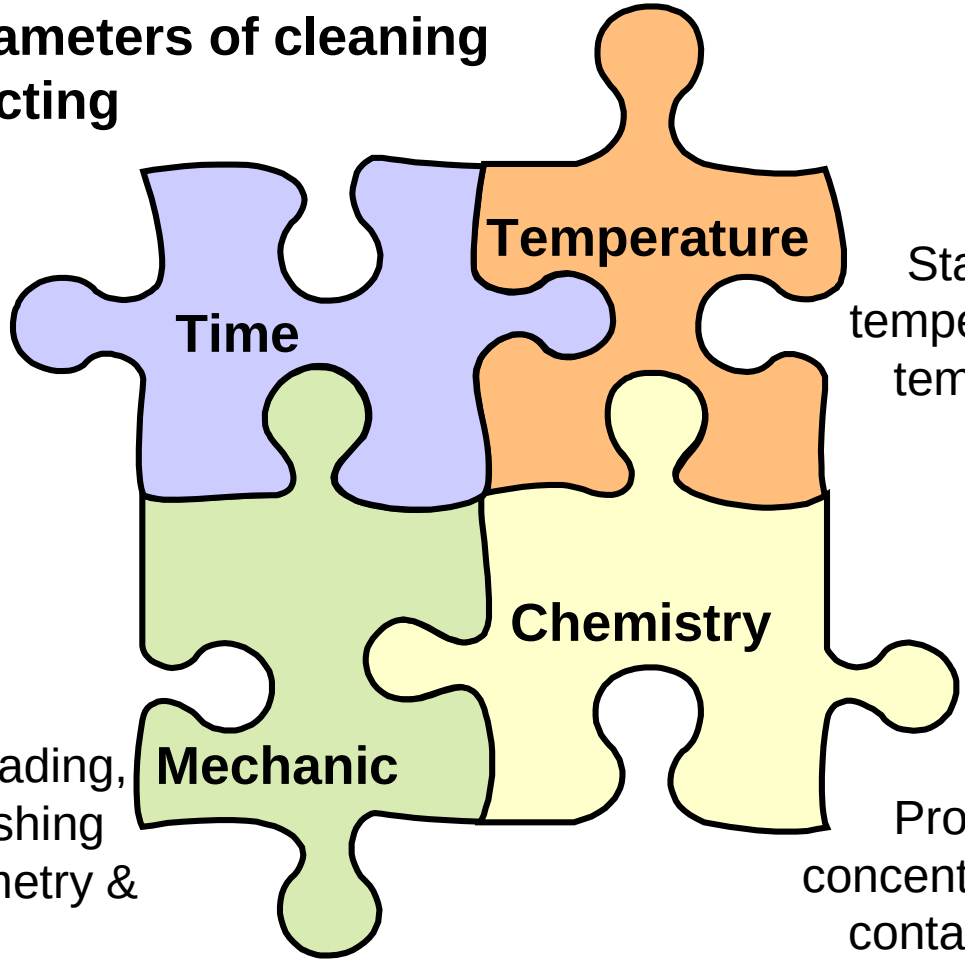
Individual tests during validation process as well as

100% functional testing of each single medical device in the reprocessing process.





Critical parameters of cleaning and disinfecting



Contact time
heating rate

Starting temperature, temperature management, temperature deviation, overheating

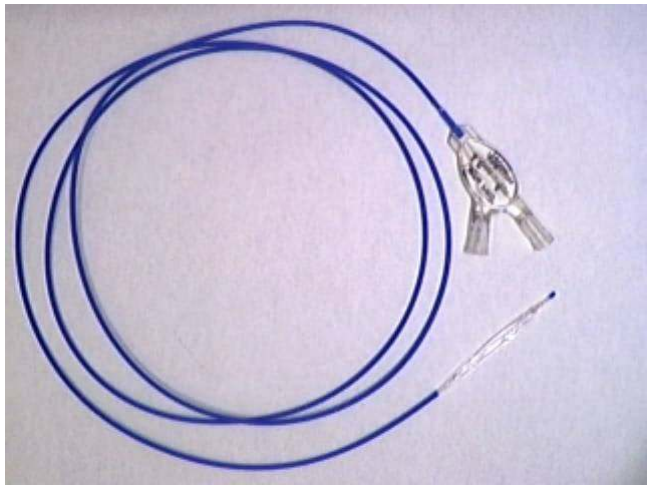
Pump pressure, loading, distribution of washing liquor, device geometry & construction,

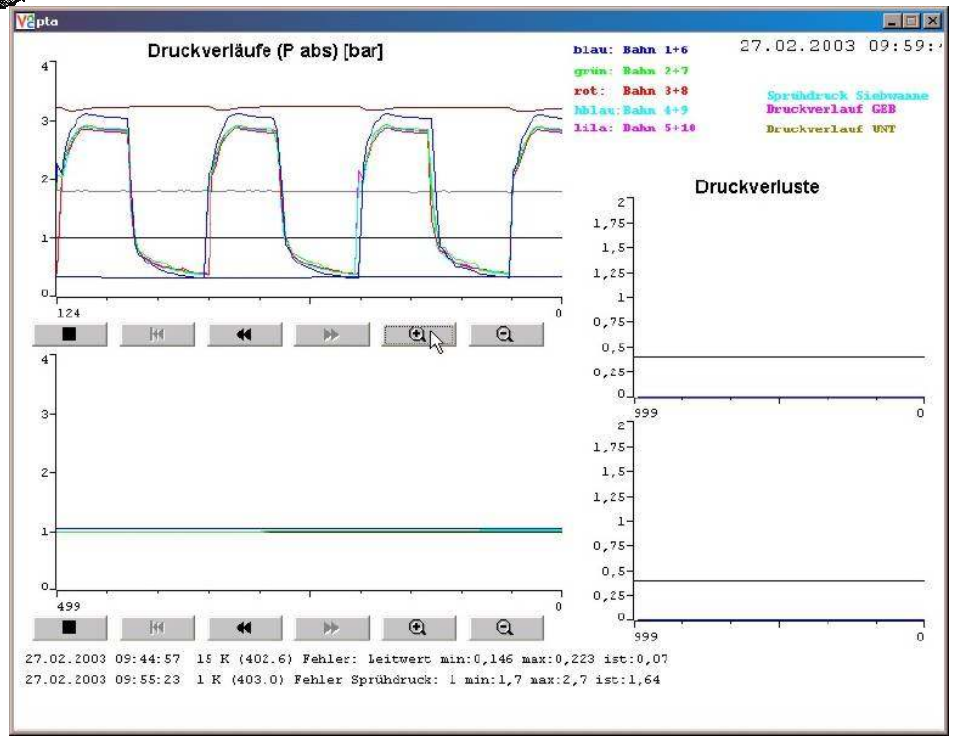
Process chemicals, concentration, water quality, contamination, cleaning principle foaming behaviour

Example for complex medical device

Balloon catheters reprocessable by developed equipment and procedures

- long narrow lumen
- dead end in the balloon
- special cleaning equipment necessary
- cleaning by alternating flushing under pressure and vacuum

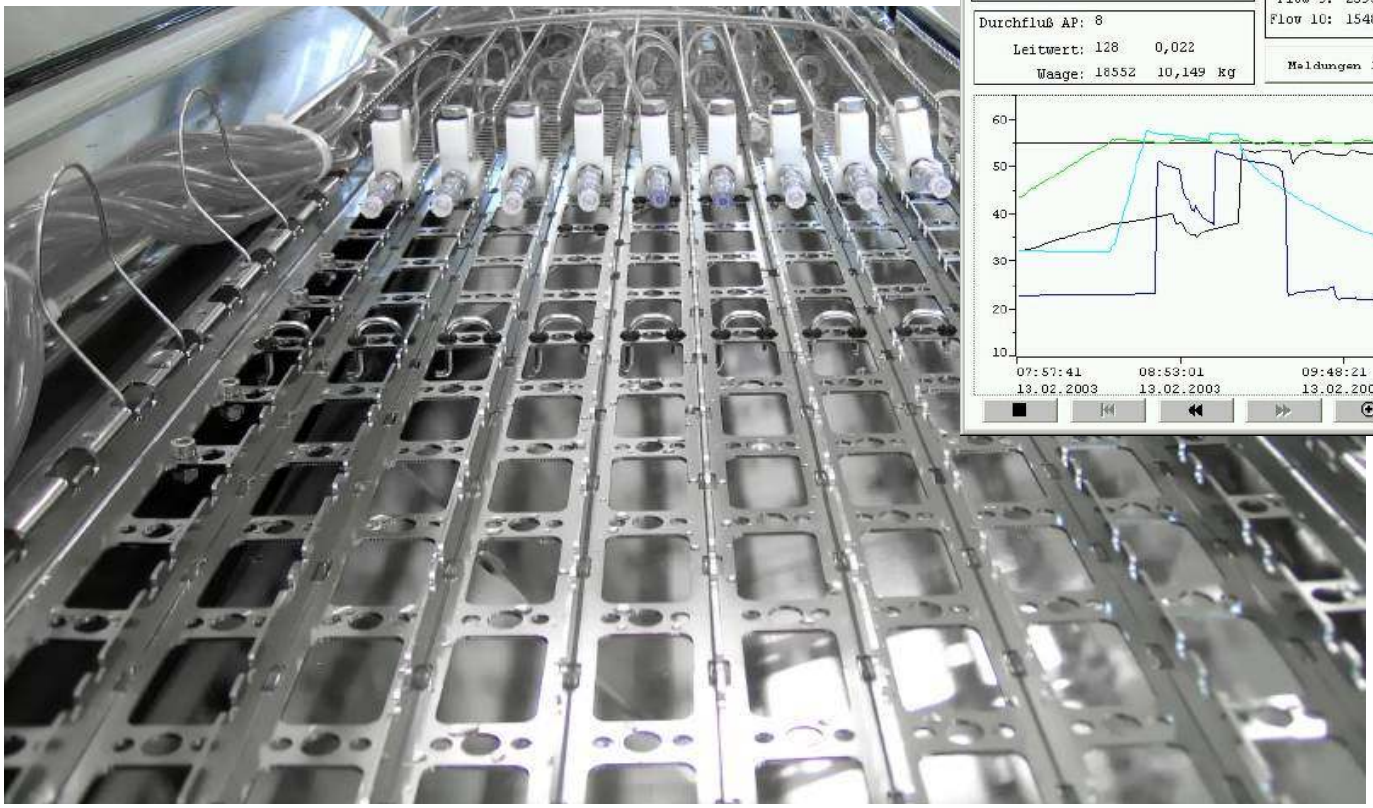


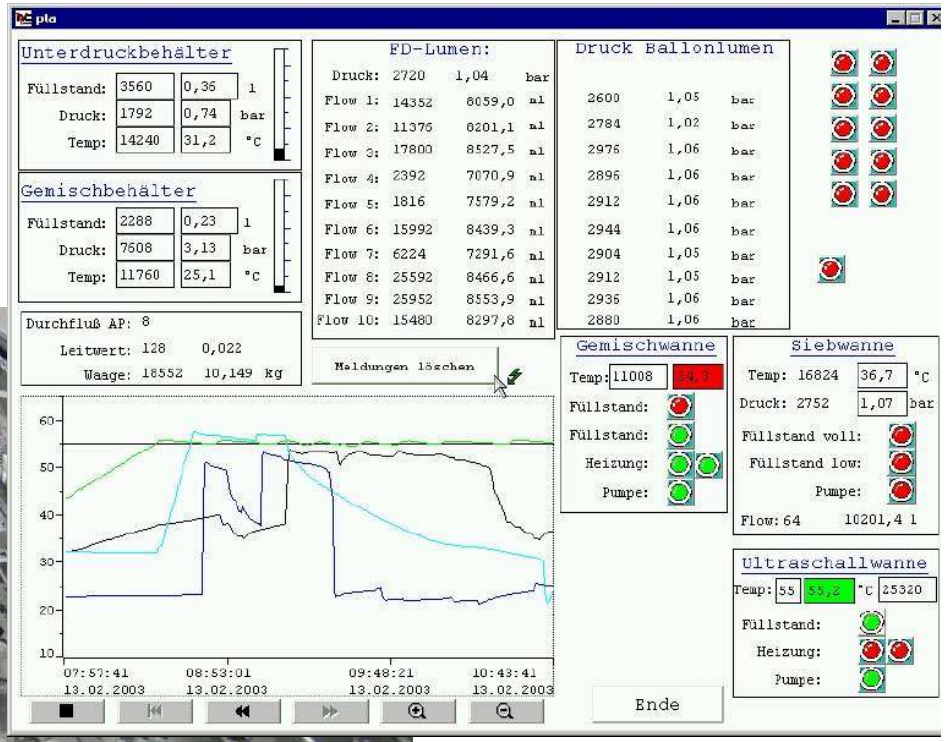


4. How to assess whether the design of a single use medical device allows appropriate cleaning and sterilization processes?

cleaning and disinfecting
Balloon catheters made reprocessable

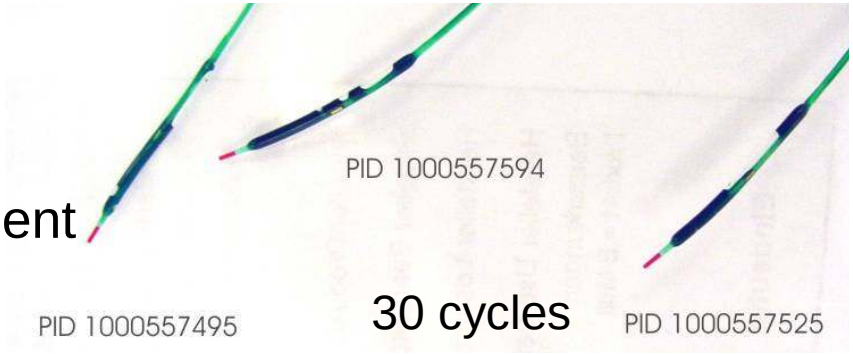
- special cleaning equipment necessary
- strong process control necessary
- process data are protocoled

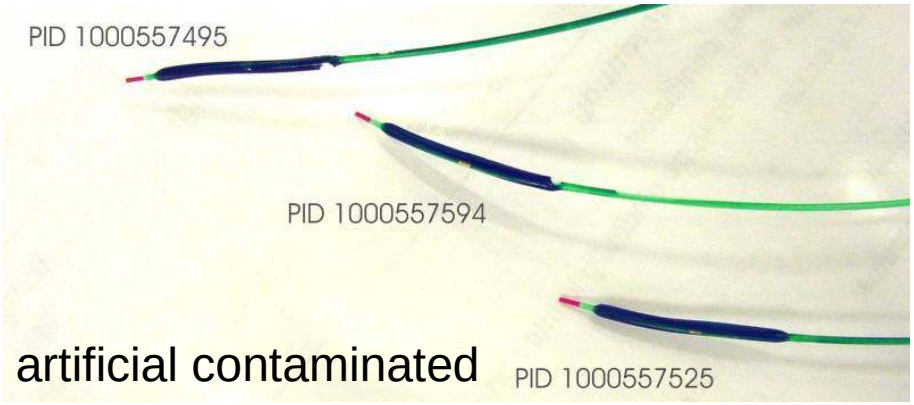


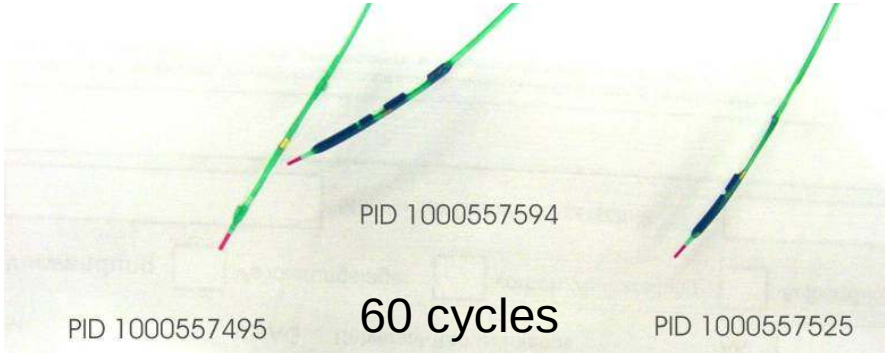


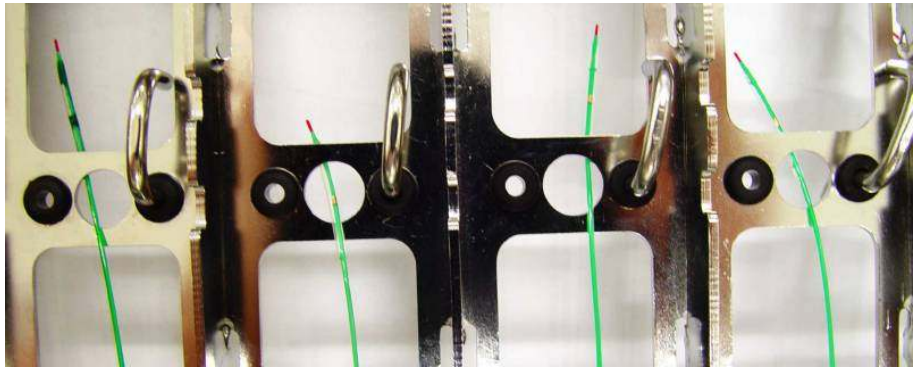
5. How to ensure an acceptable and uniform level of safety for the cleaning and sterilization processes?

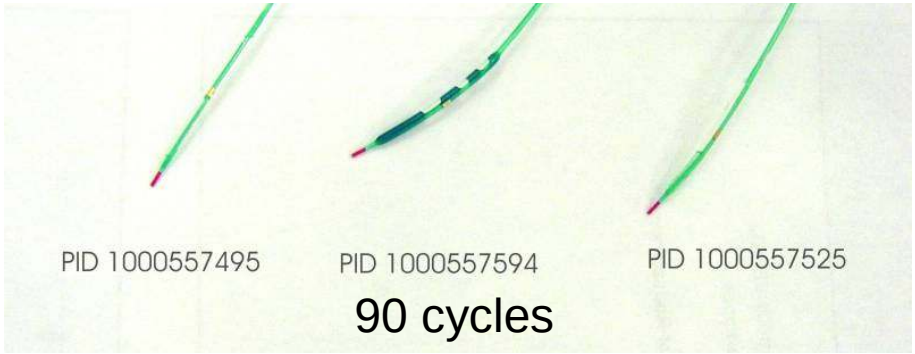
cleaning and disinfecting
Balloon catheters made reprocessable
- cleaning performance geometry dependent
- cleaning validation necessary











6. What are the ethical challenges of the reprocessing practice of single use medical devices?

Patient safety first

- High level of safety guaranteed and controlled

- No harm for the patient

- Experience in controlled reprocessing has proven that millions of devices have been safely reprocessed (Germany, USA etc.)

- Innovations and high-tech medical devices for all patients by safely reprocessed medical devices

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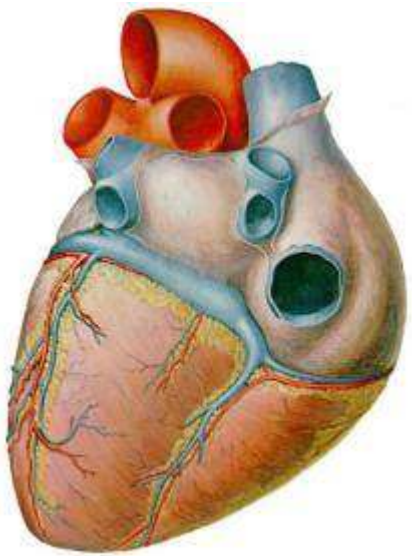
All German University Clinics
make use of professional reprocessed
medical devices

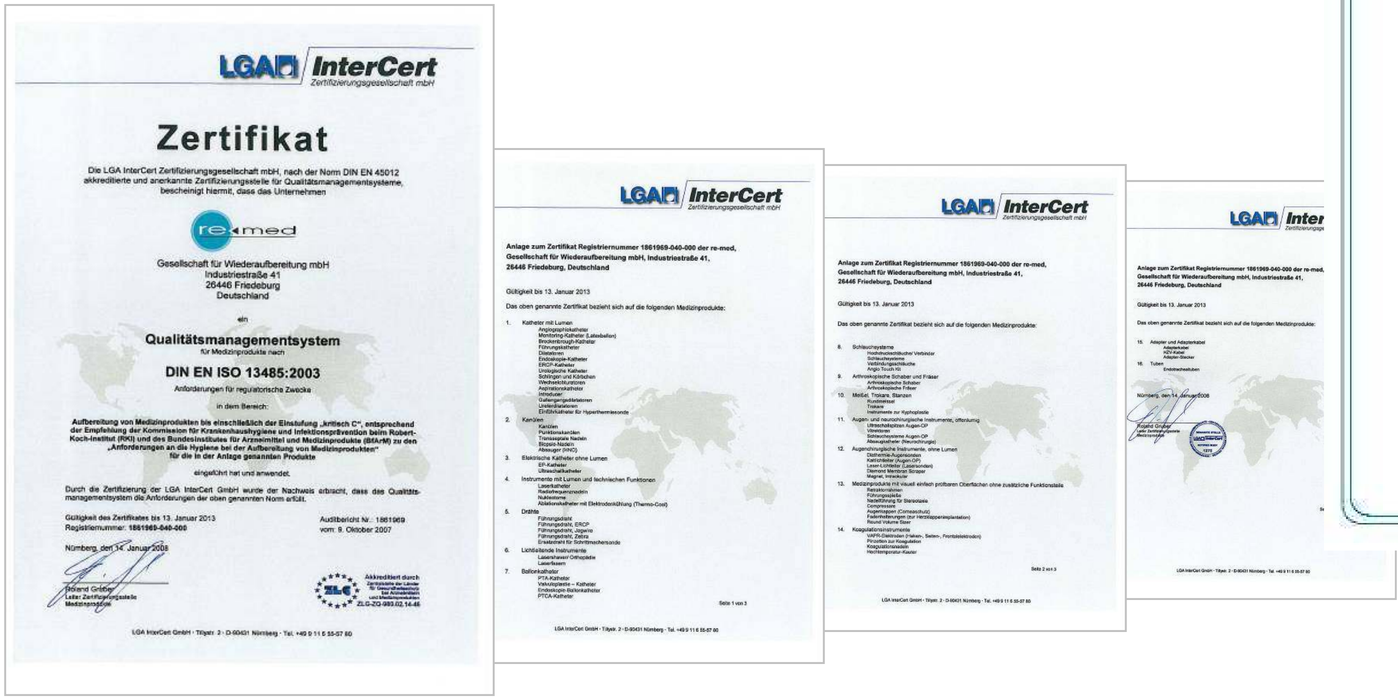
More than 70% of the German
electrophysiological interventions are
performed via professionally reprocessed
„single-use“ medical devices

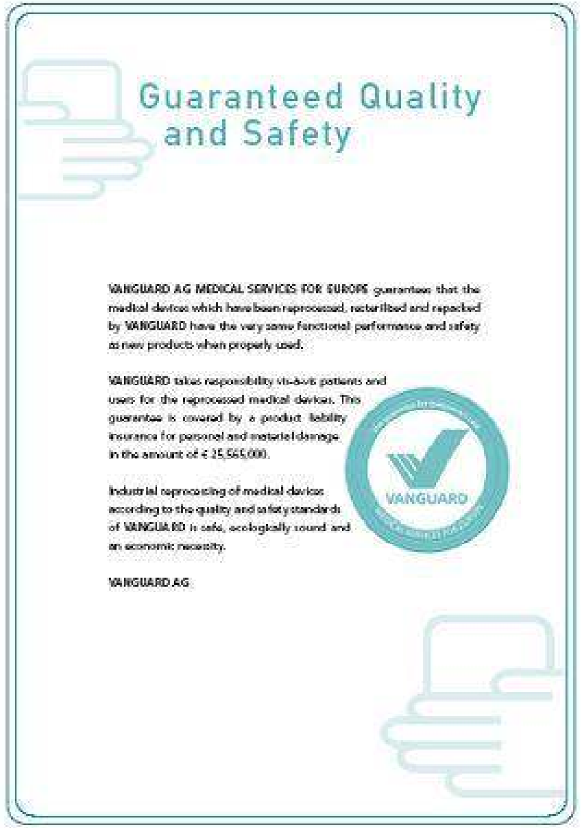


In Germany, these aspects are clearly regulated:

- the manufacturer takes over the liability only for the first use,

- the reprocessor is liable for the safety of the reprocessed medical device





Reprocessing increases the economic efficiency of health care institutions significantly

Example:

Costs for AF-ablation 2007 (double lasso, CARTO)

Ablations in Germany	without reprocessing	with reprocessing
- EP Personal (nurses / physicians)	€ 950	
- 4 catheters (2 Lasso, CS, His)	~~€ 3200~~	€1866
- CARTO catheter + other EP material	€ 2850	
- ~~NMR of the heart for 3D reconstruction~~	~~€ 500~~	
- chemistry, ECG, X-ray, echo	€ 500	
- 4 nights in hospital	€ 1000	
Total	~~€ 9000~~	€7216
DRG-reimbursement (F27Z)		
Factor 2.767 x Baserate €2750	€ 7609	
Loss / Income	~~€ 1391~~	€ 443

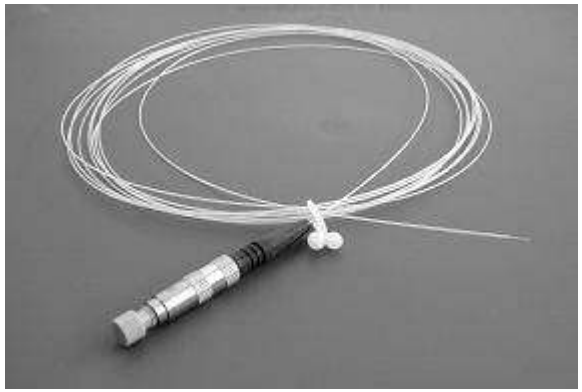
8. What are the economic aspects of the reprocessing practice of single use medical devices?

Widespread use of controlled reprocessing motivates manufacturers to:

- Provide more reprocessable medical devices

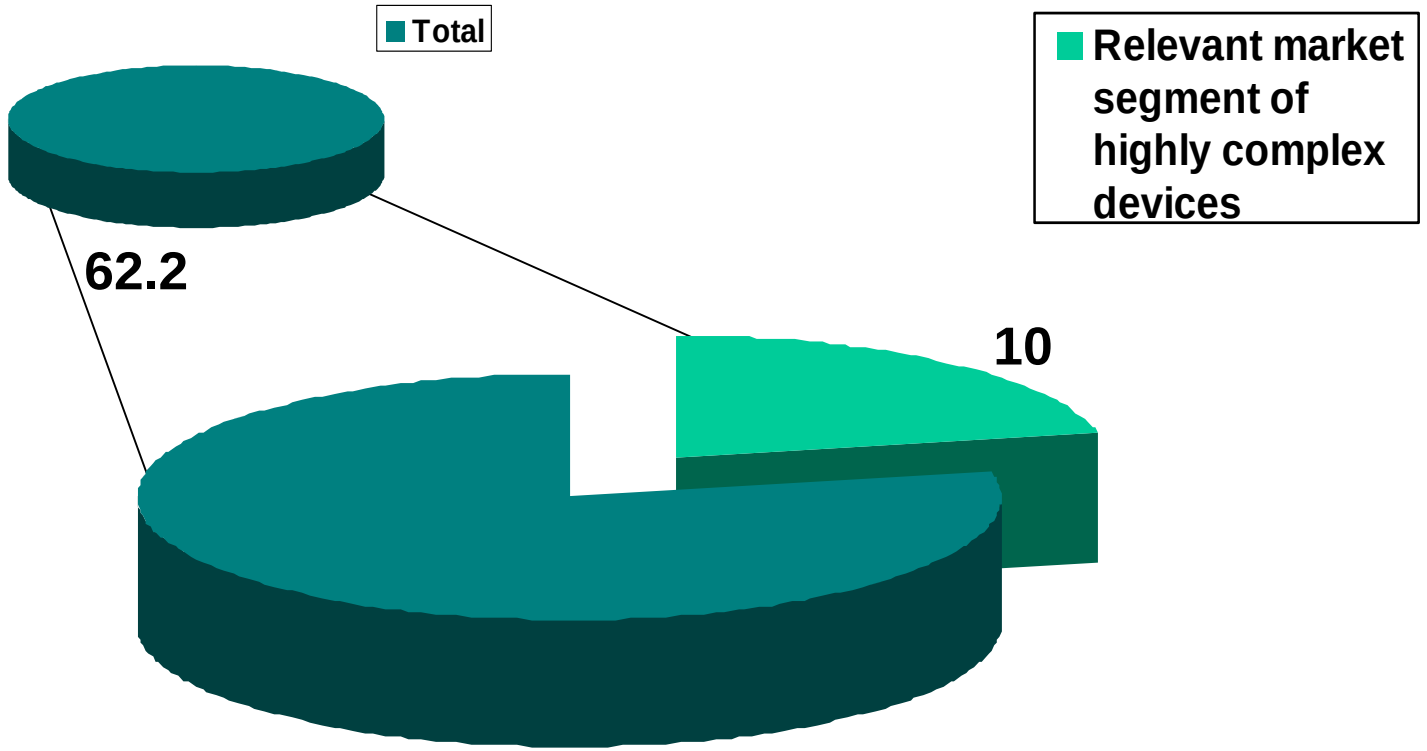
- Cooperate with reprocessors

- Improve the quality of medical devices



Reprocessing can save up to 50% of the costs in comparison to new medical devices

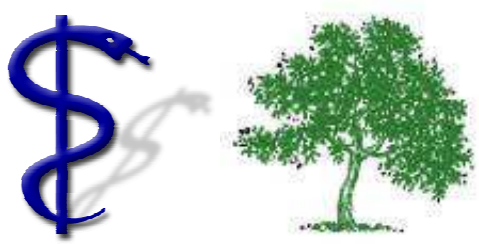
EU Market for medical devices in EURO billion



10. Is the reprocessing practice an environmental friendly practice?

Reprocessing of so called “single-use” medical devices contributes substantially the protection of the environment:

- Waste is reduced
- Resources for producing new medical devices are saved
- The amount of environmentally harmful materials (e.g. PVC) is reduced



10. Is the reprocessing practice an environmental friendly practice?

Ecological balance sheets could be a useful instrument to enable ecological assessments

But

manufacturers do not provide data about the use of resources for the production of single-use medical devices

Countries (e.g. USA, Germany, the Netherlands etc.) with Reprocessing Regulations irrespective of devices declaration as single-use or multiple-use have an experience of:

- Higher patient safety
- Increased cost effectiveness
- Environmental advantages

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Thank you for your attention!

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