

Eucomed White Paper on the reuse of single use devices

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Executive summary

In recent years, great advances in the design, manufacture and uses of medical devices have provided patients with enormous benefits during surgery and treatment. However, some important safety, ethical and legal issues arise when such devices, originally designed and labelled for single use, are, despite the manufacturers' express instructions, refurbished, repackaged and reused. This practice is undertaken mainly for the alleged economic benefit of the users' institutions, usually hospitals.

The refurbishment of single use devices involves cleansing, sterilising, repackaging and otherwise fixing them to render them as close as possible to their original quality, performance and functionality. However, such processes are rarely adequate enough to eliminate the risks of cross-infection, and can often cause deterioration of the component materials. The use of refurbished single use devices can lead to an increase in hospital acquired infections (HAI), one of Europe's most serious medical challenges. In addition, they can potentially cause harm or death to the patient by infection or mechanical breakdown.

The practice is considered ethically insupportable, since patients are placed at unnecessary risk, are uninformed and their interests are subordinated to hypothetical and unsubstantiated economic benefits to the user, usually a hospital. The economic benefits, if any, are seen to be overestimated. The costs of dealing with HAI, additional complications, administrative overheads and eventual litigation are rarely calculated or included in total cost benefit analyses.

In much of Europe the practice is heavily discouraged, but not universally illegal; exceptions to this rule are France, Spain, Italy and Portugal. The practice is condemned by the World Health Organisation and in the USA, reprocessors are considered manufacturers. In Australia, a legal framework exists for the re-manufacturing of single use medical devices. Current EU directives do not prevent a so-called refurbishment industry from re-selling refurbished single use devices.

Eucomed strongly recommends that EU measures are developed to introduce effective Europe-wide provisions putting patient-safety aspects first when it comes to medical devices designated as single use.



Introduction

Medical devices have revolutionised the way healthcare is delivered; patient outcomes have been significantly improved. Consider minimally invasive surgery and the progress from major surgery to the use of day surgery. These changes have resulted in improvements in quality of life and at the same time, a reduction in cost. These developments are mainly due to advances in the materials used, sophisticated design and improved manufacturing techniques.

A key issue for medical devices is whether they can be adequately cleaned and sterilized between uses without loss of performance. If the answer is yes, then they can be considered safe for use on multiple patients and therefore considered multiple use devices. If not, then they are usually designated as a single use device. However, despite being categorised by the manufacturer as single use, the practice of reusing single use devices is often employed. The main reason usually given for this practice is alleged cost savings.

The important question is does the reuse of single use devices pose any risks? A good basis for assessing the risks associated with reusing single use devices is to analyse devices reprocessed within hospitals and by third parties. Scientific studies carried out by academia, health authorities, users and manufacturers often show dramatic shortcomings in sterility, cleanliness and functionality. In particular, complex devices cannot be adequately cleaned and the remaining residues pose a risk of infection from blood-borne pathogens. To enable thorough cleaning of these devices, some third party reprocessors break these products apart. However, this often has an unpredictable impact on their integrity and functionality and may make instruments more brittle. Not only is there little if any evidence on the safe refurbishment of single use devices, but significant hygienic and functional issues also exist in devices currently refurbished in-house or by third parties. Maintaining a high level of safety for all devices requires action at the point of use.

Many devices are declared multiple use. As part of the design certification, the cleaning and maintenance of these devices has been validated to comply with the standard medical practices used in hospitals. This guarantees that when used on further patients they are free of possible contaminants such as bacteria, viruses and debris. In addition, the design validation of multiple use devices provides the assurance that they will perform to the specifications guaranteed by the manufacturer. This is not the case with single use devices, which have been designed for single use and for which the manufacturer has determined no appropriate method to clean and maintain the device after its first use. In addition, they cannot guarantee that it will perform to its original standard.



This paper will consider various aspects of the refurbishment of single use devices in depth by answering the following questions:-

- Can a single use device be cleaned, decontaminated and resterilised?
- Does the refurbishment of single use devices affect their quality?
- Does the refurbishment of single use devices affect their performance?
- Does the refurbishment of single use devices affect their safety, i.e. is it possible to cross-infect patients by using refurbished single use devices?
- Is it morally or ethically justified to treat a patient with a refurbished single use medical device, which may be of lower quality, performance or cleanliness than it was when used for the first time?

The value to society of single use devices

Single use devices simplify processes within hospitals. They eliminate the need for complicated guidelines setting out procedures for cleaning, sterilising, checking functionality, labelling and tracking. A single use device is delivered sterile to the operating area, used and discarded.

Single use devices also make it possible to create innovative designs, which in turn lead to faster, more efficacious, and less risky procedures. In other words, single use devices provide treatment that would not otherwise be available.

A device is classified as single use if the complexity of its design or the materials used render it impossible to clean and maintain the device. In such cases, manufacturers must declare and label the device for single use only. Attempting to clean and reuse such devices could lead to a reduction in performance, the spread of hospital acquired infections (HAI), and in the worst case, cause the death of a patient.

Single use versus multiple use devices

Manufacturers are continually improving their designs to ensure patients are treated with state of the art medical devices. They recognise the commercial value of designing and manufacturing a multiple use device as opposed to single use items. Multiple use devices would normally command a significant premium over single use devices, resulting in increased profitability and market share accruing to the manufacturer. Up to now, even by using the current state of the art procedures, the goal of converting many single use devices, especially those that are complex and miniaturized, into multiple use devices, without a reduction in quality and functionality, has proved to be elusive.



Often claims are made that waste generated by the disposal of single use devices could be considered as environmentally unfriendly. However, any analyses of the environmental impact of single use devices should also consider the significant resources (e.g. chemicals) needed and the energy consumed during the refurbishment of devices.

What is reprocessing?

Reprocessing reusable medical devices typically consists of immediate postoperative pre-cleaning, cleaning, sterilization, repackaging, labelling and returning the device to a specified condition and performance. The owner of the device will ensure, using validated processes that the specified criteria continue to be met. Reprocessing is performed either in the hospital itself or by an outside contractor, based on the instructions provided by the original manufacturer of the device.

Importantly, in the case of single use devices, by definition, these processes have to be carried out without instructions from the original manufacturer, and without any validated evidence from the manufacturer that the device will still effectively perform its intended function.



Patient safety

Patient safety is the most crucial concern when reusing single use devices. Indeed, there are a number of issues that may compromise patient safety and these are discussed in more detail below.

The potential for cross-infection

Infection is a significant patient safety concern associated with the improper reuse of medical devices. The risk of cross-infection, or the spreading of germs, bacteria and/or disease from an infected area to a non-infected area, may increase due to the inability of the refurbishment process to completely remove viable micro-organisms from devices not designed to be cleaned. This may be due to the geometry, for example, in the case of narrow lumens. Cross-infection could also be due to the type of material used, such as heat sensitive materials, preventing the use of steam sterilization; a recommended method of sterilization for hospitals. If viable micro-organisms are not completely removed they could be transferred to the next patient. Interestingly, in a study carried out at the University in Tuebingen, researchers found that none of the refurbished single use instruments tested, which included biopsy forceps and papillotomes, were effectively cleaned, disinfected or sterilized. This was because cleaning methods passed the contamination further into the lumens of the disposables forceps ¹. In a further example, a single use bladder pressure transducer cover was not changed between patients, resulting in cross-infection due to the presence of Pseudomonas aeruginosa. One patient developed septicaemia and died of a sub-arachnoid haemorrhage².

The inability to clean and decontaminate devices

Any satisfactory cleaning process must access all parts of the device to allow complete removal and decontamination. At the end of that process the chemicals used must also be completely removed. This process should be validated to establish that it will consistently provide clean and residual free devices. Examples of features of devices that are difficult to clean include acute angles, coils, long or narrow lumens and specialist surface coatings.

The residues from chemical decontamination agents

Some materials used in device manufacture can absorb or adsorb certain chemicals, which will then gradually leach over time. For example, disinfectants like glutaraldehyde may be absorbed by plastics and leach out during use², resulting in chemical burns or the risk of allergic reactions by the patient or user.



The alteration of component materials

Exposure to chemical agents, such as cleaning agents and chemical sterilants, may cause corrosion and/or changes in the materials of the device. Exposure to elevated temperatures or pressure during the sterilisation process may also alter the properties or cause degradation of the device material. For example, plastics may soften, crack or become brittle².

The mechanical failure of devices

All devices experience stress during each cycle of reuse. Devices intended for reuse have had this stress taken into account and evaluated by the manufacturer. However, in the case of refurbished single use devices, this is not the case and reuse may lead to unpredictable fatigue-induced failure and fracturing. Examples of where this may be important include single use drill burrs, saw blades and craniotomy blades. To indicate the impact of mechanical failure in the clinic there is the example of a single use lithotriptor stone retrieval basket. When refurbished it appeared to be satisfactory for reuse. However, during the procedure the cable snapped when it was tightened, resulting in the basket remaining inside the patient². Further surgery was required to retrieve it.

Reactions to endotoxins

Endotoxins are Gram-negative bacterial breakdown products and can be a significant problem if a device has a heavy bacterial load after use. It is very difficult to then adequately remove this load by cleaning. The sterilisation process will not inactivate the toxins, even if it is effective at killing the bacteria. These non-viable toxins are very dangerous and can lead to life-threatening toxic shock.

Removal of biologics

It is important that any sterilization process ensures that both bacteria and viruses are inactivated and cannot be transmitted. To this end, the potential for viral transmission and infection after reuse of single use catheters has been reviewed by the Regional Public Health Laboratory in Gronignen, The Netherlands³. The study showed that after rigorous cleaning and sterilization, viruses were still present in 30% of the catheters.

In addition to the inactivation of the bacteria or viruses, medical devices for implantation into humans or for usage during invasive procedures must also be free of contamination from particulate matter from bacteria or viruses, which may act as pyrogens. The remains of dead bacteria and bacterial components alone may induce an inflammatory immune response⁴.

Removal of prions

The abnormal proteins associated with prion diseases such as Creutzfeldt-Jacob disease (CJD) and variant Creutzfeldt-Jacob disease (vCJD) are very



resistant to all conventional methods of decontamination and sterilization. Prion diseases are fatal, infectious, neurodegenerative disorders with no known immunization or treatment. Natural transmission of human prion diseases is not well understood because it is difficult to locate the source of transmission after a long period. While numbers have risen slowly to date, it remains entirely possible that a substantial epidemic of variant CJD will occur over the coming years.

In the UK alone 1,147 cases of confirmed CJD deaths have been reported since 1990⁵ and ineffective cleaning of surgical instruments may be a vector for the transmission of HAI and also for transmitting prions responsible for the CJD. To assess the potential for the transmission of prions via instruments, the University of Southampton analyzed 260 instruments obtained from nine UK National Health Service (NHS) trusts. Although not all instruments showed signs of microbial colonization, over 60% showed a high degree of protein soiling. Besides the risk of transmitting prions, such potentially hazardous material is also known to contribute to inflammation and surgical shock⁶. In another study, researchers from the National Hospital for Neurology and Neurosurgery in London found that 30% of the laryngoscope blades studied had lymphocytes present after reprocessing⁷. Their conclusion was that since there is no routine sterilization method available to deactivate prions, single use devices should be used and used once only.

The transmission of CJD via neurological probes, in spite of repeated cycles of cleaning and sterilisation, is well known. Indeed, recent research from Scotland has revealed that temperatures, even above 138°C⁸, which are routinely used to sterilize surgical instruments in British hospitals, does not inactivate CJD. Moreover, classical CJD has been transmitted from person to person by medical procedures⁹. The Scientific Committee on Medicinal Products and Medical Devices attached to the European Commission reported that "the transmission of CJD by silver electrodes used for stereotactic electroencephalography and by neurosurgical instruments had been described in single cases. In all these cases, the carrier of infectivity (i.e. tissues or instruments) was derived from or in close contact with the central nervous system of individuals infected with CJD. Whether those individuals suffered from overt CJD or were still in the incubation period is not always known"¹⁰.

The observation that there is a growing resistance to inactivation of prions following certain procedures has implications for the disinfection of surgical instruments suspected of being contaminated with CJD¹¹. For many single use devices, adequate cleaning is not possible and the devices are unable to withstand the high temperatures during steam sterilization. As a consequence, some compromises have to be made in both cleaning and sterilization when single use devices are refurbished. This is a dangerous practice, which multiplies the risk of infection. To reduce the risk of transmission of these prion proteins during surgical procedures, the UK Medicines and Healthcare Regulatory Agency (MHRA) strongly advises against the reuse of single use devices because of the risk of transmission of vCJD from one patient to another¹². Therefore, the dangers are obvious, but until a great deal more is



known about prion diseases, the only sure method of avoiding the risk of spreading CJD during medical procedures is to encourage the use of single use device technology and to prevent the reuse of single use devices.

Removal of hepatitis

The hepatitis B virus is highly infectious and can be spread by sexual contact, child delivery and contact with blood from an infected person. The virus can also be contracted by a patient or health care workers, through contact with a contaminated medical device or transfusion of infected blood or blood products. Research has shown that the greater the difficulty in cleaning devices such as those used for modern laparoscopic procedures, the greater the risk of non-compliance with cleaning protocols put in place to avoid hepatitis infections. There have been documented outbreaks of the more serious hepatitis C virus in Australia and a possible link to the reuse of single use medical devices, which led 22 hospitals discontinuing reuse altogether¹³.

The risk of transmitting the hepatitis B virus via surgical instrumentation has been evaluated by the University of Sydney¹⁴. After usage of angioscopes on hepatitis B (DHBV) infected ducks, the instruments were then used in hepatitis B naïve ducks. For unclean devices, the transmission rate of the hepatitis B virus was 90% and even after ethylene oxide (ETO) sterilization the transmission rate was 18.5%. This shows that there is a significant risk of cross-infection of patients with the hepatitis virus when instruments are not or indeed cannot be cleaned. The authors postulated that the presence of narrow lumen or residual protein shielding within the lumen may compromise effective inactivation of hepatitis viruses, with the potential risk of patient to patient transmission.

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Technical aspects

Design for reuse

A medical device made for multiple use must work as indicated by its manufacturer after every time it has been reprocessed. The manufacturer will validate the device for multiple use and provide adequate reprocessing instructions at the time the device is placed on the market. The development process often includes multiple redesigns and compromises in respect to the functionality and dimensions in order to produce an instrument which can be safely reused. Several design iterations are necessary to ensure devices can be reprocessed, where possible with automated processes.

Design for single use

Manufacturers design and validate a device for its intended use. For single use devices, testing and validation are targeted to limit initial failure, as opposed to multiple use devices, which are designed and tested to ensure reliability for a number of usages.

The design process includes research on the materials selected, their biocompatibility, and extensive pre-clinical testing and performance validation of the device in use. For a first-to-market new design this almost certainly requires a clinical trial on humans. Today, risk management is applied to the entire lifecycle of a device. But who defines what is critical to quality, how such a criticality assessment is conducted and how this is translated into the design? Manufacturers continuously survey customer requirements and analyse how a device is used and possibly misused. Based on this assessment, critical design and manufacturing parameters are (re-) established and controlled.

It is not important to test as many parameters as possible, but it is essential to test the right parameters. Therefore, a manufacturer must know how the device is used and misused and translate this into critical material, design and manufacturing parameters. This ensures that customer-defined quality will be designed and manufactured into the device.

Can a reprocessor achieve the same quality and safety level as the manufacturer, considering that he cannot influence the original design and manufacturing processes? A single use device is designed with maximum performance and functionality in mind and any refurbishment may damage or alter it in a non-predictable and often dangerous manner.

A reprocessor's validation is often limited to process and group validations of similar products. For the validation the worst-case product and the worst-case condition of a used single use device are selected. However, as the reprocessor does not have the manufacturer's proprietary design knowledge,



the worst-case products are selected based on experimental criteria, which may not be correct. Elements that make the selection of the worst case scenario even more difficult can be:

- Non-homogeneous batches and the unknown quality of the used devices
- No knowledge of confidential model-specific design, test methods and manufacturing parameters
- No economic system to identify ongoing design changes of the single use devices.

As a result of these uncertainties, to validate a process for the refurbishment of single use devices that guarantees equal quality to a new device may be not economical, if it is possible at all.

The Belgian Commission d'évaluation pour les dispositifs médicaux (Medical Devices Assessment Commission), which is responsible for assessing any accidents/incidents that occur in connection with medical devices and which advises on possible health risks linked to certain medical devices, believes that validation is needed for all forms of refurbishment, which cannot always be ensured¹⁵. This validation implies a precise understanding of a series of essential parameters; something that is impossible in certain situations where there are several lots of homogenous equipment.

Packaging, labelling and shelf life

An integral part of device integrity and product safety is the device specific packaging, which often includes custom packaging to prevent damage in transit. Manufacturers operate quite complex transit testing programmes to ensure the functionality of often high tech complex devices at the point of use.

To ensure users are informed about the correct usage of medical devices, manufacturers supply instructions with the device where required. Safety relevant information, such as expiry date and important information identifying the correct size is given on the product's label. Losing such important information during the reprocessing cycle may lead to significant safety gaps.

Device aging studies are based not only on the length of time a device remains sterile, but also on the aging of materials such as plastics, coatings or lubricants.

Examples of the challenges posed by reusing single use devices

It is impossible to reuse a large number of medical devices, simply because they are not designed to be taken apart for adequate cleaning, or to perform as specified after first use. In addition, many of the materials utilized in the various components of single use medical devices, both plastics, glues and metals, may not withstand the chemical environment of the disinfecting



solutions utilized. Also, the temperatures required for autoclave sterilization may deform many components and subsequently compromise their performance and safety. This has been the topic of much discussion, as highlighted below.

In an article by the Canadian Medical Device Technology Companies (MEDEC), the authors refer to a 2001 review where several device manufacturers conducted studies on the effects of refurbishing single use devices by hospitals¹⁶. Reprocessed single use devices were retrieved from hospitals in the United States and in Europe. In total, 136 devices were obtained from hospitals on both continents and included clip appliers, clamps, staplers, cautery devices, tracers and electrophysiology (EP) catheters. Examination revealed that at least half of these products had packaging defects, were contaminated with residual blood or tissue, and/or experienced functional failures.

In the same article, MEDEC referred to a German report by Andreas Beck¹⁷ where 727 angiography catheters and guide wires were studied for the effects of refurbishment. The devices were collected from local health institutions and examined for signs of deterioration. The results showed numerous physical variations in devices refurbished by hospitals, including nicks, kinks, roughness, erosion, tears and changes in material properties. The study also evaluated single use devices refurbished by third party reprocessors and found they also contained numerous defects. The author concluded that the refurbishment of devices intended for single use by both healthcare facilities and third party reprocessors is inappropriate and a risk to patient safety.

In the UK, the Committee on the Safety of Devices has debated¹⁸ at length the need to ensure that small orthopaedic screws are supplied designated for single use. Previously, they had been supplied as non-sterile and required sterilisation prior to use. If they were not used during an operation they were then re-sterilised in preparation for the next one. This Committee believed that after several sterilisation cycles the performance of the screws would deteriorate.

Case reports of patient harm have been noted with reused medical devices, such as central venous catheters, cardiac catheters, pressure monitoring domes, ophthalmic devices and intravenous catheters. These reports highlight incidents of death, infectious disease transmission, pyrogenic reactions, and device failure. The scientific evidence section of this paper describes a selection of such events in detail.

Reprocessing trocars

Trocars are instruments used to provide access during minimally invasive surgery. Malfunction especially for shielded trocars may lead to severe consequences including the puncturing of vessels such as the aorta and significant bleeding. Similarly, cracks caused by reprocessing of so-called blade trocars poses the risk of the tip shattering upon insertion leaving sharp



pieces of plastic in the patient. Correction often requires long procedure times to remove sharp objects.

Shielded trocars rely on a shield that is pushed over the sharp blade by a spring mechanism after insertion. This is designed to function within milliseconds. Reprocessing often leads to corrosion of the spring, which in turn leads to a slower response of the shield mechanism. This malfunction leaves the knife exposed for a longer period, with potential consequences for the patient.

The reprocessing of bladeless trocars raises two issues. In order to make the device more robust, the tips are molded into the trocar body, which limits the risk of the tip becoming dislodged during usage. This safety design is removed by reprocessors, who break off the tip in order to clean the device. Gluing the tip to the trocar has long been known by manufacturers to be insufficient. The second issue is material compatibility. Cracks in the tip are frequently identified, highlighting the limited robustness and impact of previous usage as well as the temperatures and chemicals used during reprocessing (Fig. 1).



Figure 1. Damage observed in reprocessed bladeless trocars.

Based on a study by Ethicon Endo-Surgery Inc. "Reliability Development Lap Materials Analysis Report: Examine the submitted Reprocessed Instruments for Evidence of Prior Use – on Bladeless Trocars", March 3, 2004.



Steam sterilization

It is widely accepted that autoclaving devices at 134°C for a minimum of 18 minutes and usage of 1N sodium hydroxide for 15 minutes is the preferred method for reducing the likelihood of the transmission of infectivity¹⁹.

A significant number of single use instruments, including catheters, are made of plastic and are not able to withstand such treatment. Even single use surgical devices such as stapling devices will be damaged or significantly changed. This makes adequately sterilizing many single use devices almost impossible. Figure 2 documents the deformation of stapling devices sterilized with what is likely to be steam.

Figure 2. A) Surface marks and deformation on a linear cutter caused by prolonged exposure to high temperatures. B) The white plastic tip of a linear cutter has become separated slightly, exhibiting a crack and blood and body fluid residues.

A)



R0038 Linear Cutter TLC75: Surface marks and deformation were caused by prolonged exposure to high temperature.

B)



R0039 Linear Cutter TLC75: White plastic tip is shown separated slightly, exhibiting a crack and blood and body fluid residues.



Public health aspects

Hospital acquired infection (HAI)

Throughout Europe, there is great concern about HAI, and major efforts are being extended in an attempt to eradicate this problem. It is regularly reported that hospital wards have been closed for cleaning following an outbreak of an infectious agent.

The UK National Audit Office estimated that in 2004 the rate of HAI in the UK ran at 9%, including some 5000 deaths. The cost to the UK NHS is over ≤ 1.5 billion/£1 billion each year. They also compared the UK with other countries and found the rate of HAI to be between 4% and 10%²⁰.

In Belgium it is estimated that there are approximately 108,100 cases of HAI per annum leading to as many as 3000 deaths a year²¹.

A single use device may be impossible to clean properly. By allowing refurbishment of these devices it is possible to transfer contaminated debris from patient to patient and hence increasing the potential for cross infection. Ensuring the correct use of single use devices eliminates a potential source of HAI²².

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Ethical aspects

Medical ethics

The patient is the ethical centre of healthcare. All who participate in patient care, directly or indirectly, are ethically obliged to provide adequate and appropriate care and to safeguard the patient's right to make informed healthcare decisions. Patients, due to their condition, require a greater degree of assistance and protection than persons who are not ill.

Medical ethics is based on the principles of beneficence (a duty to promote good and act in the best interest of the patient and the health of society) and non-maleficence (the duty to do no harm to patients). Information should be disclosed whenever it is considered to be material to the patient's understanding of his or her situation. Medical ethics also require that patients be fully informed of the risks and benefits of medical procedures²³. It requires the healthcare professional to inform the patient of the nature of the proposed treatment and disclose material risks that would influence the patient's decision whether or not to proceed. It should, therefore, be a principle to inform patients that single use devices are being reused and why.

For instance, consider two patients, A and B, both scheduled for cardiac catheterization. Patient A is treated with a new, single use device with no risk of infection transmission by the catheter. Moreover, neither the patient nor physician have to worry about any functional changes from previous uses. In contrast, patient B may be put at risk when treated with a reused single use device, without any corresponding therapeutic benefit, and without their knowledge or consent. Ethically, this is simply unacceptable. One cannot put patients at risk when there is a safer option of treatment.

Non-patient benefit

With regard to the patient, the primary question concerns the risks posed by being treated with a refurbished device intended by the manufacturer for single use. Besides non-treatment and any other less invasive procedures, the patient could be treated with a new device at no extra cost to them and avoid any potential complications. In effect, patients are put at non-quantified risk in their treatment, with no corresponding benefit other than allegedly contributing to savings for the hospital.

Different levels of healthcare provision

The question remains, who decides on which patients receive a single use medical device for the first time, and on which patients a single use device is to be used for the second or even third time?

Even if the patient has the choice between an intervention with a non-reused single use device and a refurbished single use device at a lower cost, this is



not ethical. It would lead to a different level of medical treatment depending on the financial resources of the patient.



Legal and liability aspects

Legal aspects

All manufacturers placing devices on the EU market are required to adhere to a set of Directives (Directive 93/42/EEC, Directive 98/79/EC and Directive 90/385/EEC).

Directive 93/42/EEC concerning medical devices specifies that the labelling of devices indicate 'for single use'²⁴ when they have been designed, manufactured and certified for single use. These devices are not accompanied by instructions for appropriate reprocessing as is required for devices declared by the manufacturer to be reusable. The manufacturer of a single use device may expect lawfully that:

- The device be discarded after its first use
- The manufacturer will not be responsible nor liable for any subsequent processes performed or later reuse.

Therefore, when the device is not discarded after its first use, all information²⁵ provided by the original manufacturer such as labelling, instructions for use, declaration of conformity and markings are no longer valid and those affixed to the device will be eliminated before any possible further processing.

Single use devices, which must always be labelled as such, are, by definition, for single use only. So, medical devices marked as single use devices are not intended to be reused. Only reusable medical devices, which are provided with instructions on the processes required for reuse, may be used more than once. Provided the information given by the manufacturers on how to reprocess the device is followed, the device should be suitable for reuse.

The Medical Devices Directive does not cover the reprocessing and the reuse of devices labelled "for single use".

Liability aspects

When a single use device is reprocessed and reused outside the manufacturer's instructions there are a number of issues that should be considered when assessing liability:

1) When a hospital decides to reuse a device it typically remains the owner of the device and refurbishes it or has it refurbished by a subcontractor. In both cases, the hospital is the refurbisher of the device. It shall at all times be responsible for the 'refurbished device' and the original manufacturer can and should not be held responsible for such a refurbished device. Exceptions are those medical devices that are explicitly intended by the manufacturer to be reusable. The safe reuse of these devices is obviously dependent



on the extent to which the hospital (or its subcontractor) has followed the instructions and processes for safe reprocessing.

When a device is used more than once, the process applied to render it appropriate for use is defined in Appendix 1. In brief, a reprocessed device has undergone routine maintenance, disassembly, cleaning, decontamination and sterilization, whilst a refurbished device must be restored to its original specifications, with documented evidence to show the initial conformity to the specifications given by the manufacturer still apply. A fully refurbished device must have been rebuilt or made as new from used devices.

- 2) Patients and users are entitled to expect that the quality of the 'refurbished' device is equivalent to the quality of the original device. They should also be informed if the treatment will be performed by such a device. In addition, doctors should comply with their deontological duties, which require choosing the treatment option that is most appropriate for the patient, which typically is the one with the least risk for the patient.
- 3) It is also important to underline the liability aspects when single use devices are reused. Directive 85/374/EEC establishes the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product. Producer has a wide meaning i.e. any participant in the production process or any person putting its name, trademark or other distinguishing feature on the product. The <u>original manufacturer</u> is in any event considered as a "producer", but also the <u>reuser (i.e. the hospital in the case of "reprocessed devices" and the manufacturer for "refurbished devices" and "fully refurbished" devices)_can, under certain circumstances be considered as a "producer" for the purposes of the product liability rules.</u>

From a legal point of view, the hospital itself will always be responsible for its reuse of single use devices in contradiction with the indications of the original manufacturer. The responsibility of the original manufacturer having labelled his products as 'single use' will not cover the reuse of single use devices by the hospital. Indeed, under the EU Directives, the manufacturer is only responsible for the quality and the efficacy of his product when it is used in accordance with its intended purpose.

Yet in practice, the manufacturer will likely be caught up in any action resulting from a defect in the refurbished single use device. It is therefore important that any regulatory action in the field of refurbishment ensures that the link to the original manufacturer is taken away, since he should not and cannot be held responsible for any refurbished or fully refurbished medical device.



Costs relating to liability

What is the current position of insurers? Cornelius Erbe from the German health insurance company Deutsche Angestellten-Krankenkasse (DAK) stated that reimbursement covers costs for single use products. He therefore expects that those ensured by the DAK will be treated with new single use devices only. He also indicated that he considers it to be fraud if a service that has been paid for is not delivered²⁶.



Economic aspects

Is refurbishment really cost saving?

Very little data has been published to support the claims made by the refurbishing industry that savings can be achieved by refurbishing single use items. At first glance, it appears very attractive to send a single use device for refurbishment and get it back at a lower price than a new device. If this process is repeated many times, the overall apparent savings could be considerable.

However, when the hidden costs are included, a dangerous mirage of cost savings is revealed, that may significantly reduce projected savings.

Examples:

- 1) The possible cost of treating HAI
- 2) Possible costs of using sub-optimal instruments
- 3) Cost of administration of the refurbishment activity within the healthcare establishment
- 4) Costs resulting from hospital liability when reprocessed single use devices cause harm, which would not be present if fresh single use devices were used (e.g. hygiene, shift in functionality).

In some cases you do not have to go that far. For example, a recent study on biopsy forceps²⁷ has shown that the total cost of using single use devices is 30% less compared with reusable devices. Differences in quality and procedure time were not even factored into this study.

The financial considerations of refurbishment and reuse of single use devices can be summarised as follows:

• There is an unsubstantiated expectation that the reuse of single use devices represents a significant cost-saving potential to the healthcare systems.

However,

- In the very few studies that estimate the true, overall cost of refurbishment and reuse, it is generally assumed that reuse represents an unacceptable increase in patient risk
- No study to date has answered the fundamental question, how can the refurbishment and reuse of single use devices be performed, and at what cost, in a way that meets the identical quality standards of the new device, thus eliminating the problem of increased patient risk?



Knowledge of costs

The reuse of single use devices is reported by the refurbishment industry²⁸ to deliver significant cost savings to healthcare systems by those who promote this concept. The argument against this is that the current cost reduction potential is immensely exaggerated because current refurbishing and reuse procedures of single use devices involve an increased risk to patients (compared with the use of a 'fresh' single use device).

Proponents of reuse sometimes argue that savings will be passed onto patients in the form of improved, more easily accessible services. However, this is a weak argument for the following reasons:

- 1. In private hospitals, any savings will partially be returned to investors as dividends
- 2. It is not guaranteed that savings will directly accrue to the patients subjected to the risk, because savings may well be applied to other hospital service areas
- 3. If the savings from the reuse of single use devices are deemed to be of benefit to the patient, no matter how remote or indirect, should they not have the right to decide how the savings are spent?

The conclusion is that only the purchasing department will benefit financially. Such benefits may have some indirect positive impact on patient care. However, it remains that any beneficial impact accruing to a particular patient is outweighed by the increased risks.

When reviewing the available literature, it is apparent that the comprehensive financial aspects of refurbishment and reuse of single use devices are very poorly investigated and described. This is either because such studies only indirectly address the issue of refurbishing of single use devices, or because the scope of the studies are very narrow. For example, they may only look at a single type of device²⁹. Furthermore, most studies lack a truly comprehensive view of the cost associated with the reuse, either because they completely lack a calculation at the macroeconomic level, or because they do not effectively incorporate any costs associated with the increased risk of the reused device³⁰. In fact, most investigations concerned with financial aspects do not even apply commonly agreed guidelines for Health Technology Assessment (HTA)³¹.

The main complication in performing true cost-benefit calculations in relation to refurbishment and reuse of single use devices is the challenge created by the increased patient risk involved. How can a price be assigned to increased patient risk? Some studies touch directly upon the problems associated with creating a true financial cost-benefit analysis³², while others ignore this complication entirely and therefore reach questionable financial conclusions.³³

Quantifying the price of increased patient risk may seem unethical, impossible, or both, but some studies attempt just that³⁰. These models try to estimate the costs associated with treatment of the negative effects of



refurbished and reused devices. This is done under the assumption that refurbishment and reuse will automatically represent an increased patient risk. The existence of the risk is fully accepted, and all that remains is to assign a cost to it. Clearly, this question is fundamentally flawed. The only logical question is:

How can a refurbished single use device perform according to the quality standards of a new single use device, with zero additional risk to the patient, and what would be the associated cost? This question has not yet been answered by any study.

Hidden costs

It is suspected that the calculation of savings due to the use of refurbished single use devices, made by the refurbishment industry, is based on simple arithmetic. The calculation is thought to compare the price of a 'fresh' single use device with that of a refurbished single use device, multiplied by the number of relevant procedures. It is far too simplistic to say the resulting figure would realistically represent the true cost savings accruing from the use of such devices.

For a complete calculation, other costs need to be taken into account, such as:

- **Personnel costs**: Cost of employing technical and qualified personnel for pre-cleaning immediately after the point of use, assembly, dismantling and replacement activities, maintenance and cleaning, repairs, wear and tear, sterilisation, sterilisation checks (chemical and biological), packaging, etc. In addition, personnel and/or costs for longer procedure time, re-operation and infections should be considered.
- **Investment costs:** Costly apparatus (capital equipment), buildings (designated for storage/spare parts); centralised sterilisation unit and special apparatus (autoclaves, machines for washing the devices, ultrasonic baths, means of cleaning, chemical products, disinfectants, lubricants, etc).
- Administrative costs: Systems used to communicate the results and establish traceability, managing reserves of spare parts/stock, distribution, transport, insurance premiums, documentation, validation procedures, auditing third party refurbishers, recording accidents and injuries involving members of staff, etc.
- **Utility costs**: Cost of providing the utilities associated with the sterilisation process (electricity and water consumption [including drainage]).
- Miscellaneous costs: Overheads, protective clothing (gloves, masks, safety glasses, double-thickness packaging materials), provision of safety training in connection with the re-utilisation of instruments, cost of treating post-operative infections and handling complaints,



compliance with the Good Manufacturing Practice (GMP) and Good Documentation Practice (GDP) norms, etc.

• **Cost of monitoring bodies** with appropriate jurisdiction (e.g. Medical Devices Department of the Federal Public Pharmacy Inspection Service)

This does not include the hidden costs related to the risks of using refurbished single use devices, such as HAI, complications, litigation etc.



Regulatory Framework

Within Europe, there is a wide diversity in terms of legislation relating to the reuse of single use devices. For example, whilst France has banned this practice, Germany has guidelines regarding reprocessing but not with respect to refurbishment. In the US, guidelines are in place for the reuse of single use devices. The following section provides a brief overview of the position both in Europe and in the US with regard to reusing single use devices. A list of definition of terms used in this section is provided in Appendix 1.

The regulatory framework at EU level

Medical devices are covered, at European level, by three Directives specific to various categories of medical devices. These Directives, which set out the regulatory requirements necessary for the safe placing of medical devices on the EU market, have been transposed into national legislations.

These directives are:

- Directive 90/385/EEC concerning active implantable medical devices
- Directive 93/42/EEC concerning medical devices (MDD)
- Directive 98/79/EC concerning *in vitro* diagnostic medical devices

According to the above Directives, a medical device can be marketed and/or brought into service for the first time in the EU only if it complies with the requirements laid down in the Directive itself 'when duly supplied and properly installed, maintained and used in accordance with its intended purpose'³⁴. From this basic requirement, one can assume that European citizens are entitled to expect treatment exclusively with devices complying with the requirements of the Directives. With regard to 'intended purpose', the MDD means (article 1.2g) 'the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials'. In other words, the patient is covered by the benefits of the legislation only when treated with a device according to its specific use, identified by the manufacturer, and indicated on the label.

When a device is intended by its manufacturer to be used only once, the manufacturer has the obligation to inform the user by specifying on the label that the device is intended to be used only once on a patient and then discarded (point 13.3.f of Annex I of the MDD). When a device is intended by its manufacturer for multiple use, the manufacturer must give information about the appropriate processes required for the device to be able to be re-utilised, including cleaning, disinfecting, repackaging and, if applicable, the method of sterilisation (point 13.6 h) of Annex I to the MDD). No information is given in the MDD regarding the reuse of single use devices. Even the revised text of the 93/42/EEC Directive (Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007) neglects to mention



anything about the reuse of single use devices. However, the European Commission has been asked to analyse the situation and to submit a report on this issue to the European Parliament and to the Council by September 2010. Based on this report the Commission shall submit any additional proposal "it may deem appropriate in order to ensure a high level of health" (Article 12a, MDD).

The use of a device outside its specifications is not covered by the Directives. Therefore, it has to be seen as an off-label use. As with the pharmaceutical field, this can only be done under the responsibility of the medical professional and within the limits imposed by national legislation if existing.

Regulatory framework in EU member states (including Switzerland)

Spain, Italy, Portugal and France have formally or through the interpretation of their local Health Authority, banned the reuse of single use devices. Germany requires proof from the reprocessor that the reprocessing procedure is safe and provides strict guidelines for the documentation and validation processes of the device to ensure the safety of patients, users and third parties.² The UK has issued a strong statement cautioning against reuse. It is of particular interest to analyse the situation in the UK, where the MHRA has re-published a note on the issue². In Belgium, the political debate to allow refurbishment is still active.

The situation in France

France addressed reuse quite early on, and now bans it. In July 1999 the highest French court, the Cour de Cassation, ruled that reuse is a deception of the patient³⁵. This is because:

- The patient, who faces the risk, has no benefit from being treated with a reused rather than a new single use device and is not informed
- Is charged exactly the same price for the refurbished device as for the new device.

This led to a ruling of the court in Montpellier in March 2000 that the reuse of CE-marked single use devices was illegal. At that time there was no regulation banning the reuse of all devices. The basis of the ruling was the requirement that devices must be used as intended by the manufacturer, and that the reuse of single use devices was considered off-label use. A similar law did not previously exist for non-CE marked devices.

In June 2001 a law was published banning the reuse of any single use devices irrespective of CE marking³⁶.



The situation in Germany

In Germany the issue of HAI is even more dramatic. According to research by the German hygienist Klaus-Dieter Zastrow^{37,38,39}, 800,000 patients acquire an infection every year, resulting in 40,000 deaths and costing approximately €3 billion annually. It is becoming more difficult to manage due to the increase of antibiotic resistance in Germany.

Among the many elements giving rise to HAI, the reuse of single use devices that have not been designed to be cleaned and sterilised is very important.

German law neither regulates refurbishment to the same level as manufacturing nor bans the refurbishment of single use devices. Existing regulations address reprocessing only and do not differentiate between single use devices and multiple use devices relating to reprocessing. These regulations do tolerate refurbishment by hospitals and third parties. However, certain requirements exist. Whoever is performing reprocessing for others must register this activity and conform to German regulations on reprocessing. Allowing reprocessing of single use devices requires guidance documents and recommendations for applying quality systems standards such as EN 13485. This is possible because devices are not newly placed on the market and consequently the liability, including responsibility for the new device, is transferred to the owner of the device. This is typically the hospital or user. The responsibility for hygiene and performance is also included in this liability⁴⁰.

The German authorities have published guidelines on 'Hygienic Requirements for Processing of Medical Devices'⁴¹. This recommendation provides excellent guidance on reprocessing in general. It is a risk-based approach, with increasing requirements depending on the invasiveness of the device and the ability to steam sterilise it. This guidance is a thorough approach to enhancing the safety of reprocessing, but it cannot and does not address the specific issue of the refurbishment of single use devices. Issues such as the labelling of the device itself, vigilance reporting and design controls are not addressed. While the document is a worthy addition to the regulatory framework, it does not replace the need to address the refurbishment of single use devices in a regulation, or to ban the practice, as in France.

In November 2003 a survey was carried out on behalf of the German industry association, BVMed, and DGVP, a patient association⁴². In this survey involving 1000 people, it was apparent that the general public had very limited information about the practice. The main results were that 87% of the population were not aware that single use devices are used more than once, 22% considered that reuse of single use devices was justified on financial grounds, and 91% wanted the right to refuse to be treated with a refurbished single use device.



The situation in the UK

The British MHRA has issued a bulletin³⁵ warning against the reuse of single use devices and drawing attention to the legal responsibilities of refurbishing single use devices:

 User organisations, professional users and reprocessors who prepare single use devices for further episodes of use may be transferring legal liability for the safe performance of the product from the manufacturer to themselves, or the organisation that employs them.

The MHRA bulletin goes on to list the potential for offence according to English law:

 If a refurbished device is supplied to another legal entity and the device is not fit for its intended purpose, the reprocessor and professional user may be committing an offence or contravening national guidance under one or more of the following:

Health and Safety at Work Act 1974

Such activities may contravene the provisions relating to 'general duties' and expose patients or staff to risk.

Part 1 of the Consumer Protection Act 1987

There may be exposure to civil liability, with payment of damages for any injury caused to another person by the device, either on the basis of negligence or under the strict liability provisions of Part I of the Consumer Protection Act 1987, if the device is found to be defective (i.e. does not provide the expected level of safety).

The General Product Safety Regulations 2005

The General Product Safety Regulations apply when the device is intended for consumers or likely to be used by the consumer. They apply to the:

(a) **Producer** – a manufacturer or importer. This includes a person who reconditions a product but only if he is not subject to the Medical Devices Regulations. It also includes any professionals in the supply chain whose activities may affect the safety of the device

(b) **Distributor** – professionals in the supply chain whose activities do not affect the safety properties of the device. A producer is also required to provide consumers with relevant information to enable them to assess any such device for placing on the market.



The Medical Devices Regulations 2002

Medical devices manufactured and placed on the market within the UK and throughout the European Union (EU) are subject to specific regulation. These require that medical devices now placed on the market carry a CE marking. This denotes compliance with a number of essential requirements covering the safety and performance of the medical device.

Standards for Better Health

The Department of Health published Standards for Better Health (SfBH) in July 2004. All NHS organisations are required to take the SfBH into account when developing, providing and commissioning healthcare. The Healthcare Commission will use the standards as a key component of their assessments. Part b of core standard C4 (in the First Domain – safety) is particularly relevant to medical devices and ensures 'all risks associated with the acquisition and use of medical devices are minimised'.

The situation in Belgium

In Belgium, the debate on refurbishment has prompted the National Medical Devices Association (UNAMEC) to publish a document²⁰, which echoes the MHRA arguments.

In particular the UNAMEC document specifies that:

The original manufacturer is, in principle, solely responsible for the safety and utilisation of his medical device within the limits of its intended use and any items mentioned on the labelling.

The manufacturer is responsible for the first use of a product designed for single use. Some Belgian legal experts, as well as recent jurisprudence, suggest that even though they are subject to the law regarding factual responsibility regarding their products, manufacturers must anticipate some reasonable abuse. In the case where a manufacturer knows that his product has already been used for several years without his instructions for use being taken into account, such re-utilisation cannot be simply classified as unanticipated use although this is clearly an off label use.

In contrast, the Conseil supérieur d'Hygiène (Superior Health Council), a scientific body under the aegis of the Federal Public Health Service, Security of the Food Chain and the Environment, is defending the following position: Any re-utilisation or use of a medical device against the manufacturer's instructions is not subject to the Royal Decree of 18/03/99 (the transposition into Belgian Law of Directive 93/42/EEC). The manufacturer is only responsible for the quality and the functioning of the medical device when it is used for the purpose for which it is intended. If an institution nevertheless



decides to re-utilise the device, everybody involved within that institution is responsible for the quality and the functioning of the medical device. In other words, this includes the hospital pharmacist and the person responsible for carrying out the sterilisation process, as well as the doctor who reused the medical device and the hospital's director.

Total responsibility (legal and regulatory) for a refurbished product rests with the facilities authorizing and with those performing the refurbishment. The original manufacturer cannot have control or responsibility for the refurbishment of a single use device. This includes damage due to handling, performance testing to product specification, labelling (which includes expiry dating relative to the materials as well as sterilization), and packaging considerations. Conversely, the reprocessor may undermine mitigation through risk management for the device.

Regulatory framework outside the EU

The situation in the USA

The United States has regulations addressing the reuse of single use devices, whereas most other countries provide limited or no regulatory framework to determine efficacy of the reprocessing. Introduced in 2002, the Medical Device User Fee and Modernization Act (MDUFMA) outlines US specific provisions for regulating the refurbishment of single use devices. To meet this regulation, the reprocessor is tasked with providing evidence of the safety of the refurbished device, to the US Food and Drug Administration (FDA), principally via a 510(k) submission.

The situation in Australia

In Australia, the Therapeutic Goods Administration, the national regulator for medical devices, in 2003 introduced a national regulatory framework for the re-manufacture of single use devices for the purpose of reuse⁴³.

The position of the World Health Organization (WHO)

The WHO has stated 'the safest and most unambiguous method for ensuring that there is no risk of residual infectivity on surgical instruments is to discard and destroy them by incineration ... this strategy should be universally applied to those devices and materials that are designed to be disposable.'⁴⁴



Key findings and scientific evidence

Scientific studies – a reality check

A solid basis for the discussion on the reuse of single use devices is scientific evidence in published articles and research by users, academia, health authorities and manufacturers.

When reviewing the reuse of single use devices, the following areas should be addressed:

- Level of cleanliness that can be achieved for single use devices and the impact of materials left on the products after reprocessing such as chemicals and organic materials
- Sterility of refurbished single use devices
- Functionality and performance of the device after usage and reprocessing
- Prion diseases such as the CJD
- Contamination with bacteria, viruses or prions.

The following section provides extensive evidence surrounding the reuse of a variety of single use devices including catheters, harmonic scalpels, endoscopic stapling devices, biopsy forceps, clip appliers, ophthalmic devices and shaver blades.

Reprocessing catheters

Studies on the reuse of single use devices go back to the early 1980's when the impact of reusing catheters was researched. In 1982, the British Medical Journal⁴⁵ reported an increasing risk of thrombosis for reused catheters. Patients treated with refurbished catheters rapidly developed thrombi on 'second hand' flotation catheters; a condition usually not seen that quickly with a new device.

Electrophysiology (EP) catheters

Although scientific evidence exists regarding the impact of contamination, the term 'sterile dirt' has been used to downplay the impact of contamination on patients and has been extensively discussed. In 1999, Edward K. Li from Biosense Webster Inc. conducted a thrombogenicity study together with the NAMSA laboratories on refurbished EP catheters, which were awaiting reuse after reprocessing by hospitals and third party reprocessing firms⁴⁶. Tips of refurbished catheters were tested in an *in vivo* thrombogenicity test and compared with unused catheters. The results showed a significant increase in thrombosis on refurbished catheters, which was associated with significantly increased risk to the patient (Fig. 3).



Figure 3. Reprocessed catheter tips contaminated with proteins from previous patients



Angiographic instruments

Prof. Andreas Beck conducted a comprehensive study on angiographic instruments¹⁶. A total of 1320 instruments including catheters and guide wires refurbished by hospitals and third party reprocessors were studied. The devices were collected from German health institutions and examined for contamination and signs of deterioration. The results showed physical damage of products such as nicks, kinks, roughness, erosion, tears and changes in material properties. Third party reprocessing did not show a significant improvement and more than 40% of third party refurbished devices displayed marked damage. In the case of teflon-coated wires, they 'were full of defects in every case' (Fig. 4).

Figure 4. A) PTCA balloon catheter refurbished by a third party and soiled with contrast medium and blood. B) A comparison of a PTCA balloon and a household match demonstrating the small size of the catheter and how difficult it would be to ensure effective cleaning of such a small device.







Consequences of using refurbished single use catheters

Prof. Beck also observed other problems. As well as contamination and damage, in three cases refurbished single use devices either broke or were severely contaminated. As a result, additional surgery was required to retrieve components such as catheter tips and wires. Moreover, tread dissection of an artery was necessary because a refurbished balloon catheter could not be deflated due to contamination (Fig. 5).



Figure 5. A) Contamination of a reprocessed catheter prevents deflation of the catheter resulting in severe damage to the iliac artery requiring vascular bypass surgery. B) During removal of a reprocessed balloon catheter the catheter tip and wire were lost requiring surgical intervention to retrieve those parts left in the patient.

A)





Clinically measurable differences in re-stenosis using new versus refurbished single use catheters

Clinically measurable differences in using new or refurbished PTCA balloon catheters have been found during a study by the Center for Cardiovascular Diseases, Rotenburg an der Fulda, Germany⁴⁷. In all primary failures using resterilized balloon catheters, new ones of the same nominal diameter were successful. Reused catheters did show a higher stenosis rate (potentially caused by the increased diameter of the previously stretched device) and more importantly the re-stenosis rate after reuse was higher, requiring another intervention.

Contamination of catheters not removed during reprocessing

From 1999 until today, the medical devices industry has conducted various studies with similar results. During an analysis of 27 refurbished catheters used in cardiac catheterization,⁴⁸ more than a quarter (26%) of devices were contaminated with blood and proteinaceous material; four out of eight PTCA catheters (50%) had residuals of contrast media (Fig. 6). Contamination was typically found inside the narrow lumen and included material from previous patients and material most likely added during the refurbishment procedures such as aluminum. Furthermore, physical damage due to the incompatibility with the harsh reprocessing environment such as flaking markers or kinks along the fragile catheter body were found (Fig. 7).



Figure 6. A) Proteinaceous contamination on the inner surface of a guiding catheter. B) XPS Scan / Spectrum confirming that the reddish contamination is blood. C) Scanning electron micrograph (SEM) photograph to confirm the presence of a red blood cell





Figure 7. A) Flaking marker on a reprocessed balloon catheter, which may result in release of particles into the patient's bloodstream. B) Marker of a new balloon catheter. C) Aluminium contamination in the lumen of a balloon catheter.







Changing the material properties of catheters by reprocessing

Catheters are often made from soft plastics to reduce patient discomfort and stress to inner vessels as far as possible. Soft tips are added to the catheters to further reduce the negative impact to the patients and modern catheters are coated to reduce infection or to increase the floating of catheters in the blood stream. Such coatings may well be removed from the catheter during reprocessing as they were not designed to withstand disinfection and cleaning procedures. Reuse and reprocessing also has an impact on the physical parameters such as the flexibility; with increasing reprocessing products become more brittle and rigid. The National University of San Juan⁴⁹ found that catheters were less soft with increasing reprocessing, documented by increasing glass transition temperature and changes in molecular weight, documenting changes in the plastic itself and increased surface roughness. Possible clinical adverse events resulting from those changes include leaching of toxic agents, more rigid devices leading to breakage, increased retention of proteins in the rough surface and increased bacterial adhesion due to the topography modification.

Another challenge when reusing catheters is that it is difficult to predict when a catheter will degrade to a degree that it will break. When and if depends on the type of polymer used and how it is manufactured. While some plastics degrade over time and show signs of wear others seem to fail spontaneously (Fig. 8).



Figure 8. A) Degradation-time curves demonstrating how different polymers degrade over time. B) Photograph showing kinks along a reprocessed single use catheter as a result of previous usage or reprocessing.



David L. West et al. "Scientific & Regulatory Consideration for the Review and Approval of Reprocessed Single Use Devices Pre - market Submissions".

B)

A)



A12 kinks along body of a catheter, product is not fit for use

Evidence documenting clinical safety and performance of refurbished single use devices

In 2006 the Italian Health authority and the University in Trento, Italy conducted a study on 'Reuse of single use medical devices for interventional



cardiology⁵⁰. The conclusion of the study was that clinical trials to document clinical safety do not exist as of today and may not be justifiable due to ethical constraints. The researchers found that with an increasing number of sterilization cycles a significant number of EP catheters could no longer be sterilized. After four cycles 2.9% of the devices were non-sterile, leaving the question of whether the required sterility assurance level of 10⁻⁶ could be reached at all.

The fact that even devices considered less difficult to reprocess present significant risks after reprocessing has been demonstrated in a German study⁵¹. EP catheters refurbished by a reprocessing firm showed markings and contaminations (Fig. 9). As shown in the Trento study, such contamination may be a cause of thrombosis, as well as contribute to non-sterility.

Figure 9. A reprocessed EP catheter showing markings from reprocessing as well as the remains of contamination.



A reported incident with a reused single use EP catheter

Reprocessing of EP catheters leading to serious complications has been demonstrated by an incident reported to the German health authorities in early 2000. An electrode from an EP catheter used inside a patient's heart, trapped the heart valve of a young African athlete and led to an insufficient heart valve (Fig. 10). Although the investigations did not lead to a clear identification of the cause, it is possible that the design of the single use catheter might have been the cause. It is a known fact that plastics shrink when reprocessed under higher temperatures and this shrinking is not taken into account during the design and manufacture.

Figure 10. A third party refurbished EP catheter resulting in an insufficient heart valve. As the electrodes separated the heart valve was locked between the electrodes.





Surgical and minimally invasive surgical devices – harmonic scalpels

In recent years, significant improvements have been made in the development of surgical devices. Surgery is developing from open, to minimally invasive and recently to non-surgically invasive procedures. Benefits of these procedures include shorter hospital stays, a quicker return to work and less pain, directly translating to a better quality of life.

Instruments required for such procedures, which are often miniaturized, multifunctional high technology devices, are frequently refurbished. Studies conducted by medical device manufacturers on refurbished single use clip appliers, clamps, staplers, cautery devices and trocars from hospitals in the US and Germany⁵², tested the devices for material integrity, contamination and performance against manufacturers' specification. Performance tests were conducted on refurbished and new devices in parallel. The results of examination of 42 refurbished devices were as follows:

- 16 devices (38%) had open packaging (damaged seals, punctured or torn packaging)
- 23 devices (55%) were contaminated with blood and tissue (Fig. 11)
- 11 devices (26%) had physical defects
- 11 devices (26%) failed the functional test.

New devices did not show any of these defects.

Figure 11. A refurbished single use harmonic scalpel showing silicone and dried body fluids and tissue on the teflon clamp pad.



Reprocessing of devices with long shafts, such as single use endoscopic scissors and endoscopic scalpels

In 2001, Roth, Heeg, and Reichl studied the effects of hospital-recommended cleaning and sterilization practices on single use laparoscopic instruments^{53,54}. The instruments included endoscopic scissors and endoscopic harmonic scalpels. The instruments were purposely contaminated with blood, then cleaned, disinfected and sterilized using hospitalrecommended techniques and finally examined. The results showed all instruments in the study group remained contaminated after cleaning. Moreover, sterilization could not eliminate the challenge microorganisms completely. The authors concluded that this could lead to the opportunistic growth of organisms or viruses and result in increased risk for the patient. This



study documented that devices not designed to be cleaned do withstand all currently available manual or automated cleaning methods. In order to be effectively cleaned a device must be designed for cleaning.

When attempting to flush the single use devices a distribution of the contamination rather than cleaning was achieved (Fig. 12). In the same study, 114 clinically used devices received from the European market were evaluated. All devices were refurbished and sterilized and were awaiting use on the next patients. The results showed that 33% of the devices were incomplete, 11% of the sterile barrier packaging was damaged and 18 out of 27 devices tested were non-sterile. Most of the inspected devices showed residual contamination in the hinges and under the isolation coats (Fig. 13). This was especially true for harmonic scalpels. These findings indicate that the cleaning agent penetrates into the device and dilutes the blood but cannot then be flushed out of the device. Therefore, contamination and disinfection solution remain in the devices. In summary, none of the devices meet current standards for cleaning, disinfection and sterilization. More importantly, none of the refurbished single use instruments were suitable for use in humans.

Figure 12. Demonstration of the distribution of contamination rather than removal as assessed using the radionuclide method of detection.



Figure 13. Demonstration of the contamination on a reprocessed single use harmonic scalpel



Clinical relevance of reprocessing high tech surgical devices such as harmonic scalpels

In 2006, the clinical performance of refurbished single use harmonic scalpels was assessed⁵⁵. The results of the *in vivo* animal tests demonstrated that new devices provided superior hemostasis, which is essential for a device used in minimally invasive surgery where the control of bleeding is of utmost importance. It was also found that refurbished devices reached higher temperatures, which may result in tissue damage away from the surgeons



view. This study demonstrated that refurbished single use harmonic scalpels do not perform like new devices during surgery. Consequently, it cannot be claimed that refurbished devices are equivalent; a key consideration is whether this additional risk is acceptable.

Breaking devices open as part of the reprocessing process

It is very difficult and often impossible to clean single use medical devices. Therefore, some firms, in particular third party reprocessing firms, have started breaking products apart in order to access the often narrow and complex geometrical structures of those devices. Parts destroyed when breaking the devices into pieces are replaced or glued together. Other components, which wear off during usage, are replaced by components viewed as being similar by the refurbishment firm⁵⁶. Such activities are conducted without a full assessment to document safety levels required by the MDD for new devices (Fig. 14).

But what is the impact when devices such as the harmonic scalpel are refurbished? Researchers analyzing third party refurbished surgical devices found that the replacements made during refurbishment were often unsatisfactory⁵⁷. Once the devices had been broken apart, the components were replaced with parts having a different geometry. In particular, clamps essential to securely hold a teflon pad in place were removed, creating a potential risk of blade breakage.

Figure 14. A) The replacement of a rotation knob upside-down, a product that would never normally leave the manufacturers. B) Damaged bushing as a result of improper assembly during reprocessing. C) A replacement pad (front) with different geometries and unknown biocompatibility.



Sterility after devices such as harmonic scalpels are broken apart

In 2003, the HygCen Institute in Schwerin conducted a sterility test for 19 ultrasonic cutting devices refurbished by a third party⁵⁸. Seventeen instruments showed packaging damage due to the use of inadequate packaging and three of 19 devices tested were non-sterile. Since the devices were broken apart prior to cleaning, the reason for the high number of non-sterile devices is not clear and it was speculated that the sterilization method, in this case low temperature ETO at 37°C, may be a contributing factor. ETO sterilization is known to be effective only if products are completely dry and if



the ETO gas can reach all areas. As a study performed by SMP GmbH showed, it is very difficult to ensure reprocessed harmonic scalpels are completely dry. The SMP researchers found water inside third party refurbished harmonic scalpels (Fig 15)⁵⁹.

Figure 15. Water can be seen on the inside of the push rod.



Endoscopic cutters and stapling devices – reprocessing without disassembly and with usage of chemicals for disinfection and cleaning

In an attempt to clean complex devices such as endoscopic cutter and staplers, reprocessors usually use harsh chemicals not compatible with the materials used for the manufacturing of single use devices. In another study performed by SMP, reddish brown contamination was found over the entire length of refurbished endoscopic stapling devices⁶⁰. These devices are used in surgery, where exact performance and cleanliness is essential (Fig. 16). Comparison with new, unused devices documented that this contamination in fact results from the refurbishment and previous usage.

Figure 16. Reddish brown contamination observed over the full length of the third party reprocessed endoscopic stapling device



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What is the potential impact of using reprocessed stapling devices during surgery?

Besides the known issues of introducing foreign chemicals or proteins into the human body, there is also a risk of decreased performance. For example, additional force could be required during usage of the device to perform routine functions. Moreover, blockage could lead to an inability to remove the device from stapled vessels, requiring the device to be cut out of the patient.

Reprocessing of single use biopsy forceps

In a study in 1999, researchers from the University in Tübingen, Germany, analyzed ten refurbished single use biopsy forceps⁶¹. These devices had been sterilized by the reprocessing hospital and labeled as sterile. When analyzed, 90% of the refurbished devices were found to be non-sterile. The poor sterilization results achieved for these instruments were not unexpected, since effective cleaning is the prime precondition for successful sterilization and the geometry of single use biopsy forceps prevents removal of all contamination (Fig. 17).

Figure 17. A) The coil of new, unused biopsy forceps. B) The coil of reprocessed biopsy forceps



Pictures: Klaus Roth, SMP

Reprocessing of clip appliers

The Department of Health Policy at the Tokyo Medical and Dental University in Japan conducted a study on endoscopic clips⁶². The results of the *in vitro* study showed contamination of the endoscope clip appliers with debris. The study demonstrated that the clip holding power was reduced for the refurbished clips, which is important in the minimization of post operative leakage.



The fact that endoscopic clip appliers are difficult or even impossible to clean was demonstrated in an earlier study conducted by a medical device manufacturer. The level of contamination meant that the devices failed to function properly due to the amount of debris located in the clip feed track (Fig. 18)⁶³. In this study, which reviewed devices typically used in minimally invasive surgery, 55% of devices were contaminated, 38% were found to be non-sterile and 50% of the devices were out of specification. Out of specification devices may contribute to the findings of the Japanese study indicating lower holding forces.

Figure 18. A) A mass of blood and proteinaceous material ejected from a reprocessed clip appliers after first firing. B) Contamination of the clip applier resulting in malfunction due to the build up of debris in the clip feed track. C) Contamination of an MIC clamp.

A)

B)



C)



Reprocessing ophthalmic devices

There have been longstanding safety concerns with the reuse of single use surgical devices for ophthalmic surgery because of the risk of transmitting spongiform encephalopathies (TSE's) or other viruses such as HIV, herpes, or hepatitis B and C. Additionally, there are also concerns regarding toxic anterior segment syndrome (TASS) through the exposure to toxins from reused single use instruments. TASS is a sterile postoperative inflammatory reaction caused by a noninfectious substance such as bacterial endotoxin entering the eye⁶⁴. Outbreaks of TASS are a serious issue and may be caused by contaminated devices. This was explored in an article by Carol Ruehl, RN, CRNO. In this article, a series of photos taken with a scanning

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electron microscope were used to illustrate the increasing signs of degradation that take place with phaco tip reuse. Additional photos in this article demonstrated this same process occurring with reused tubing where tiny particulate matter gathered within the tubing as it was reused. This could then have been introduced into the next eye. This illustrates a very real concern with the reuse of single use devices, specifically single use devices with small nooks and crevices, which cannot be sufficiently cleaned for reuse without physical damage to the device. In addition, reprocessing of single use devices introduces additional uncontrolled variables that can contribute to damage to tip bevel, as well as additional contaminants or debris and damage to the surface finish. Using Scanning Electron Microscopes (SEMs), Fig. 19 illustrates biological materials collecting in reused tubing, as well as phaco tip degradation. A brand new tip is also pictured for comparison.

Figure 19. A) Biological materials collecting in the reused tubing. B) Degradation and material erosion of the reused phaco tip. C) A new phaco tip for comparison.



Reprocessing of shaver blades

To assess the quality and level of cleanliness of refurbished single use shaver blades, the Department of Orthopedic Surgery at the Loma Linda University in California compared seven new and 27 refurbished single use shaver blades. Of the refurbished shaver blades, 48% had detectable levels of protein and 63% were contaminated with nucleic acid⁶⁵. All of the refurbished blades showed some level of damage or wear. In contrast, none of the new controls showed any damage or contamination. In functional tests, menisci were cut with refurbished and new shaver blades. The smoothness of the surface is an important factor for the quality of the surgery and this was evaluated using laser scanning cytometry. Cutting with new devices led to a smoother surface than with the refurbished shaver blades. The rough edges resulting from use of the refurbished shaver blades may well contribute to additional pain for the patient after surgery.

These findings support an earlier study conducted by the SMP and NMI^{66,67}. This investigation showed that due to the high number of revolutions of the inner tube, the bearing regions were under greater stress, showing strong inhomogeneous layers often combined with material defects and particles. In a simulation of reprocessing, even with high pressure rinsing,



none of the single use shaver blades could be cleaned. Multiple failures occurred and contamination was found on the refurbished shaver blades (Fig. 20).

Figure 20. Various abnormalities observed in reprocessed single use shaver blades

A)

B)

C)

D)



Numerous small particles on the inner shave blade

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 1 56111-SHAV-05-01

Strong inhomogeneous oxidation and lots of small particles on the inner surface of the shave blade

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 2 56111-SHAV-05-02 Electron microscopic investigation of a shave blade showing heavy inhomogeneous oxidation and lots of small particles on the inner surface.

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 5 56111-SHAV-05-02 Innumerable particles, defects and cracks surrounding the weld on the surface of the inner shave blade.

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 2 56111-SHAV-23-02

Contaminated coatings on the outer surface of the shave blade.

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 4 56111-SHAV-14-02-02

E)



2 mm









Electron microscopic investigation of a shave blade showing particles, defects and cracks surrounding the weld on the surface of the inner shave blade.

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 5 56111-SHAV-23-02 Destroyed polymer-surface and contamination at the outer casing.

Source: Investigation of Clinical Reprocessed Shavers, NMI, Tübingen 2001, MNI LM-Analyse Fig 2 56111-SHAV-14-02-01

Considerable signs of use and cracks in the outer shave blade shank.

Source: Evaluation of Reprocessed Blades by 2004

G)

F)



Reprocessing in the public media

While initially discussed solely within the medical fraternity, interest in the reuse of single use devices has escalated over recent years. Tragic events such as the death of a nine year old boy during a relatively simple surgical procedure due to negligence and the reuse of a single use breathing tube worth little more than 1 Euro, have led to this surge in media interest⁶⁸.

In the US, several articles by the Washington Post have documented the issues inherent in the reuse of single use devices. For example, the death of Daniel Blejer who died from CJD, which his wife believes he contracted during brain surgery⁶⁹. The importance of this issue is further highlighted by the case of a cardiologist who found that a refurbished single use catheter became separated in the body of a child during surgery⁷⁰. Since then he has refused to reuse any single use products.

The Associated Press⁷¹ has reported of the tragedy of Sean, a boy who is unable to eat or drink by mouth and must be fed by a permanent nasogastic tube. The family alleged the injury occurred because the tip of the plastic breathing tube, which was not intended by the manufacturer for reuse, had been bent during reprocessing, cleaning and heat sterilization.

In 2006, the German TV station ARD showed documentation on reuse of single use devices. In one report, a refurbished single use respiration tube burst during surgery. The patient was in a coma for two weeks and suffered a heart attack and a string of complications due to the burst respiration tube⁷². In March 2007, the Kontraste journalists followed up with a second investigation. According to the German Society for Hospital Hygiene, 'every year, half a million people are infected with dangerous germs in hospitals. One reason is a lack of hygiene.' The journalists asked the question 'but who would have even considered single use medical devices in this context?' The Austrian heart surgeon Prof. Felix Unger commented 'the recycling of single use equipment is totally unauthorized at this time and is unacceptable for our patients. The practice of re-using instruments introduces an additional source of danger into the operating theatre'. Upon request of the TV station, Klaus Roth, one of the leading researchers specializing in the cleaning of medical devices, analyzed refurbished shaver blades. He found blades were damaged, contaminated with cleaning agents and in one case even a steel wire was found. These findings were similar to those of the Loma Linda University discussed earlier⁷³.



Conclusions

This paper has described all the issues surrounding the reuse of single use devices. There is now a wealth of evidence to suggest that patient safety is compromised if single use devices are reused. The inability to adequately clean, decontaminate and sterilize the devices as well as the potential failure of the device on repeated use are important reasons why Eucomed strongly recommends against the use of single use devices more than once. Whilst some countries have implemented legislation banning this practice, other countries are still turning a blind eye to the reuse of single use devices. Europe-wide measures are required to ensure patient safety is no longer compromised by the repeated use of single use devices.



Q&A

Q1. Can a single use device be cleaned and sterilised efficiently?

Single use devices are not designed to be cleaned and sterilized. The geometry of many devices prevents proper cleaning. Materials may degrade or absorb chemicals used during the cleaning process or simply will not withstand multiple sterilization cycles. Many single use devices are designed to withstand a single gamma sterilization cycle only and its geometry does not allow for methods such as ETO or steam.

Q2. Does reprocessing of single use devices affect the sterility of the device?

Single use devices are designed to meet the statistical criteria for achieving one instance in one million of being delivered to the final user in a non-sterile condition. This can only be achieved when devices are manufactured and sterilized starting from homogeneous lots. Used single use devices cannot be considered as part of a homogeneous lot. (NB. Sterility is defined worldwide in this way as it is impossible to test without destroying it.)

Q3. Does the refurbishment of single use devices affect their performance?

There is a high probability that initial usage and reprocessing alters the performance of the device. This is due to mechanical, chemical and thermal stress put on materials specifically chosen to achieve maximum performance for a single usage and not to achieve any reliability for repeated usage and reprocessing. Many modern devices include coatings or lubrications washed away during refurbishment.

Q4. Is it possible to cross infect patients by using refurbished single use devices?

Biological residues are often found in refurbished single use devices. Some may cause pyrogenic reactions even if the device is correctly sterilized, others (e.g. prions) cannot be eliminated by sterilization and therefore carry a high potential of contamination and the risk of infecting the next patient.

Q5. Is it moral or ethical to treat a patient with a refurbished medical device of unknown and potentially lower quality, performance or cleanliness than when it was used on the previous patient?

Eucomed considers that no patient should face these risks.



Q6. Is it financially advantageous to reprocess single use items rather than use them according to the manufacturers' instructions?

Eucomed warns users of reprocessed single use devices of the mirage of sustainable cost savings. There is no evidence that the refurbishment of used single use devices represents savings if all hospital activities (e.g. pre-cleaning or longer procedure times) are taken into account.

Q7. What is the legal and regulatory position of reusing single use instruments?

As of today, whilst there is no European legislation on this issue, the practice of reprocessing used single use devices is prohibited by law or by interpretation of the national Competent Authorities in many EU member states and tolerated in other member states.



Appendix 1 Definitions used in this paper

The following clarifications provide an explanation in plain terms of some of the definitions contained in this text.

Reprocessing: Steps needed such as routine maintenance, disassembly, cleaning and sterilization to allow safe reuse as defined and evaluated in the pre-market conformity assessment.

Refurbishing: Restoring the device to its original specifications with documented evidence that the initial conformity assessment of the medical device is still valid, regarding safety, reliability, intended use and essential requirements.

Full refurbishment: Refurbishing, rebuilding, or making as new from used devices, a product capable of a new useful life, either for its original intended purpose, or with new specifications or a different intended purpose, validated to perform in accordance with current best practice.

Validation: Confirmation by examination and provisions of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled (FDA CFR 820.3(z)). Confirmation that the device is fit for its intended use. For medical devices this confirmation usually requires clinical evidence.

Single use device: A device intended to be used only once on a single patient.

Intended purpose: The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and / or in promotional materials.

Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market.

Essential requirements: Design and product criteria, which must be met to ensure a high level of patient and user safety when the device is used as intended by the manufacturer.



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