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Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers;
Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
Part 5: Test soils and methods for demonstrating cleaning efficacy (Technical Specification)
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**Appendix 6:**

**On reprocessing flexible cystoscopes and bronchoscopes**

**Commentary of the Commission for Hospital Hygiene and Infection Prevention, the Federal Institute for Drugs and Medical Devices and the RKI**

*In accordance with the "Hygiene Requirements for Reprocessing Medical Devices" [1], flexible cystoscopes and bronchoscopes which are being used for diagnostic purposes have to be considered as "semi-critical B" medical devices , which are – unlike i.e. coloscopes – being used in sterile bodily cavities or pushed into normally sterile areas of the bronchus. This requires lower germ counts (sterility; see table 1, index 2 of the recommendation) [1]. The regular passage through the physiologically colonised urethra or the pharynx and the trachea and the limited possibilities to sterilise flexible endoscopes have lead to numerous inquiries of users and prompted these detailed explanations as an appendix to the recommendation.*

A flexible cystoscopy is a diagnostic measure which, compared to the use of rigid cystoscopes that can be steam sterilised, is considerably more gentle for patients. However, adequate methods of sterilisation (i.e. EO sterilisation) are only available in very few facilities. In view of the above and considering the available information on infection risk and the efficiency of adequate disinfection procedures, the reprocessing of flexible endoscopes used in cystoscopy has been assessed separately. Consequently, the reprocessing of flexible endoscopes used in cystoscopy without final sterilisation seems justifiable under the condition that suitable measures for cleaning, disinfection and re-rinsing are being implemented according to written-down standard working instructions. This evaluation holds equally true for bronchoscopes. In this context, we would also like to point to the "Hygiene Requirements for the Reprocessing of Medical Devices and Additional Endoscopic Instrumentation " [2] and the recommendation "Hygiene Requirements for the Constructional-Functional Design and Instrumental Equipment of Endoscopy Units" [3].

In this context, **disinfection and re-rinsing** need to be outlined separately. **Instrument disinfectants with CE marking and based on glutaraldehyde, orthophthaldialdehyde or peracetic acid** [4] which have been proven effective against bacteria, including mycobacteria (testing should include M. avium) and viruses (declared as "virucide", see working group "viruzidal activity" 2004) [5] and which have been designed for this field of application by the manufacturer are suitable for the final disinfection. We emphasise the need for a thorough prior cleaning because of possible impairment of the effect due to debris from the preceding use on a patient [4, 6, 7]. Reference is further made to the instructions of the

endoscope manufacturer as laid down in the manual on the material compatibility of specific medicinal products with the endoscopes.

Specific formulas (that is medicinal products which contain for example glutardialdehyde in a nonionic surfactant solution, peracetic acid salts in a buffer solution) can deviate from the pure active substance solutions in their characteristics relevant to the application (i.e. effect, material compatibility, stability). Instructions on pure active substance solutions can therefore only serve as a guideline and have to be completed with the specifications of a disinfectant by the manufacturer. While the substances listed above have proven to work well, there are no recommendations for specific methods such as "electrolysed" or "super-oxidised" water yet [8-11].

All outer and inner surfaces of the endoscope have to be re-rinsed with suitable sterile or sterile-filtrated water after the disinfection. This step in the reprocessing procedure has to ensure that the endoscope and the patient do not suffer any damages because of residues from the previous treatment and prevent that the endoscope is re-contaminated. If the reprocessing is not carried out immediately before using the endoscope, it has to be stored in a dry place and in such a way as to prevent contamination.

In order to ensure consistent quality of the effective procedure, preference should be given to automated procedures. As a minimum standard, the implementation has to be carried out according to standard working guidelines put down in writing and by suitably trained staff. Interventions in areas of the urogenital system which are in close proximity to the bladder have to be carried out using sterile medical devices. Concerning the reprocessing of endoscopic accessories, reference is made to the recommendation "Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation " [2].

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## Appendix 7:

### Reprocessing of Ultrasound Probes for use in Gynaecology

Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI). The BfArM and RKI were informed by health offices and gynaecologists about the issue of insufficient reprocessing of ultrasound probes for transvaginal use in everyday practice. According to them, it is common use to put a latex cover over these ultrasonic probes as the only protective measure and to discard the cover after the examination. This procedure is not in line with the required diligence that is necessary when reprocessing semicritical medical devices according to the joint recommendation [1] of the BfArM and the Commission for Hospital Hygiene and Infection Prevention at the RKI and constitutes a violation of the required patient and user safety. When handling the cover, smear infections or cross-contamination cannot be ruled out. Therefore, the probe has to be disinfected after each examination (after removing the cover) so as to kill bacteria, fungi and viruses[2].

According to the essential requirements for medical devices (Council Directive 93/42/EEC, Annex 1, section 13.6), the instructions for use must contain information on the appropriate processes to allow reuse if the device is reusable. Manufacturers of ultrasonic probes for transvaginal use are therefore obliged to provide, together with the instructions for use, information on at least one effective and material compatible disinfection procedure with the above-mentioned spectrum of activity. The effectiveness when using recognised methods has to be proven by expert opinions.

The additional use of a cover during the examination shall remain unaffected by this requirement. Due to current events, we would like to point out that we consider instructions in a manual concerning the alternative use of disinfectants or covers which emphasise that the latter procedure has no impact on the material aging process and therefore increases the durability of a product as a deception under the required user and patient safety as these instructions indirectly recommend to refrain from a disinfection.

In a letter dated 21 January 2005, manufacturers of ultrasonic probes for use in gynaecology were asked to immediately take action if the user information on transvaginal use of ultrasonic probes were not in line with the requirements listed above. The manuals should be changed immediately and the users should be provided with the necessary information in a suitable way and as quickly as possible.

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If you have any questions concerning reference number 4306/05, please contact:

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## Appendix 8:

**Reprocessing of ultrasonic probes with mucous membrane contact**

More information about the Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI) of 17 February 2005:

After the publication of the Joint statement of the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI) on the Reprocessing of Ultrasound Probes for use in Gynaecology (Recommendation of 17.02.2005; in German), we were told by representatives from different medical fields that the sometimes insufficient information by the manufacturer on the reprocessing of ultrasonic probes as well as uncertainties concerning the required procedure for the users is not limited to the transvaginal use but consists a general problem for the application of probes with mucous membrane contact.

Once again, we have written to manufacturers of ultrasonic probes and associations of manufacturers of medical devices and asked them, if they haven't already done so, to immediately include at least one effective and material compatible disinfection procedure that kills bacteria, fungi and viruses into the manual and to provide the necessary information on disinfection to the users of these ultrasonic probes as quickly as possible.

Additionally we would like to draw your attention to the fact that, while paying attention to the manufacturers' instructions, the operator or user bears responsibility for the correct reprocessing of medical devices and their proper application that does not put the safety and health of patients, users or third parties at risk.

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## Annex A: Laws, Ordinances, Directives

- Council Directive 90/385/EEC of 20 June 1990 relatingto implantable medical devices
- Council Directive 93/42/EEC of 14 June 1993 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
- Medical Devices Act (MPG)
- Ordinance on Medical Devices (MPV)
- Ordinance on Installing, Operating and Using Medical Devices (Medical Devices Operator Ordinance (MPBetreibV)
- Medical Devices Safety Plan Ordinance (MPSV)

**Occupational health and environmental protection:**

- Biological Agents Regulation (Bio StoffV).
- Ordinance on Occupational Health Care (ArbMedVV)
- Chemicals Act (*Chemikaliengesetz*)
- Hazardous Substances Ordinance (*Gefahrstoffverordnung*)
- Radiation Protection Ordinance (*Strahlenschutzverordnung*)
- Waste Avoidance and Waste Management Act (*Abfallgesetz*)
- Technical Rules for Biological Agents (TRBA) 250
- Technical Rules for Hazardous Substances (TRGS) ( 300, 401, 440, 513, 525, 555; 900, 905)

## Annex B: Standards

If the provisions of the standards referred to are complied with, accepted engineering practice is deemed to be fulfilled. This collection comprises the standards to be observed under aspects of hygiene from which the standards matching the planned reprocessing work must be selected in each case. For testing that serves to ensure technical-functional safety, additional standards may have to be observed, as appropriate.

The column "Sections of the Annex" cross-references the underlying standards and the corresponding sections of the Recommendation. The standards with particular **practical** relevance are **highlighted in grey**(see also DIN Taschenbücher 169, 263, 265, 469 und 475). This part of the Annex is regularly updated (see also www.named.din.de).

**Annex B Standards**

| **Standard harm. under Dir.** | **Standard** | **Title** | **Sections of the Annex** |
|---|---|---|---|
| 93/42/EEC | DIN EN 285 | Sterilization - Steam sterilizers - Large sterilizers *(applies up to and including installation qualification)* | 1.3, 1.4, 2.2.5 |

| Standard harm. under | Standard | Title | Sections of the Annex |
|---|---|---|---|
| 93/42/EEC<br>90/385/EEC<br>98/79/EC | DIN EN 556-1 | Sterilisation von Medizinprodukten — Anforderungen an Medizinprodukte, die als "STERIL" gekennzeichnet werden (Sterilization of medical devices - Requirements for medical devices to be designated "STERILE") Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden (Part 1: Requirements for terminally sterilized medical devices) | 1.3, 1.4, 2.2.5 |
| | DIN EN 867-5 | Nichtbiologische Systeme für den Gebrauch in Sterilisatoren (Non-biological systems for use in sterilizers) Teil 5: Festlegungen von Indikatorsystemen und Prüfkörpern für die Leistungsprüfung von Klein-Sterilisatoren vom Typ B und vom Typ S (Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilisers Type B and Type S)<br>*(Parts 1, 3 and 4 replaced by DIN EN ISO 11140-1, 3 and 4; see also DIN EN ISO 18472)* | 1.3, 1.4, 2.2.4, 2.2.5 |
| | DIN EN 868 | Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte (Packaging for terminally sterilized medical devices)<br>Teil 2: Sterilisierverpackung — Anforderungen und Prüfverfahren (Part 2: Sterilization wrap - Requirements and test methods);<br>Teil 3: Papier zur Herstellung von Papierbeuteln (festgelegt in EN 868-4) und zur Herstellung von Klarsichtbeuteln und -schläuchen (festgelegt in EN 868-5) — Anforderungen und Prüfverfahren (Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods);<br>Teil 4: Papierbeutel — Anforderungen und Prüfverfahren (Part 4: Paper bags - Requirements and test methods); | 1.3, 1.4, 2.2.4 |

| Standard harm. under | Standard | Title | Sections of the Annex |
|---|---|---|---|
| | | Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien und Kunststoff-Verbundfolie — Anforderungen und Prüfverfahren (Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods);<br>Teil 6: Papier für Niedertemperatur-Sterilisationsverfahren — Anforderungen und Prüfverfahren (Part 6: Paper for low temperature sterilization processes - Requirements and test methods);<br>Teil 7: Klebemittelbeschichtetes Papier für Niedertemperatur-Sterilisationsverfahren — Anforderungen und Prüfverfahren (Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods);<br>Teil 8: Wiederverwendbare Sterilisierbehälter für Dampf-Sterilisatoren nach EN 285 — Anforderungen und Prüfverfahren (Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods);<br>Teil 9: Unbeschichtete Faservliesmaterialien aus Polyolefinen — Anforderungen und Prüfverfahren (Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods);<br>Part 10: Teil 10: Klebemittelbeschichtete Faservliesmaterialien aus Polyolefinen — Anforderungen und Prüfverfahren (Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods);<br>*(; Part 1 replaced by DIN EN ISO 11607-1)* | |
| 93/42/EEC<br>90/385/EEC<br>98/79/EC | DIN EN 980 | Symbole zur Kennzeichnung von Medizinprodukten (Symbols for use in the labelling of medical devices)<br>*(see also Draft 'Entwurf DIN EN ISO 15223-1')* | 2.2.6 |

| Standard harm. under | Standard | Title | Sections of the Annex |
|---|---|---|---|
| 93/42/EEC<br>90/385/EEC | DIN EN 1041 | Bereitstellung von Informationen durch den Hersteller von Medizinprodukten (Information supplied by the manufacturer of medical devices) | 2.2.6 |
| 93/42/EEC | DIN EN 1422 | Sterilisatoren für medizinische Zwecke — Ethylenoxid-Sterilisatoren — Anforderungen und Prüfverfahren (Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and testing) | 1.3, 1.4, 2.2 5 |
| 93/42/EEC | DIN EN 13060 | Dampf-Klein-Sterilisatoren (Small steam sterilizers) | 1.3, 1.4, 2.2 5 |
| 93/42/EEC | DIN EN 14180 | Sterilisatoren für medizinische zwecke — Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren — Anforderungen und Prüfung (Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing)<br>*(applies up to and including installation qualification)* | 1.3, 1.4, 2.2 5 |
| 93/42/EEC | DIN EN ISO 25424 | Sterilisation von Medizinprodukten — Niedertemperatur-Dampf-Formaldehyd — Anforderungen an die Entwicklung, Validierung und Routineüberwachung von Sterilisationsverfahren für Medizinprodukte (Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices)<br>*(replaces DIN EN 15424)* | 1.3, 1.4, 2.2.5 |

| Standard harm. under | Standard | Title | Sections of the Annex |
|---|---|---|---|
| 93/42/EEC (other than Part 5!) | DIN EN ISO 15883 | Reinigungs-Desinfektionsgeräte (Validierung und Betrieb)(Washer-disinfectors (Validation and operation)<br>Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (Part 1: General requirements, terms and definitions and tests);<br>Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für chirurgische Instrumente, Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw. (Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware etc.);<br>Teil 3: Anforderungen an und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für Behälter für menschliche Ausscheidungen (Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers);<br>Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes);<br>Teil 5: Prüfanschmutzungen und -verfahren zum Nachweis der Reinigungswirkung (*Technische Spezifikation*) (Part 5: Test soils and methods for demonstrating cleaning efficacy (technical specification))<br>Teil 6: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für nicht invasive, nicht kritische Medizinprodukte und Zubehör im Gesundheitswesen.(Part 6: Requirements and tests for washer-disinfectors employing thermal | 1.3, 1.4, 2.2 2 |

| Standard harm. under | Standard | Title | Sections of the Annex |
|---|---|---|---|
| | | disinfection for non-invasive, non-critical medical devices and healthcare equipment); | |
| 93/42/EEC<br>90/385/EEC<br>98/79/EC | DIN EN ISO 14971 | Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte (Medical devices - Application of risk management to medical devices) | 1.2, 1.3, 2.2.3 |
| 93/42/EEC<br>(Parts: 1, 3, 4-7, 9, 11-18)<br><br>90/385/EWG<br>(Parts: 1, 4-7, 9, 11-13, 16-18) | DIN EN ISO 10993 | Biologische Beurteilung von Medizinprodukten (Biological evaluation of medical devices)<br><br>Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (Part 1: Evaluation and testing within a risk management system)<br>Teil 2: Tierschutzbestimmungen (Part 2: Animal welfare requirements)<br>Teil 3: Prüfungen auf Gentoxizität, Karzinogenität und Reproduktionstoxizität; (Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity);<br>Teil 4: Auswahl von Prüfungen zur Wechselwirkung mit Blut (Part 4: Selection of tests for interactions with blood); | 1.3, 1.4, 2.2.5, 2.2.8 |