Re-use of single use medical devices?
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Industrial Ethylene Oxide Sterilization of Medical Devices: What Hospitals Need to Know About Re-Sterilization of Single Use Devices.

Contact Information: Paul J. Sordellini
North American Sterilization & Packaging Company
17 Park Drive
Franklin, NJ 07416 USA
Tel: 001.908.884.8845
Email: Sordellini@att.net
Is there still reuse of single use medical devices?

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<td><strong>Total:</strong></td>
<td>10 of 13 <strong>yes</strong></td>
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<td><strong>EU:</strong></td>
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<td><strong>Non EU:</strong></td>
<td>5 of 5 <strong>yes</strong></td>
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« The absence of evidence doesn’t mean the evidence is absent. »
What can I Sterilize In the STERRAD® 100S Sterilizer?

Typical Devices Sterilized in the STERRAD® 100S Sterilizer:

- Stereotactic equipment
- Defibrillator paddles
- Electrosurgery instruments
- Endoscopic dilation
- Cranial pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- rigid endoscopes
- Laryngoscope blades
- Tissue sheaths
- Cryosurgery

- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser handpieces, fibers, and accessories
- Optical lens (diagnostic, magnifying)
- Pigmentation handpieces
- Dopplers
- Shaver handpieces
- Radiation therapy equipment
- Thermocouple probes
- Video cameras and couplers
- Telescopes/walking elements and sheaths

If you have a question about whether your particular device can be sterilized in the STERRAD 100S, please call the device manufacturer or call ASP at (800) STERRAD.


Remember, the user’s guide has a variety of detailed information on how to effectively use your STERRAD 100S Sterilizer.

33 Technology Drive, Irvine, California 92618

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U.S. Version

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
How To Determine What Can Be Sterilized In STERRAD® 100S Sterilizer

1. Is the reprocessable medical device made of the following materials?
   - Aluminum
   - Brass
   - Delrin® acetal resin (polyacetal)
   - Ethylene vinyl acetate (EVA)
   - Glass
   - KRATON™ Polymers
   - Neoprene
   - Nylon® (nylonamide)
   - Polycarbonate
   - Polystyrene
   - Polyetherimide (ULTEM® Polymers)
   - Polymethyl methacrylate (PMMA)
   - Polyphenylene sulfone (Radel®)
   - Polypropylene
   - Polyurethane
   - Polyvinyl chloride (PVC)
   - Silicone elastomers
   - Stainless steel
   - Teflon® (polytetrafluoroethylene)
   - Titanium

   If the answer is “No” or “Don’t Know,” please call the medical device manufacturer for information on how to properly sterilize this device.

2. Does the reprocessable medical device have a lumen?
   - No
   - Yes

   If the answer is “Yes,” proceed with processing.

3. Is the lumen made of stainless steel, polyethylene, or Teflon®?
   - No/Don’t Know
   - Yes

   If the answer is “Yes,” proceed with processing.

4. Proceed with processing if the lumen conforms to the dimensions listed below:
   - Single Stainless Steel Lumen
     - Inside Diameter
       - 1 mm or larger: 125 mm or shorter
       - 2 mm or larger: 250 mm or shorter
       - 3 mm or larger: 400 mm or shorter
   - Teflon®/Polyethylene
     - Inside Diameter
       - 6 mm or larger: 310 mm or shorter
   - Lumen lengths
     - 0 mm, 125 mm, 150 mm, 200 mm, 250 mm, 310 mm, 400 mm

   If the lumen does not conform to these dimensions, please call the medical device manufacturer for information on how to properly sterilize this device.
Single use devices should not be reprocessed in a Sterrad sterilizer.
Il riutilizzo dei dispositivi medici monouso per cardiologia interventistica

Re-use of single-use medical devices for interventional cardiology
Figure 1. Schematic diagram summarizing components of the electrophysiology (EP) laboratory.
Figure 1
Worsening of the polymeric shaft in electrophysiology and ablation catheters after reprocessing. Scratches and indentations number per area unit could be related to both clinical use and mechanical-manual brushing in cleaning procedures. From left to right: new device, 1, 4, 8 cycles regenerated devices.
Figure 2
Nanometric topography of the polymeric shaft in electrophysiology and ablation catheters after reprocessing with gas plasma sterilization.
The original surface morphology underwent progressive roughening at nanometric level induced by the chemical and physical etching effect of the sterilization technique.
The probability that your processed medical devices reached sterility is directly proportioned to how much you know about sterility...

By Josy
Can we reconcile the health and safety of the patient with re-use?
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community:
Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.
ANNEX I
ESSENTIAL REQUIREMENTS

8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.
Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.
EU moves to improve safety of medical devices

The safety of medical devices such as surgical equipment or implants is to be significantly improved after the adoption of a proposal by the European Commission, today by the European Parliament. There will be stricter rules for the use of potentially toxic materials, for which adequate labelling will be required. Furthermore the safe single use of devices is enhanced. A study will be done to see how better reprocessing of devices can be achieved. Apart from this, specialized medical software will fall under the scope of the new Medical Device Directives, which have been updated in the light of new technological developments. The European Parliament vote is based on a compromise, reached with the Council, which is expected to adopt the package shortly.

Commenting on the vote, Commission Vice-President Günter Verheugen, responsible for enterprise and industry policy, stated: “This is good news, as today’s vote allows for enhanced patient protection and supports medical progress and innovation. It will improve the functioning of the internal market, and strengthen the competitiveness of European industry.”

Medical devices have become an increasingly important health care sector and have an increased impact on health and health care expenditure. Medical devices encompass some 10,000 types of product, ranging from simple bandages and spectacles, through life sustaining implantable devices, to the most sophisticated diagnostic imaging and minimally invasive surgical equipment. The public expects that such medical devices meet the highest safety standards.

The new legislation will clarify essential elements for safety of medical devices such as clinical evaluation and conformity assessment, as well as bringing new, positive, provisions such as those aimed at increasing transparency. The package agreed today aims at reinforcement in the following fields:

To bring clarification to the area of reprocessing of medical devices, the definition of the term ‘single use’ and subsequent labelling will be uniform within the EU; Manufacturers should avoid the use of carcinogenic, mutagenic or toxic to reproduction (CMR) substances used in medical devices. A total ban of these substances is not possible without banning many medical devices which are indispensable for the protection of health. But the following improvements are foreseen:

- The issue of the medical devices combined with cells and tissues of human origin, the so called “combined products” will not be tackled. Other planned legislation should deal with this question, such as the Regulation of advanced therapy medicinal products.
- As design for patient safety initiatives, the manufacturer should place particular emphasis on the working environment in which device is used and possible reduction of potential accidents.

Additional information, including the Commission proposal, can be found at:

http://ec.europa.eu/enterprise/medical_devices/revision_mdd_en.htm
Cartoon 41 - The Emancipated Patient

"Just one more question! You are not using any reprocessed single-use devices on me, right?"
The crucial question is if no alternatives are available, what is the bigger risk for the patient: not to intervene or to intervene with a resterilized device?
« The CSSD has the duty to protect the interests of the patient. »
Thank you