

# Reuse of single-use devices in Europe

IFIC Congress, Santiago/Chile 2008

Walter Popp

Infection control / Hospital hygiene  
University Hospital Essen  
Germany

E-mail: [walter.popp@uk-essen.de](mailto:walter.popp@uk-essen.de)  
[www.uk-essen.de/krankenhaushygiene](http://www.uk-essen.de/krankenhaushygiene)



## Medical device market in Europe

Total industry is currently worth 64 Billion €.

Yearly growth of 5-6 %.

Yearly research investment of 4 billion €.

Single-use products increasing.

Declaration as single-use or multiple use based only on decision of manufacturer.

Single-use products:

Hospital: Safer and more expensive.

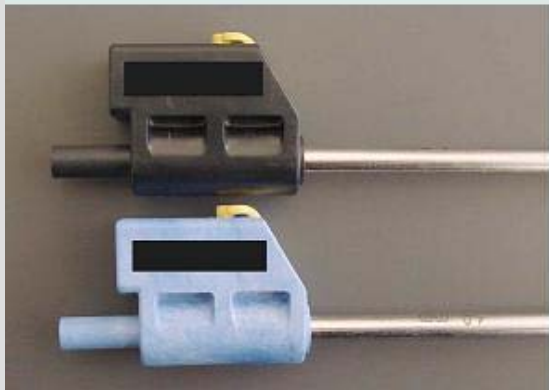
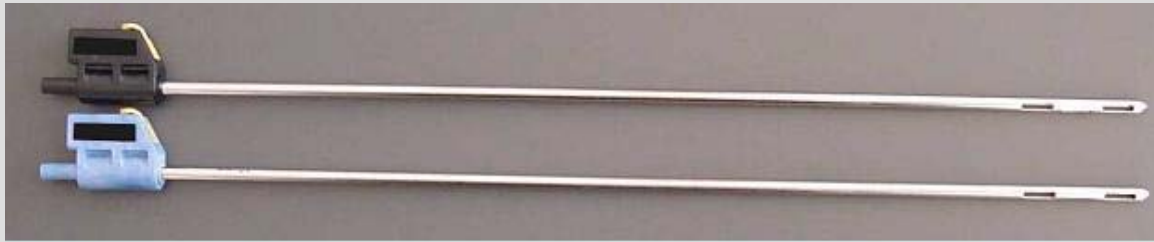
Manufacturer: Cheaper (no development of reprocessing recommendations), more devices sold.

(European Commission: Synthesis document – Outcome of the first public consultation on the reprocessing of medical devices, May 2008; EAMDR (European Association for Medical Device Reprocessing; SUPROMED 2007)



# Liposuction cannula

„Single use“ – multiple use



(blue „multiple use“ / black „single use“)

(left „multiple use“ / right „single use“)



According to EAMDR (European Association for Medical Device Reprocessing)

**COUNCIL DIRECTIVE 93/42/EEC  
of 14 June 1993  
concerning medical devices**

Does not distinguish between single-use and multiple-use devices.

No differentiated classification of single-use and multiple-use devices.

No standard for reprocessing defined.

**DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE  
COUNCIL  
of 5 September 2007**

(7) Particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients' safety or health. It is therefore necessary to provide clarification on the definition of the term 'single use', as well as to make provision for uniform labelling and instructions for use.



## **European Commission**

### **Synthesis document – Outcome of the first public consultation on the reprocessing of medical devices, May 2008**

„Reprocessing“ means situations where a product was previously used on a patient and is being made suitable to be used again, but may also cover some situations such as:

Where product's shelf life has expired and it was never used on a patient.

Where a product was not used on a patient, although the package was opened.

Where a product was on the sterile field during a surgical procedure but was not used on the patient.



## **European Commission**

### **Synthesis document – Outcome of the first public consultation on the reprocessing of medical devices, May 2008**

Reprocessing means

the cleaning,  
disinfection and  
sterilization of a medical device,  
including related procedures, as well as the  
functional testing and  
repackaging.



## **European Commission**

### **Synthesis document – Outcome of the first public consultation on the reprocessing of medical devices, May 2008**

Reprocessing can be done either in the hospital or by an outside contractor.

Reprocessing of reusable devices:

90 % in-house, 10 % external.

Performed on the basis of the instructions provided by the original manufacturer.

According to some respondents, even traditional multiple-use devices cannot be indefinitely reprocessed.

Reprocessing of single-use devices:

In-house vs. external no data available.

Carried out on the basis of procedures developed by the user or the reprocessing service provider.

Estimated 10-20 % of single-use devices are in fact multiple-use devices, technically reprocessable for a limited number of times.



## **European Commission**

### **Synthesis document – Outcome of the first public consultation on the reprocessing of medical devices, May 2008**

Cost savings up to 50 % for certain devices,  
e.g. electrophysiology / ablation catheters.

Estimation for Austria (SUPROMED):

Medical devices market around 730 Mio € per year.

Cost savings by reprocessing may be 60 – 200 Mio €.

Savings may be up to 90 % when reprocessed inhouse.



**Example of an external provider:**

**Vanguard – leader in European market of reprocessing of high technology instruments**

France, Poland, UK, Denmark, Switzerland, Germany, Belgium.

Cooperation with 1.450 hospitals in Europe.

114 Mio € turnover.



## Reprocessing of single-use medical devices in EU

| Regulated/accepted under high quality standards   | No legislation but performed without quality standards                             | Not recommended but (illegally) performed without quality standards           |
|---|--|---|
| <p>Germany<br/>Netherlands<br/>Denmark<br/>Sweden<br/>Belgium<br/>Slovakia<br/>Finland</p> <p>In assessment:<br/>Austria<br/>Luxembourg<br/>Czech Republic<br/>Slovenia</p> | <p>Estonia<br/>Latvia<br/>Lithuania<br/>Malta<br/>Cyprus<br/>Greece<br/>Poland</p> | <p>France<br/>UK<br/>Ireland<br/>Portugal<br/>Spain<br/>Italy<br/>Hungary</p> |

According to EAMDR (European Association for Medical Device Reprocessing), El Mundo 9-17-2005



## Germany

### Medical Devices Act (MPG)

Reprocessing is „cleaning, disinfection and sterilisation – including the associated working procedures as well as testing and restoration of technical safety – of medical devices after use for the purpose of reuse, which as per their definition have only a low microbial load or are sterile when used“.

### Medical Devices Operator Ordinance (MPBetreibV)

Recommendation by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

Risk classes for medical devices: non-critical (low risk), semi-critical (intermediate risk), critical (high risk).



## **Reprocessing of medical devices:**

Technology for reprocessing (machinery, equipment).

Personnel (training, instruction).

Production environment (e.g. clean room, GMP).

Media (water treatment, air conditioning ...).

Documentation (traceability).

Certification of quality management system according to EN ISO 13485

(Medical devices -- Quality management systems -- Requirements for regulatory purposes).

Test equipment (hygiene, function).

Validation of procedure.

**Responsibility** for patients and users of reprocessed products, e.g. insurance of some millions €.

According to EAMDR (European Association for Medical Device Reprocessing)



## **Validation of procedure**

Definition of upper frequency of reprocessing  
(maximum 5 for most devices).

Up to 50 % of some devices not functional even  
after first reprocessing.

Parameters depending on manufacturer!

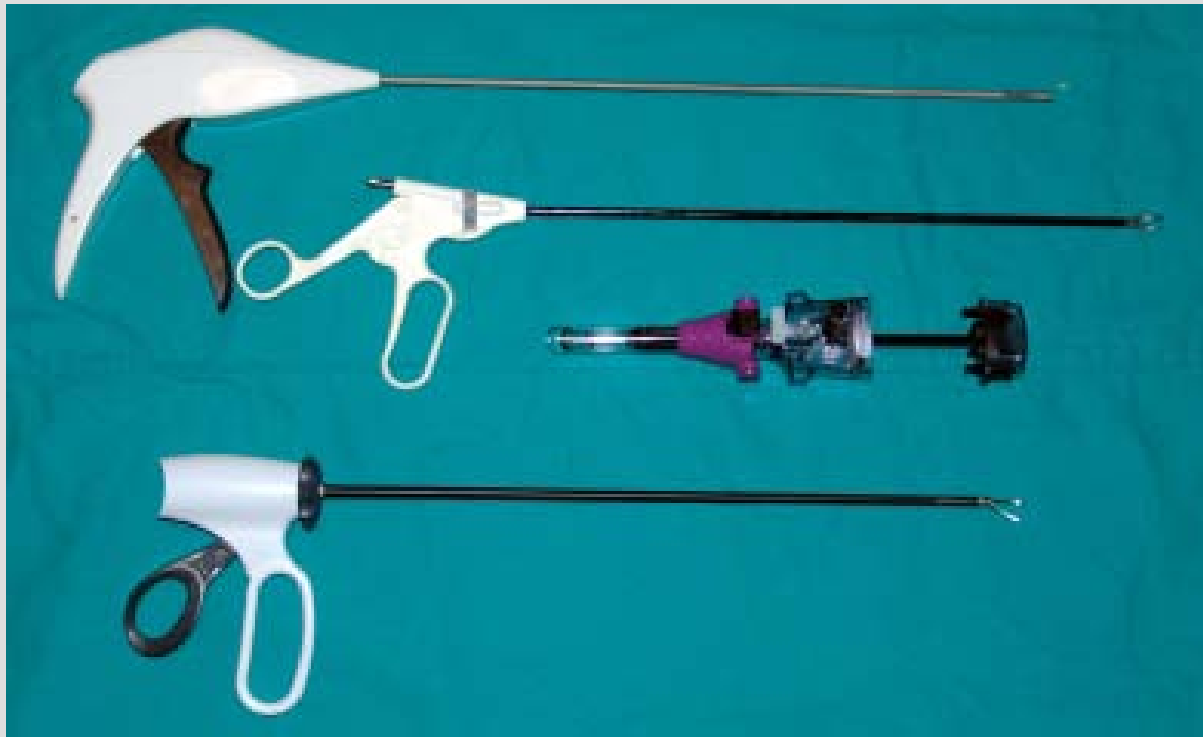
Economical benefit not in every case.



## Reprocessing of Ultracision scissors

Ultracision scissors for single use, once reprocessed, on comparison to multiple-use ultracision scissors:  
No difference with respect to function and comfort of use, but 200 € cheaper.

(Gärtner et al., poster at DGCh congress, 2006)



**Reprocessing of multiple-use devices also depends on men:**

Microsurgery instrument - not dismantled correctly before reprocessing

