

## 502.C006-A1 refurbishment of re-usable surgical instruments



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Ateos medical AG, Schachenallee 29, CH-5000 Aarau

**This instruction is applicable to all reusable instruments of Ateos medical AG. This instruction shall assure the competent refurbishment of reusable surgical instruments according to international standards (EN ISO 17664 <sup>2</sup>).**

According to the classification of the Robert Koch Institute<sup>1)</sup> implant associated instruments for joint replacement are to be classified as critical instruments.

- Critical instruments:** penetrate the skin or the mucosa or are in contact to blood, blood products or sterile drugs.
- **Critical instruments A:**
    - Without particular requirements for the refurbishment
    - One-piece instruments with simple design and function (Retractors, Hammer, Osteotom)
  - **Critical instruments B:**
    - One or multi-part instruments with complex geometry with voids, gaps, or screw threads (hip broach, multi-piece impactor, saw guides with slot)

### Symbols:



For further information see packaging insert of the product and product specific surgical technique



Security Advice

### Information for the user or the institution set in charge of the secure refurbishment of the instrument.

#### General information:



For complex instruments which have to be specifically disassembled for cleaning see product specific surgical techniques, where directions for the treatment are provided (disassembly – assembly instruction).



If not specified differently in the product specific surgical technique the number of possible refurbishment cycles is limited by the wear and tear of the instrument or by other detectable damages that may limit the usability.

- Ultrasonic cleaning is allowed for all instruments.
- Cleaning and Disinfection agents: cleaning- disinfection and sterilisation procedures have to be validated according to the valid standards.
- The use of non softened water has to be avoided. The final rinsing steps should be done with de-ionized water to avoid scaling.
- For the disinfection and cleaning cleaning-energetic agents, without protein-fixing effects with or without antimicrobial properties should be used. The details of the specific manufacturer should be considered.
- For precleaning it is preferable to use cleaning agents without protein-fixing effects.



Instruments with metal components may no longer be stored in sodium chloride solutions – Corrosion Risk

- Deposit of cleaning agent remnants on the instrument should be avoided.
- Alkaline cleaning agents may only be applied in case of products specifically approved for instrument cleaning. Approved neutralizing solvents should be used after alkaline cleaning. Afterwards, the instrument should be flushed with de-ionized water.
- Surface treated aluminium components of instruments (anodized, ematal coating) should be cleaned with ph- neutral cleaning agents. Afterwards, the components should be flushed with de-ionized water.

### **Manual Cleaning Procedure**



The transport of contaminated instruments from the operating room to the refurbishment institute should take place in enclosed systems. Cutting instruments should be secured.

- All residual blood, tissue and disinfection agents should be removed directly after use to ensure an efficient refurbishment. Residual tissue should not dry out on the instrument. The time span of 6 hours between use and cleaning should not be exceeded.
- The temperature should not exceed 43°C during removal of residual tissue.
- Instruments with cavities can be flushed entirely on the inside with approved methods. (water beam)



Instruments are to be disassembled for cleaning according specification in the specific surgical technique.

- Synthetic brushes or cleaning pistols should be applied for manual cleaning. Metal brushes should not be applied.
- Pressurized air should be applied for manual drying.

### **Mechanical Cleaning Procedure**

- Chemical and thermo chemical applications are approved for disinfection by machines.
- The basket of the cleaning reservoir should be loaded in a way that fluids can flow easily to ensure an efficient refurbishment. Complex instruments should be positioned carefully. It is to be avoided that instruments cover other instruments.
- Under normal conditions cleaning and disinfection should take place under a standard machine cycle.
- The instruments should be taken out of the machine for reassembly after the cleaning program. Elongated storage in an enclosed machine should be avoided.

### **Quality Check**

Every instrument should be visually checked for residues and eventually cleaned accordingly.



Every instrument should be visually checked for damage and exchanged if necessary.



Instruments which are assembled before sterilisation according to their specific surgical technique, should be assembled according to the valid leaflet and to be checked for function.



Instruments which should be treated with an agent before sterilisation according to their specific surgical technique should be treated with an agent which is approved for usage with autoclave approved instruments.

### **Packaging for Sterilisation**

After arranging in instrument in specific trays, the instruments should be stored in a sterilisation container wrapped in a cloth, or in an approved sterile packaging.

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## Sterilisation

Validated installations and procedures should be applied for fractioned vapour sterilisation.

Typical Sterilisation Cycle:

- Pre vacuum
- 134°C / 2bar / 5 Minutes or 18 Minutes,
- 30 Minutes drying



If sterilisation with Ethylenoxid (ETO) is required, it is described in the product specific surgical technique as such.

## Storage

Instruments should be stored cool and dry at a safe place.

## Literature

Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten – Empfehlungen des Robert Koch Institutes und des Bundesinstitutes für Arzneimittel und Medizinprodukte; 2001 44:1115-1126; Springer-Verlag 2001.

DIN EN ISO 17664 2004-05: Sterilisation of medical products – Information from manufacturer for refurbishment of re-usable medical products.

Manufacturer	
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