

Re-use of single use medical devices ?

Wim Renders



DO NOT REUSE







Annual EFHSS and MSÜD Conference 2004
Altin Yunus Hotel, Cesme, Izmir, Turkey
5-7 May 2004

Industrial Ethylene Oxide Sterilization of Medical Devices: What Hospitals
Need to Know About Re-Sterilization of Single Use Devices.

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Is there still reuse of single use medical devices?

Total:	10 of 13 yes
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EU:	5 of 8 yes
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Non EU:	5 of 5 yes
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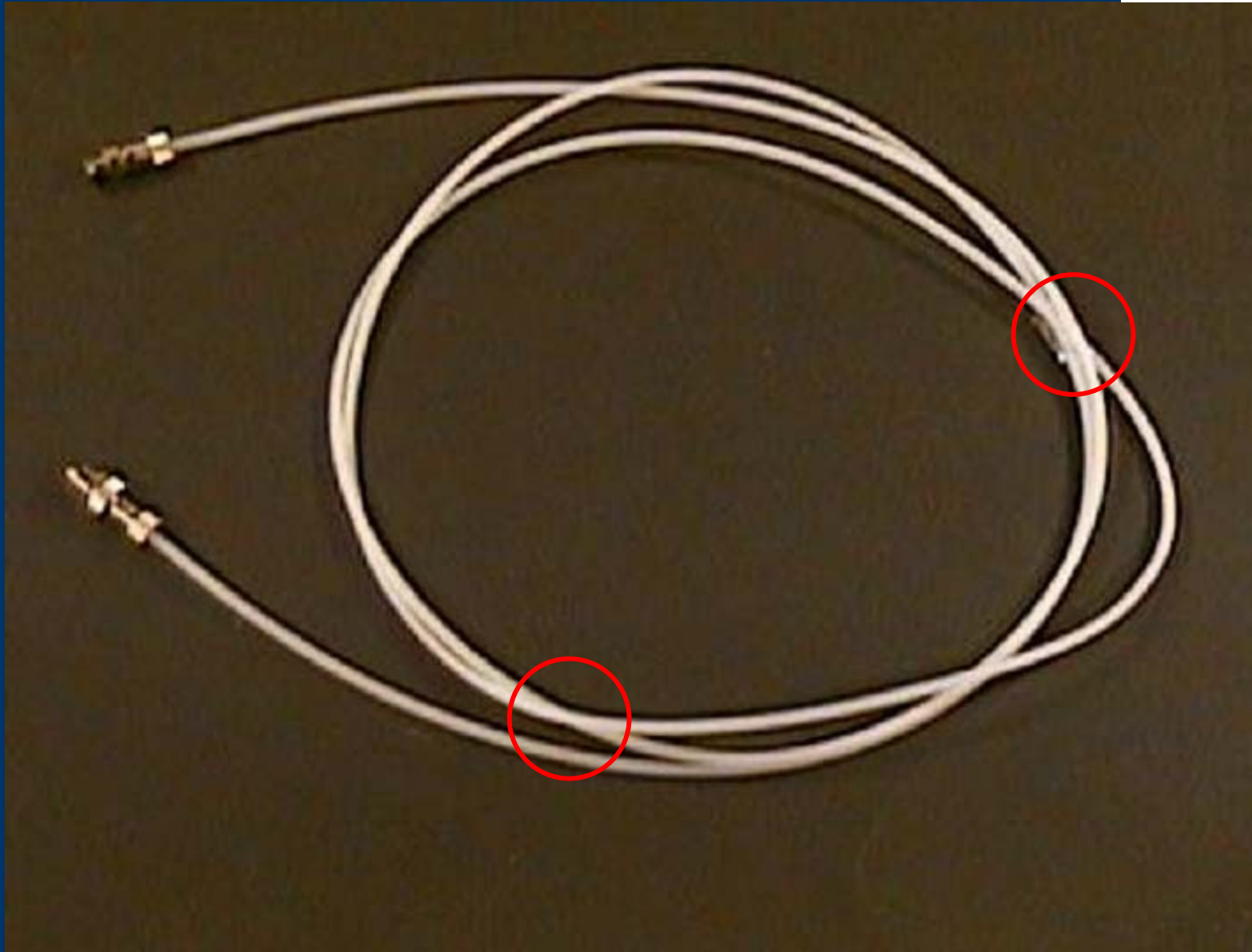
« The absence of evidence doesn't mean the evidence is absent. »







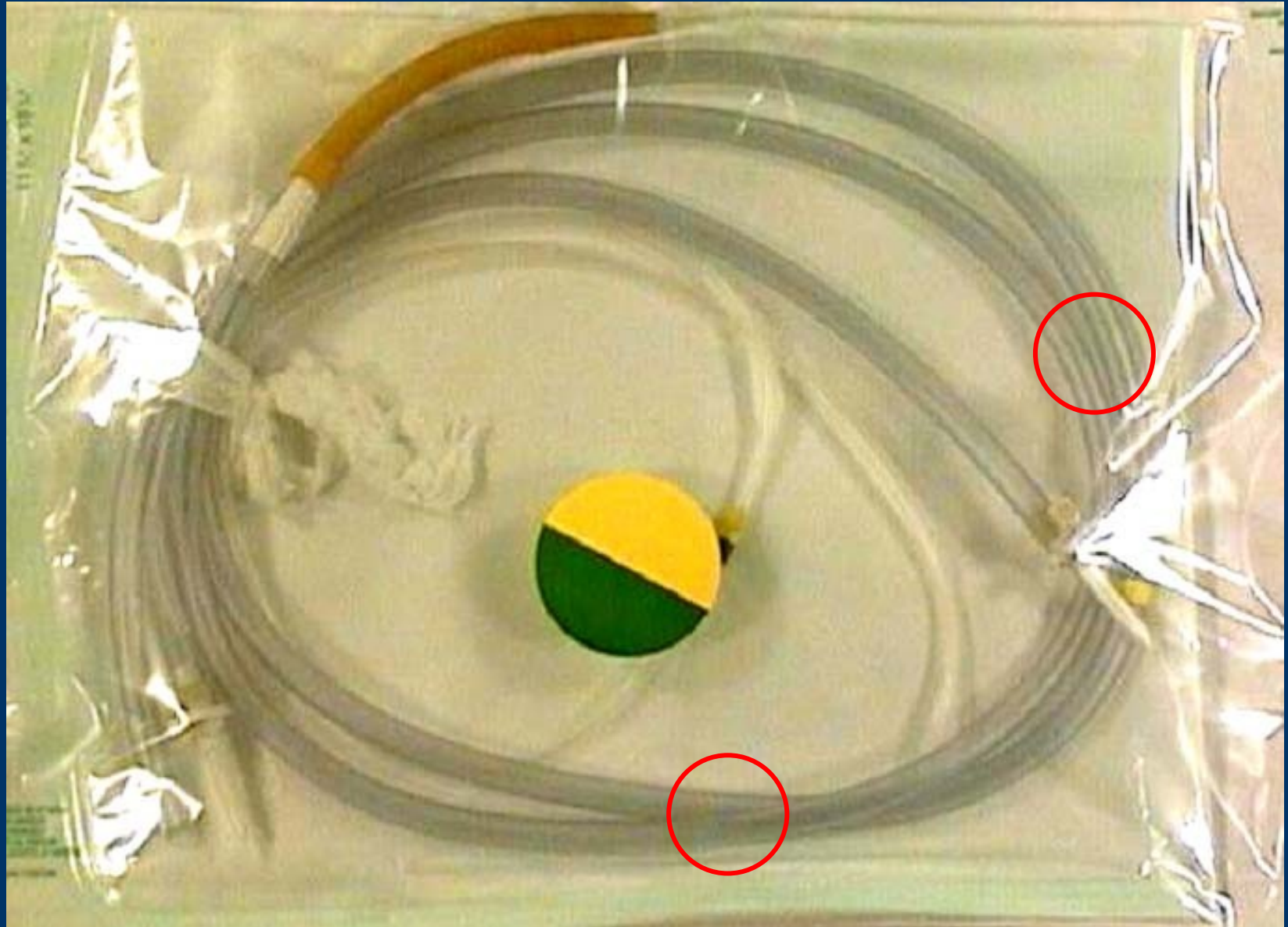




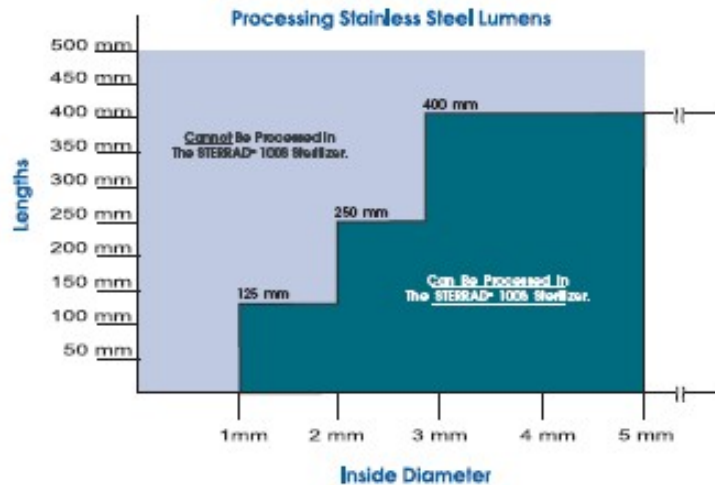












What can I
Sterilize
In The STERRAD®100S Sterilizer?

Typical Devices Sterilized in the STERRAD® 100S Sterilizer

- Stereotactic equipment
- Defibrillator paddles
- Electrocautery instruments
- Esophageal dilators
- Cranial pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- Rigid endoscopes
- Laryngoscope blades
- Tracer sheaths
- Cryoprobes
- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser hand-pieces, fibers, and accessories
- Ophthalmic lenses (diagnostic, magnifying)
- Pigmentation hand-pieces
- Cupplers
- Shaver hand-pieces
- Radiation therapy equipment
- Ultrasound probes
- Video cameras and couplers
- Refectoscope/working elements and sheaths

If you have questions about whether your particular device can be sterilized in the STERRAD Sterilizer, please call the device manufacturer or call ASP at (888) STERRAD. Visit our website at www.sterras.com.

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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AD-82874-02 Rev. 2
U.S. Version

ASP 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)*
- Ethylvinyl acetate (EVA)
- Glass
- KRATON™ Polymers
- Neoprene
- Nylon® (polyamide)*
- Polycarbonate
- Polyethylene
- Polyetherimide (ULTEM® Polymers)
- Polymethyl methacrylate (PMMA)
- Polyphenylene sulfone (Radel®)
- Polypropylene
- Polystyrene
- Polyurethane
- Polyvinyl chloride (PVC)
- Silicone elastomers
- Stainless steel
- Teflon® (polytetrafluoroethylene)
- Titanium

No/Don't Know



Please call the medical device manufacturer for information on how to properly sterilize this device.

* May have limited life after repeated sterilization.
Delrin®, Nylon®, and Teflon® are registered trademarks of the DuPont Corporation.
KRATON™ Polymers is a trademark of KRATON Polymers LLC.
ULTEM® Polymers is a registered trademark of the GE Company.

Yes

2 Does The Reprocessable Medical Device Have A Lumen?

No

Proceed with Processing.

Yes

3 Is The Lumen Made Of Stainless Steel, Polyethylene, Or Teflon®?

No/Don't Know



Please call the medical device manufacturer for information on how to properly sterilize this device.

Yes

4 Proceed With Processing If The Lumen Conforms To The Dimensions Listed Below

Single Stainless Steel Lumen

Inside Diameter	Length
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	Length
6 mm or larger	310 mm or shorter

* Validation testing for this lumen size was conducted using a maximum of 10 lumens per lot. Sterilized loads should not exceed the maximum number of lumens validated by this testing.

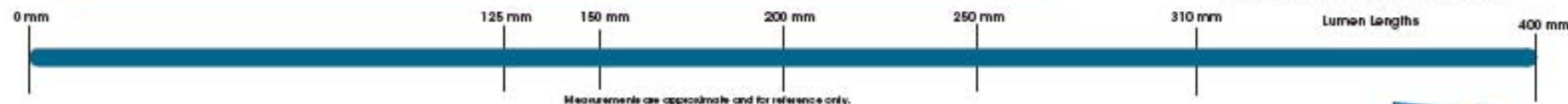


If the lumens do not conform to these dimensions, please call the medical device manufacturer for information on how to properly sterilize this device.

Inside Lumen Diameter

- 1 mm, 3 Fr, .039 in
- 2 mm, 6 Fr, .079 in
- 3 mm, 9 Fr, .118 in
- 4 mm, 12 Fr, .158 in
- 5 mm, 15 Fr, .197 in
- 6 mm, 18 Fr, .236 in

mm = millimeter, Fr = French, in = inch



STERRAD® 100S Sterilization System



Most instruments and devices made of the following materials can be processed in the STERRAD[®] 100S Sterilization System:

- Aluminum
- Inerts
- Isobutyl acrylate resin (polyisobutyl)
- Ethyl vinyl acetate (EVA)
- Glass
- EPOXY™ polymer resins
- Fluoropolymers
- Nylon® (polyamide)
- Polycarbonate
- Polyethylene (PE)
- Polyethyleneterephthalate (PET) polymers
- Polypropylene
- Polyvinyl alcohol (PVA)
- Polyethylene glycol (PEG)
- Polyurethane
- Polyvinyl chloride (PVC)
- Silica or silicones
- Strainless steel
- Teflon® (PTFE)
- Titanium

* May have limited life after repeated sterilization.

Medical devices must be processed in accordance with the medical device manufacturer's instructions. Check the instructions before placing any device in a STERRAD® Sterilizer.

Implantable items should not be sterilized in a STERRAD® Sterilizer.

Single-use devices (SUD) should not be re-processed in a STERIS AD[®] Sterilizer.

Some examples of devices that can be processed in the STERRAD® Sterilizer are:

- Stereotactic equipment
- Multifactorial paddles
- Radiotherapy treatment units
- Bilateral treatment units
- Video cameras and accessories
- Surgical power equipment
- Digital endoscopes
- Ultrasound probes
- Cryoprobes
- Drapages
- Endoscopic instruments
- Fiberoptic light cables
- Batteries for power equipment
- Trocar sheaths
- Laryngoscope blades
- Laser handpieces, fibres, accessories

If the instrument has a lumbar, please refer to the brochure *What Can I Stretch in the STERRAD 700S Starter?* located in the Product Section at www.sterrad.com, or call ASP Customer Support at (888) STERRAD to request a brochure copy.

Remove all blood, tissue and soil from instruments using a detergent cleaner, following the manufacturer's instructions. Clean the instruments thoroughly to remove any residue. Dry oil free (completely rid of contact with instrument for proper function). Compressed air may be used to blow moisture out of lumens and other hidden zones.



Techniques can be packaged to sterilize with the different systems.

STERAD[®] and APPTAD[®] sterilizers use a two-compound for use in the STERAD[®] Sterflow, as they have been designed to allow optimal diffusion of hydrogen peroxide and plasma around all parts of the load. Cooling systems are standard for both Sterad and APPTAD. All bags have been tested and cleared for use in STERAD[®] sterilizer, and may



Single use devices
should not be re-
processed in a Sterrad
sterilizer

When using these products, writing the contents on STEERAD® SealGum™ Chantrel
indicators helps you avoid waste and contamination of the pouch contents.

Double pointing of a number of small testaments in parallel opening onto the stable fold may be produced. Select points close to the inner pouch rim to place inside the outer pouch without folding. Both pouches should have the chest side facing in the same direction.



Use polypropylene wrap or Mega STEAD® Instrument Tray Holders to secure delicate instruments in the trays. STEAD® and APTIMA® Instrument Trays can be certified in either polypropylene wrap or in STEAD® Real Protection.



Place a chemical indicator strip in each tray prior to wrapping to provide another level of security. The blue compound will indicate possible lead presence, should not be placed in the wrapped item. (It is activated from heat.)

Indicate the weight, such as 500 gms with 500GALP. Seal the tray. The color will change to golden yellow or higher during the distribution trip, indicating that the tray has been opened to indicate possible counterfeit tablets (patent infringement of a pure polystyrene tray for each one).

Use to label the kit and the contents.



And the goal post should be placed on edge loads on secondary tray. Posture should be placed in the tray in that the dog sits in a posture like the upper side of the seat back.



Contents of the bag should be gently packed and placed in all sizes of bags of packaging. Provide at least 1 inch of space between the inside bag and the outside bag and the top of the bag. Place 1 inch of space between the inside bag and the outside bag. A single seal pouch should be placed in the top of the bag. A single seal pouch should be placed on each side of the bag. The pouch should be placed in the top of the bag. The seal of the pouch should be placed on each side of the bag. The seal of the pouch should be placed on each side of the bag.



The following list of practices has been shown to increase the possibility of STERRAD® Sterilizer cycle cancellation or positive Biological Indicator results.

Selection of Items to be processed

- Induction of cellulites such as buck twigs, goose sponges, paper instrument covers or wooden applicator sticks
- All items in the head made of the same materials, either all metal instruments or all synthetic items (such as polyethylene, nylon, silicone, PVC)

Instrument preparation and packaging

- Incomplete drying of lumens in instruments or tubing
- Items wrapped in barrier materials containing paper
- Foam pads in instrument trays

Loading the sterilizer

- Stacking of instrument trays
- Placing instrument trays in a edge in order to fit more items in the sterilizer
- Inserting the sterilizer shelf upside down
- Putting a large number of items in the sterilizer so that metal instruments contact the radio-frequency electrode
- Load configured so that metal instruments are in contact with the walls or door of the sterilizer

Important

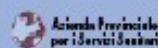
Please review the STERRAN® 100S Sterilization System Operator's Guide for complete instructions on the proper use of the sterilizer.





**Il riutilizzo dei dispositivi
medici monouso per cardiologia
interventistica**

Re-use of single-use medical
devices for interventional cardiology



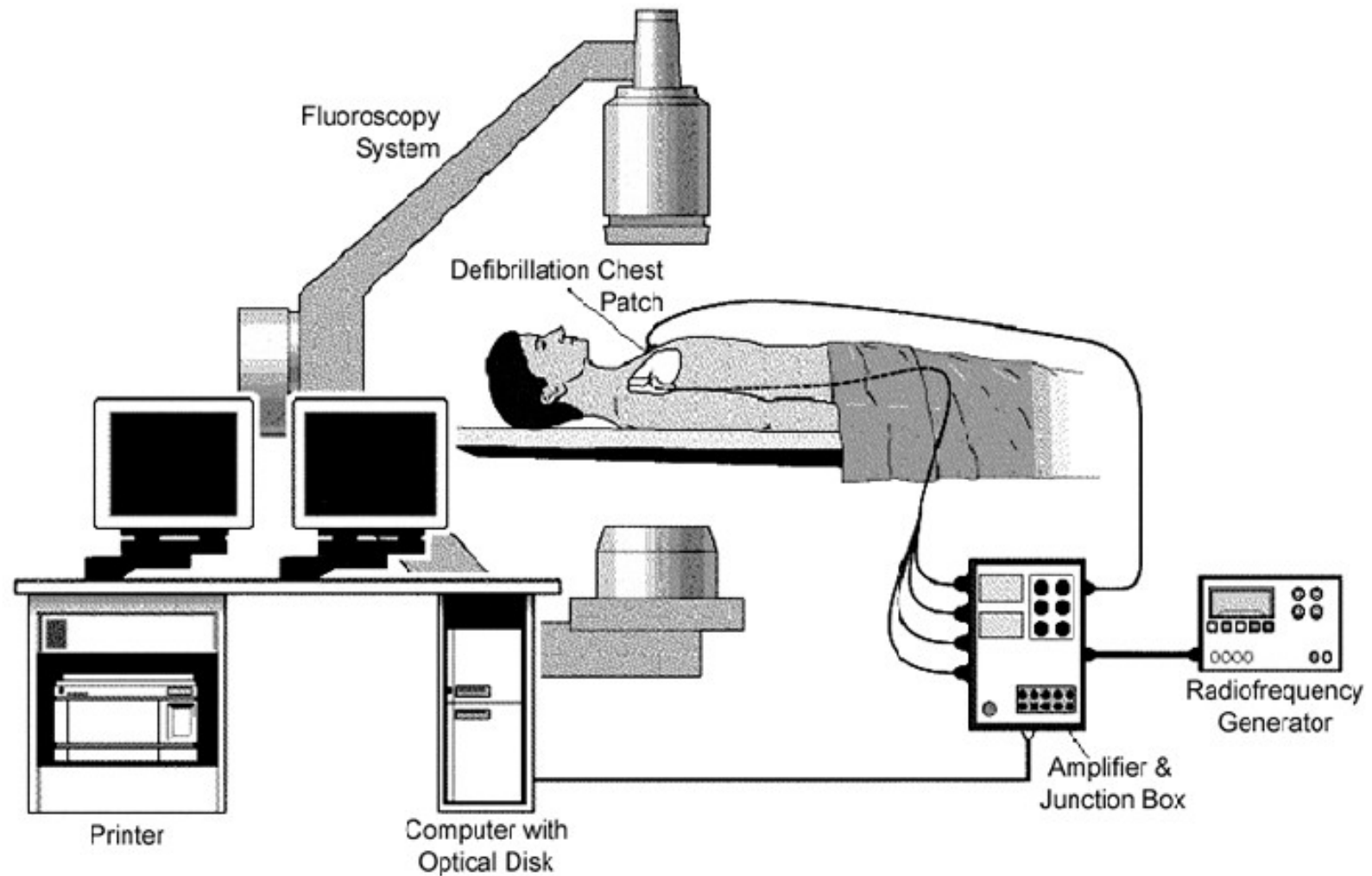


Figure 1. Schematic diagram summarizing components of the electrophysiology (EP) laboratory.

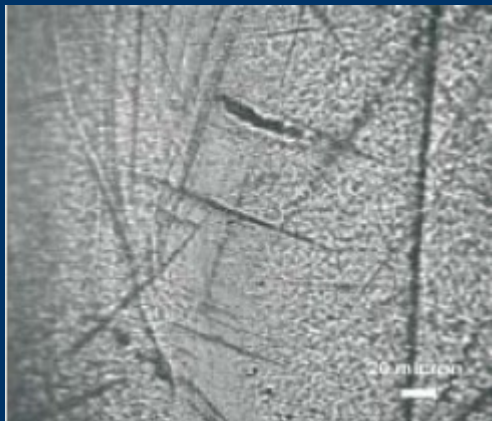
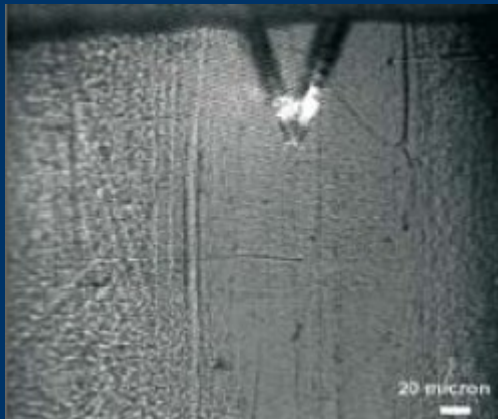


Figure 1
Worsening of the polymeric shaft in electrophysiology and ablation catheters after reprocessing. Scratches and indentations number per area unit could be related to both clinical use and mechanical-manual brushing in cleaning procedures. From left to right: new device, 1, 4, 8 cycles regenerated devices.

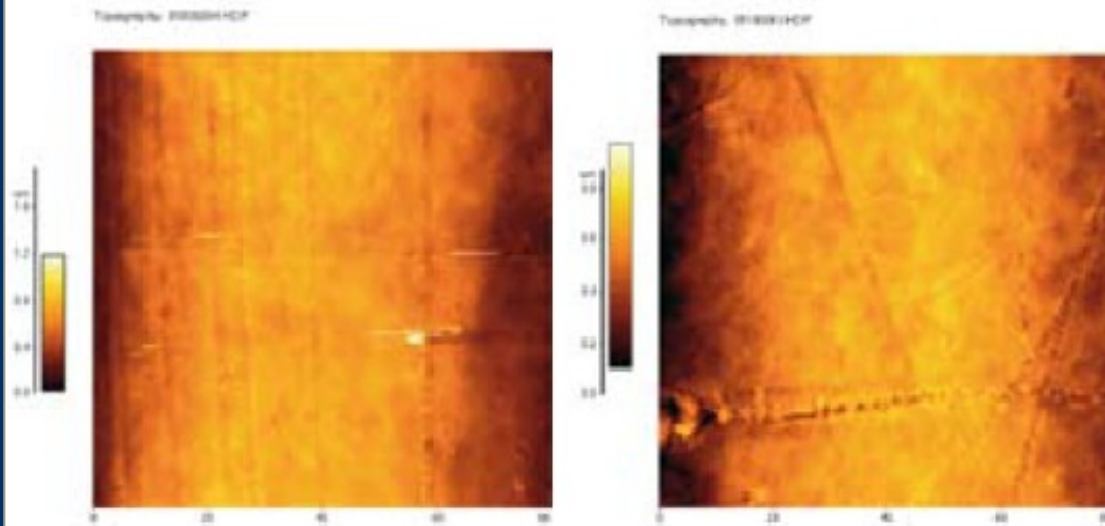
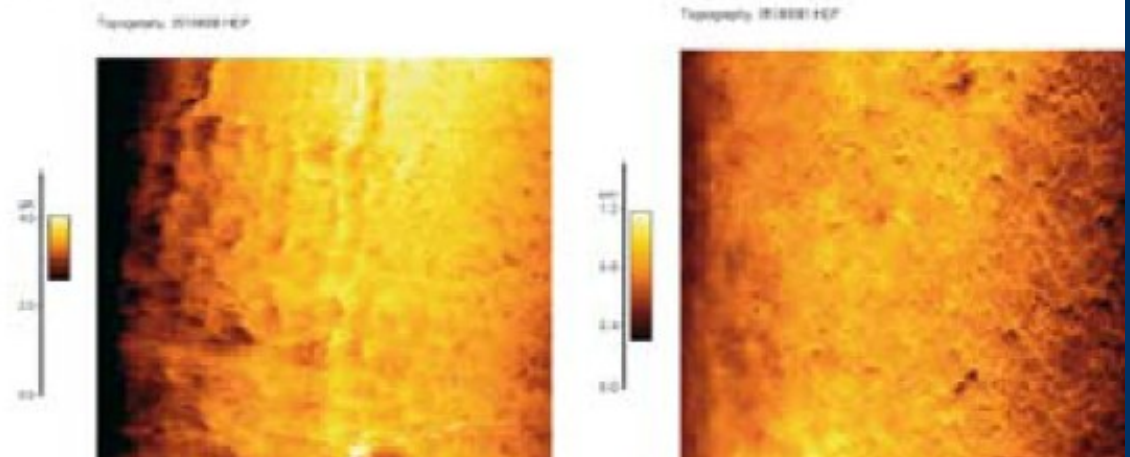


Figure 2

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. From left to right: new device, 1, 4, 8 cycles regenerated devices. (F. Tessarolo et al. Appl. Surf. Sci. 2004;238:341-6.)

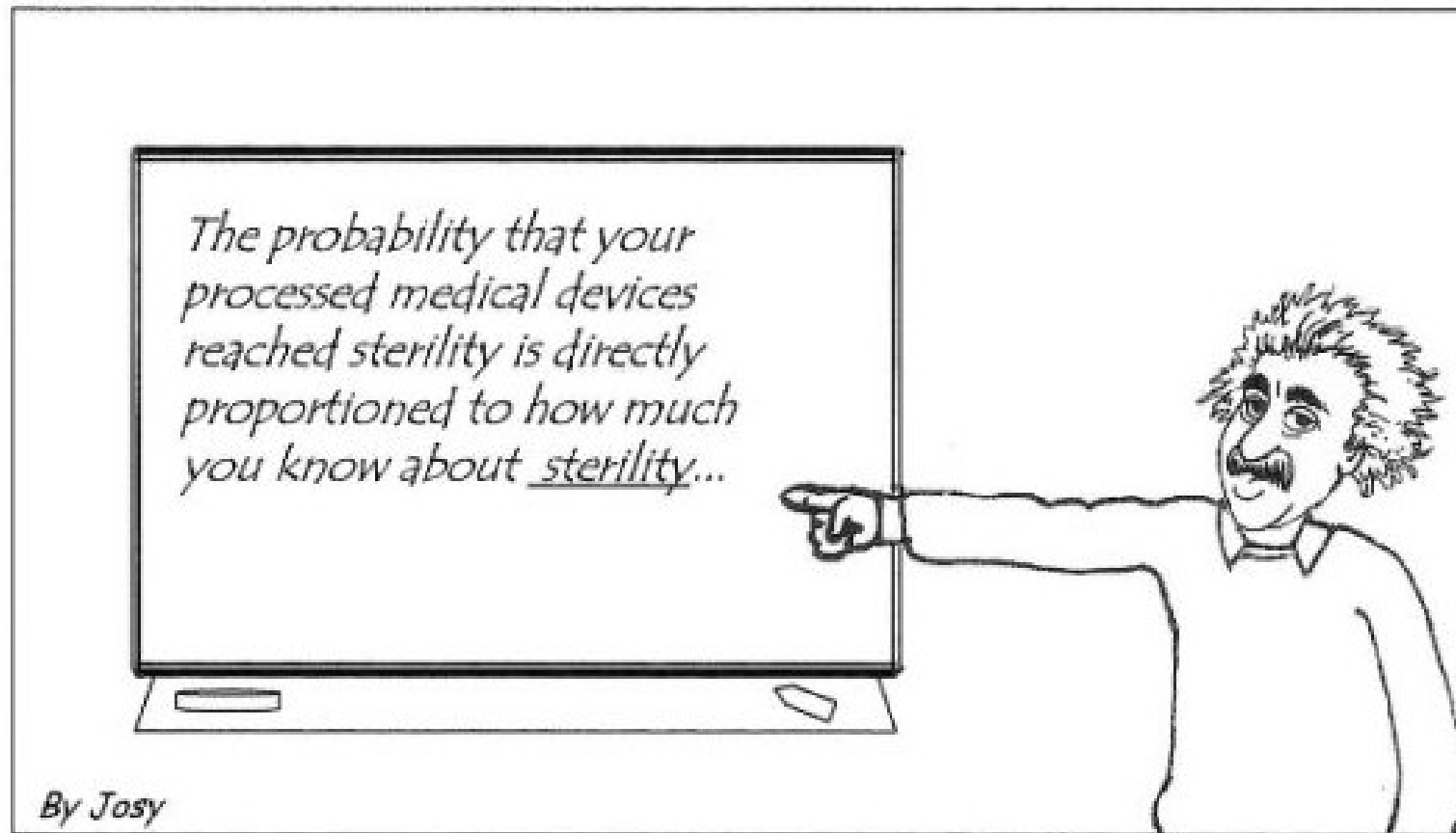










Cartoon 60 - Einstein's Theory of Relatives...

Einstein's Theory of Relatives...

Can we reconcile the health and safety
of the patient with re-use?



31993L0042

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Official Journal L 169 , 12/07/1993 P. 0001 - 0043

Finnish special edition: Chapter 13 Volume 24 P. 0085

Swedish special edition: Chapter 13 Volume 24 P. 0085

ES	CS	DA	DE	ET	EL	EN	FR	IT	LV	LT	HU	MT	NL	PL	PT	SK	SL
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[MORE INFO](#)

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

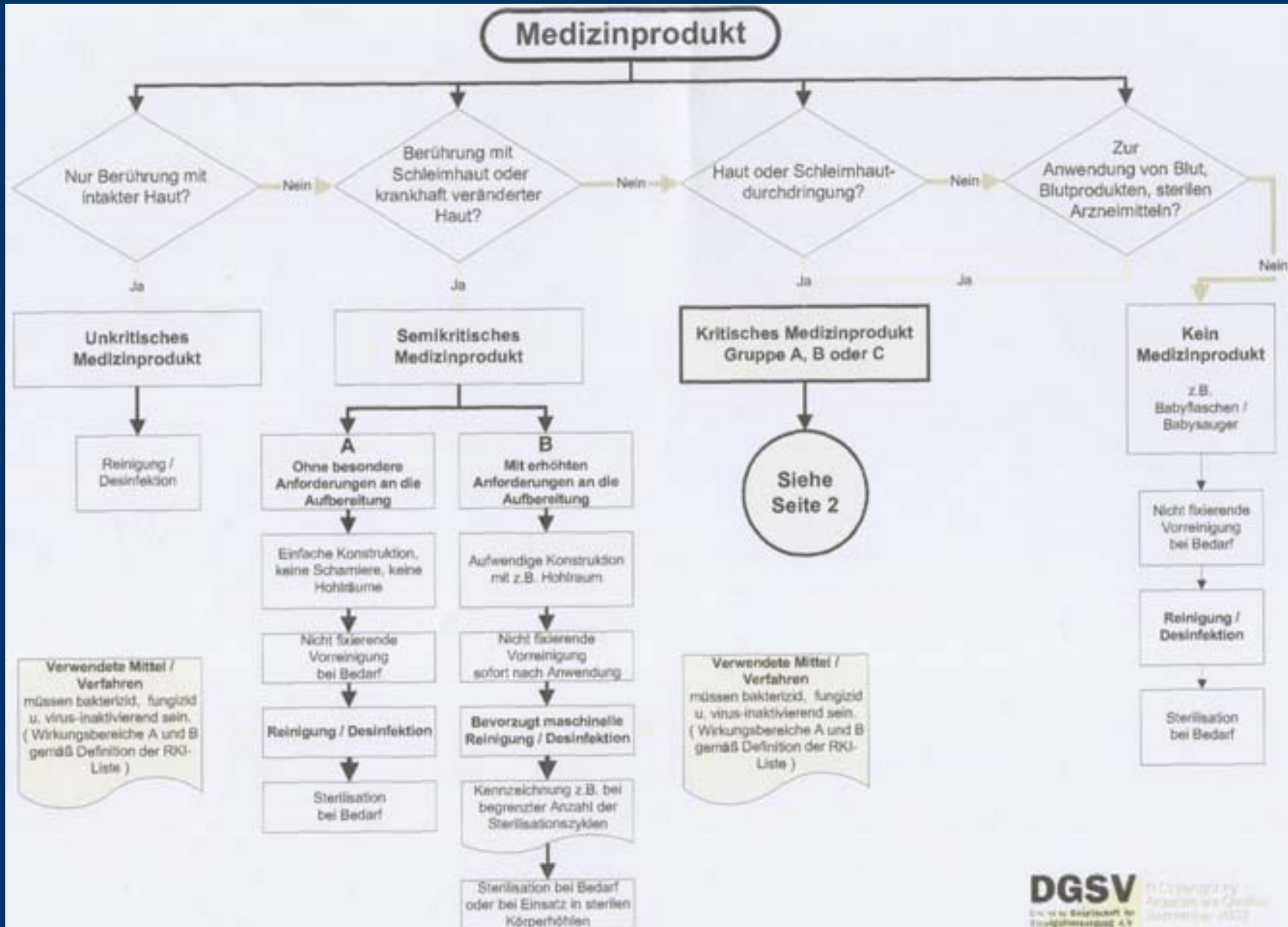
Placing on the market and putting into service

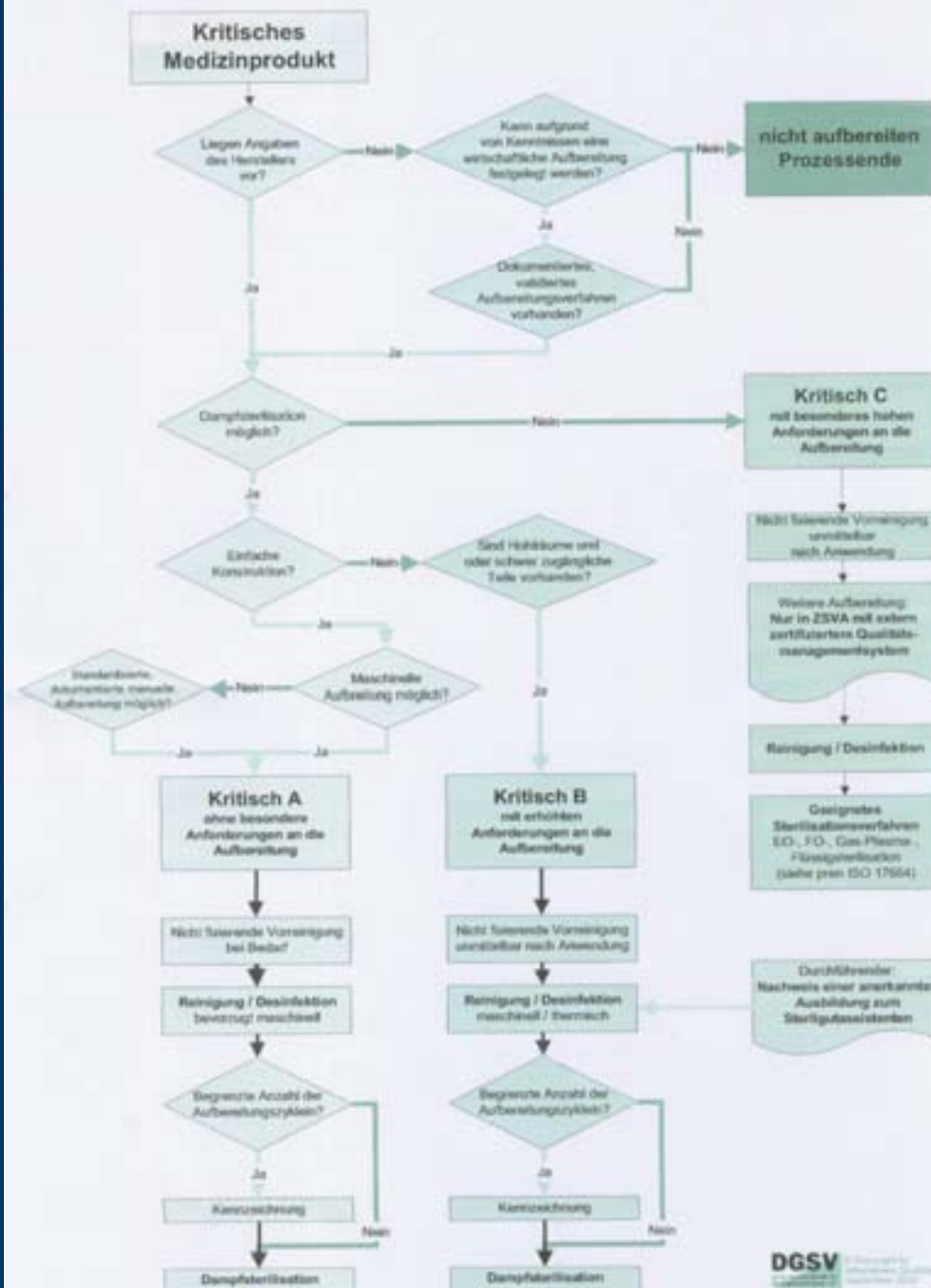
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USS+DG[®]
APPOSE[®]

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single use skin stapler remover
extracteur de retrait des agrafes cutanées à usage unique
Einweg-Hautklammerentformer
Extrahör Cutaneo Klammern
Extractor de grampes para piel de un solo uso
Extrator de grampes da pele descartável para uso único
Eénmalig gebruikte huidnagels verwijderaar
Eénmalig gebruikte huidnagels verwijderaar
アポーズ ステープルリムーバー

医療器具許可番号: 130Y1145

使用説明書: 欄外参照

輸入元: オートスーチャージャパン株式会社
東京都世田谷区用賀4-1-0-2



BEFORE TO USE SEE INSTRUCTIONS.

使用前に取扱説明書を熟読して下さい。



SINGLE PATIENT USE.
再使用不可。



Seal integrity guaranteed unless package opened or damaged. Do Not Reenter Seal.

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
U.S. patents: 4,391,402; 4,400,392; 4,458,835; 4,581,080; Des. 269,459.
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Brussels, 29th March 2007

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 products, 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:

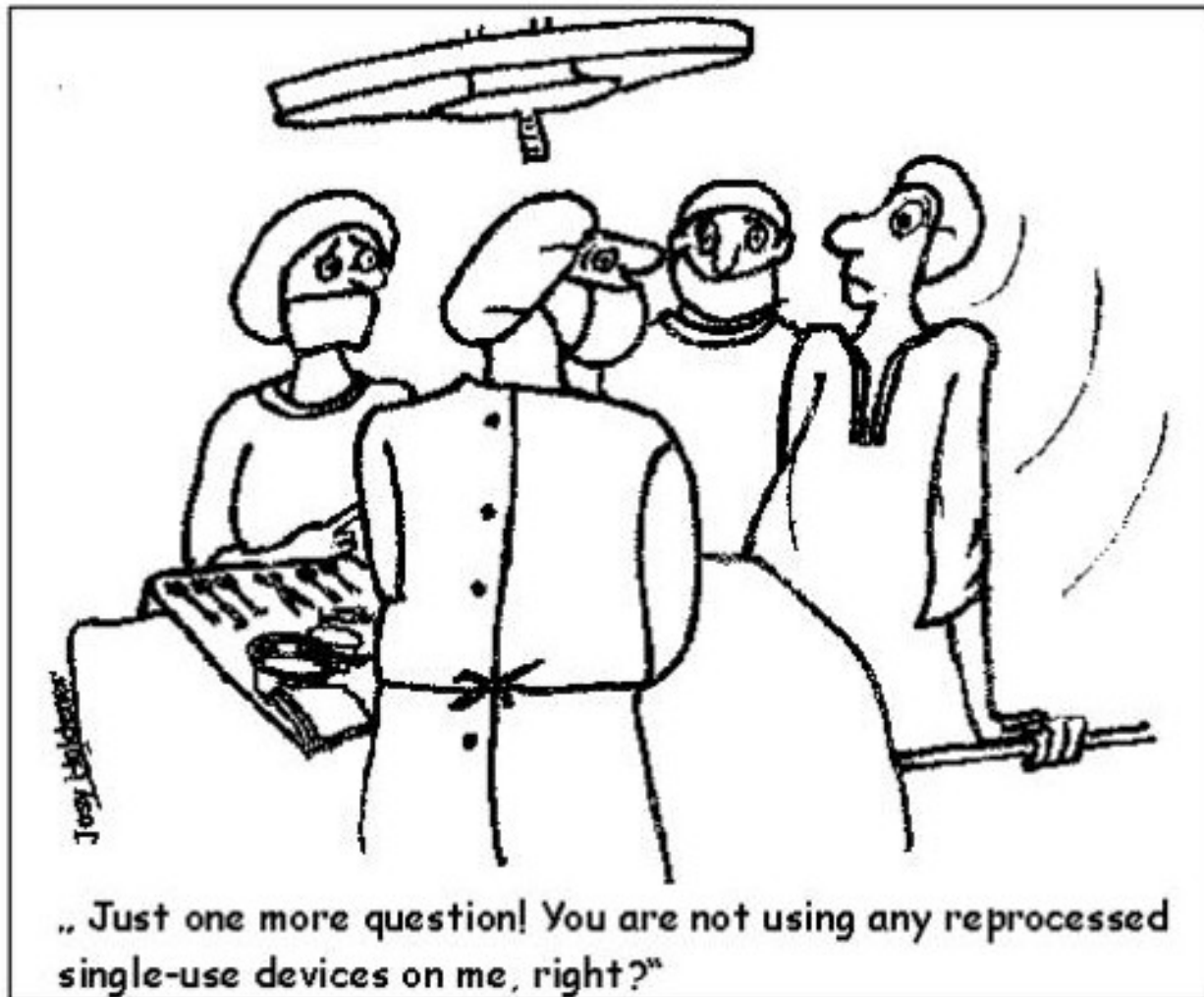
To bring clarification to the area of reprocessing of medical devices, the definition of the term 'single use' and subsequent labelling will be uniform within the EU.

- 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**.

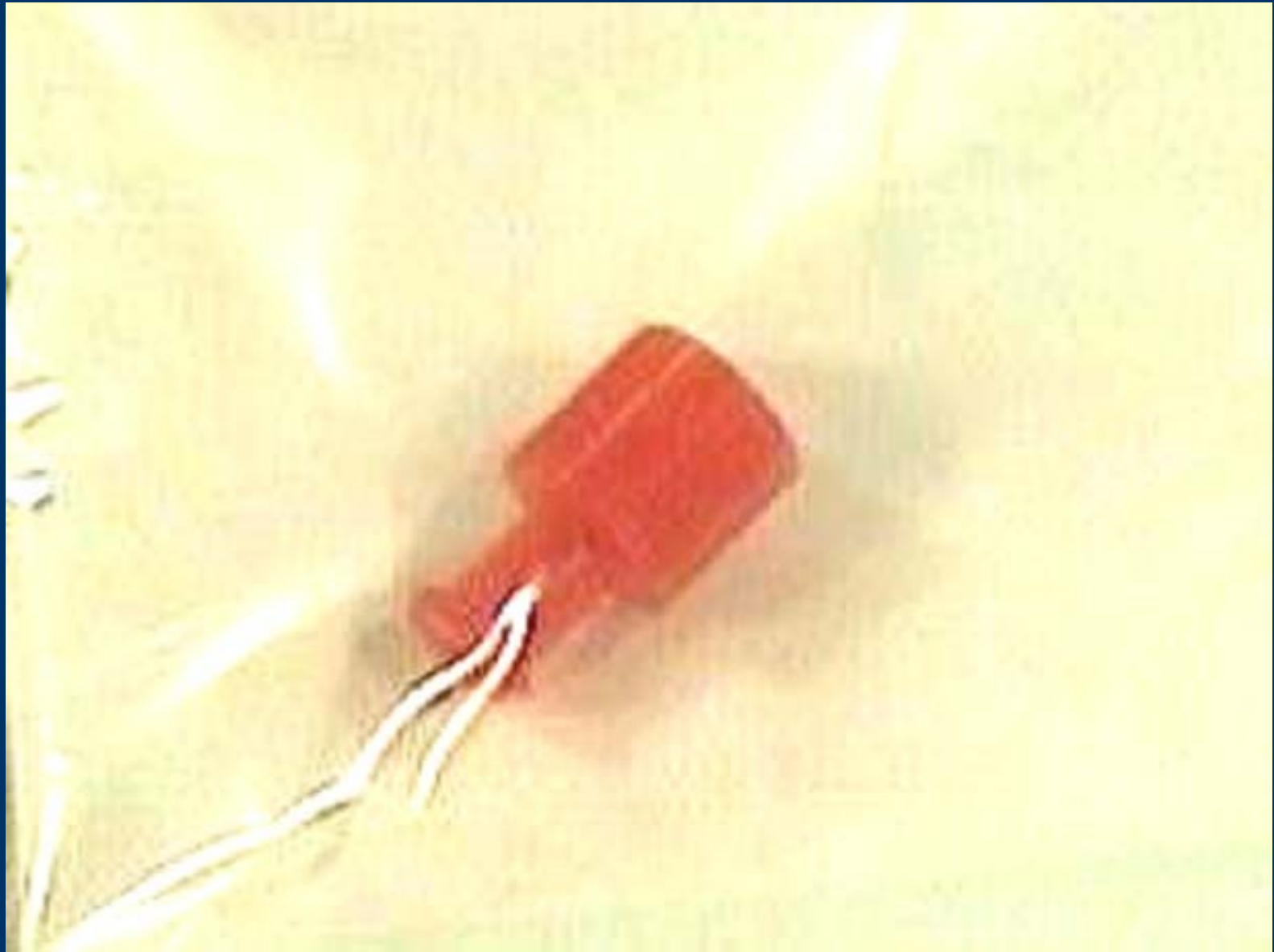
Additional information, including the Commission proposal, can be found at:

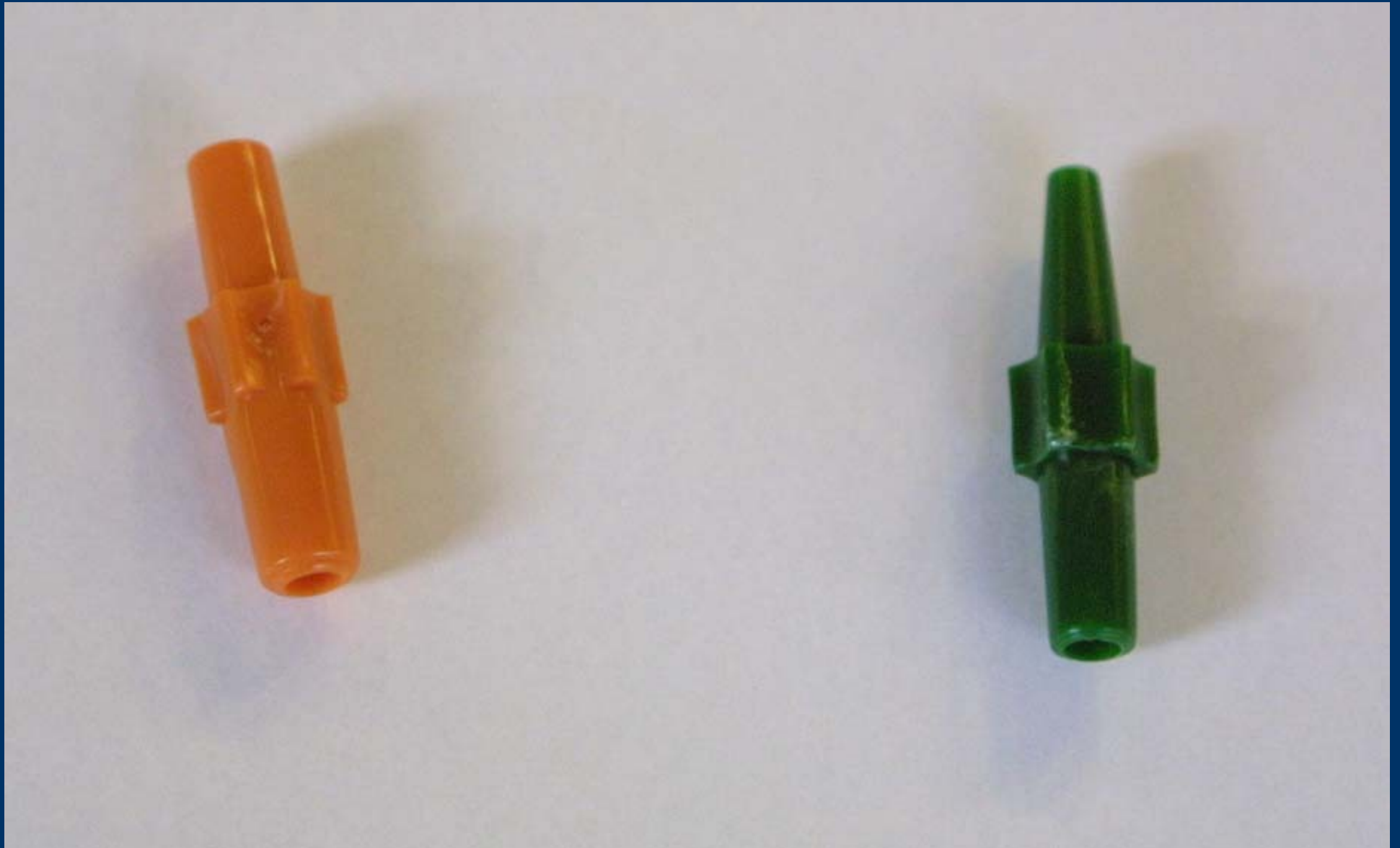
http://ec.europa.eu/enterprise/medical_devices/revision_mdd_en.htm

Cartoon 41 - The Emancipated Patient



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?

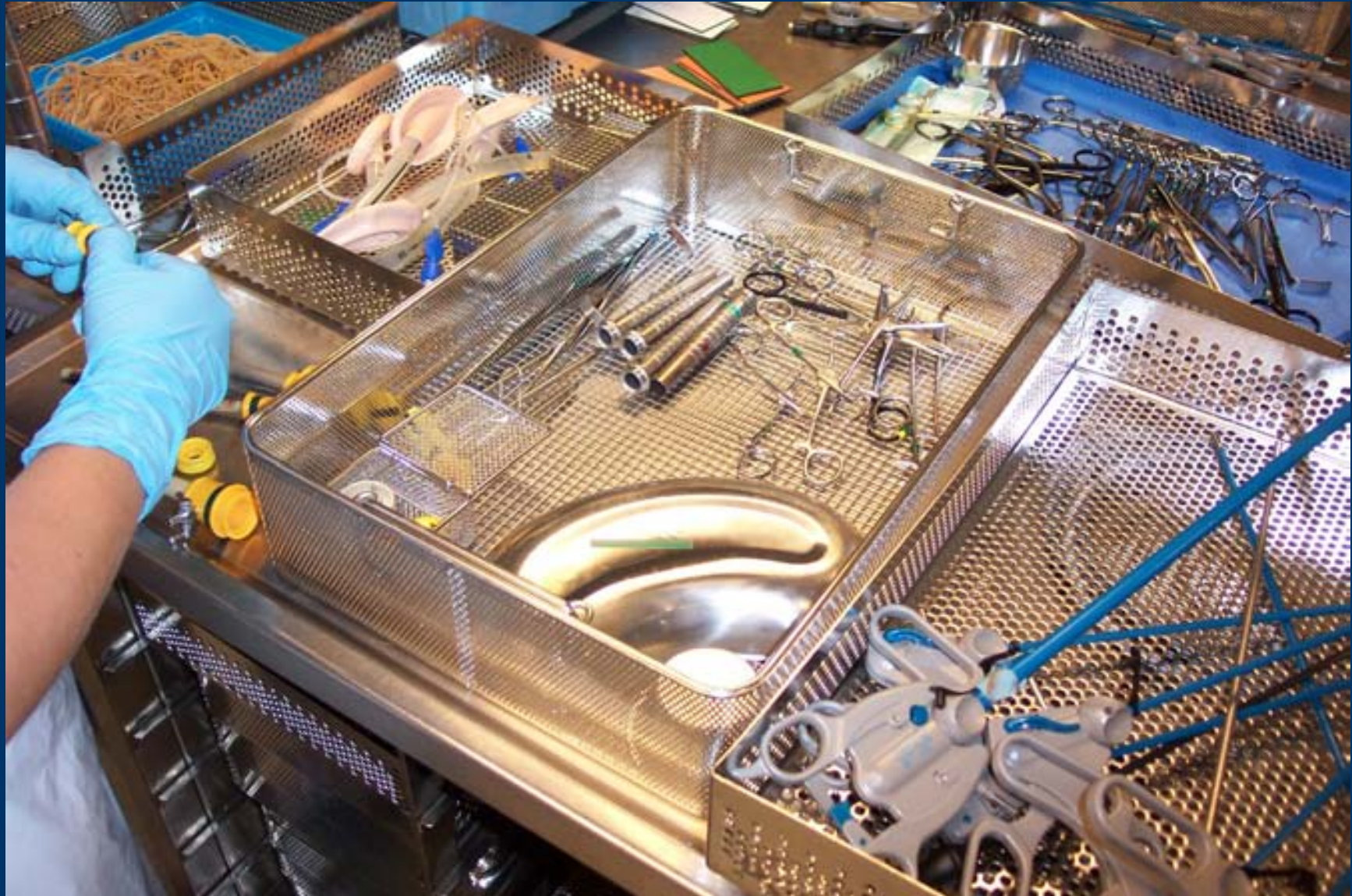
























« The CSSD has the duty to protect the interests of the patient. »

Thank you