3. The MHRA has decided not to allow Class I devices because we don't have good controls for these and they don't feel comfortable allowing re-manufacturing with a paper-only process. Class I devices are also very cheap so there is very little savings potential.
4. Neither the UK or EU will require informed consent. If the products are CE marked, there is no reason to require this because they are proven to be the same or equivalent.
5. The evidence we have collected actually indicates that in many cases failure rates for re-manufactured devices are lower because the re-manufacturers have to test every device.
6. OEMs are expected to try to limit the success of remanufacturing. It is interesting that J&J has a re-manufacturing business but they actually use this to trap the customer and undermine remanufacturing. They will sell their own products through both channels but intentional provide bad service on re-manufactured devices. They also work to reduce the yields on remanufactured devices so that the hospital doesn't save as much as they thought they would.
7. I think this is critical to actually generate savings. In addition to direct savings, we expect re-manufacturing to result in competition against the OEM that causes them to reduce prices. The ultimate level of savings will also depend on competition among re-manufacturers.
8. The savings will also depend on supply. Savings will be higher if there is local manufacturing. It will also be higher if there is ample supply. To maximize savings, we are hoping to actually gain access to used French devices. If we rely solely on local product, there will be supply constraints.

欧州１－７　Vanguard

Vanguard

8:30 a.m. – 12 p.m.

Tuesday, February 9, 2016

Berlin

See presentation from Viola Vahle. Product catalogue provided and represents all product types available in the German market.

Overview

Reprocessing has a long history in Germany with regulation dating back to 2002. As a company, we have been around since 1998. We began specifically for the purpose of reprocessing and we reprocess both single use and multi-use devices. We sell re-processed single use devices (SUDs) to 12 countries within Europe but Germany is our largest market.

The primary regulatory guidance can be found in the KRINKO document published by the Robert Koch Institute (KRINKO), a quasi-governmental body created to help improve hygiene standards. Currently, the industry is regulated as a service; however, with new EU rules pending, it is likely that this will change and that the system will be harmonized with the EU and will be product/sale focused. The new EU rules are expected in June and will probably be largely based on the regulatory model used by the US FDA. The UK has also chosen to follow the CE model.

In Germany, there are no restrictions on what can be reprocessed. It is left to the hospital or commercial reprocessor to take responsibility and to make the right choice. However, per KRINKO, there are agreed upon standards for reprocessing. As a result of these standards, very few hospitals choose to reprocess class II or III devices. As the certification of a NB and the validation process establishment is to comprehensive and to specific. The majority of in-hospital reprocessing is for low-risk Class I products but, as you know, even these can be quite dangerous if they aren't handled properly.

We collect and sell in 12 European countries. We have validated processes for 3,700 products. The majority of single use medical devices are not offered because it isn't economically feasible to do so. For example, we used to reprocess PTCA balloons but the market has evolved such that the prices for these products to sustain the process required to reprocess them. As a result, it is cheaper for customers to just buy a new product.

For Germany, we are strictly a service provider. Under this structure, we collect, reprocess and return used SUDs to the hospital. Our staff trains the hospitals but the hospitals take on the primary responsibility for collections. Used devices are placed into UN-approved vessels and then transferred to us via third-party logistics companies. These are the same companies that transport other types of packages. Per ADR-UN guidance, the used products are in a closed and sealed vessel. For products traveling a longer distance, we also add an extra plastic wrapper to further seal the vessel. If the seal on

a vessel is broken, we will not reprocess the device because we don't have assurance for how it has been handled and don't know what may have happened to it since it left the hospital.

Each hospital fills out a transfer from and signed the paper to confirm packing requirements as of our contract have been meet The hospital also send us the original manufacturer's label so that we can scan and include all OEM information from the label e.g.the lot number , ref number, name, use before date for the product. This is requiredl in the event of a recall.

The rules for transporting medical waste are outlined in the "ADR." If you look at this document you will understand what is needed.

We have regular pick up schedules for collected devices –; however, the hospital can also call to arrange a pick-up. Delivery/turnaround time for the devices takes up to two weeks. Max Box location in a hospital is three weeks.

As part of the process, we enter into contracts with the hospitals. The contracts outline the terms of collection and also mandate that the hospital not send products that have been used by patients with CJD, HIV, Hep C, and other infectious diseases. We also preclude those who have been subjected to nuclear isotopes. Our process is such that it is okay even if there is a mistake and these products are collected; however, we want this as an extra safety measure and we also don't want our staff to be unnecessarily exposed to products that have been exposed to these patients. It is an extra safety measure. We also require that the hospital not pre-treat or disinfect the devices. We want complete control of all stages of reprocessing. If we don't, our process enables us to identify problems so that an unsafe product is never brought into service use;. We strongly oppose as any disinfectant or chemical or sterilization could damage the device.

We don't reprocess products that are expired and we won't reprocess products with missing labels. This is an extra safety measure and this requirement is also part of our service agreement with the hospital. We also don't want to incur the additional cost of validating processes for products that are expired.

R&D Lab Visit

As part of the R&D process, we re-engineer each of the products and must develop and validate a re-manufacturing process – how the product will be handled, disinfected, disassembled, and reassembled, etc. This is a complex process that requires a combination of tests, including visual inspection under a microscope, mechanical testing, analysis by a mass spectrometer, infrared spectrometer, biocompatibility testing, and bioburden testing. Most of this is done in-house but we do outsource some of the biocompatibility and bioburden testing to third party labs.

To ensure that our methodologies remain current despite potential changes in the underlying OEM device, we review each new product lot by microscope and infrared spectrometer. In our case, we do not provide replacement parts as part of our process. The reason for this is that, in Germany, we operate under a service model. We never swap parts between one device and another version of the same device .

All re-manufactured devices are subject to 100% function testing or inspection. We also test for prions and other proteins.

As mentioned, we have validated processes for 3,700 products but we don't choose to remanufacture all of these. We initially started with a list of 35,000 potential products but most of these were eliminated due to economic considerations. There are some products that we don't yet have the technology to reprocess or that we don't reprocess due to ethical considerations. Pacemakers are a good example of a product we aren't able to reprocess today. In the future, this may be possible. The limitations depend on both the underlying technology used by the OEM and re-processing technologies. As new technologies develop, I think we will be able to reprocess more.

Product development usually takes 6-9 months.

Factory Visit

Manufacturing is done in a Class V clean room and our facility has an ISO 13485 certification just like the OEM. Air conditioning meets Class V requirements and we use highly purified water for the final rinse a step higher then just osmosis water .Which is not required by law but VA standard.

As a first step, collected product arrives in a bin. The label is taken, scanned, and entered into our system and the devices receive an initial ultrasonic bath soak.

Each device is laser etched with a tracking number using a JAG4 laser based on GS1 standards. Other companies use tags or other methods but we prefer the laser and our process is validated for this. The tracking number is important because it enables us to track the number of use, lot number, and other details from the original label. For Germany, we also need to track the hospital the device was collected from since the device will go back to the hospital. This device marking activity also most likely makes Vanguard are ready in compliance with the forthcoming UDI requirements of all device manufacturers.

The original manufacturer's logo is left on the device. This isn't necessary because the name of the manufacturer is also on the product label; however, removing the logo could damage the product, is costly, and offers know benefit to the patient.

The process varies a bit by product but, generally, after the label has been scanned and a tracking number assigned and etched, the product is dis-assembled. It is then cleaned using a validated process and custom machinery. Product that has been cleaned is then placed in a warming cabinet to remove moisture. After this, we conduct visual inspection with a microscope to look for surface damage and changes to shape. We also do 100% function testing, resistance & leakage testing (for some devices) and chip testing for those implanted with a chip.

As you may know, companies like J&J have started to include chips in their device for the sole purpose of preventing reuse. They say the purpose is safety but the real reason is that they want to make things harder for re-manufacturers.

In Germany, the government tells the manufacturers that since they have decided to label products SUDs that they have no right to the economics beyond the single use. If they would like to have more than this or would like to influence, they should label the devices as multi-use.

After chip testing / reprogramming, we re-assemble the device, test it using the original OEM console and then it is packaged and sterilized just as the OEM device is. Requirements for IFUs vary. Under the

service model, the hospital can use the original IFU from the OEM. Under the sales model, we create our own IFU. In many cases, these are actually an improvement on the OEM IFU.

On a similar note, we occasionally run OEM devices through our rigorous testing processes. Because OEMs only batch test, you would be surprised by how often there are problems with the underlying OEM device (e.g., leekages). Because we test ever single product, we don't have this problem. It is labor-intensive and costly but it is worth the effort.

For sterilization, we use ethylene oxide and follow OEM standards. Our product have one year validity and can be send of straight after sterilization no gasing out time is required, also our loads are a mix of products we did validated the ETO for that.

Labels vary depending on whether or not the product falls under the service model or the sales model. If the service model, we include the name of the hospital (and this is where the product goes). In the sales model, we do not need to do this. In the sales model, we also label the device as being for single-use – i.e., similar to the OEM, the product won't be suitable for in-hospital reprocessing; however, it can be re-manufactured again by us (in which case, it will receive a new label).

The number of times a device can be re-manufactured depends on the device, our process, and the economics of the reprocessing. In theory, a device may be able to withstand being recycled 5 times. However, we may choose to do it only 3 because the extra cost of getting the product an additional 2 uses isn't worth it.

The number of permissible cycle times varies by manufacturer, the specific device, and the process used. You can't just say that EP ultrasound catheters can all be used a minimum of 5 times. In some cases, the answer is 1. In some cases, the answer may be 8. It is our responsibility to develop and validate a process and determine the number of allowable times. For those countries that require a product submission, this is part of the submission process.

Market Penetration and Pricing

EP catheters are one of the largest categories for us. I'd estimate that in the US, 25% of EP ultrasound catheters are re-manufactured. For Germany, the number is closer to 50%. The rule of thumb is that the selling price for a remanufactured device is 50% but it varies. In terms of reimbursement, in all of the markets we deal with, the reimbursement is a lump sum for the procedure (i.e., DRG) and there is no distinction between reimbursement for a new device and a re-manufactured device.

Informed Consent

None of the regulators that we work with require informed consent. Informed consent doesn't make sense because the devices are equivalent to the OEM device. Informed consent is used when there is a different and there is additional risk to the patient. It would be unfair to require informed consent and it would also be a deterrent to sales.

Hospitals don't have to get informed consent when they use generics or choose other products on behalf of their patients. Why would they need to for re-manufactured devices? Airplane manufacturers

re-manufacture tires. They don't have to tell their passengers or customers because there is no difference in the product. Same is true for re-manufactured SUDs.

Reverse Engineering

Reverse engineering is useful because it helps us recreate the OEM device and validate the appropriate remanufacturing process??? . OEMs will never tell you what we need to r know of their product It is important that the regulator understand that we can re-engineer a device but that doesn't mean we know exactly what an OEM has put in their submission. The OEM could show slightly different test data or measure something different. The products can still be equivalent despite this. For example, it is possible that the re-manufacturer will measure something from point A to point B and that the OEM will choose to measure the same thing from point C to point B. The data shown can be different but still be reporting the same thing. Because the re-manufacturer doesn't have access to the original submission, they can get close to presenting the same information but they'll never be able to match what was submitted exactly even if the underlying product is the same.

OEM Response

OEMs also try to do what we call the "dirty picture show." They show regulators an example of a dirty device that was used. These examples are always old and always from a hospital that has reprocessed in an unregulated way. It is important to understand that we use different processes and are highly regulated -- to an equal or higher standard. As a result, our adverse events are no different than those of the OEM and sometimes we even have fewer.

In terms of liability, we take full liability. In Germany, the liability is clear because of the service model and our liability guarantee , for CE markets where products are sold, we take on product liability and responsibility. Same thing but just one liability insurance is for service provider other for manufacturer.

The single use designation is created by the manufacturers because they want to make money. Everyone knows that many of the devices can be reused if done properly. Of course OEMs try to stop the industry but it is for economic, not safety, reasons.

OEMs try to sue us all the time. They are always looking for something. In Germany, the government has been good at telling them that if they want more than the value of a single use, they need to label their products that way.

Ironically, we are also working with some OEMs that sell equipment with a disposable label. One model that some are considering is using us to reduce the cost of the disposable and reduce their own manufacturing costs by eliminating the need to manufacture a new device for each use.

Single-use medical devices: UK guidance on re-manufacturing

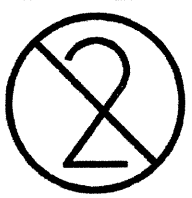
Contents

1 Executive summary

This document applies in the UK only, and sets out the UK's position on **re-manufacturing single-use devices** (SUDs).

Key points:

- Anyone who re-manufactures a single-use device has the same legal responsibility for it as the original manufacturer.
- Single-use devices may be re-manufactured for use in the UK. However, the company must meet all relevant criteria under the appropriate Medical Devices Directive and place a CE-mark on their product to attest conformity with the legislation.
- A re-manufactured single-use device should only be used on an individual patient during a single procedure.
- The packaging or device must have the symbol below, which means do not reuse / use only once / single-use.



This document is aimed at:

- All companies who re-manufacture medical devices that were originally 'single use'.
- All providers of medical devices.
- Chief executives and managers of organisations where medical devices are used.
- Healthcare professionals who use medical devices.

2 Introduction

There is a clear difference between a re-manufactured single-use device (SUD) and a reprocessed one. We outline the differences below.

Re-manufacturing SUDs involves a company, prior to placing the product on the market, confirming the conformity of the re-manufactured SUD to the relevant Medical Device Directive [1] and place a CE-mark on their product. The company must demonstrate, to the satisfaction of a notified body, that the re-manufactured device can clearly meet all appropriate criteria of the relevant Medical Devices Directive]. The company must confirm validity and surety of all re-manufacturing processes and accepts all liabilities and obligations for the SUD.

Note: class I medical devices are excluded from this policy. The MHRA considers that class I products should not be re-manufactured as there would be no external or independent assessment of CE-mark compliance.

We expect any healthcare organisation that chooses to use re-manufactured single-use medical devices to have a contract with a specific re-manufacturer. As part of the re-manufacturing contract, the healthcare organisation should always return the SUDs to the same re-manufacturing company.

Reprocessing SUDs is where a person or organisation, contrary to the manufacturer's instructions, cleans and sterilizes the medical device and it goes back into the healthcare environment. The reprocessed medical device has all the markings of the original manufacturer. There might be nothing to show that the device has been used before, nor any indicators that the reprocessing method is effective. If the reprocessed medical device doesn't work as originally intended, there would be questions about who is liable for it.

The MHRA advises **against** reprocessing single-use devices. See separate guidance document xxxxxx.

The MHRA is aware that a number of companies are re-manufacturing SUDs and placing them back on the market and that these devices comply with the requirements of the relevant Medical Devices Directive and have a legitimate CE mark.

The European Union (EU) legislation on medical devices is currently being revised. When this is finalised, the MHRA will review this guidance and update it if necessary.

3 Details of re-manufacturing single-use devices

The re-manufacturing company has to demonstrate to a notified body that the re-manufactured single-use device clearly meets **all appropriate criteria** of the relevant Medical Devices Directive in terms of performance and safety. The company also has to confirm to the notified body the validity and surety of all re-manufacturing processes, and that they meet all post-market surveillance requirements.

The single-use device may be re-manufactured, by the same company, for a limited number of times. The number of re-manufacturing cycles will have been validated, by the re-manufacturer, to ensure all device functionality, performance and safety parameters are

being met. It is the re-manufacturer's responsibility to track the number of times the device is re-manufactured and reused. Once the re-manufacturing cycles have been reached the device must be disposed of by the re-manufacturer. If during the re-manufacturing process the device fails to meet any aspect of functionality, performance or safety, the company must dispose of the device.

The re-manufactured single-use device must clearly display all the original manufacturer's identifiers. The re-manufacture company must also clearly display their own identifiers on the device, i.e. company name, full address and serial number or unique identifier. Packaging and instructions for use must clearly state that this product has been re-manufactured from the original.

After the first use of the single-use device, the original equipment manufacturer (OEM) is no longer responsible for the product if it is not disposed of. The healthcare facility can return used SUDs to their contracted single use device re-manufacturer. The re-manufacturer's responsibility for the device starts when the healthcare facility places the used product into the re-manufacturer's 'bins' or "return's package" which would be sited at a hospital or clinic.

If a re-manufacturer receives a single-use device from a hospital which has any indication that it has been re-manufactured or reprocessed by a different facility, they should dispose of the product.

The re-manufacturer accepts all liabilities and obligations for the re-manufactured single-use device. For example:
(This is not an exhaustive list of examples, and does not replace the legal requirements as set out in the Directives, but merely gives guidance on areas)

Technical documents

The re-manufacturer will need to show that the re-manufactured SUD will continue to perform as originally intended by the OEM, without additional risk to the patient or end user. Before applying to a notified body for the CE mark, the re-manufacturer must have technical documents and where applicable clinical evidence about the device that shows how the device conforms to the requirements of the relevant Directive.

For all medical devices belonging to class III, and for medical devices belonging to class IIa and IIb on a representative basis, the design of the medical device and its compliance with the Essential Requirements and quality assurance system must be examined by a notified body.

The manufacturer or the EU authorised representative must keep copies of the technical documentation for a period of at least 5 years. In the case of implantable devices the manufacturer must keep the documentation for at least 15 years after the last product has been placed on the market.

Decontamination, cleaning, sterilization and bioburden

As part of the bioburden assessment the re-manufacturer must have validated SUD decontamination, cleaning and sterility processes. The processes should include tests for cytotoxicity, sensitisation, endotoxins, prion/TSE and irritation. Each test should also screen for the presence of toxic and leachable materials.

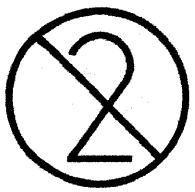
To ensure on-going integrity of the decontamination and sterility processes, and as part of the bioburden verification, the re-manufacturer must undertake periodic audits of their processes. The audits should follow international and national standards and guidance from appropriate governing bodies.

Labelling

The labelling must clearly state that the medical device is a re-manufactured device. The re-manufacturer's name, full address and authorised representative (if applicable) should be clearly stated. For further identification should the OEM undertake a and safety action, the labelling should have the original manufacturer's name and product's serial number or unique identifier.

The MHRA is concerned with having safe products available for use. We have not considered the intellectual property of the OEM or their permission for their name/product being used.

All legal obligations under the relevant directive should be followed and if this device is for single use once re-manufactured it should bear the symbol:



Risk management

As part of ensuring good quality systems the re-manufacturing company should show the notified body that they comply with the standard ISO 14971 'Risk Management for Medical Devices' [2]. This standard defines the requirements of risk management systems for medical devices, detailing best practices throughout the life cycle of the re-manufactured single-use device, including a risk analysis identifying all possible risks and associated mitigation strategies.

Post-market surveillance

The SUD re-manufacturers are subject to the same requirements for adverse event reporting as the OEM.

Within the framework of quality management and as part of post-market surveillance activities, the re-manufacturer must have a continuous monitoring process to identify any changes the OEM makes to components, materials or specifications. There are a number of routes for doing this:

- continuous market observations or safety information (e.g. FSNs) published by OEM
- published FDA approvals or safety information
- safety information from competent authorities
- information from end users
- incoming goods inspection for all devices
- electrical, material, performance and safety assessments conducted on all devices during re-manufacturing
- manufacturing and outgoing goods inspections for all devices.

The re-manufacturer's post-market surveillance team is responsible for managing any product safety notification or recall that the OEM has implemented and which has an impact on a re-manufactured device.

In addition to the previous points:

- should the OEM undertake any design changes to the SUD, the re-manufacturer must assess the significance of the change and confirm through their own testing if modifications are required to the re-manufacturing production process to accommodate the OEM design. If there is an OEM modification that results in a safety-related action for re-manufactured devices, the re-manufacturer is responsible for completion of the safety related action.
- if during re-manufacturing of the device a problem is identified which affects the safety of the OEM's device, the re-manufacturer must inform the OEM of the issue.

The re-manufacturer would also be expected to have post-surveillance systems in place to:

- trace the re-manufactured device to the batch or serial number of the original device
- record who the supply the re-manufactured device to should any regulatory action be required

4 Legal implications, negligence and regulatory requirements

Medical devices re-manufactured and placed on to the market in the UK and in the rest of the European Union (EU) are subject to specific legislation.

The Medical Devices Directive 93/42/EEC states the following:

(i) In the definitions: 'single use device' means a device intended to be used once only for a single patient;

(ii) A manufacturer's indication of single use must be consistent across the Community;

(iii) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request.

It is clear that anyone who re-manufacturers a SUD and passes it to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations [1] as the original manufacturer of the device.

5 Healthcare facility responsibilities

A healthcare facility that uses re-manufactured single-use devices must have a contract with a re-manufacturer. The healthcare facility should always return the product to the same re-manufacturing company. As part of the legislative conformity assessment the re-manufacturer will have established the maximum number of cycles a device can be re-manufactured. When the device can no longer be re-manufactured it will be destroyed by the re-manufacturer.

At no time should a re-manufactured single-use device be **reprocessed** by the hospital, or any third party. Once the re-manufactured product is used the healthcare facility should

either place the used product into the re-manufacturer's 'bins' or "return's package" which would be sited at a hospital or clinic.

Glossary

The following terms have been defined for the purpose of this bulletin:

Cleaning – A process that physically removes contamination but does not necessarily destroy micro-organisms.

Decontamination – A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes of decontamination are commonly used: cleaning, disinfection, sterilization.

Disinfection – A process used to reduce the number of viable micro-organisms but which may not necessarily inactivate some bacterial agents, such as certain viruses and bacterial spores.

Endotoxin – Is a toxin lipopolysaccharide, formed by the breakdown of the cell wall of Gram-negative bacteria. Bacterial endotoxins can be active even if the bacteria from which they are released are killed.

Legal entity – An individual, institution or organisation that has its own existence for legal or tax purposes e.g. a corporation, partnership or trust.

Manufacturer – The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under its own name. This can be a company or an individual.

Medical device – Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of:

- control of conception
- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or physiological process.

Placing on the market – The first making available in return for payment or free of charge of a device, (other than a device intended for clinical investigation) with a view to distribution and/or use in the market, regardless of whether it is new or refurbished.

Re-manufacturing (of single-use devices) – a re-manufacture of single-use devices must clearly meet all criteria of the relevant Medical Devices Directives. The re-manufactured, single-use device must carry a CE mark, obtained by the re-manufacturing company, specifically for the commercial re-manufacturing of single-use devices.
Re-manufacturing of single-use devices is different to reprocessing. Re-manufacturing is where a company obtains a CE mark for the commercial re-manufacturing of single-use devices.

Reprocess – To make good the device for reuse by any or a combination of the following processes:

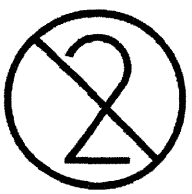
- cleaning
- disinfection/decontamination
- sterilization
- refurbishment
- repackaging.

Note: the manufacturer of reusable devices should provide validated reprocessing instructions along with the device.

Reuse – Another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing between each episode.

Single-use – The expression 'single-use' means that the medical device is intended to be used on an individual patient during a single procedure. It is not intended to be reprocessed and used on another patient. The single-use device should either be discarded, or if appropriate, returned to a re-manufacturer of single-use devices.

The symbol below is used on medical device packaging indicating 'do not reuse' and may replace any wording.



Some single-use devices are marketed as non-sterile but require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use. (Symbol reproduced from BS EN 980:2003 'Graphical symbols for use in the labelling of medical devices', with permission from: BSI, 389 Chiswick High Rd, London W4 4AL. E-mail cservices@bsi-global.com, tel: 020 8996 9001).

Sterilization – A process used to make an object free from all viable micro-organisms including viruses and bacterial spores.

References

1. The Medical Device Directives
   - Directive 93/68/EEC [CE Marking]
   - Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
   - Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma
   - Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices
   - Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
   - UK Regulations:The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618 (as amended)

2. ISO 14971 'Risk Management for Medical Devices'

The German version of this guideline [Bundesgesundheitsbl 2012 • 55:1244–1310] shall be taken as authoritative. No guarantee can be given with respect to the English translation.

Hygiene Requirements for the Reprocessing of Medical Devices

Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"
This text replaces the corresponding recommendation of 2001, published in the *Bundesgesundheitsblatt* 44 (2001):1115-1126.

Specific aspects, such as the reprocessing of flexible endoscopes and endoscopic accessories, the topic of CJD/vCJD as well as the fleshing out of specific aspects of the central recommendations are discussed in the applicable annexes.

Overview of the annexes

Annex 1
On the term "suitable validated procedures"

Annex 2
Re: Section 2.2.3 Technical-functional safety testing

Annex 3
Commissioning and operation of washers/disinfectors (WD) for the reprocessing of medical devices (checklist)

Annex 4
Commissioning and operation of small-scale sterilisers for the reprocessing of medical devices (checklist)

Annex 5
Overview of requirements on reprocessing units for medical devices

Annex 6
Staff expertise

Annex 7
Measures for minimising the risk of a transmission of CJD/vCJD through medical devices

Annex 8
Hygiene requirements for the reprocessing of flexible endoscopes and endoscopic accessories

Essential content from the "Recommendations for the supervision of medical device reprocessing" produced by the Working Group on Medical Devices (AGMP), have been taken into account, particularly in some of these applicable annexes.

The recommendations apply, in principle, irrespective of the location where the reprocessing is carried out, both in the inpatient and outpatient sectors. Of decisive importance for the nature and scope of the measures, is the complexity of the medical device as well as its previous use and its use after reprocessing.
The recommendation "Infection prevention in dentistry – requirements for hygiene", published in the *Bundesgesundheitsblatt* 49 (2006):375-394, contains examples to assist with use in practice.

The use of categories of evidence

At this point, one would generally find an overview of the categories of evidence used in the recommendation. However, the hygiene requirements for the reprocessing of medical devices constitute, in some respects, an exception within the framework of the recommendations of the Commission for Hospital Hygiene and Infection Prevention.

It constitutes an area in which recommendations are issued, jointly, by the Commission for Hospital Hygiene and Infection Prevention as well as the Federal Institute for Drugs and Medical Devices. In the case of the reprocessing of medical devices, the established procedures developed experimentally; as a result, the effective cleaning, disinfection and sterilisation derive from the corresponding laboratory tests and technical standards ('best practice'). It is for this reason that these requirements result less from the tests that form the basis for the categories of evidence underlying other recommendations from the Commission for Hospital Hygiene and Infection Prevention and which, in 2010, were once more adjusted to meet the high demands on evidence-based recommendations in medicine (*Bundesgesblatt* 2010 (53):754-756). As a result, in many cases, the measures described are therefore based on aspects of the continuous activity to secure the necessary, standardisable, reproducible, effective processes to achieve the specifications while, at the same time, guaranteeing the technical-functional safety of the medical device and the documentation of these processes (MPBetreibV). This is highligted, in the specific context, by the indication 'QM'.

1. General Provisions

Medical devices that are contaminated with pathogens can be a source of infection for humans [1-3]. The use of such medical devices thus requires previous reprocessing, for which defined requirements have been established.

These essentially result from:

- statutory provisions for the protection of patients, users and third parties (e.g. those responsible for reprocessing) (see Appendix A, legal provisions) [4];
- the known limits of methods used for reprocessing [2, 5-25] and
- the necessity to always guarantee that the tried and tested methods are of a constantly high and verifiable quality (quality management, QM[1]) within the context of an established quality management system [26, 27].

The **requirements set out in this document apply to** the reprocessing of medical devices and components of such devices, including accessories, which are intended:

[1] Definition of the use of QM. The abbreviation 'QM' can be found, in this context, in the text, when a described measure serves to assure the quality of reprocessed medical devices or the reprocessing procedures themselves. With a view to the fulfilment of predetermined specifications (in this case, cleanliness, low microbial contamination (the state subsequent to proper disinfection),sterility, function and safety of use) it is closely associated with the definition and objectives of validation.

- to be brought into contact with or inserted into the human body;
- to be used for conveying or banking blood, blood constituents, other body fluids or body tissues or changing the biological or chemical composition thereof, for subsequent use in humans or
- to be used for conveying liquids, gases or other preparations for the purpose of an infusion, reinfusion, perfusion or other administration to or introduction into the human body

Reprocessing normally **comprises** the following individual steps:

a) proper **preparation (e.g. pre-treatment, collection, pre-cleaning** and, where applicable, **disassembling** the used medical devices and their swift and safe **transportation** to the reprocessing site, while avoiding injuries, contamination and damage,
b) cleaning, if necessary intermediate rinsing, disinfection, rinsing and drying,
c) **inspection for cleanliness** and **integrity** (e.g. corrosion, material condition), where appropriate, repetition of step b) and identification, e.g. for the purpose of deciding whether to repeat reprocessing in cases where the number of repetitions is limited,
d) maintenance and repair
e) functional testing

and, if required,

f) **labelling**

as well as

g) **packaging**

h) **and sterilisation.**

Reprocessing ends with the medical device's documented **release** for use (QM, see also 2.2)

Reprocessing before use is also required if the packaging of a medical device, which is sterile in compliance with its intended purpose, has been opened or damaged, and the medical device has not been used, or if a medical device, which is to be used in a sterile state was not delivered in this state in the first place, and is to be reprocessed according to the manufacturer's instructions or if its expiry date has passed (see also 2.1).

The chain of necessary measures must be optimised since weaknesses in one of the aforementioned individual steps can adversely affect the subsequent steps and so compromise the overall result (e.g. improper cleaning which compromises the effectiveness of disinfection or sterilisation) [1-9, 11-25, 28-31].

Therefore, all individual reprocessing steps must be adapted to suit

- the medical device (especially its intended use and function and its construction and materials),
- previous reprocessing and
- previous and subsequent use of the medical device

and must always **guarantee the outcome in a traceable (see documentation) and reproducible manner** by using validated methods.
The reprocessed medical device must be perfectly functional, in line with its **intended use**, and guarantee all **safety-relevant requirements** without restrictions. The entire reprocessing procedure and the reprocessed medical device may not jeopardise the safety of patients, users or third parties.

This further implies that, for reasons of occupational health and safety and to avoid the contamination of other medical devices, contamination of the environment must be minimised as far as possible during reprocessing. This is also the reason why disinfecting cleaning must be performed, if necessary. Surfaces must be disinfected at least once a day and in the event of contamination.

Reprocessing must ensure that the reprocessed medical device poses **no risk to health** when it is subsequently used, specifically focusing on

- infections,
- pyrogenic reactions,
- allergic reactions,
- toxic reactions
- changed technical-functional properties of the medical device.

Reprocessing and the consistent compliance with the requirements imply the installation and maintenance of a quality management system (QM).

Reprocessing must be performed in accordance with accepted engineering practice and take state-of-the-art science and technology into consideration. Regarding reprocessing management, explicit reference is therefore made to the **standards** listed in Annex B (see Annex B: Standards).

1.1 Responsibility

Reprocessing carries with it a great responsibility ("fully controllable risk"). **Due diligence** implies compliance with all of the following requirements. For reasons of **in-house organisation** and the required **quality management, responsibilities** for all reprocessing steps must be specified and documented before medical devices are reprocessed (QM).

Proper and appropriate reprocessing requires the implementation and documentation of a **corresponding risk assessment and classification** of the medical devices to be reprocessed (QM; s. 1.2.1) [26].

On this basis, the person in charge of reprocessing (the operator) shall **specify in writing (see Table 1)**, taking account of the manufacturer's instructions (see DIN EN ISO 17664):

- whether,
- with which methods
- and under what conditions (e.g. rooms, work equipment, staff qualification)

medical devices that are operated within his/her area of responsibility, are reprocessed and stored (QM, Medical Devices Operator Ordinance (MPBetreibV)).

All individual steps involved in the **implementation in practice** of the methods used are to be specified before reprocessing. In this respect, it must be ensured that the persons in charge are indeed able to fulfil their tasks by virtue of their **positions and qualifications** (QM, MPBetreibV; required technical knowledge). A high **level of education** and regular **instructions** are of decisive importance (QM; see also Table 1) [26]. For the required technical knowledge, reference is made to the applicable Annex No. 6 "Staff Expertise" as well as the information resources offered by public corporations and professional societies such as the DGSV (German Society for Sterile Supply).