Reuse of single-use medical devices
Towards an European harmonization

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Outline

• Brief history of single use medical devices (SUDs)
• SUDs reprocessing and reuse
• The EU framework on SUDs
• Critical issues in reprocessing SUDs
• Evidences from Italy: reprocessing feasibility of electrophysiology and ablation cardiac catheters
During the 1960s and the early 1970s, most medical devices made of glass, rubber, or metal were generally considered to be reusable and were reprocessed mainly by hospitals.

In the late 1970s and the two following decades, clinical medicine has undergone substantial changes:

- new minimally invasive techniques (e.g. endovascular and laparoscopic intervention)
- new instruments (complex manipulations through small incisions, with the effector portion of the device located some distance from the operator’s hand, demanding stable and predictable performance).

During this same period, patients and clinicians concern rise about the risk of infectious disease transmission (human immunodeficiency, hepatitis B and C viruses).

One solution to both demands was found in single-use devices (SUDs), shaped from newly developed fabrication materials and advances in manufacturing techniques, and intended to be discarded after use on a given patient.
Although a number of advantages are related to the use of disposable goods in medicine, single-use devices are typically more costly on a per-use basis.

SUDs are relatively expensive to purchase and their one-patient/one-product nature made necessary enlargement of hospital inventories and the resulting stream of medical waste.

These aspects have led to the interest in reprocessing and reuse of these devices.

Many hospitals began to explore the reprocessing and a limited reuse of products intended for single use, initially using on-site facilities as they have traditionally done with multiple-use metallic surgical instruments.

As single-use products became more complex, hospitals began to turn to third-party reprocessors to handle reprocessing needs.
The EU framework on SUDs

Directive 93/42/EC

**Distinction** between reusable and single use devices.

- For the reusable medical devices, the manufacturer must provide information on the appropriate process to allow reuse, including cleaning, disinfection, and packaging and, where appropriate, the method of sterilisation to be used, and any restriction on the number of reuses.

- The medical devices intended for single use must bear on the label an indication that the device is for single use.

The EU framework on SUDs


**Definition:** “single use device” means “a device intended to be used once only for a single patient”

**Market harmonization:** The manufacturer’s indication of single use must be consistent across the Community.

**Address concerns about patient safety:** insert the following provisions as regards the reprocessing of medical devices:

"Article 12a

Reprocessing of medical devices

The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.

In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection."

A questionnaire was published on Commission’s website from 6th July 2007 to 15th August 2007.


Reprocessing as a practice is generally perceived to mean

the cleaning, disinfection and sterilization of a medical device, including related procedures, as well as the functional testing and repackaging, carried out on a medical device after it has been put into service, for the purpose of reuse.

A fragmented regulatory framework is present within the European Community.

In some Member States, reprocessing practices on ‘single-use’ medical devices are regulated or accepted under quality standards, in some it is not recommended or explicitly prohibited, and in some Member States regulation just does not exist.
The Commission services organized a workshop on 5th December 2008 with the aim to get a clearer picture of the reprocessing practice, in particular on public health, economic and environmental aspects of the reprocessing of single use medical device.

The outcome of this workshop was published on the Commission’s website on 18th May 2009.
EUCOMED: European Medical technology industry association

Conclusions

This paper has described all the issues surrounding the reuse of single use devices. There is now a wealth of evidence to suggest that patient safety is compromised if single use devices are reused. The inability to adequately clean, decontaminate and sterilize the devices as well as the potential failure of the device on repeated use are important reasons why Eucomed strongly recommends against the use of single use devices more than once. Whilst some countries have implemented legislation banning this practice, other countries are still turning a blind eye to the reuse of single use devices. Europe-wide measures are required to ensure patient safety is no longer compromised by the repeated use of single use devices.

EAMDR: European Association of Medical Devices Reprocessors

Closing request

The development of the health care market with regard to medical devices and increasing reprocessing show that patient safety and economic savings cannot be complied with without a framework. EAMDR calls upon the national governments and the European Commission to analyse how a European regulation as recommended above can be implemented at national and European level. High quality reprocessing in all member states can only be guaranteed if it is done independent of the labelling chosen by the manufacturer. It has to be kept in mind that reprocessing in general is an important part for the provision of hygienic, fully functioning and safe medical devices for being used in a patient. It contributes significantly to the success of the treatment.
The Risks are Controllable

Report by the European Commission on the issue of the reprocessing of medical devices – commented by German experts

The reprocessing of single use medical devices is well-established in Europe. However, questions about the risk for patients and users arise constantly. The European Commission presented recently a kind of risk survey. The report strikes German experts as basically accurate but unbalanced.

For experts like Prof. Axel Kramer and Prov. Marc Kraft, Director of the Department of Medical Technology at the TU Berlin, the crucial criteria is that a product specific validated reprocessing procedure exists. If the product is marked as a single use or reusable device, in the end is irrelevant.

“The validation of the reprocessing procedure has to exclude a raise in risk. In that case there are neither hygienic nor technical-functional threats”, thus Marc Kraft.

“While cleaning contaminations of the surface of medical devices are removed, regardless whether those are particles, microorganisms or prions. When the prions are removed of the surface, they do not need to be inactivated anymore, which is in fact more difficult than the inactivation

http://www.md-institute.com
The Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for its scientific opinion on the safety of reprocessed medical devices marketed for single use.

Three major hazards:
- remaining contamination,
- persistence of chemical substances used during the reprocessing process,
- alterations in the performance.

One specific problem:
- elimination of prion contamination (only relatively aggressive cleaning methods, not compatible with the commonly used materials, can ensure prion inactivation).

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf
In the absence of quantitative data, it is not possible to quantify the risk associated with the use of reprocessed single use medical device.

To identify and reduce potential hazards, the whole reprocessing cycle starting with the collection until sterilisation and delivery, including functional performance, needs to be evaluated and validated.

...the Commission will assess which are the appropriate measures to be put forward in the context of the Recast of the Medical Devices Directives with regards to the reprocessing of single use medical devices in order to ensure a high level of protection for patients.
Medical devices EU Directive is currently under revision.

A proposal for a new “Regulation on medical devices” was released on September 26th, 2012.

**Article 15** is about “Single use devices and their reuse”

**Definition:** ‘Reprocessing’ means the process carried out on a used device in order to allow its **safe reuse** including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device.

Reprocessing of single-use devices is considered as manufacture of new devices so that the reprocessors must satisfy the obligations incumbent on manufacturers.

1. Reprocessors of SUDs are manufacturers
   Need for quality system.
   New CE mark on reprocessed device

2. Only originally CE marked SUDs can be considered for reprocessing

3. Critical SUDs (Class III) can be reprocessed only if safe according to scientific evidences

4. Commission shall establish and update a list of reprocessable critical SUDs

Article 15
Single-use devices and their reprocessing

1. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.

2. Only single-use devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.

3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.

4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

5. Identity of the reprocessor shall be reported on the label and in the instruction for use. Identity of the original manufacturer shall be removed from the device/packaging and shall be mentioned in the instruction for use.

6. Member States retain the right to maintain or impose a general ban on this practice including the transfer of SUDs to another Member State and the access of reprocessed SUDs to their market.

Critical issues in reprocessing SUDs

**Safety:** infective risk, cross infections, materials degradation, toxic residuals release, endotoxins, prions, …

**Efficacy:** performance, devices functionality, mechanical properties, surface properties, package efficacy…

**Cost effectiveness:** purchasing cost for reprocessed SUDs and new devices, risk analysis, collection cost, pre-cleaning cost, logistics, personnel training…

**Ethical aspects:** patient informed consent, inequity of health-care services, distributive justice in allocating scarce resources, …

**Legal aspects:** liability of reprocessed device, responsibility in case of adverse event, free market competition, device cost reimbursement, …

**Environmental aspects:** raw materials consumption, use of water and energy, green aspects, …
Our experience

In 2001, the Trentino Province (Northern Italy) funded a five years long project on the safety and efficacy of reprocesses devices for interventional cardiology intended for single use only.
Percutaneous catheters for cardiac electrophysiology and ablation
Multidisciplinary approach

Chemical-physical and functional characterization of new and reprocessed devices:
- New Devices/Materials identification
- Reprocessed materials properties
  - Surfaces topography
  - Surfaces chemistry
- Functionality testing on synthetic tissue/organ phantom

Biological analysis and material-tissue interaction:
- Bioburden characterization
- Decontamination/Cleaning efficiency
- Biocide treatments activity
- Sterility
- Pyrogenic status

Juridical and economic context:
- Ethical and legal issues
- Cost analysis for the introduction of a reprocessing policy
Device characterization and critical components individuation

Regeneration protocol definition

Material testing

Functionality testing

Biological tests

Outcomes:

Individuation of techniques for protocol validation

Safety quality Controls and Guidelines

Regeneration protocol optimisation
Multidisciplinary approach

Chemical-physical and functional characterization of new and reprocessed devices:
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- Sterility
- Pyrogenic status

Juridical and economic context:
- Ethical and legal issues
- Cost analysis for the introduction of a reprocessing policy
Evaluation and quantification of reprocessing modification in single-use devices in interventional cardiology

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\textsuperscript{d}Care and Rehabilitation Department, Azienda Provinciale per i Servizi Sanitari, 38100 Trento, Italy
\textsuperscript{e}Department of Physics, University of Trento ITC-IRST, 38050 Povo, Trento, Italy

Available online 3 August 2004
Reprocessed materials: shaft surface topography

Micro-roughness increasing

Nano-roughness increasing

Exponential fit:
Y = C + D[1 - exp(-x/t)]

C = 290 ± 60 Å
D = 630 ± 180 Å

t = 7 ± 4 cycles
Radiofrequency Ablation on Heart-equivalent Phantom. Functionality Testing of Percutaneous Single-use Catheter.

Francesco Tessarolo, Paolo Ferrari, Renzo Antolini, Giandomenico Nollo

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Abstract. Aim of the presented experimental and theoretical model was to characterize the power deposition process in cardiac catheter ablation. A dedicated set-up, based on a transparent temperature-sensitive gel-phantom was developed. A liquid crystal film was used to map the temperature distribution during RF deposition. An infrared acquiring system and a post-processing image software were used to define the heating zone and to quantify the device specific heating fingerprint. Experimental results were compared to a thermal conduction model with spherical symmetry, showing good agreement for ablation time 100–500s. Differences between model and experimental results were explained by deviation of the real heating pattern from spherical geometry.

INTRODUCTION

Cardiac trans-catheter ablation is a valid alternative to drug therapy and cardiac surgery in the treatment of myocardial arhythmias [1–3]. The deep comprehension of the radio-frequency (RF) heating mechanism and the characterization of the functional properties of the devices are mandatory to guarantee the expected clinical outcome. Furthermore, testing the functionality effectiveness of ablation catheters allows
Tissue equivalent phantom for simulated use

Heating fingerprint characterization

Power delivery quantification and termistor calibration control

Functionality testing: ablation efficiency
A novel phantom for in vitro quantification of electrophysiology catheter slipperiness: Implementation and testing

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Introduction
The use of electrophysiology and ablation catheters (EP) for the treatment of cardiac arrhythmias is a valid alternative to cardiac surgery. The clinical use of these devices requires the insertion of the catheter shaft through the major blood vessels to the heart. Catheter functionality and material surface properties need to be thoroughly characterized for safe use. As in a previous study on PTCA catheters (1), one of the most critical parameters to assess is the friction force required for catheter insertion and extraction, which accounts for surface slipperiness and material-vessel interaction. This study aimed to realize and test a new experimental set-up to characterize and quantify the lubricious properties of the cardiac catheter shaft in vitro. Considering the interest in reusing these medical devices, we assessed the system suitability to evidence any variation in catheter slipperiness after regeneration.

Materials and methods
We realized a venous phantom using a polyamide pipe (6 mm inside diameter, 110 cm in length), bent into three equivalent sections according to the three spatial directions x, y and z. The pipe was plugged
Synthetic femoral vein for friction characterization

Identification of significant parameters and correlation with the number of sterilization cycles

Functionality testing: friction & slipperiness

Total energy for device extraction

<table>
<thead>
<tr>
<th>Reprocessing cycles</th>
<th>% variation of Energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>6</td>
<td>100</td>
</tr>
<tr>
<td>8</td>
<td>150</td>
</tr>
<tr>
<td>10</td>
<td>200</td>
</tr>
</tbody>
</table>

Graphs showing:
- Reprocessing cycles vs. % variation of Energy
- Load (N) vs. Position (mm)
- Media totale, Load (N) vs. Position (mm)
Multidisciplinary approach

Chemical-physical and functional characterization of new and reprocessed devices:
- New Devices/Materials identification
- Reprocessed materials properties
  - Surfaces topography
  - Surfaces chemistry
- Functionality testing on synthetic tissue/organ phantom

Biological analysis and material-tissue interaction:
- Bioburden characterization
- Decontamination/Cleaning efficiency
- Biocide treatments activity
- Sterility
- Pyrogenic status

Juridical and economic context:
- Ethical and legal issues
- Cost analysis for the introduction of a reprocessing policy
Different experimental protocols for decontamination affect the cleaning of medical devices. A preliminary electron microscopy analysis

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Available online at www.sciencedirect.com

Pre-Sterilization protocols efficiency
Pre-Sterilization protocols efficiency

RESULTS (SEM):

(Protocol I)

(Protocol II)

(Protocol III)

(Protocol IV)
RESULTS (CQM):

- **Pseudomonas aeruginosa**

![](chart.png)

- **Pre-Sterilization protocols efficiency**

CFU/sample over 24h and 48h for different protocols:

1. Chlorocleaner
2. Enzymatic detergent
3. Phenolic water emulsion
4. Phenolic emulsion Enzymatic detergent
5. Control

**Protocol 1, 2, 3, 4, 5**
Sterility and Microbiological Assessment of Reused Single-Use Cardiac Electrophysiology Catheters

Francesco Tessarolo, PhD; Iole Caola, MS; Patrizio Caciagli, MD; Giovanni M. Guarrera, MD; Giandomenico Nollo, PhD

OBJECTIVE. To assess the performance and limitations of a reprocessing protocol for nonlumen electrophysiology catheters by testing the sterility of reprocessed devices and defining the maximum number of reprocessing cycles sustainable by the device in hygienically safe conditions.

DESIGN. Simulated use, reprocessing, and testing of the catheters.

SETTING. Microbiology and virology department of a public health diagnostic laboratory.

INTERVENTIONS. Seventy-three catheters were collected after clinical use on patients. The first group of devices was tested for sterility after 1 cycle of reprocessing. By the repetition of simulated use (blood inoculated with bacteria) and reprocessing (decontamination, cleaning, and hydrogen peroxide gas plasma sterilization), we obtained 39 sample devices reprocessed 2 times, 26 reprocessed 3 times, 28 reprocessed 4 times, 36 reprocessed 5 times, and 22 reprocessed 6 times. Devices were cultured for 28 days in tryptase soy broth.

RESULTS. We tested 208 catheters with 6 cycles of reprocessing and 4 inoculated bacteria species. No devices tested positive for the inoculated strains until the fourth cycle of reprocessing. One of 35 catheters showed the growth of the inoculated strain Bacillus subtilis after 5 cycles of reprocessing, and 1 of 22 catheters showed growth of this organism 6 cycles. After the second reprocessing, 7 of 36 devices showed growth of gram-negative bacteria other than the strain inoculated.

CONCLUSIONS. Reprocessing according to the reprocessing protocol was insufficient to guarantee device sterility after 5 reuses. Cleaning with enzymatic solution revealed good cleaning properties with efficient bioburden reduction. Storage intervals of longer than 24 hours during reprocessing should be avoided to limit contamination or bacterial overgrowth. Technical considerations suggest the introduction of reprocessing procedures only in hospitals with considerable workloads.

Infect Control Hosp Epidemiol 2006; 27:1385-1392
METHODS: Sterility efficiency up to 6 cycle of reprocessing on devices:
### RESULTS:

<table>
<thead>
<tr>
<th>Lot</th>
<th># devices tested</th>
<th># non sterile</th>
<th>% non sterile</th>
</tr>
</thead>
<tbody>
<tr>
<td>I regeneration</td>
<td>54</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>II regeneration</td>
<td>36</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>III regeneration</td>
<td>24</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>IV regeneration</td>
<td>28</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>V regeneration</td>
<td>35</td>
<td>1</td>
<td>2.7%</td>
</tr>
<tr>
<td>VI regeneration</td>
<td>22</td>
<td>1</td>
<td>4.8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>199</strong></td>
<td><strong>2</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Sterility was **assured up to 4 cycles** of reprocessing. Further reuses might compromise material properties and favour bacterial persistence.
- Sterility assessment is in **accordance with surface analysis** which suggests a maximum number of $7\pm4$ cycles.
Efficiency in endotoxin removal by a reprocessing protocol for electrophysiology catheters based on hydrogen peroxide plasma sterilization

Francesco Tessarolo\textsuperscript{a,*}, Iole Caola\textsuperscript{b}, Giandomenico Nollo\textsuperscript{c}, Renzo Antolini\textsuperscript{c}, Giovanni M. Guarrera\textsuperscript{d}, Patrizio Caciagli\textsuperscript{b}

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Received 21 September 2005; received in revised form 28 April 2006; accepted 7 May 2006
Pyrogenic status

**MATERIALS and METHODS**

**Three steps analysis:**

- Retrieval efficiency tests
  - Preliminary depyrogenation
  - Inoculum with 40 EU
  - Elution procedure
  - Average retrieval computation

- Endotoxins quantification tests
  - Sample elution
  - Endotoxins quantification
  - Pyrogenic status definition

- Depyrogenation test
  - Inoculum with high amount of endotoxins (200 EU)
  - Device reprocessing
  - Residual endotoxin detection
  - Depyrogenation efficiency computation
RESULTS and CONCLUSIONS

Standard clinical use did not represent a source for endotoxins contamination.

15/15 reprocessed clinically used catheters were non pirogenic (<20 EU/device).

In vitro pyrogenic loads of 40, 80, 200 EU/device were reduced to less than 11 EU/device.

NOTE:
The use of tap water, manual cleaning and inadequate storage of partly processed devices could increase the pyrogenic load in a significant way.
Multidisciplinary approach

Chemical-physical and functional characterization of new and reprocessed devices:

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- Functionality testing on synthetic tissue/organ phantom

Biological analysis and material-tissue interaction:

- Bioburden characterization
- Decontamination/ Cleaning efficiency
- Biocide treatments activity
- Sterility
- Pyrogenic status

Juridical and economic context:

- Ethical and legal issues
- Cost analysis for the introduction of a reprocessing policy
Need of an (European) harmonization for reprocessing activity regulation
Reprocessing single-use cardiac catheters for interventional cardiology. A cost-minimization model for estimating potential saving at departmental scale and national level

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*These authors contributed equally to this work
Economic issues: costs analysis

Creation of a economic model for savings computations

Regenerated device cost

\[
[i \frac{P_K}{n} + (n - 1) \frac{P_R}{n}] + \frac{S}{n} + C + \frac{G_K}{3N} + \frac{G_R}{3N}
\]

- \( P_K \) = new device price
- \( P_R \) = regeneration price
- \( i \) = regeneration tax
- \( G_K \) = contract assignment cost
- \( G_R \) = fixed cost for regeneration servicing
- \( N \) = total number of used catheter
- \( S \) = disposal cost
- \( C \) = cleaning and packaging cost
- \( n \) = utilization number
Economic issues: potential saving

Distinction between:

Diagnostic devices
EP catheters

Therapeutic devices
Ablation catheters

41.2% (26.8 - 42.7)

32.9% (23.8 - 37.7)
Potential savings: sensitivity analysis

Variation of the regeneration rate.
The number of uses has been set to 6

Variation of the number of uses.
The regeneration rate has been set to 0.95

Diagnostic devices
EP catheters

Therapeutic devices
Ablation catheters
Economic issues: costs analysis

• The **average number of regenerations** and the **regeneration rate** are basic variables for saving computation. The higher the two variables, the larger the economical benefit.

• Real cost savings should be carefully assessed, and might be nullified:
  • for small amount of clinical procedure
  • variation in new devices price.

• Reduction of waste quantities, water and energy consumption, but also global consumption of raw materials and primary energy deserves closer attention for both economical and ecological aspects.

• Risk assessment of the reprocessing policy may be potentially followed by economical implications.
Reprocessing Recommendations

• The reprocessing protocol should be conceived according to material properties and design of the specific device model.

• The efficacy of any reprocessing protocol should be verified by safe, reproducible, and regularly updated investigation techniques able to provide deep analyses of materials, functionality, and biological aspects.

• Essential quality tests should be performed on every reprocessing cycle and on every single device.

• Maximum number of reprocessing cycles should be specified according to devices features, use conditions, and reprocessing protocol.

• Pre-sterilization processing conditions are critical for sterilization success (water quality, detergent type, storage time and storage conditions before starting reprocessing procedures).

• Decontamination, cleaning, and washing procedures, together with sterilization techniques could induce chemical, physical and morphological modifications on the treated surfaces and potential toxicity of the sterilized device (residuals of disinfecting and sterilizing agents, degradation and byproducts of sterilization, etc...).
Project final Report:

“Re-use of single use medical devices - SICC-SIX project results overview. Part I”.


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Book Chapter:

“Critical issues in reprocessing single-use medical devices for interventional cardiology.

F. Tessarolo, I. Caola and G. Nollo

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Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology

Francesco Tessarolo, Iola Caola and Giandomenico Nollo

1. Introduction

1.1 Single-use vs. multiple-use medical devices. During the 1960s and the early 1970s, most medical devices made of glass, rubber, or metal were generally considered to be reusable. This concept did not change until the late 1970s, when medical devices started to enter the market labelled "single-use only".

During this decade, clinical medicine saw substantial changes, with traditional open surgical procedures giving way to minimally invasive techniques such as endoscopic and laparoscopic interventions. Both procedures required new instruments for the surgeon and his or her team.

In the field of interventional cardiology, devices were used that did not come in contact with the patient’s blood. These include the catheter control module and the catheter sheath, which are cleanable and reusable. The other part of the device, which came in contact with the patient’s blood, was disposed of after use. The entire length of the catheters was protected during the entire procedure inside the sterile disposable sheath, thus creating a robust solution.

Once their role in both fields was found in single-use devices (SUDs), clogged from newly developed biocompatible materials (polyurethane) and to be discarded after use on a given patient. Consequently, the past three decades have seen an explosion in the production and use of single-use medical devices, stemming from a desire to improve patient safety and decrease the risk of cross-contamination and infections in both fields.

1.2 SUDs reprocessing

Although a number of advantages are related to the use of disposable goods in medicine, single-use devices are typically more costly or a per-unit basis. SUDs are relatively expensive to purchase, and their disposal or reprocessing rate is necessary for the proper maintenance of hospital inventories and the resulting storage of medical waste. These aspects have led to the interest in reprocessing and reuse of these devices. Many medical devices are currently covered by the EU’s medical device regulations, which have introduced a regulatory framework for reprocessing. Some single-use medical devices are reusable, while others cannot be reprocessed. Current legislative requirements state that devices that have been certified as single use, initially using-disposable facilities, may now traditionally used and reprocessed, whereas some single-use devices, like single-use products from blood samples, have been regulated for single use only as medical products. Future prospective regulatory proposals aim to address this issue and provide a clear framework for reprocessing medical devices.
References


