Recommendations by the Quality Task Group (93)

Reprocessing implants, supplied in an unsterile state, for orthopaedics and traumatology – Part 2

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General requirements to be met by the operator

If sterile implants are procured and fitted, the manufacturer is responsible for their irreproachable quality. However, if the operator purchases non sterile implants, they must be reprocessed, and this generally entails cleaning, disinfection and sterilization. This means that it is now the operator who is responsible, including for any risks arising.

The manufacturer supplying non sterile implants must provide detailed reprocessing instructions in accordance with EN ISO 17664. The latter must be strictly observed by the reprocessor.

Following risk assessment, a decision must be taken as to whether the respective institution is able to reprocess the implants needed, or any part thereof, in accordance with the manufacturer's instructions. The legal regulations applicable in Germany in this regard are EN ISO 14971 [2], VDI Directive 5700 [3] and the KRINKO/BfArM Recommendation [4].

It may also be necessary to verify whether the technical equipment needed is available or can be procured. If the manufacturer's instructions are formulated in an ambiguous or too general a manner clarification must be sought in writing from the manufacturer, e.g. of the following points:

Basic technical requirements	Key words	Specific requirements
Manual preliminary tasks	– If nec., assembly – Clean and disinfect worktops	– Clean working area, – Gloves – Hygienic protective clothing – Minimize/control baseline total microbial count (cfu) – Inspection and verification
Automated cleaning and disinfection	– Inserts – If nec., rinse hollow bodies – If nec., dismantle – Chemical products (what can/cannot be used – Cycle times Temperatures – Cleaning pressure – Water quality	– Positioning within WD (avoid dead spaces) – Suitability of detergents /ingredients on label – Ingredients of other process chemicals used in WD – Have the chemical products' manufacturer document and check the tolerable residues – Demineralized water, (endotoxin content) – Validated process pursuant to MPBetreibV Para. 4 Inspection and verification
Packaging and labelling	– Packaging and labels suitable for sterilization process – If nec., assemble – Device-specific inserts, if nec., connect devices	– 93/42/EEC Section 13 – Traceability back to manufacturer's product ID data (BATCH, serial no., etc.) – Packaging contents – Label and adhesive autoclavable – Inspection and verification
Sterilization	– Process sequence (cycle times, temperature) – Steam quality – Endotoxins	– Positioning in autoclaves – Demineralized water, endotoxin content – Validated process pursuant to MPBetreibV Para. 4 – If nec., run half cycle checks
Storage	– UV light protected – Dustproof – Dry (ambient humidity) – Restricted access	– Shelf life assured – Storage parameters ok. – Specify expiry date

Reprocessing implants supplied in an unsterile state must not negatively impact patient safety. Therefore the quality of the reprocessed implants is subject to the same requirements applicable to the quality of implants supplied by the manufacturer in a sterile condition.

Cleaning and disinfection – positioning

For cleaning and disinfection a validated process must be used as stipulated by the legal regulations. The pertinent literature, e.g. the current guidelines compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) on validation, does not contain any specific requirements for implants supplied in a non sterile state. In general the same cleaning and disinfection processes used for surgical instruments are used here too.

The implants must be positioned such that they are secured against movement generated by the circulating water and that they cannot cause any mutual mechanical damage. This applies e.g. for the still commonly used screw benches where the screws are positioned close to each other (Fig. 1).

Water circulation must not be impeded e.g. by gaps/crevices. This could make it difficult to successfully remove all soils and chemical residues from the cleaning/disinfection process (Fig. 2).

The process chemicals used must be compatible with the implant materials. Incompatible process chemical could result in visible changes. Whether an implant with such visible changes can still be used for the intended purpose must be queried.

To avoid contamination with particles, implants must not be cleaned or disinfected together with other used medical devices. Ideally, a dedicated washer/disinfector should be available for implants.

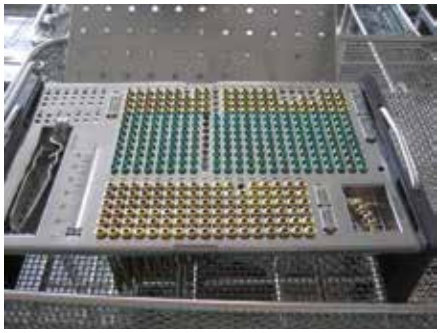

Fig. 1: Screw bench

Fig. 2: Incorrect positioning

Control measures following cleaning and disinfection

Damaged implants must not be used, see Recommendation 91 by the Quality Task Group. Hence, all reprocessed implants undergoing repeated reprocessing should be regularly ➜ **INSPECTED** for mechanical damage or surface changes. If the manufacturer has set a limit on the number of reprocessing cycles permitted, this limit must be observed and documented in writing.

➜ **IMPLANTS UNDERGOING REPEATED PROCESSING** should be regularly inspected for mechanical damage or surface changes.

Inspection for absence of residues

One of the quality objectives of cleaning is to assure perfect cleanliness, i.e. all surfaces must be free of proteins, carbohydrates, fats and other organic or inorganic substances and particles. Inspection for absence of particles is an inherently onerous task, in particular when even microscopically small particles have to be identified.

Risk analysis must be carried out to ensure the water used is free of endotoxins. The endotoxin content must be measured if necessary.

Packaging, sterilization and storage

Only ➜ **PACKAGING MATERIALS** permitted by the manufacturer may be used for packaging. The bioburden must be regularly checked before sterilization (100 – 1000 cfu). A validated sterilization process must be used.

The storage conditions, including temperature and ambient humidity, must also be regularly checked and documented.

➜ **PACKAGING MATERIALS** may only be used if they are permitted by the manufacturer.

Note: water quality and endotoxins

The water quality used for rinsing following cleaning and disinfection and for steam sterilization must meet specific demands with regards to ➜ **ENDOTOXINS**. Endotoxins are bacterial disintegration products that can induce several physiological reactions in the human body. They are classified as one of the groups of pyrogens (heat-resistant substances that can trigger fever on entering the human blood circulation). Of particular importance are the lipopolysaccharides (LPS) released from disintegrating Gram-negative bacteria.

The FDA as well as the French standard Afnor XP S94 – 091 [6] have set the maximum number of endotoxin units (EU) as 20 EU per implant, and as 2.5 EU per implant when there is contact with cerebrospinal fluid.

Analysis is performed with the Limulus test (Limulus amebocyte lysate [LAL]). This test is not applied by all test institutes.

Hitherto, no importance has been attributed to the endotoxin content for automated medical device reprocessing in general. Any microorganisms entering the WD in the rinse water will to a large extent be killed, but not removed, during thermal disinfection. This problem could be solved by using an appropriate particle filter.

➜ **ENDOTOXINS** can induce e.g. fever. In the USA and in France limit values for endotoxins are stated per implant.

➜ **TASS** is caused by endotoxins.

From ophthalmology it is well known that ➜ **TOXIC ANTERIOR SEGMENT SYNDROME** (TASS), an inflammation of the anterior eye chamber, contracted during cataract operations is not caused by microorganisms, but e.g. by the heat-resistant endotoxins released from lysed bacteria.

Summary

On reprocessing implants supplied in a non sterile state, the operator assumes full ➜ **RESPONSIBILITY** for the sterile product produced, including for any resultant risks. Hence risk analysis must be carried out to establish whether, and for which parts, purchase of non sterile implants can be contemplated. Following risk analysis, the reprocessing risk must be evaluated by the operator who must then decide whether this should and can be accepted.

The economic feasibility must be verified while taking account of the reprocessing and or device-specific validation costs and time investment.

In addition to appropriate technical fittings, well-trained and experienced personnel are needed in the CSSD and for process validation to meet these stringent requirements.

Increasing more importance is given to traceability of the implants used. To that effect, the manufacturer's specifications (e.g. the BATCH number) for each implant must be recorded and forwarded to the user so that this information can be documented in the patient file.

➜ **RESPONSIBILITY** for reprocessing implants supplied in an unsterile state is assumed by the operator.

Conclusions

Against a background of the aforementioned requirements, of the obligation to verify the bioburden and endotoxin content of the water and to assure the protection of patients, users and third parties as stipulated by the Medical Devices Directive, the German Society of Sterile Supply (DGSV e.V) expresses the view that there is an urgent need to ➜ **SWITCH** to implants supplied in a sterile condition. Based on risk analysis and risk assessment of the processes used to reprocess implants, and keeping in mind the fittings and technical facilities available in the majority of reprocessing units in Germany, the DGSV Quality Task Group can only conclude that the residual risk arising from reprocessing implants supplied in a non sterile state cannot be adequately reduced and that hence in future only sterilized implants should be procured.

For some time now the implant manufacturers have also been marketing many sterile implants as an alternative to the non sterile implants. If these implants are used, continuous ➜ **TRACEABILITY** will be assured.

Attention must also be paid to the issue of the economic feasibility of reprocessing. If implants are to be reprocessed in conformance with the pertinent regulations, the ➜ **COSTS** will be higher than currently projected because of the extensive inspection and verification measures to be implemented by the reprocessing personnel.

Good cooperation must be assured between the reprocessor and users as well as with the implant manufacturer to answer questions related to the reprocessing of implants and solve problems.

During the drafting of this recommendation there were numerous discussions within the Quality Task Group because some passages contain operational guidelines rather than concrete operating procedures. In addition to informations on reprocessing of implants, this recommendation shall also encourage discussion of existing problems.

The goal is to find a solution, preferably applicable to all interfaces with other departments, for the handling, application and/or reprocessing of implants which should be acceptable and practicable for all and should ensure the safety of patients, users and third parties alike. ■

➜ **A SWITCH** to implants supplied in a sterile condition is urgently needed.

➜ **TRACEABILITY** is assured for implants supplied in a sterile condition.

➜ **REPROCESSING COSTS** for implants will be higher than currently projected because of extensive inspection and verification measures.

References

1 EN ISO 17664 "Information to be provided by the manufacturer for the processing of resterilizable medical devices"
2 EN ISO 14971 "Application of risk management to medical devices"
3 VDI Guideline 5700: Reprocessing hazards – Risk management in reprocessing of medical devices – Measures for risk control; Bundesgesundh.bl. 2014: 1393–1401.
4 KRINKO/BfArM Recommendation: Hygiene requirements for the reprocessing of medical devices
5 Guidline compiled by the DGKH, DGSV and AKI for the Validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices
6 Afnor XP S94 091