Recommendations by the Quality Task Group (91)

Implants for Orthopaedics and Traumatology

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General

Thanks to medical progress, the use of implants has become a recognized treatment standard across many medical disciplines (in both the inpatient and outpatient sectors). In 1995, 13.5 million people in Germany were aged over 80 years. By 2050 that figure is projected to rise to an estimated 45 million. Our society has developed into a sedentary population, and many people are also overweight. In addition to ageing, this leads increasingly to signs of wear and tear of the skeletal system, back pain and arthritis. Besides, the rise in risky leisure activities as well as accidents on the roads and on the ski slopes are making corresponding demands on reconstruction surgery.

To meet these demands, the medical technology industry is developing increasingly more technically sophisticated implants, with the implant integration time, stability and resilience as well as durability playing a key role. To fit the implants as per the needs of the individual patient, surgeons dispose of a vast array of plates, screws, nails, etc.

➜ **IMPLANTS** are mostly supplied by the manufacturer in an unsterile state.

➜ **REPROCESSING** is carried out after placing the implants in an implant tray.

In the majority of cases in everyday practice these ➜ **IMPLANTS** are supplied by the manufacturer in an unsterile state. For example, at the user's premises screws are placed in a dedicated box and/or implant tray and then ➜ **REPROCESSED**.

The implications of repeated reprocessing on quality and the resultant changes have raised numerous questions in everyday practice; these will now be addressed in this paper.

General requirements to be met by the manufacturer

Implants and accessories are made from a variety of materials and have different surfaces structures. They are single-use devices and, as per their intended purpose, they must only be used once.

Implants and accessories may be supplied by the manufacturer in either a sterile or an unsterile state.

Table 1 lists a number of materials commonly used to manufacture implants.

➜ **BEFORE MARKETING AUTHORIZATION** is granted, manufacturers have to carry out numerous tests.

In a press release from 2013, the German Medical Technical Association (BVMed) explicitly stated that before medical devices are granted ➜ **MARKETING AUTHORIZATION**, the manufacturer must carry out risk analysis and risk assessment to demonstrate safety, conduct a clinical assessment to demonstrate performance and effectiveness as well as have in place a comprehensive quality management system.

Table 1

Materials	Quality	Standard		Price for round material 30 mm Ø/kg
Steel	X2 CrNiMo 18 15 3	ISO 5832-1	ASTM F 138	10.20
	REX 734	ISO 5832-9	ASTM F 1586	15.31
	P 2000	DIN 14452	–	20.41
Co-based alloys	Co Cr28Mo6	ISO 5832-9	ASTM F 1537	71.43
	CoNiCrMo	ISO 5832-6	ASTM F 562	66.33
	CoNiCrMoWFe	ISO 5832-8	ASTM F 563	66.33
Titanium	Grade 1 – 4	ISO 5832-2	ASTM F 67	30.61
	TiAl V4 (ELI)	ISO 5832-3	ASTM F 136	35.71
	TiAl Nb7	ISO 5832-11	ASTM F 1295	40.82

Standard EN ISO 14971 as well as another comprehensive regulation stipulate the parameters to be assessed [1]. Several laboratory tests and clinical assessment are needed to assure as far as possible the safety and performance of a medical device before it is used on people.

Synthetic materials, e. g. carbon-fibre-reinforced polyetheretherketone (PEEK) must be viewed as being particularly critical since their leachable substances and ➜ **BIOLOGICAL ACTION** must be taken into account.

➜ **BIOLOGICAL ACTION** must be taken into account especially for synthetic materials.

Standard EN ISO 10993, 1 – 20 describes the biocompatibility tests, which also include the influence exerted on cell cultures [2].

The manufacturer defines the assessment limits and is responsible for compliance with them. For devices reprocessed on the user's premises, that responsibility may be passed on to the user.

➜ **BIOCOMPATIBILITY ASSESSMENT** takes account of, among other things, the nature and duration of contact.

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The contact time can vary as follows:

1. short term < 24 h
2. long > 24 h–30 days
3. continuous > 30 days

Implants which are in contact with:

- Body surfaces such as the skin, mucosa or damaged parts of the skin
- From outside with the interior of the body such as with the vascular system, tissues, bones, dentin or circulating blood
- Tissues/bones or blood

In all cases the cytotoxicity, and for implants also the toxicity and genotoxicity, must be assessed. The manufacturer of implants supplied in a sterile state is responsible for guaranteeing that these criteria are met.

If implants are partially or completely reprocessed before use by the user, the corresponding ➜ **REPROCESSING INSTRUCTIONS** must be supplied by the manufacturer. These must meet the provisions of EN ISO 17664 [3].

➜ **REPROCESSING INSTRUCTIONS** according to EN ISO 17664 must be supplied by the manufacturer.

The manufacturer's warranty no longer applies in the event of mechanical alterations to implants, e.g. due to bending. These can in turn lead to changes in stability and in the surface structure.

General requirements to be met by the reprocessor

Implant reprocessing must not negatively impact patient safety. Therefore the quality of the reprocessed device is subject to the same ➜ **REQUIREMENTS** as the quality of implants supplied in a sterile state by the manufacturer.

➜ **QUALITY REQUIREMENTS** are the same for reprocessed devices as for implants supplied in a sterile state by the manufacturer.

The manufacturer's instructions for reprocessing the implants must absolutely be observed. It is not possible to reprocess the implants without the manufacturer's instructions.

Problems encountered in everyday practice

➜ **REPEATED REPROCESSING** of implants is currently still routinely practised in surgical departments and in many hospitals. This presents several risks for the Central Sterile Supply Department (CSSD) and calls for urgent action.

➜ **REPEATED REPROCESSING** of implants presents several risks for the CSSD.

Implants are medical devices of the most diverse geometry and dimensions, ranging from e. g.:

– Simple bone screws to complex cannulated multi-part compression screws,
– Mini-fragment screws and large-fragment screws,
– Cannulated vertebral column implants,
– Multi-part fracture clamps with a highly complex design,
– Stable-angle, threaded plate systems,
– Vertebral body replacement device featuring a complex multi-part structure
– Cannulated intramedullary nails, etc.

There are implant trays with a selection of implants of various sizes and lengths made of different types of steel and of other materials.

Traceability – the batch no. – is not assured for any of the items.

➜ CHANGES TO THE SURFACES were observed in titanium implants despite having used validated automated reprocessing processes as prescribed by the manufacturer.

Fig. 1: Mechanical damage in a screw caused by automated reprocessing

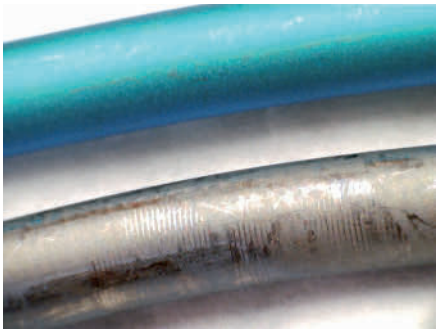

Fig. 2: Surface discoloration in titanium caused by reprocessing

➜ PRESERVATION the biocompatibility and surface structure of implants cannot be guaranteed after repeated reprocessing.

Reprocessing titanium implants

In studies on how titanium implants responded to reprocessing, visible **➜ CHANGES TO THE SURFACES** were observed despite having used validated automated reprocessing processes as prescribed by the manufacturer.

Based on the findings of that study, the main problems encountered when reprocessing titanium implants can be summarized as follows:

- Screws stored in screw trays sometimes remain there for years and are thus reprocessed time and again, leading to visible mechanical damage (Fig. 1). To date the impact that this has on the stability of the respective screws has not been investigated. So far manufacturers have not imposed any limit on the maximum number of reprocessing cycles. Indeed, if such limits had been imposed it would not be possible to observe them in practice in the absence of clear labelling of each and every implant to that effect.
- There are surface discolorations (Fig. 2). These have implications not only for the colour but also for the surface structure, and can thus promote adhesion of impurities.
- Some implant trays do not lend themselves to reprocessing in a washer-disinfector (WD) because of their construction, since cleaning of all parts of the surfaces cannot be guaranteed (spray shadowing). Besides, there are also often problems when drying the latest range of synthetic trays.

An important advancement would be to have screw trays in which the screws would not come into contact with each other when reprocessed in a WD so as to prevent mechanical damage. That applies for both titanium and stainless steel screws.

Chemical influences exerted on titanium surfaces

SMP, a test institute in Tübingen, blames these alterations on various interactions between titanium and the detergent components:

- If oxidative components (H_2O_2) are used in a detergent or detergent additive, these cause yellow-orange discoloration since they give rise to formation of titanium oxide.
- If activated chlorine is used it changes the surface topography and hence the bioadhesion properties.
- Phosphoric acid (neutralizing agent) also leads to changes in the topography and to reduction of foreign elements and, accordingly, to changes in biocompatibility
- Caustic soda can result in apatite layer formation on surfaces
- TiO_2 grids can become contaminated with foreign ions.

Conclusion

In summary a CSSD or RUMED (Reprocessing Unit for Medical Devices) cannot guarantee that the biocompatibility and surface structure/topography of implants will be **➜ PRESERVED** if they are repeatedly reprocessed.

The KRINKO/BfArM Recommendation [4] states: "Functionality of the reprocessed medical device must be fully preserved as per its intended purpose and the device must meet all safety requirements without any restriction. The entire reprocessing process and the reprocessed medical device must not endanger the safety of patients, users or third parties".

Part 2 of this publication shall give a summary of recommendations for users, aimed at increasing safety when reprocessing unsterile implants.

References

1 EN ISO 14971: Application of risk management to medical devices
2 EN ISO 10993 Part 1 – 20 Standard series on biological evaluation of medical devices
3 EN ISO 17664 Information to be provided by the manufacturer for processing resterilizable medical devices
4 KRINKO/BfArM Recommendation: "Hygiene requirements for reprocessing medical devices", 2012