

Re-use of single use medical devices

Wim Renders







- Members
- Communications
- Conferences & Congresses 
- Courses & Seminars 
- Questions & Answers 
- Discussion
- CEN
- Publications
- Education
- EFHSS WebShop
- Industrial Partners
- Commercial Announcements
- Related Sites & Links 
- Vacancies
- Humour
- Guestbook



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EFHSS Events

Annual EFHSS and NfS Conference 2006

May 18th to May 20th, 2006 in Lillehammer, Norway

 Conference programme update

 Deadline for the registration of posters for the Poster Prize extended to April 10th, 2006

EFHSS News

new question 1137: Quality indicators in CSSD

07 March 2006, 06:30 [GMT]

EFHSS Related Sites & Links

new link added: DAS - Dezenfeksiyon Antisepti Sterilizasyon Dernegi (Turkey)

06 March 2006, 14:56 [GMT]

EFHSS Questions and Answers

answer to question 1135: Indicators Class 5 vs Class 6

06 March 2006, 13:26 [GMT]

EFHSS Questions and Answers

answer to question 1132: Sterile/dirty instrument/set transportation

06 March 2006, 11:22 [GMT]

EFHSS Questions and Answers

new question 1134: Regulations in CSSD

06 March 2006, 01:43 [GMT]

EFHSS Questions and Answers

EFHSS Questions and Answers - Questions

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Category Sort By Sort Order
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Questions 1 to 50 of 1142 Questions sorted by Last Posting (descending)

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[4](#)
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[10](#)
[11](#)
[12](#)
[13](#)
[14](#)
[15](#)
[16](#)
[17](#)
[18](#)
[19](#)
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[21](#)
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	Question	Topic/Subject	Author	Replies	Category	Last Posting
NEW	Q01142	Bowei & Dick test	dr.ghaneema Kuwait	0	Steam Sterilization	11/03/2006 09:07
NEW	Q01141	Sterilization of Bone Graft	Intisar Quritum Kuwait	0	Spacial Requirements	10/03/2006 17:09
NEW	Q00205	Fumigation with formaline in cleanrooms	Gabriela Bodea	5	Low Temperature Sterilization	10/03/2006 05:42
NEW	Q00896	Use of lubricating milk	Sudip Kumar Saha United Arab Emirates	3	Spacial Requirements	10/03/2006 02:57
NEW	Q01140	Manufacturers of plasma sterilization systems	Tatiana Belarus	1	Low Temperature Sterilization	09/03/2006 18:30
NEW	Q01139	Low steam formaldehyde tape	Oline Webb India	0	Low Temperature Sterilization	08/03/2006 14:06
NEW	Q01120	Sterrad	Barbara United States	1	Low Temperature Sterilization	08/03/2006 14:04
NEW	Q01136	T-DOC Superuser	Mohd Tazri Singapore	1	Miscellaneous	08/03/2006 10:44
NEW	Q01138	CSSD Conference in general	Doreen Chong Singapore	1	Miscellaneous	08/03/2006 10:32
NEW	Q01137	Quality indicators in CSSD	Mohammed Matar	0	Miscellaneous	07/03/2006 11:16
NEW	Q01135	Indicators Class 5 vs Class 6	Anu Tammemae Estonia	1	Steam Sterilization	06/03/2006 14:56
NEW	Q01132	Sterile/dirty instrument/set transportation	Mohd Tazri Singapore	1	Transportation	06/03/2006 13:26

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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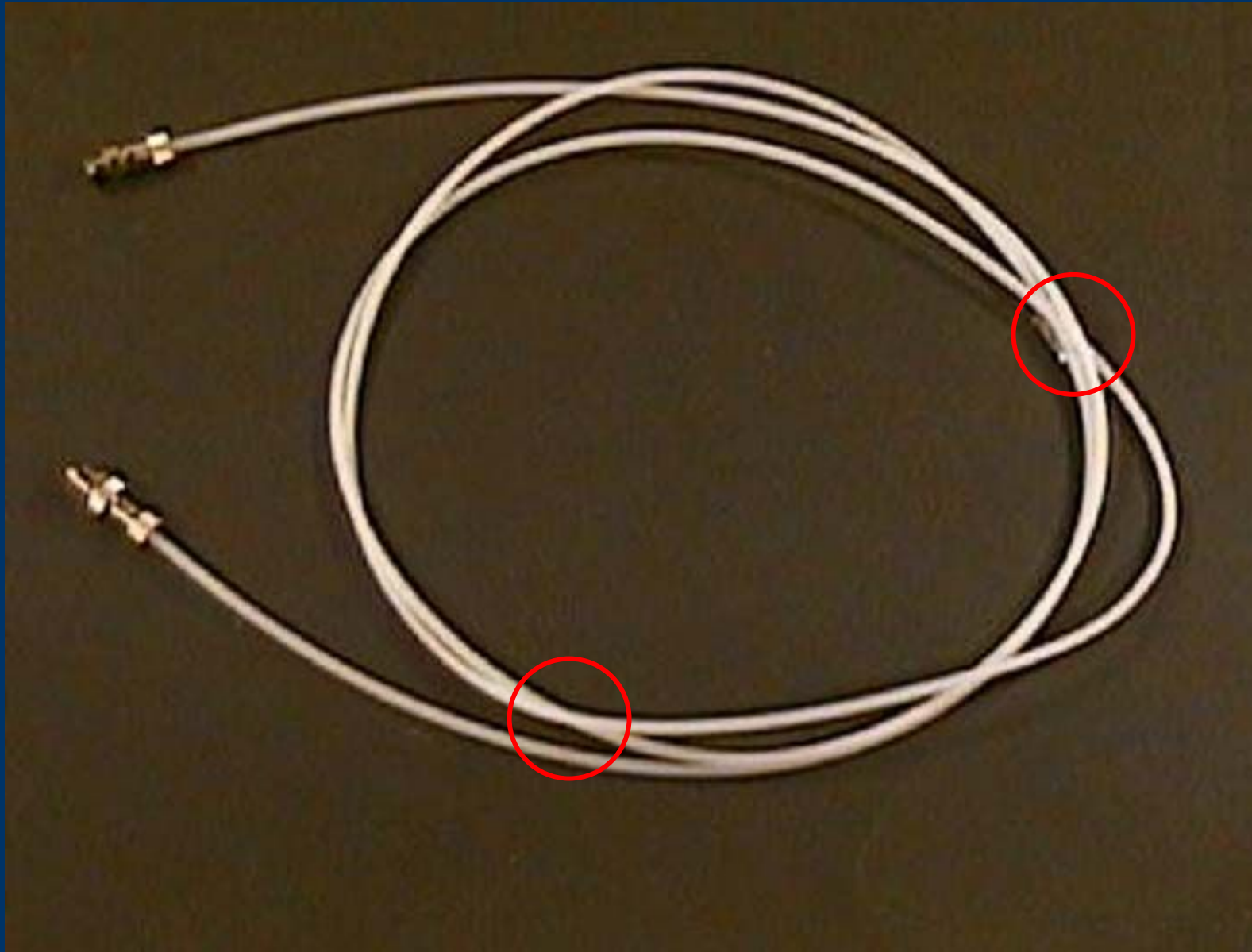


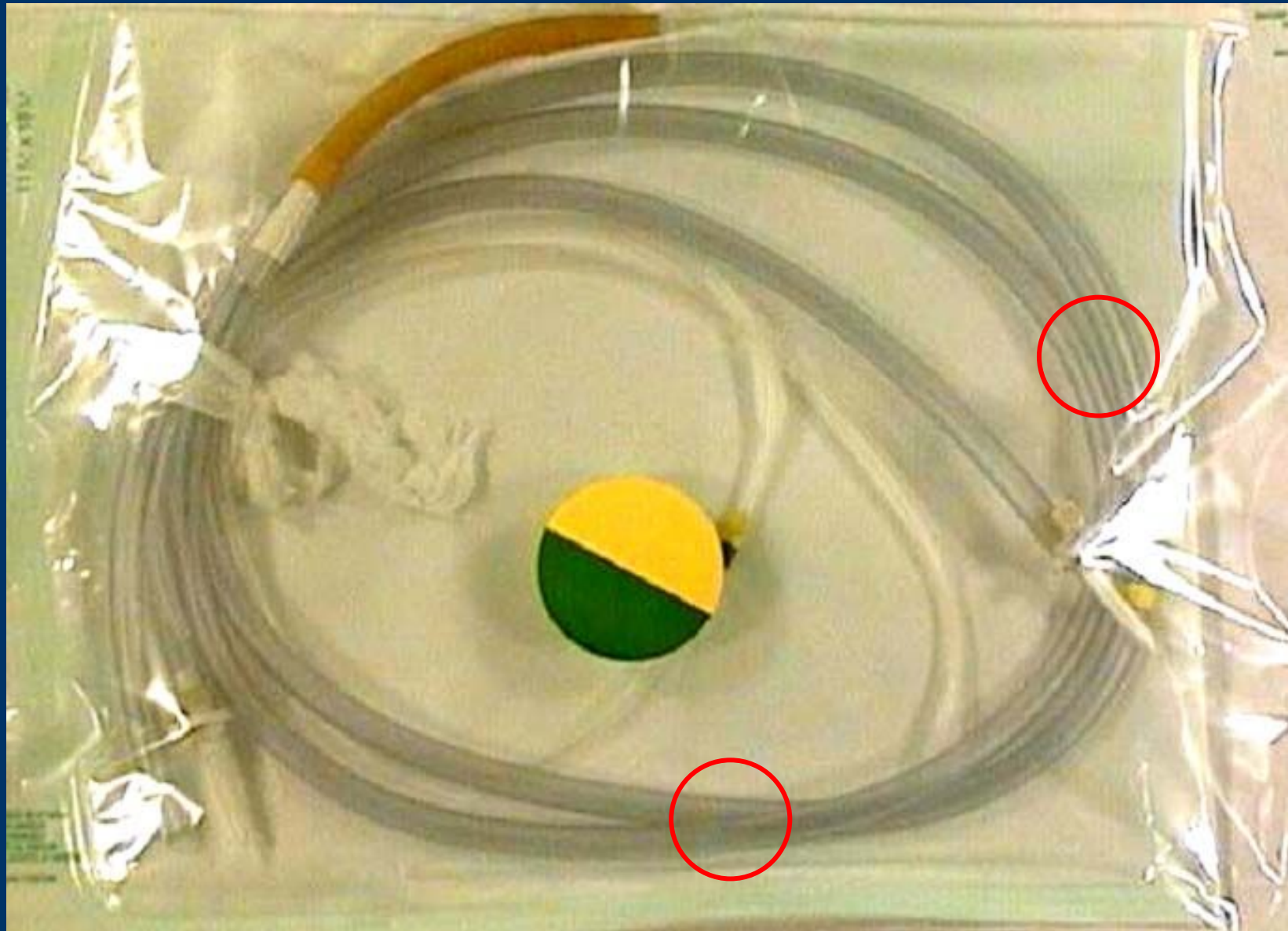




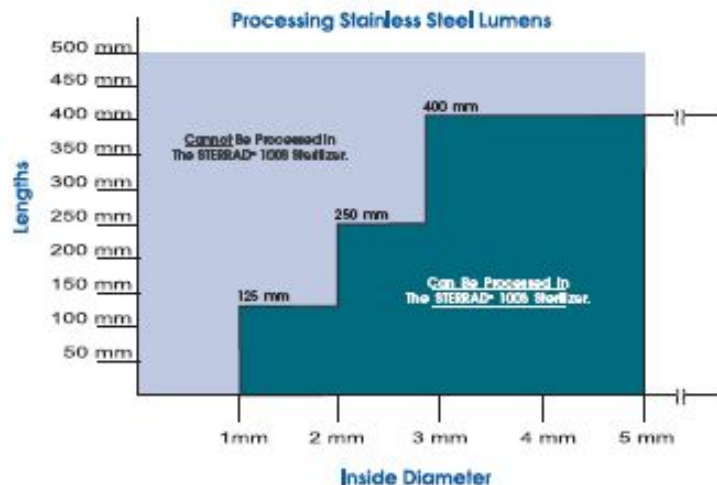












Typical Devices Sterilized in the STERRAD® 100S Sterilizer

- Stereotactic equipment
- Defibrillator paddles
- Electrocautery instruments
- Esophageal dilators
- Crank/pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- Rigid endoscopes
- Laryngoscope blades
- Trocar sheaths
- Cryoprobes
- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser hand-pieces, fiber, and accessories
- Ophthalmic lenses (diagnostic, magnifying)
- Pigmentation hand-pieces
- Copplers
- Shaver hand-pieces
- Radiation therapy equipment
- Ultrasound probes
- Video cameras and couplers
- Resectoscope/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.sterrad.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

© ASR 2002
AD-83679-02 Rev. 2
U.S. Version



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

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 | - KRATON™ Polymers | - Polyetherimide (ULTEM® Polymers) | - Polyurethane |
| - Brass | - Neoprene | - Polymethyl methacrylate (PMMA) | - Polyvinyl chloride (PVC) |
| - Delrin® acetal resin (polyacetal)* | - Nylon® (polyamide)* | - Polyphenylene sulfone (Radel®) | - Silicone elastomers |
| - Ethylvinyl acetate (EVA) | - Polycarbonate | - Polypropylene | - Stainless steel |
| - Glass | - Polyethylene | - Polystyrene | - 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 load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

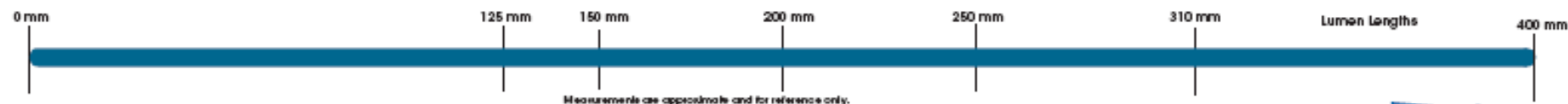


If the lumens do not conform to these dimensions, please call the medical device manufacturer for information on how to properly sterilize this device.

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





ReDis

Gesellschaft für Wiederaufbereitung
in der Medizin mbH

Gecertificeerd door:

MED/CERT

ISO 9001 / ISO 13485

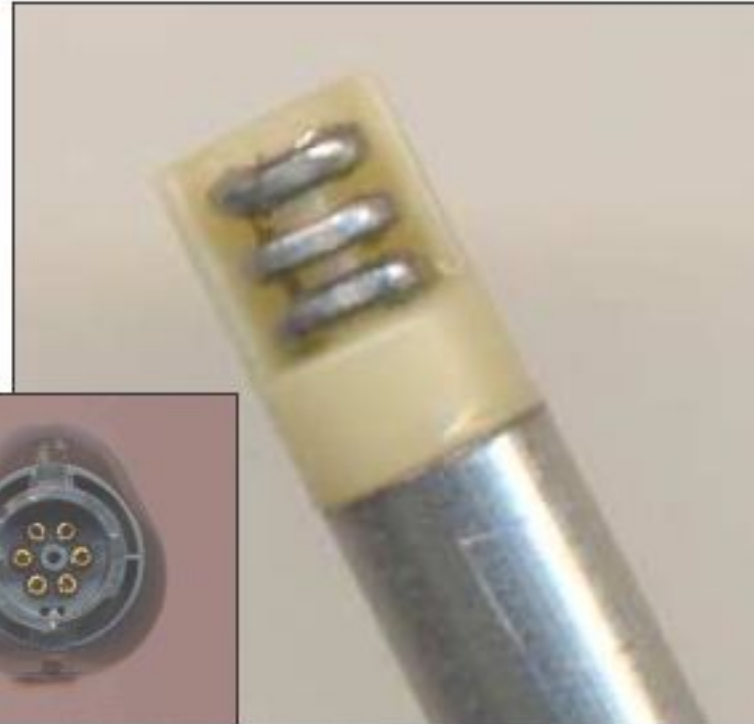
www.redis.de

Beoordeling van het reinigingsproces

ReDis



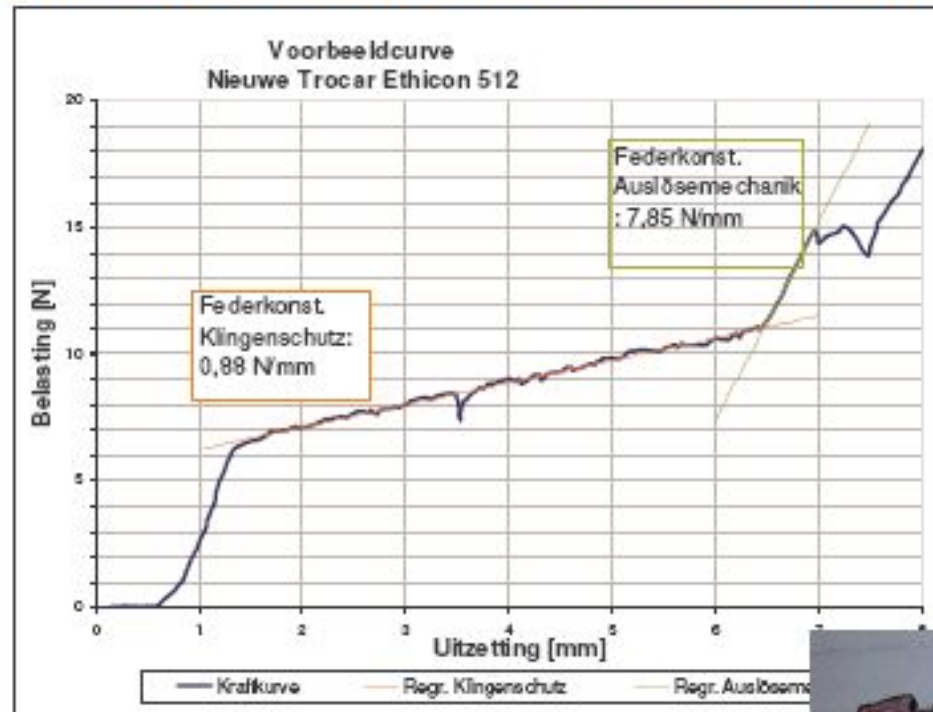
- Caviteiten
- Lumina
- Moeilijk bereikbare materiaal-overgangen
- Oppervlakte-structuur



Techniek

Electrische / Mechanische Functionaliteit

ReDis



Krachtcurve van een trocar



Techniek

Controle van de parameters

ReDis

- Veerkracht
- Elektrische functionaliteit
- Isolatie



Krachtmeting van een trocar

Grondstoffen Materiaal-analyse

ReDis

Demonteren van producten
(op onderdeel niveau)



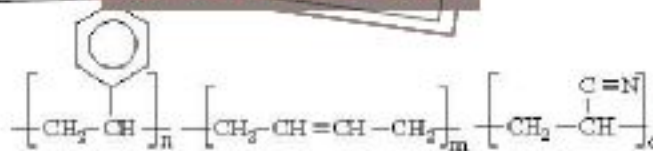
PTFE ist ein fluorhaltiges
Molekülstruktur.



Onderzoeken van
fysische eigenschappen

2,15 g/cm³
320 °C
260°C
-200°C
Wasseraufnahme bei Normalklima ISO 62 0,01 %

Wasseraufnahme bei Normalklima ISO 62



Dichte ISO 1183	1,05 g/cm ³
max. Temperatur kurzzeitig	100 °C
max. Temperatur dauernd	80 °C
min Anwendungstemperatur	-30 °C
Wasseraufnahme bei Normalklima ISO 62	0,45 %
Wasseraufnahme bei Wasserlagerung ISO 62	1,6 %

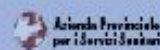
Bepaling van de
chemische eigenschappen





Il riutilizzo dei dispositivi medici monouso per cardiologia interventistica

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



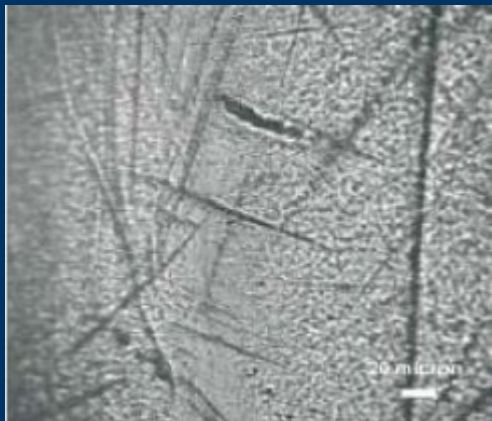


Figure 1
Worsening of the polymeric shaft in electrophysiology and ablation catheters after reprocessing. Scratches and indentations number per area unit could be related to both clinical use and mechanical-manual brushing in cleaning procedures. From left to right: new device, 1, 4, 8 cycles regenerated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

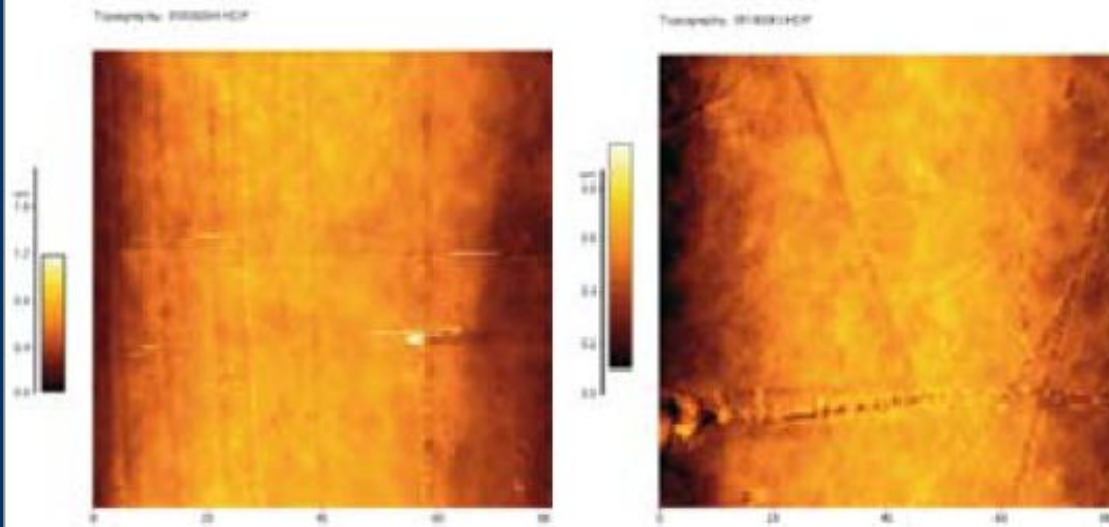
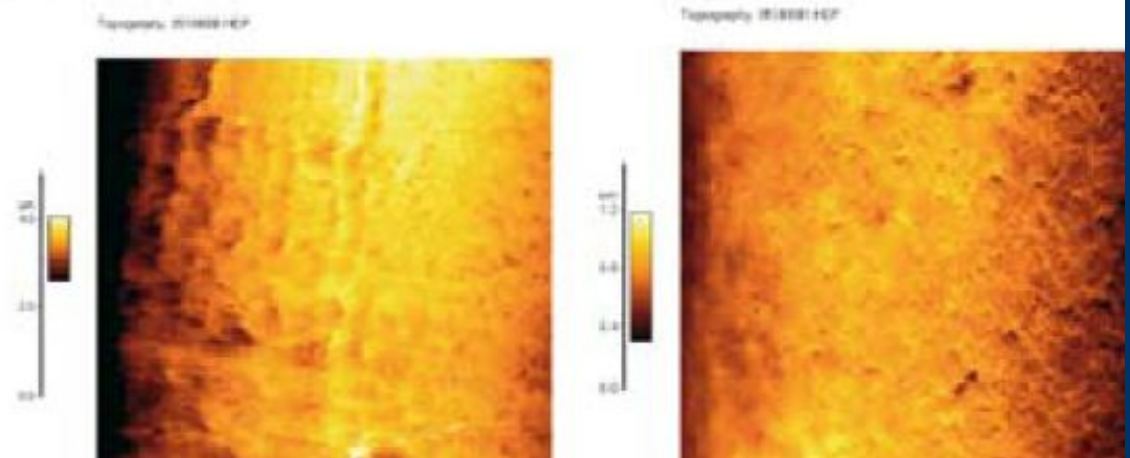


Figure 2

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.)



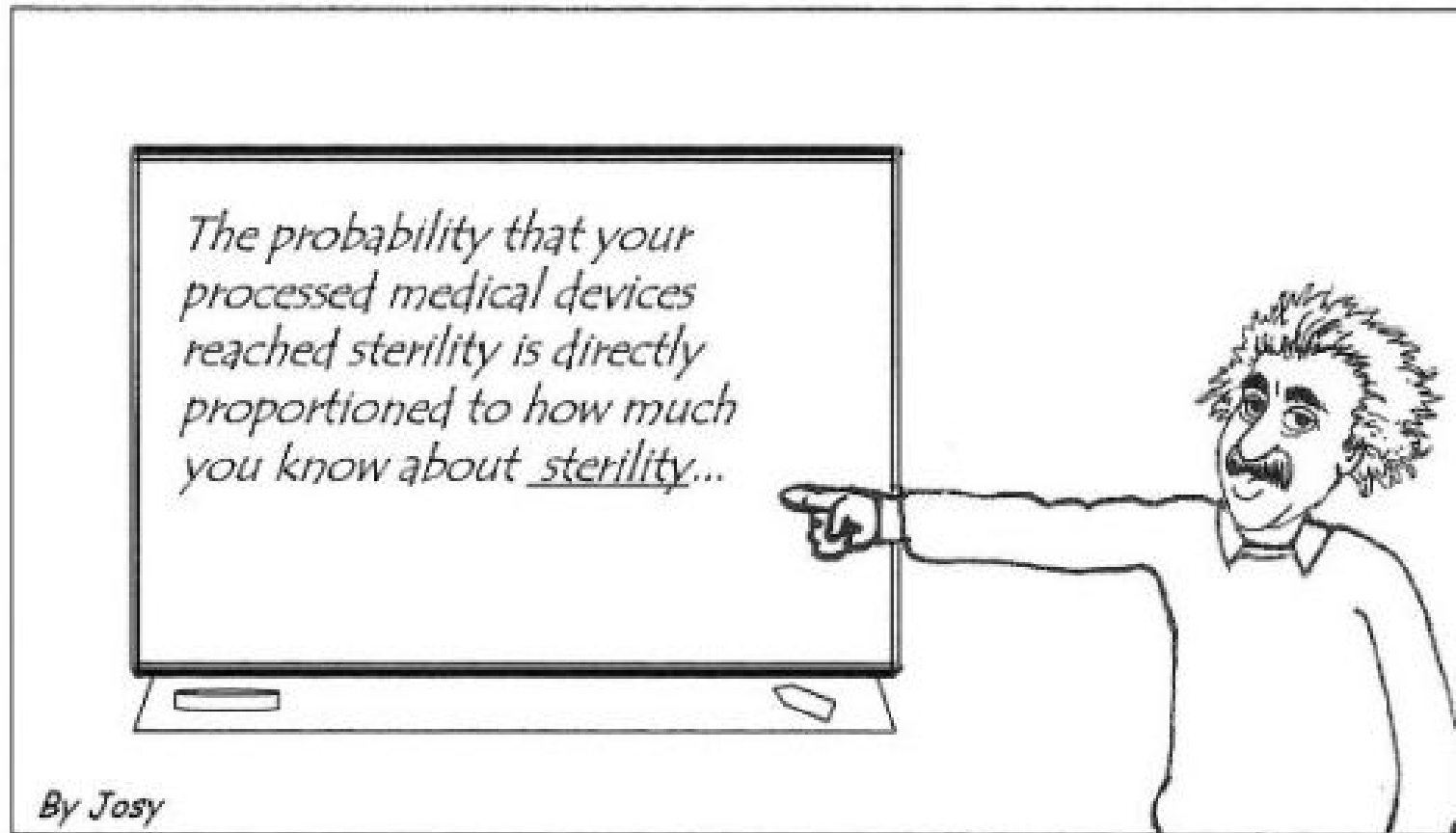








Cartoon 60 - Einstein's Theory of Relatives...



Einstein's Theory of Relatives...



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
html	html	html	html	html	html	html	html	html	html	html	html	html	html	html	html	html	html

[▶ 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 12

Particular procedure for systems and procedure packs



ANNEX IV

EC VERIFICATION 1. EC verification is the procedure whereby the manufacturer or his authorized representative established in the Community ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.

ANNEX V

EC DECLARATION OF CONFORMITY (Production quality assurance) 1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the Community surveillance referred to in Section 4.

ANNEX VI

EC DECLARATION OF CONFORMITY (Product quality assurance) 1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3 and must be subject to the surveillance referred to in Section 4.



1



USS†DG†
APPOSE*

8886803912

single use skin staple remover
instrument de retrait des agrafes cutanées à usage unique
Entweg-Hautklammerentferner
Estrattore Cutaneo Monouso
Extractor de grapas para piel de un solo uso
Extractor de grampos da pele descartável para uso único
Eegssable huidnietjes verwijdertangetje
Eragdags hud stapler borttagare
アポーズ ステープルリムーバー

医療用器具許可番号: 13BY1145

使用期限: 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

PRIOR 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。

Sterility guaranteed unless package opened or damaged. Do Not Resterilize.

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; 4,406,392; 4,458,835; 4,591,086; Des. 269,459.

© 2000 United States Surgical. All Rights Reserved. Made in Mexico.

Vertrieb Durch: B. Braun-Dexon GmbH 34283 Spangenberg.

Distribuido por: B. Braun-Dexon SA. C. Fructuós Gelabert,

6 08970 Barcelona, España.

United States Surgical, a division of Tyco Healthcare

Group LP, Norwalk, CT 06856.

Tyco Healthcare UK Ltd., Gosport, PO13 0AS, UK.

*Trademark.

10000-04062

502113



0123



HDPE



(01) 20388868039122

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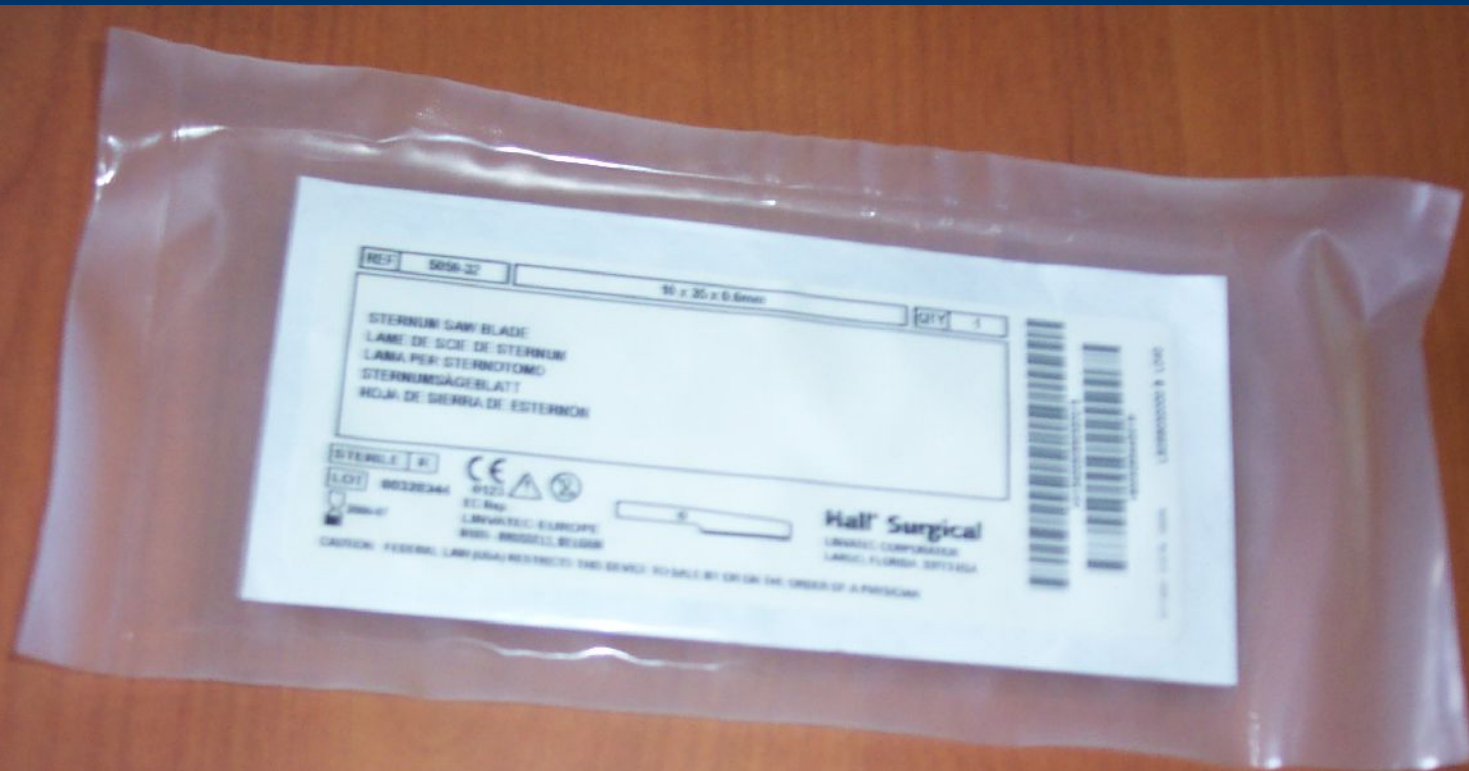
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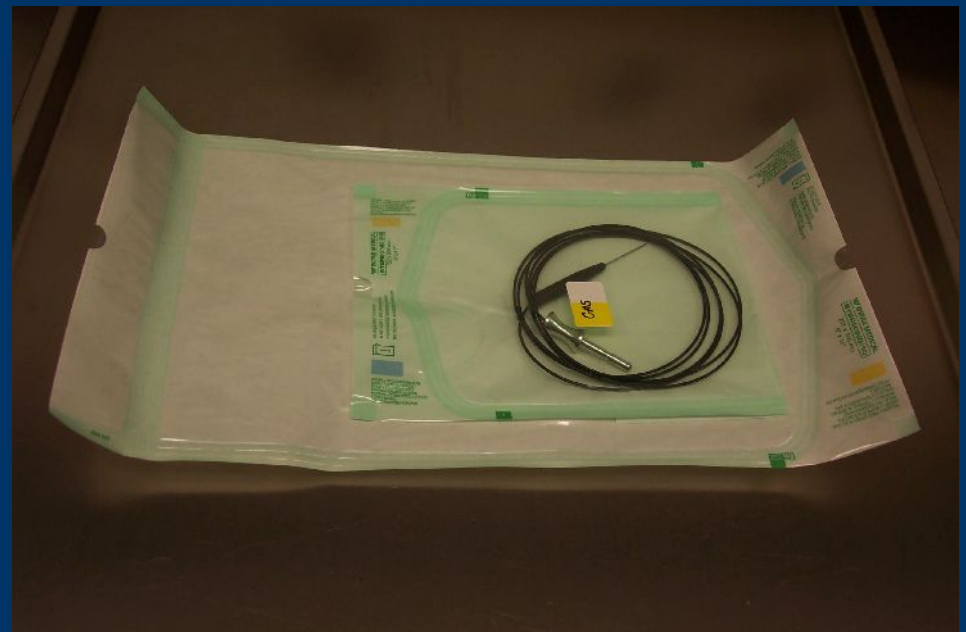
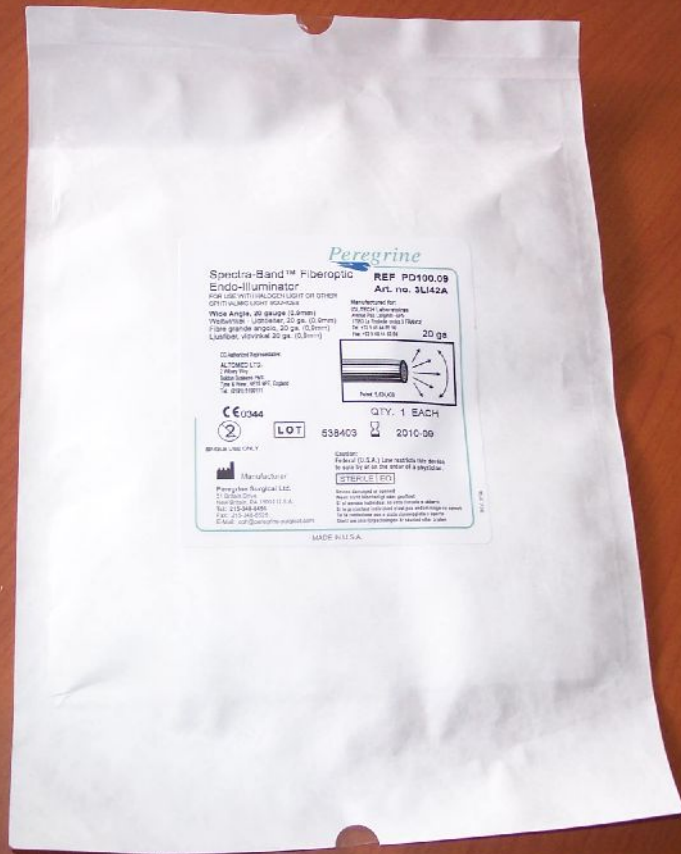
2008-02







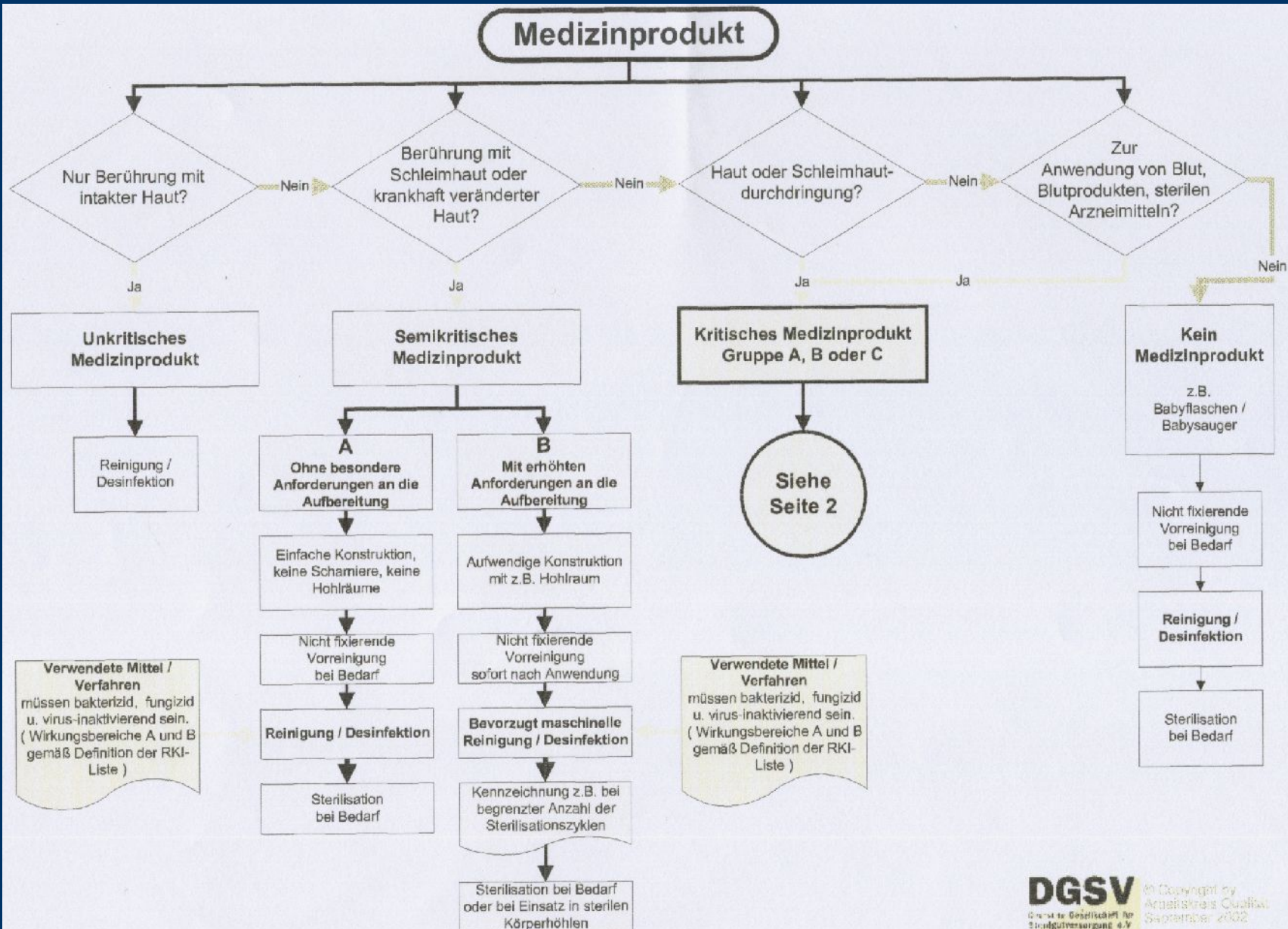


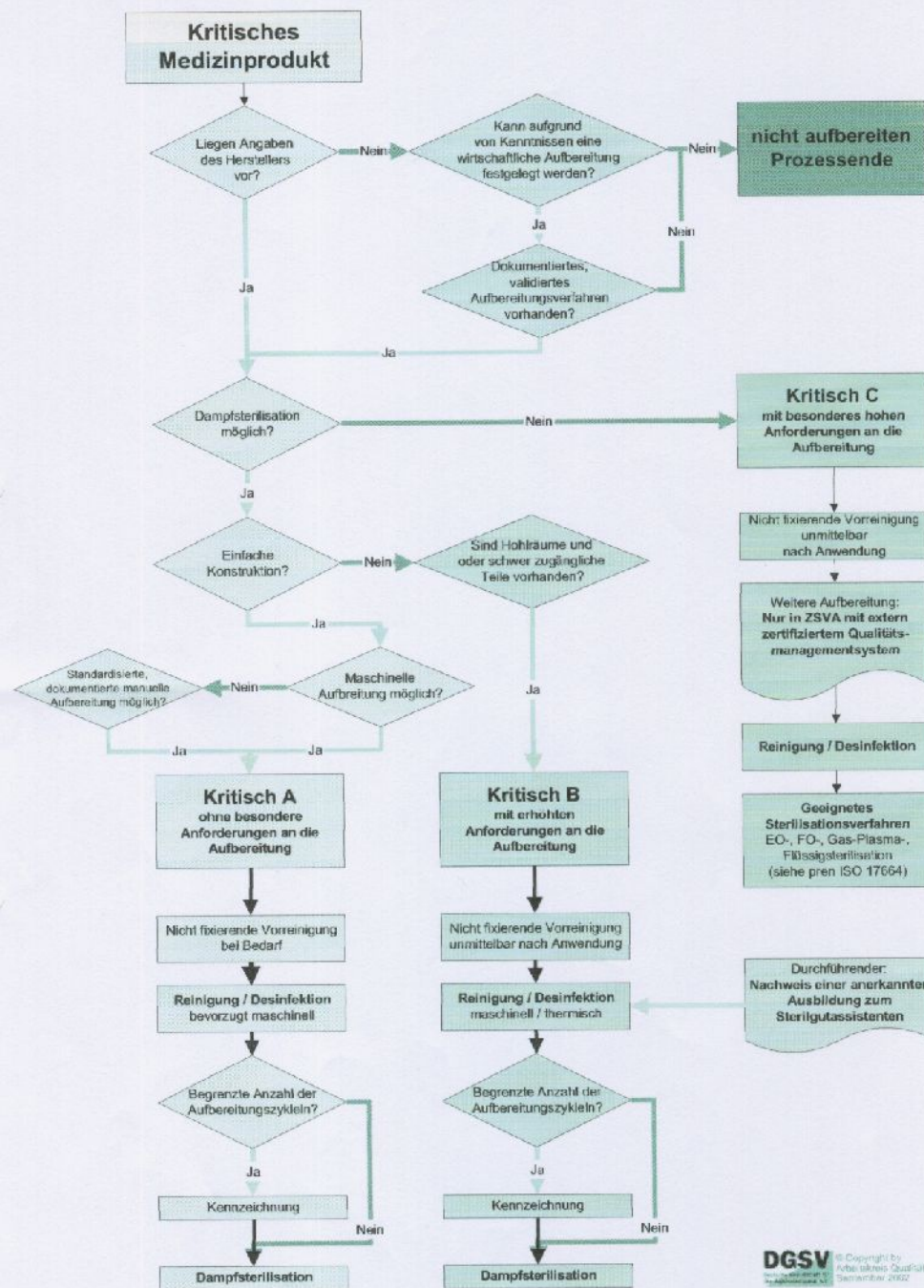


"ANNEX XIII - CONTROLLED REPROCESSING

1. The instructions for use shall specify the number of uses the device has been approved for.
2. If the manufacturer has not acquired information on validated procedures for a safe re processing or has not developed validated procedures for a safe re processing or judges a safe re-use as impossible, he may label the device as 'single use'. The label limits the liability of the manufacturer to the first use of the medical device.
3. The labelling as 'single use' does not impede third parties to develop validated procedures to be approved by a notified body. If a validated procedure for the reprocessing and consequent re-usability of a medical device has been demonstrated to a notified body, the single-use labelling will be considered as disproved and it is the duty of all Member States to allow reprocessing pursuant to the said validation procedure.
4. If no validated procedures can be demonstrated for a medical device, reprocessing of single-use labelled medical devices is prohibited."

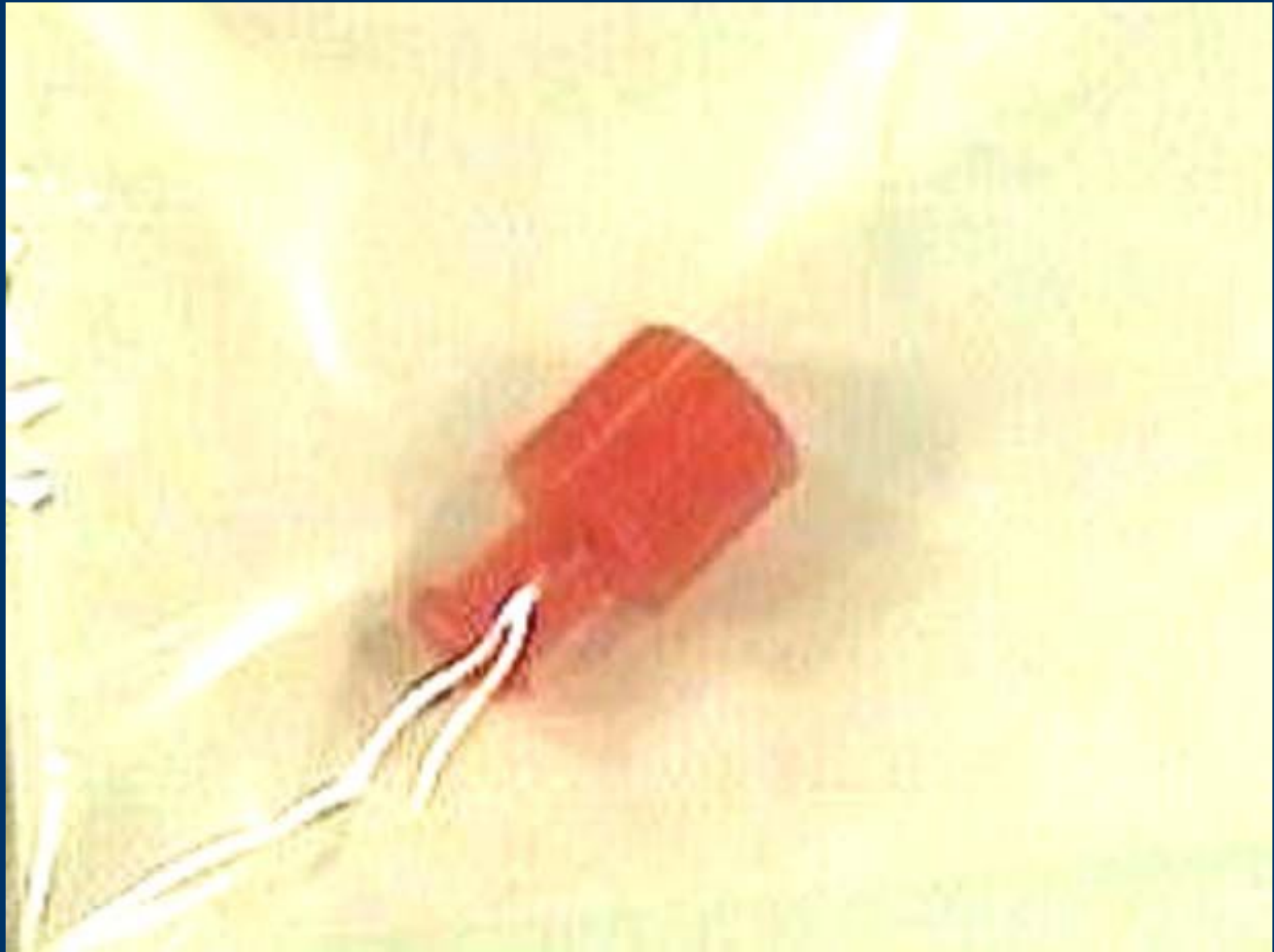






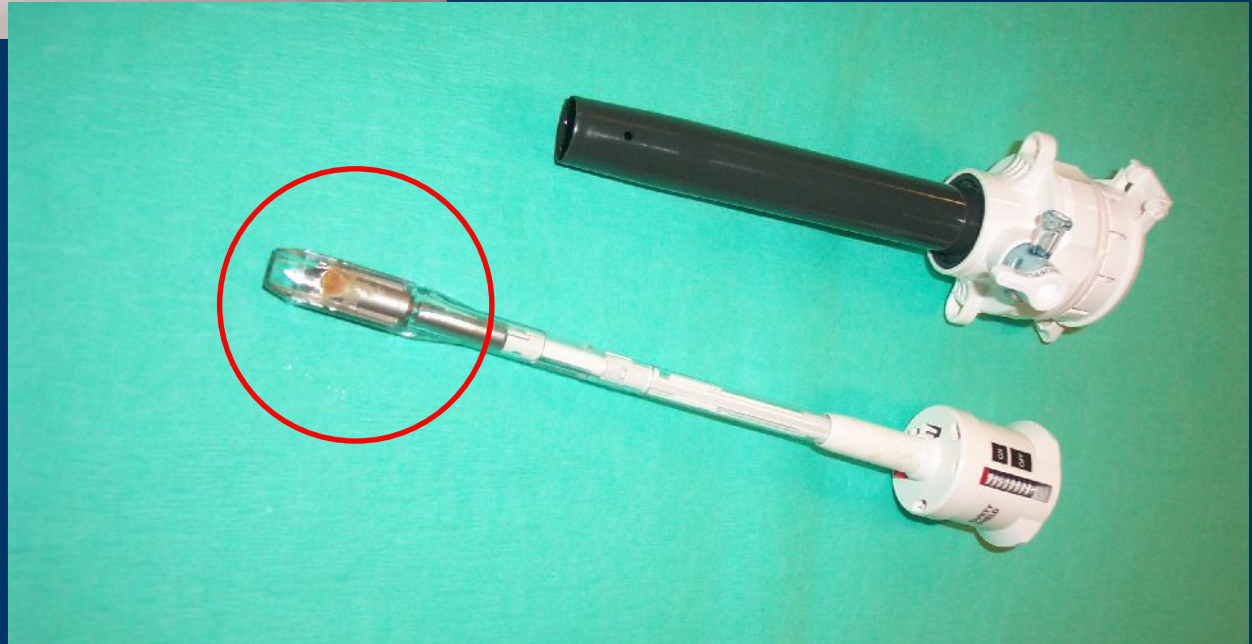
Cartoon 41 - The Emancipated Patient





















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