Ethical and hygiene aspects of the reprocessing of medical devices in Germany

Ethische und Hygiene-Aspekte der Aufbereitung von Medizinprodukten in Deutschland

Abstract

Based on safety and quality principles, for each medical device (MD), regardless of its declared status as single- or multi-use device, careful considerations must be made. This includes assessment whether reprocessing is economical and ecological meaningful, and technical feasible. So far, however, in Germany reprocessing of declared single use MD is legally allowed, provided that the above aspects are well covered. The purpose of this paper is to elucidate, when circumstances allow reprocessing of declared single-use MD. For reprocessing of single use MD the following preconditions must be fulfilled:

• The security level of the reprocessed MD must be equivalent to the status of the newly delivered item; this means that a patient is not exposed to a higher risk through a reprocessed disposable MD than through the new, i.e. un-processed product.

• The reprocessing must be based on a detailed risk assessment and risk analysis, and must be described in detail regarding selection of the reprocessing method. Additionally, all necessary safety- and quality assurance measures must be stated.

• The reprocessing measure needs to be accompanied with a quality management system which determines and documents the responsibility of all stages of reprocessing; where the corresponding reprocessing procedures are well defined; and the efficacy of the procedure is proven by product-specific or product-group-specific tests and reports. The process must be validated according to recognised methods of science and technology, taking into account potential negative influences of the reprocessing on the properties of the material and the technical and functional safety. For reprocessing of MDs of the category Critical C the quality assurance must be certified by an accredited certifying body.

Keywords: reprocessing, medical device for single use, medical device for repeat use, requirements on reprocessing, quality management, certifying of reprocessing

Zusammenfassung

Im Interesse der Wahrung der nachhaltigen Entwicklung ist für jedes Medizinprodukt (MP) unabhängig von seiner Deklarierung zum Einmal- oder Mehrfachgebrauch zu überprüfen, ob die erneute Aufbereitung hygienisch, funktionstechnisch, ökonomisch und ökologisch (Ressourcenverbrauch) sinnvoll ist. Sofern diese Kriterien erfüllt sind, ist in Deutschland auch die Aufbereitung von zum Einmalgebrauch deklarierten MP juristisch zulässig. In diesem Zusammenhang wird erläutert, wann der Sachverhalt der Aufbereitung definitionsgemäß zutrifft. Zur Aufbereitung von zum Einmalgebrauch deklarierten MP müssen folgende Voraussetzungen erfüllt sein:

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• Die Sicherheit muss dem Neuprodukt entsprechen, d.h. der Patient/die Patientin darf durch das aufbereitete Einwegprodukt keiner höheren Gefährdung ausgesetzt werden als durch das neue, nicht aufbereitete MP.

• Der Aufbereitung muss eine detaillierte Risikoanalyse mit Begründung der Auswahl des Aufbereitungsverfahrens und aller Sicherheitsprüfungen vorausgehen,

• Es ist ein etabliertes Qualitätsmanagement nachzuweisen, in dem die Zuständigkeit für alle Schritte der Aufbereitung geregelt und dokumentiert wird, die Aufbereitungsverfahren definiert sind, die Wirksamkeit der Verfahren durch produkt- oder produktgruppenpezifische Prüfung und eine Validierung nach den anerkannten Regeln der Technik unter Berücksichtigung von Wissenschaft und Technik belegt sind sowie negative Einflüsse der Aufbereitung auf die Materialien und technisch-funktionelle Sicherheit durch adäquate Prüfverfahren ausgeschlossen sind. Für die Aufbereitung von MP kritisch C muss eine Zertifizierung durch eine akkreditierte Zertifizierungsstelle vorliegen.

Schlüsselwörter: Aufbereitung, Medizinprodukte zum Einmalgebrauch, Medizinprodukte zur Mehrfachgebrauch, Anforderungen an die Aufbereitung, Qualitätsmanagement, Zertifizierung

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The following opinion is rendered on the basis of the common recommendation of the Commission for Hospital Hygiene and Infection Control (Kommission für Krankenhaushygiene und Infektionsprävention) at the Robert Koch Institute (RIK) and the Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) regarding the “hygiene requirements for reprocessing medical devices” [1] as well as of the joint opinion of the Board of the German Society of Hospital Hygiene (DGKH) and the Central Authority of the countries for Health Protection regarding Medicinal Products and Medical Devices (ZLG) [2].

Ethical and (economic) concerns

The global challenge facing mankind is sustainable or, as the case may be, future-proof development (sustainable development).

Sustainable development is development that is intended to meet the needs of today’s generation, without threatening the possibilities for future generations to choose their own needs and their own lifestyle. The objectives and contents of this concept cannot be developed simply through the inclusion of the term in as many statutes as possible. Nor is it enough for the state alone to make allowances for sustainable development. Instead, the aim must be to fill the outline of sustainable development with specific content. Every scientist is called upon to interpret the concept of sustainable development against the background of the discipline he/she represents and thereby contribute to the design of the concept.

Main focuses of sustainability from hygienic point of view are the reduction of the environmental impact by material entries, the use of alternative resources, minimisation of risks for human and environment, choice of environment-friendly products and procedures (compatibility, biodegradation, bioaccumulation), saving of resources and no induction of resistance by antimicrobial agents.

The decision as to whether to reprocess medical devices in preparation for re-use, or to dispose of medical devices following a single use is an example of a situation in which the benefits and risks have to be weighed up against each other carefully in terms of the concept of sustainable development.

In protecting against viruses, protecting the ill, or as the case may be, protecting healthy citizens against infection competes with the protection of the environment against the introduction of ecotoxicologically relevant antimicrobial agents, particularly via wastewater, as well as with the resources consumed (in terms of energy, water and chemicals) in order to prevent and combat infection, including the resources needed to manufacture the medical device.

The concept of sustainable development is also postulated in this special area for the harmonisation of the various spheres of interest of conserving the beauty and survival of nature, culture and habitat for all living creatures. Sustainable development must therefore be formulated as the basis for decisions on the ecologically responsible use of medical devices as well as of anti-microbial substances and procedures.

The process of sustainability begins with the selection of medical devices. Insofar as the safety standard of various medical devices (MD) with the same intended purpose regarding prevention against infection and functional
safety is the same, then only economic and ecological considerations determine the choice. Here, it is the case that, regardless of whether the medical device is declared for single-use or for repeated use, the reprocessing is all the more worthwhile the greater the input of materials and resources for the production of the medical device concerned.

In the case of single-use medical devices, such as, for example, syringes, the ratio of the material input for manufacture is disproportionate to the resources used and to the hygiene ensured through the reprocessing, so that this medical device is to be disposed of following a single use.

**Ensuring the function and hygiene certainty when reprocessing medical devices**

The first two steps in processing a medical device is to carry out a detailed risk analysis combined with an assessment of sustainability (so-called sustainability check), which forms the basis for the decision as to whether the device can be reprocessed. The issue here is the identification of critical areas, which could, if modified, affect e.g. the functional, immunological, toxicological or hygienic characteristics of the medical device.

With regard to the reprocessing of medical devices declared as single-use products, it should be clarified whether characteristics of the material and the construction allow the device to be reprocessed without causing damage and without limiting the function of the device. In cases where the intention is to reprocess used medical devices, the RKI and BfArM reprocessing guidelines require the establishment of a system of quality management with the following individual steps:

- Formulate objective
- Define responsibilities
- Risk assessment and classification of the medical devices
- Validate and document the process
- Compile procedural instructions and operating instructions
- Draw up a plan for routine examinations
- Education and training of the staff.

For the reprocessing of MDs with particularly high demands as to the reprocessing (Critical C) the quality assurance should be certified by a certifying office accredited in accordance with DIN EN 13485 in combination with the requirements set forth in the RKI-BfArM guideline by the Central Authority of the Counties for Health Protection regarding Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, ZLG). The submission of this proof of certification is a prerequisite for the award of contracts to an external reprocessor.

The procedural instructions must define all necessary reprocessing steps, stating responsibility in detail, i.e. intake control, pre-treatment, cleansing, disinfection, rinsing, drying, results testing, care, repair, performance test, labelling, packaging, sterilisation, documentation and coding.

As a prerequisite for the selection of the reprocessing procedure, the medical devices are to be subjected to risk classification in non-critical, semi-critical A and B and critical medical devices (A, B or, as the case may be, C). When reprocessing medical devices declared for single-use, as is the case when reprocessing multi-use devices, the basic principle that patient safety must demonstrably not be put at risk by the processing, nor may the functionality of the reprocessed medical device be affected applies.

In the case of reprocessing disposable materials however, the manufacturer’s responsibility is transferred to the operator or, as the case may be, to the reprocessor, which demands comprehensive quality management.

**Requirements when reprocessing medical devices**

The RKI-BfArM recommendation [1] demands that, during the use following reprocessing of a medical device no risk of damage to health, in particular in terms of

- Infections,
- Reactions caused by pyrogens,
- Allergic reactions,
- Toxic reactions

may be triggered by altered technical-functional characteristics of the medical device.

The reprocessing is to be carried out under observation of the manufacturer’s statements. Insofar as any deviation is made from the statements of the manufacturer concerning the reprocessing, this must be justified and documented. It must furthermore be ensured that the functionality for the fulfilment of the intended purpose and the product safety of the reprocessed medical device are guaranteed in full.

In the case of medical devices for which it is considered necessary for product safety, the assessment of the reprocessing safety should not be limited to checking the validation data and the proof of sterility, but rather supplemented by additional tests, such as, for example, tests for absence of pyrogens, absence of cytotoxicity and evidence of the technical functional safety.

For this reason, each reprocessing requires a quality management system that determines and documents the responsibility for all stages of reprocessing: in which the corresponding reprocessing procedures are defined; the efficacy of the procedure is proven by product-specific or product-group-specific tests; and a validation pursuant to the recognised rules of technology, taking into account current science and technology is proven and negative influences of the reprocessing on the properties of the medical device...
material and the technical-functional safety are excluded by way of adequate testing procedures.

The completed reprocessing procedure for the reprocessed medical device is to be documented according to the following points of emphasis: the parameters used as the basis for the decision as to the release; the result of the batch test; documentation of the process parameters and comparison with the process parameters of the validated process; evaluation of the intactness of the packaging and the drying, date, batch number, batch content, release signature; in the case of third-party reprocessing, company address and complete traceability. The records and evidence are to be submitted to the responsible authorities on demand. Only if these requirements, which are set out in detail in the RKI-BfArM recommendation [1], have been fulfilled is the reprocessing of medical devices permissible. This applies in particular if a medical device, which, according the manufacturer’s declaration is intended exclusively for single use, is to be reprocessed after use.

When does the case of ‘reprocessing’ apply?

1. Following use of a medical device and intended renewed use on the same patient or another patient following interim storage.
2. In the case of accidental opening of or damage to the sterile packaging, as well as upon expiry of the use-by date.

If re-sterilisation takes place in these cases, this must be carried out under conditions analogous to those used in the manufacturing process (i.e. same validated procedure, same monitoring of material properties etc.); insofar as this is not transferred to the manufacturer, product liability is also transferred to the operator/reprocessor for this type of partial reprocessing.

3. In the case of complications connected with an implant, which makes a revision of the transplant bed together with temporary and/or long-term removal of the implant and re-implantation in the same patient necessary, it is not permissible to store the implant aseptically and to re-implant it without complete processing, i.e. either a new implant or an implant reprocessed in accordance with the quality criteria stated above must be used.

Conclusion

Even if a manufacturer has declared his medical device as being only for “single use”, reprocessing is possible subject to the condition that this is carried out using an appropriately validated procedure in a hygienically defined environment, on the basis of an adequate material and functionality test, with qualified staff and with complete process and release documentation. The reprocessed medical device may not differ from the original product in terms of characteristics relevant to safety or function.

Records of the overall procedure and of specified random tests must have been kept. In all cases of intended reprocessing, it must be examined whether reprocessing actually results in a saving of resources and costs, taking into account the conditions described here.

Risk assessment of reprocessing

Reprocessing of medical devices is an essential part of the antinfective multibarrier strategy, although at present on the value of reprocessing for infection control no valid statement is possible; only data exist of contamination rates as well casuistic of infections after usage of reprocessed medical devices. For instance the bacterial contamination of coloscopes and duodenoscopes differ between 20 and 60% and consecutively some hundred infections inclusively HBV and HCV are reported after gastroscopy and bronchscopy [3]. Especially endoscopic biopsy is an independent risk factor (odds ratio 5,2) for transmission of HCV [4]. After steam sterilisation 42 of 57 sterilised endoscopic instruments (Germany, Japan, USA) and 20 of 25 reusable biopsy tongs were non sterile; after ethylene oxide sterilisation on 9 of 10 single use biopsy tongs up to 50 cfu were found [5]. In dental practises the lumen of hand pieces were reprocessed only in about 10% [6]. This is only the point of the iceberg. The consequence is the necessity of consideration between decentralised, central or industrial reprocessing with the premises the same security level. A differentiation between single and reusable devices seems to be contra productive, because such a differentiation could tempt according to kind of the medicine product into an overestimation or underestimation of the necessary risk assessment for the processing. Independent of the type of usage a thoroughly analysis of save reprocessing is necessary. For reusable devices the recommendations of the manufacturer is the basis for reprocessing, but not seldom they are missing. For single use devices the reprocessor compiles processing regulation on the basis of risk assessments and bears the responsibility for the functional qualities relevant for safety. The test extent and test expiry should be declared in a special frame directive to reprocessing, in the future for the hygienic and material safety further detailed work must be done in comparable manner like for new products on the base of a risk analysis specific for the product. The release of a reprocessed single use product should be along with a safety declaration by an independent authority.
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