

Reuse backgrounder

Executive summary

- An increasingly large number of hospitals in the European Union reprocess and reuse medical devices designed for single use in the belief that this can save money. This assumption is incorrect. Unlike reusable devices, single use medical devices (SUDs) are not designed to be de-assembled, de-contaminated, re-assembled and reused. Their safety and functionality can be jeopardized by reprocessing, with the following potentially severe consequences for the patient:
 - Infection;
 - Injury;
 - Diagnostic Errors;
 - Ineffective Care.
- This ultimately leads to **increased costs and unacceptable standards of care.**
- **Patients are not informed about this practice and the related risks. Patients do not have the choice.**
- **Clinicians are often unaware about the decision taken by hospitals to reprocess SUDs and are equally unaware that they are exposed to liability as a result.**
- The reprocessing of medical devices designed for single use, in violation of their instructions for use, **should be prohibited** in the European Union, and strict controls should be put in place by public health authorities in the Member States.

What is "single use" technology?

Single use medical devices have been developed in response to the need to avoid cross infection and thus to increase standards of care. Technology has further evolved to the extent that single use devices can now deliver patient care which is not possible with conventional reusable instruments.

While initially single use devices were developed at the request of healthcare providers to limit infection and cross contamination (single use syringes, for example), they are today often miniaturized high performance devices, the result of advances in technology. They are available as single use devices only, due to the critical performance and sterility needs. Single use technology enables procedures that otherwise would not be possible.

Today, such sophisticated single use instruments and devices are being reprocessed and reused, with the risk of harming the patient. Action to prevent this is urgently required.

Single use medical devices are not designed to be reprocessed and reused. Reusable devices instead have been designed in such a way that they can be de-assembled, cleaned, re-assembled, re-packaged and sterilized.

The dangerous mirage of cost savings

With pressure growing to keep healthcare budgets under control, reprocessing of single use medical devices is becoming increasingly tempting. Many hospitals either attempt to clean the used single use medical devices themselves or outsource the job to external reprocessing companies, in the belief that they can save money. This assumption does not take all factors into account and is often incorrect.



In any economic impact assessment, one should not only look at the short-term savings achieved on the price of a new product, but also take into account the many potential additional **costs, most of which are born by society as a whole and which could result in decreased patient safety:**

Contaminated clip applicator

- Longer procedure time and hence prolonged anaesthesia;
- Patient injury and repeat surgery or intervention;
- Repeated diagnostic tests;
- Hospital acquired infection and subsequent treatment (e.g. increased antibiotics);
- Patient incapacity (absence from work, etc);
- Pain and suffering of the patient and relatives;
- Legal proceedings or out-of-court settlements;
- Negative impact on hospital reputation;
- Handling reprocessed products (administrative, transport, etc);
- And more...

The direct and indirect costs of hospital acquired infection have been estimated at over 11 billion €/year¹. It would be interesting to investigate what proportion of these infections are due to the use of reprocessed single use medical devices.

As far as ecological considerations are concerned, it is to be noted that reprocessing involves the use of powerful detergents, disinfectants, solvents and plastics which all end up as waste products.

A recent study of single use devices for interventional cardiology conducted by the **University of Trento, Italy**², concludes that in order to guarantee patient safety complete device testing is mandatory on every reprocessing cycle and on every single device. Moreover, the authors call into question the claims of cost savings and positive ecological impact of single use device reprocessing.

What is the evidence against reprocessing?

There is to date a considerable amount of documentation of the risks related to the reprocessing of single use devices (see footnote for detailed references)³. An efficient adverse patient **event reporting system** in each EU member state (in a "no blame, no shame" culture), as recommended in various recent high level patient safety fora⁴, would help to shed further light on the proportion of incidents and decline of standards of care due to the use of reprocessed single use medical devices.

1. Risk of patient contamination and diagnostic errors

In the European Union, there are approximately **3 million healthcare associated infections and 50.000 related deaths** per year⁵.

In 2003, the WHO estimated that **8.9 million people were infected with Hepatitis C and another 500 000 people with HIV**⁶. In many cases, the hospital does not know whether a patient is infected or not.

The use of single use medical devices can help to reduce hospital acquired infections. The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has recently recommended the use of single use devices to avoid cross-contamination from variant Creutzfeldt-Jakob Disease (vCJD), for example, as "at this moment, there is no validated cleaning process available for instruments that might be contaminated with TSE agents like vCJD"⁷.

However, **the use of reprocessed single use medical devices increases the risk of cross-contamination and hospital acquired infection.** This is due to the difficulty (and often impossibility) of cleaning and resterilizing single-use devices. In many cases it is not possible to guarantee that all blood, tissue and body residues have been removed.

Example

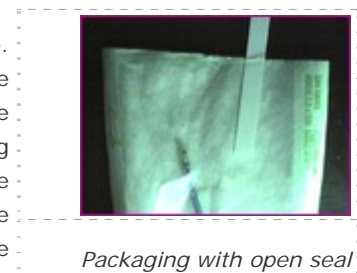
Biopsy forceps are designed to collect tissue for histological examination. Heatable biopsy forceps are used through an endoscope to cauterize and remove polyps and / or tissue specimens throughout the alimentary tract. A study found that reprocessed single use biopsy forceps were **non-sterile in 90%** of the cases examined. Limitations imposed by instrument design impeded reliable reprocessing⁸. Current standards for cleaning, disinfection and sterilization are not suitable, due to the specific design of the device (e.g. cannot be de-assembled, special coatings would be lost, etc). In addition to the risks of infection and the possible prolongation of the biopsy procedure, the results of the tests conducted on the samples of tissue extracted from the patient may be affected by the contamination of the instrument.

Example

A *balloon catheter* is made out of special blends of elastomers chosen for their softness when in contact with the vessel wall and resistance to kinking, and may have a hydrophilic coating to ensure the best performance for a single use in the blood stream. When analyzing reprocessed balloon catheters received from hospitals where the devices were awaiting to be reused, it was found that **50 % on average were contaminated** with blood and proteinaceous material or contrast media⁹. In addition to possible cross-contamination, such residues may cause a fever reaction in the patient.

2. Risk of patient injury and ineffective care

Signs of wear and tear are quite normal after initial use of any medical device. However, reusable medical devices are designed to be resistant. They can be de-assembled, cleaned, re-assembled and sterilized. They can withstand the aggressive chemicals or extreme temperatures typically utilized in reprocessing techniques. Single use medical devices are not designed to be reused. The material and functional degradation caused by use and reprocessing can make them **fail or malfunction** and cause harm to the patient. Alteration of the material surface structure and its properties such as **biocompatibility or permeability** can occur through reprocessing. Bits and pieces can "break off", injure the patient and led to repeat surgery.



Packaging with open seal

Example

A *vaginal speculum* is a hand held device consisting of dual parting blades with locking and unlocking features, which can be adjusted with one hand. The device is used to expose the interior of the vagina to facilitate visualization during gynecological or obstetrical procedures. Disposable vaginal specula are often made of high impact polystyrene, whereas reusable specula are made of highly polished surgical stainless steel. Specula come into contact with mucous membranes, diseased or damaged skin and body fluids. A reusable speculum is designed to be decontaminated. For heat-tolerant devices sterilization may be achieved in a hot air oven or in a classical steam sterilizer, and for heat sensitive devices, by ethylene oxide, low-temperature steam or sporicidal disinfectants.

Single use specula may not withstand or may be affected by the cleaning and sterilization process. The chemicals needed for disinfection may be absorbed by certain plastics, for example. These may leach out during subsequent use, resulting in chemical injury or a risk of sensitization of the patient or user¹⁰. The reprocessing may also cause the instrument to break during the medical examination, causing injury to the patient.

Example

When analyzing refurbished *balloon catheters* received from hospitals where the devices were held prior to reuse, it was found that **up to 45 % of the devices showed surface changes and defects** caused by multiple usages, reprocessing or inadequate packaging¹¹. In addition to the risks of cross-infection (e.g. HIV, Hepatitis) from blood and/or protein residues, small flakes may become detached from the surface of the

device and remain in the patient's body, posing a risk of thrombosis. The device may also break during the procedure, which can cause blood vessel damage, extend the procedure time or result in an additional surgical intervention. The patient who goes to hospital for a simple minimally invasive procedure may need to have open surgery to retrieve the broken parts.

Medical ethics and informed patient consent

It is a basic principle of medical treatment that patients should consciously agree to the form of treatment, particularly if it involves surgery and puts them at risk. That consent should be 'informed'.

However, in countries where reuse of single use medical devices is tolerated, **patients are not told that they will be treated with a reprocessed product against the manufacturer's instructions, or informed of the related risks** (described above). Informing the patient and providing the patient with a choice on something this important should be standard practice.

While reuse of single use medical device should clearly be prohibited, if this practice is nevertheless tolerated, the explicit consent of the patient should be required in every case. **The patient should have the choice to be treated with a new single use device.**

Moreover, clinicians are often unaware of decisions being taken by the hospital to reprocess SUDs and are equally unaware that they are exposed to liability as a result.

¹ UK National Audit Office estimated it at £1 billion per year for the UK. Costs will be different for other countries and will change with time, however the relative magnitudes will be similar. 1 billion £ for UK population of 59.518.000 - 7, 64 billion £ for EU population of 454.905.000 - exchange rate on 16 January 2006 : 1£ = 1, 466€ - cost for Europe: 11,2 billion €

² Reuse of single-use devices for interventional cardiology : a HCTA approach, F. Tessarolo, M. Fedel, P. Ferrari; G.M. Guarrera, C. Favaretti, C. Migliaresi, and G. Nollo, University of Trento - Funded by PAT "Fondo Unico per la Ricerca 2001" - info: tessaro@science.unitn.it

³ All the studies referred to in this section and much more can be found on a recently updated CD-Rom, available upon request from Eucomed: thecla.sterk@eucomed.be - Tel: +32.(0)2.772.22.12

⁴ Luxembourg and UK Presidency summits on Patient Safety and WHO World Alliance for Patient Safety

⁵ EU Commission, public consultation on HAI, January 2006 - Click here to view full text

⁶ See www.who.int

⁷ The Scientific Committee on Emerging and Newly Identified Health Risks published an Opinion on The Safety of Human-derived Products with regard to Variant Creutzfeldt-Jakob Disease, 28-29 September 2005.

⁸ K Roth, P Heeg, R Reichel, P Cogdill, W Bond Quality Assurance on Reprocessing Accessories for Flexible Endoscopes - Just How Clean are Cleaned Instruments Really? Central Service 1999; 7: (2)84-96

⁹ A Beck. Potential Reuse? Schnetztor Verlag Konstanz; 2001

¹⁰ SMTL report no 00/1222/1 -Issues relating to disposable and reusable vaginal specula. SMTL Report No 00/1192/1, Revision 1.20, November 2000 -Medical Devices One Liners: Issue 19, October 2002 UK Medical Device Agency

¹¹ A Beck. Potential Reuse? Schnetztor Verlag Konstanz; 2001