Instructions for Preparing Resterilisable American Eagle Hand Instruments

◊ Fundamental Observations

New instruments must always undergo a thorough cleaning and sterilisation prior to initial use as described in the section **"Steps for Instrument Preparation."**

All instruments must be cleaned, disinfected, and sterilised prior to each use. It is essential for proper sterilisation of the instruments that they have been effectively cleaned and disinfected. The user is responsible for the sterility of the instruments. Please ensure therefore that only validated methods are used for cleaning, disinfection, and sterilisation.

You should also observe the legal regulations applicable in your country as well as the hygiene-related directives from the medical practice or the hospital. Improper handling, care and use for any purpose other than the intended one may cause premature wear of the dental instruments. People who use these instruments should have knowledge of the use and handling of dental instruments, accessories, and related devices.

◊ Examination and Functional Check

It is very important that each dental instrument is inspected for breaks, cracks, or malfunctions before each use. Do not use damaged instruments.

◊ Protection of Staff and Third Parties

When dealing with any used and/or contaminated instruments, you must wear protective gloves that meet the requirements of Directive 89/686/EEC in order to ensure the utmost safety of staff dealing with contaminated instruments. Contaminated instruments must be promptly cleaned and disinfected in the preparation process but within 5 hours at the latest.

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◊ Steps for Instrument Preparation

Pre-Treatment

Remove any visible debris immediately after use – or within max. 90 minutes, before you further process the instruments individually or in a tray/cassette system. Instruments with debris must be pre-treated within max. 90 minutes after use.

Do not place in NaCl solutions / no wet removal, otherwise there is a risk of pitting or stress corrosion.

Only use an authorised solution of a combined cleaning and disinfecting agent (i.e., German Society of Hygiene and Microbiology (DGHM) approval, RKI approval, or CE marking) that does not have a protein-fixing effect - when mixing, strictly observe the recommendations of the manufacturer.

Avoid overfilling instrument trays and wash trays.

In order to manually remove coarse debris, only use a soft brush, preferably with a long handle. Under no circumstances should you use metal brushes or steel wool.

Personal protective equipment (PPE) must be used. Manual pre-cleaning should be carried out under the surface of the water - protection against splashback.

Please be aware that the disinfecting agent used during pre-treatment is only intended for personal safety and is not a substitute for later disinfection.

◊ Mechanical Cleaning

Equipment:
Cleaning/disinfecting device, cleaning agent – we do not recommend alkaline cleaners. They have a negative effect on your instruments. In addition, the required neutralisation means additional stress on the instruments.

1. Insert the instruments into the device so that they can be completely immersed.
2. Set the cycle, wash for at least X minutes*, and rinse for at least X minutes* (*Refer to the manufacturer's specifications)
3. When removing the instruments, inspect them for visible dirt. If necessary, repeat the cycle or clean manually.

◊ Manual Cleaning

Equipment:
Cleaning agent, brush, running water

1. Thoroughly rinse surface contamination off the instrument.
2. Apply cleaning agent solution onto all surfaces with a brush.
3. Rinsing - the instrument is held under running water for at least 5 seconds.

◊ Disinfection

Disinfection solutions can be used in compliance with the instructions on the label (Refer to the manufacturer's instructions). In the case of mechanical cleaning, thermal disinfection can then be carried out for 10 minutes at 93° C (For cleaning and disinfection device, refer to the manufacturer's instructions).

Use fully desalinated water for the final rinse whenever possible. Through its use, spots, coatings, and corrosion on the item being washed can be prevented.

◊ Drying

If drying is achieved as part of the cleaning / disinfection cycle, 93° C should not be exceeded.

◊ Check

Carry out a visual inspection for damage and wear. Blades should not have any nicks and should be smooth.

◊ Packaging

Packaging materials must be qualified in accordance with DIN EN ISO 11607-1.
Shaping and sealing processes must be qualified in accordance with DIN EN ISA 11607-2.

Sets:
Sort instruments into the trays provided or place onto sterilisation trays. The blades must be protected. A suitable process is to be used to package the trays.

◊ Steam Sterilisation

Hot air sterilisation is not permitted!

The steriliser and the sterilisation process must meet the applicable standards and guidelines.

According to EN 13060 small steam sterilisers, the steriliser types are divided into 3 categories:

Type B for packaged, large, hollow, and porous products.
Type N for unpackaged large instruments
Type S for products that the manufacturer of the steam sterilisers specifies

- Gravitation process (with sufficient product drying)
- Steam steriliser according to DIN EN 13060 or DIN EN 285
- Validated in accordance with DIN EN ISO/ANSI ISO 17665 (valid commissioning and product-specific performance assessment)
- Maximum sterilisation temperature 134° C (273° F); plus tolerance according to DIN EN ISO/ANSI AAMI ISO 17665
- Sterilisation time (exposure time at the sterilisation temperature) at least 30 min at 121° C (250° F) or 4 min at 134° C (273° F)

◊ Stability of substances/materials

We do not recommend the use of strong bases (pH>9), strong acids (pH <4), phenols or iodophors, as well as halogenated hydrocarbons, interhalogen compounds, strong peroxides (oxidising agents) or organic solvents as cleaning agents.

◊ CAUTION:
Higher wear to the instrument in the event of fast sterilisation.

Additional information:
When sterilising multiple instruments in one sterilisation cycle, the maximum load of the steriliser must not be exceeded (Refer to the manufacturer's instructions).

◊ Storage

The duration and conditions for storing the sterile instruments in their final packaging is determined by the barrier packaging system. We cannot provide any information on this. You can request this information from the packaging material manufacturer if it is not part of a validation according to DIN EN ISA 11607.