Reprocessing of the Surgical Kit of the Aadva Implant System

mechanical/automated cleaning and disinfection methods

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Content

1 Cleaning and disinfection

1.1 Basic information

1. Instruments are delivered as non-sterile. Prior to first use, instruments must be cleaned and sterilized using the following procedure. For proper use of disinfectants or sterilizers, refer to the manufacturer's instructions. Make sure that instruments are not damaged or contaminated. Damaged or contaminated instruments must not be used.
2. After use, immediately clean the instrument to prevent build-up of blood and/or tissue residue. Instruments must be immersed in water or a disinfectant solution immediately after use. Clean and sterilize using the following procedure.
3. Before using, visually inspect Surgical Box S for any signs of damage. Do not use if damaged. Surgical Box S must be disassembled. Clean each part thoroughly. Reassemble Surgical Box S, and place surgical instruments inside. Sterilize according to procedure below.
4. After use, immediately immerse Surgical Box S and surgical instruments in 0.9% saline solution. Do not allow blood or tissue residue to dry onto box or instruments.
5. Sort the instruments according to material groups (Stainless Steel, Titanium) and clean, disinfect and sterilize these groups separately. Instruments made of different materials must never be cleaned, disinfected, or sterilized together.

1.2 Manual pre-cleaning

1. Pay special attention when cleaning holes and narrow spaces.
2. Immediately prior to mechanical reprocessing, remove surgical instruments from tray.
3. Surgical Box S has two inserts; "Drill Insert A" for drills and drivers and "Instrument Insert B" for instruments. Remove both inserts. Position finger under right side of insert and lift – **Fig. 1 & 2**.
4. From the right side, remove all six silicon blocks from back of Drill Insert A – **Fig. 3**.
   NOTE: If the silicon blocks of Instrument Insert B are contaminated with blood, take them out as well.
5. Using a toothbrush or nylon brush, remove all blood and debris from the surface of each part of surgical thoroughly rinse instruments under running water, rotating constantly with the nylon brushes, in order to remove any adhering contamination – **Fig. 4, 5 & 6**.
6. Thoroughly rinse instruments under running water, rotating constantly with the nylon brushes, in order to remove any adhering contamination.
7. Using an appropriate magnifying device (8x magnification), visually inspect the instrument for contaminant residue. If necessary, repeat the above cleaning procedure until no contamination is visible.
   NOTE:
   Ultrasonic cleaning (optional)
   If the medical devices are heavily soiled or if it is difficult to remove coarse soiling manually (as described above), pre-cleaning in an ultrasonic bath is recommended. Make sure that the cleaning agent is compatible with the products and that the exposure times and concentrations specified by the manufacturer are observed. In addition, observe the liquid filling quantity specified by the manufacturer of the ultrasonic bath.

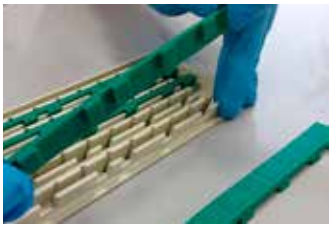

Fig. 1, 2

Fig. 3

Fig. 4, 5, 6

1.3 Cleaning and Disinfection

1.3.1 VALIDATED MECHANICAL PROCESSING

Equipment required:

- Washer-disinfector with Vario TD Program
- Mildly alkaline cleaning solution such as Komet DCTherm (1.5g powder/1L water), REF 9872 or equivalent
- Instrument racks for root canal instruments such as Miele REF E 520 – **Fig. 7**.
- Nylon brushes such as Komet REF 9873 or equivalent – **Fig. 8**.

1. Place the instruments and the parts of Surgical Box S in suitable racks – **Fig. 9**.
2. Insert racks in the reprocessing device so that spray comes into direct contact with all parts – **Fig. 10, 11**.
3. Add cleaning powder to the device following the instructions on the product label and the RDG manufacturer's instructions.
4. Start the Vario TD program (schematic program sequence) including thermal disinfection.
   Conduct thermal disinfection taking account of the AO value and national regulations (DIN EN ISO 15883).
5. When disinfection program is completed, remove parts from the disinfection device and dry.
   Robert Koch Institute (RKI) recommends drying with compressed air.
   When using racks, pay special attention to drying difficult-to-reach areas.
6. Visually inspect instruments and Surgical Box S for structural integrity and cleanliness.
   If residue is still present after mechanical processing, repeat cleaning and disinfections processes until no further contaminants are visible.

1.3.2 STANDARDIZED MANUAL PROCESSING

Equipment required:

- Nylon brushes such as Komet 9873 or equivalent – **Fig. 8**.
- DGHM/VAH-listed cleaner and disinfectant for rotary instruments, such as Komet DC1 (item code 9826/alkaline, aldehyde-free, alcohol-free)

- Ultrasonic device or instrument bath
  1. Follow steps 1-7 as described in Procedure A.1: “Manual pre-cleaning”.
  2. Place Surgical Box S and instruments into a suitable perforated container filled with cleaner and disinfectant. Place container into ultrasonic device.
  3. When using an ultrasonic device for chemical disinfection, carefully follow manufacturer’s instructions regarding solution concentration and immersion time. Immersion time begins when the last part is placed in the device.
     NOTE: In order to prevent protein coagulation, do not process at temperatures in excess of 45°C.
  4. Thoroughly rinse parts when immersion time has been completed.
     De-ionized water is recommended to prevent residue.
  5. Dry parts using compressed air.

Fig. 7

Fig. 8

Fig. 9

Fig. 10

Fig. 11

2 Inspection, functional test, and packaging

2.1 Inspection

Visually check instruments for damage and cleanliness - **Fig. 12.**
If visual residue is present, repeat cleaning procedure until no contamination can be seen.
Controls and function inspection: Discard instruments demonstrating any of the following defects:

a) Dull, chipped or broken edges
b) Warping, dents or bends
c) Corrosion

2.2 Functional test

The best way to check whether the service life of the medical device has been exceeded is to carefully inspect the product before use and test it for proper function - **Fig. 13**.

- Check the drill for sharpness and damage.
- Check products and their respective counterparts for proper assembly and functionality, e.g.: Ratchets: Check proper switching and tight fit of ratchet insert.
- Check products with PTFE or O-rings for missing or damaged rings.
  Check friction between instrument and counterpart, e.g.: Implant driver: Check sufficient clamping force between insertion instrument and implant.

Fig. 12

Fig. 13

2.3 Packaging

1. After cleaning and disinfecting of the Surgical Box S, place the inner silicon blocks back in the grooves.
   Insert the silicon blocks from left side, fitting each projection into each groove.
   Make sure that all silicon blocks fit properly, otherwise drills cannot be held properly.
2. Return both Drill Insert A and Instrument Insert B to outer case. Place drills and instruments into Surgical Box S following instructions on the box. Place instruments in correct direction.
   NOTE: a) To prevent cutting of silicon liner, place drill upside-down.
   b) To place Tapered Implant Drill Stopper into Surgical Box S, first insert Drill Stopper Holder S in the position indicated, then attach Drill Stopper into Drill Holder S. Close the lid of Surgical Box S.
3. Place individual instruments / Surgical Box S in appropriate sterilization pouches.
   Sterilization pouch should be large enough to seal without stretching.

Fig. 14

Fig. 15

3 Sterilization

1. Conduct vacuum process steam sterilization according to DIN EN 13060 specifications:

Method	Cycle	Temperature	Exposure time *	Drying time *
Superheated steam (EU**)	Vacuum process (fractionated pre-vacuum)	134 °C	3 Min.	20 Min.

* Minimum exposure times, the operating times are longer and may vary depending on the device
** EU customers must apply these steam sterilization parameters.

2. Steam must be free of foreign matter to prevent discoloration and corrosion.
3. Follow DIN EN 13060 recommended threshold values for feed water and steam condensate.
4. When sterilizing several instruments, do not exceed the maximum capacity of the sterilizer.
5. Immediately prior to surgery, remove the lid of Surgical Box S by lifting upwards.

4 Storage

The instruments must be stored dry and dust-free in the sterilization packaging, the shelf life must be observed (sterilisation sleeves / pouches ≤ 6 Month)

5 Notes

a. Wear protective clothing, cap, masks, goggles and gloves during disinfection and sterilization.
b. Prior to sterilization, make sure Surgical Box S and instruments are free of contaminants, cleaning agent and water.
c. Do not allow instruments / Surgical Box S to be contaminated after sterilization. Avoid contact with skin, fingers, saliva or non-sterile objects.
d. When not in use, store instruments and Surgical Box S separately.
e. Instruments should not be immersed in saline for a prolonged period of time.
f. Remove any rusted instruments prior to sterilization.
g. Use of chlorine or peroxide based disinfectant, strong acid water, surface active agent without rust proofing agent or peracetic solution is not recommended as this may cause rust. Additionally, for instruments made of titanium, or titanium alloy, do not use alcohol or potassium hydroxide-based disinfectants as discoloration may occur. Titanium or titanium alloy immersed in solutions containing rust proofing surface active agents may become tarnished when immersed for a long period of time, or at high temperatures.

6 General remark

1. Always comply with regional and national regulations for reprocessing instruments.
2. The processor is responsible for the efficacy of their reprocessing protocol.
   Routine review of the validated mechanical or standardized manual reprocessing procedures is recommended.
3. Any deviation from procedures described here (e.g. use of other process chemicals) should be carefully evaluated by the processor for their effectiveness and possible negative consequences.

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