Recommendations for Instrument Cleaning and Sterilization

1. DESCRIPTION
USB Medical instruments are designed to perform specialized functions in specific cardiac surgical or endoscopic procedures.

2. HOW SUPPLIED
USB Medical instruments are supplied **NON STERILE** and must be cleaned and sterilized prior to use according to the procedures described in this document.

3.
Use of these instruments in ways other than those for which the instruments were designed could result in damaged or broken instruments. Damage is possible if excessive force is applied to the retractor shaft or blades. **The HV Retractor and Blades Should Not be Dismantled.** Temperatures higher than 286°F (141°C) may damage the instrument. The manufacturer does not accept liability for direct damage or consequential damage that results from improper use or handling, in particular through failure to comply with the intended use. Instruments may only be used for their intended purpose in the corresponding medical fields by appropriately trained and qualified staff.

4. RECOMMENDATIONS BEFORE USE
Each instrument should be inspected before each use for damaged or broken components.

Do not use damaged or broken instruments.

5. CARE AND HANDLING
GENERAL INFORMATION
As an element of your responsibility for the sterility of the instruments during application, always ensure that only processes for cleaning/disinfection and sterilization are used that have been validated as appropriately specific to the device and product. Make sure that the devices used (disinfector, sterilizer) are regularly serviced and tested and that the validated parameters are observed for each cycle.

5.1. Dismantling

The instrument and blades cannot be dismantled.

5.2 Pre-cleaning:
Coarse impurities must be removed from the products directly after the application (within 2 hours maximum). Use running water or a disinfectant solution for this process; the disinfectant solution should not contain aldehyde (otherwise fixation of blood impurities can occur), should have a verified effectiveness (e.g. DGHM or FDA approval and/or CE marking) should be suitable for instrument disinfection and should be compatible with the instruments (see section 5.10).

For manually removing impurities, only use a soft brush or a clean soft cloth that is intended for this purpose; never use metal brushes or steel wool.

For pre-cleaning the inner lumen, thoroughly rinse the inside of the instrument with water or a disinfectant solution using the Luer Lock connection and a pressure gun or a disposable syringe (minimum of ten (10) 100 ml volumes). Please note that the disinfectant used in the preliminary treatment only serves personal safety and does not represent a substitute for the later disinfection stage to be carried out after cleaning.

5.3. Machine cleaning
When selecting the disinfector, it must be verified that:
- The disinfector corresponds to EN ISO 15883 and always exhibits a verified effectiveness (e.g. DGHM - Listing or FDA approval and/or CE marking);
- A tested program for thermal disinfection (minimum 10 minutes at 93°C) is used, if possible (with chemical disinfection there is a risk of disinfectant residues on the instruments);

- The program used is suitable for the instruments, and provides sufficient rinsing cycles;
- Only sterile water or water with a low bacterial count (max. 10 germs/ml) as well as water with a low endotoxin count (max. 0.25 endotoxin units/ml) is used;
- The air used for drying is filtered and
- The disinfector is regularly serviced and tested.

When selecting the cleaning agent system used, it must be ensured that:

- It is suitable for cleaning instruments made of stainless steel.
- A suitable disinfectant with verified effectiveness (e.g. DGHM - Listing or FDA approval and/or CE marking) is used – insofar as no thermal disinfection is used – and that this is compatible with the cleaning agent used and
- The chemicals used are compatible with the instruments.

The concentrations specified by the manufacturer of the cleaning or disinfecting agents must always be observed.

Procedure:

1. Place the instruments in the disinfector. At the same time, ensure that the instruments do not touch each other.
2. Start the program.
3. Remove the instruments from the disinfector after the program has finished.
4. Inspect the instruments and pack them immediately after removal.

Evidence for the suitability of the instruments for effective mechanical cleaning and disinfection has been provided by an independent accredited test laboratory with use of the disinfector G 7736 (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The process described above has been taken into account for this.

5.4. Manual Cleaning:

When selecting the cleaning agent system used, it must be ensured that:

- It is suitable for cleaning instruments made of stainless steel;
- The cleaning agent – if applicable – is adequate for ultrasonic cleaning (non foaming);
- A suitable disinfectant with verified effectiveness (e.g. DGHM - Listing or FDA approval and/or CE marking) is used – insofar as no thermal disinfection is used – and that this is compatible with the cleaning agent used and
- The chemicals used are compatible with the instruments.

Combined cleaning/disinfecting agents should only be used if the instruments have been exposed to very low preliminary contamination (no visible impurities).

The concentrations and periods of action specified by the manufacturer of the cleaning or disinfecting agents must always be observed. Only use fresh solutions, only sterile water or water with a low bacterial count (max. 10 germs/ml) as well as water with a low endotoxin count (max. 0.25 endotoxin units/ml) and only filtered air for drying.

Procedure:

Cleaning

1. Place the instruments in the cleaning bath for the specified period of action so that the instruments are sufficiently covered (if necessary, ultrasonic support or careful brushing with a soft brush). At the same time, ensure that the instruments do not touch each other.
2. Remove the instruments from the cleaning bath and rinse these thoroughly at least five times with water.
3. Inspect the instruments (see Section 5.5).

Disinfection

1. Place the cleaned and inspected instruments in the disinfecting bath for the period of action specified so that the instruments are sufficiently covered. At the same time, ensure that the instruments do no touch each other.
2. Then remove the instruments from the disinfection bath and rinse these thoroughly at least five times with water.
3. Pack the instruments immediately after removal, if possible (see Sections 5.6 and 5.7, regarding additional secondary drying).

Evidence for the suitability of the instruments for effective manual cleaning and disinfection has been provided by an independent accredited test laboratory with use of the cleaning agent Cidezyme LF/Enzol and the disinfection agent Cidex opa (Johnson & Johnson GmbH, Norderstedt). The process described above has been taken into account for this.

***CAUTION*: Failure to properly clean and dry the instruments may lead to a reduction in instrument life.**

***WARNING*: Failure to properly clean and dry the instruments may lead to inadequate sterilization.**

5.5. Inspection/Functional test
Test all instruments after cleaning or cleaning/disinfection for signs of corrosion, damaged surfaces, splintering and impurities, and remove damaged instruments (for quantitative restriction on reusability, see Section 5.11). Instruments that are still contaminated must be cleaned and disinfected again.

5.6. Servicing
The instruments should be treated with instrument oil after each cleaning and disinfection. For this, ensure that only instrument oils (white oil) are used, which are permissible for steam sterilization – allowing for the maximum sterilization temperature applied, and which exhibit a verified biocompatibility.

5.7. Packing
We recommend carrying out the sterilization in sterilization trays and sterilization containers; however, disposable sterilization packages (single or double packaging) can also be used. The packaging used must correspond to the following requirements as per EN ISO 11607 (before EN 868/ANSI AAMI ISO 11607):
- Suitable for steam sterilization (thermal stability up to at least 141 °C, sufficient vapor permeability);
- Sufficient protection of the instruments and sterilization packaging against mechanical damage and
- Regular servicing in accordance with the manufacturer's specifications (sterilization container)

5.8. Sterilization
Only the sterilization processes listed below may be used for sterilization; other sterilization processes are not permissible.

Steam sterilization
- Fractionated vacuum process[1] (with sufficient product drying)
- Steam sterilized as per EN 13060 or EN 285
- Validated according to EN ISO 17665 (before EN 554/ANSI AAMI ISO 11134) (applicable commissioning and product-specific performance evaluation)
- Maximum sterilization temperature 138°C (280°F; plus tolerance corresponding to EN ISO 17665 before EN 554/ANSI AAMI ISO 11134)
- Sterilization times – *see chart below*

Recommendations for Instrument Cleaning and Sterilization

Cycle Type	Minimum Temperature	Minimum Exposure Time
United States Recommended Parameters		
Pre-vacuum / Vacuum Pulse	132°C/270°F	4 minutes
Cycle Type	**Minimum Temperature**	**Minimum Exposure Time**
European Recommended Parameters		
Pre-vacuum / Vacuum Pulse	134°C/273°F	3 minutes

[1] Use of the less effective gravitation process must be supported by an additional product, sterilizer and process-specific validation for which the user is responsible (longer sterilization times may be necessary).

Evidence for the suitability of the instruments for effective steam sterilization has been provided by an independent accredited test laboratory with use of the steam sterilizer EuroSelectomat (MMM Münchener Medizin Mechanik GmbH, Planegg) and use of the fractionated vacuum process. The process described above was taken into account for this.

The flash sterilization method is not permissible. Also, do not use hot-air sterilization, radiation sterilization, formaldehyde/ethylene oxide sterilization, or plasma sterilization.

5.9. Storage
The instruments must be stored dry after sterilization.

5.10. Material resistance
When selecting the cleaning and disinfecting agents, ensure that they do not contain the following components:
- Strong acids and bases
- Strong oxidants
- Phenols
- Aluminum chloride
- Halogens/Halogenated hydrocarbons
- Furfural
- Methylene chloride
- Nitrobenzene

- Please only use neutral or low alkaline (< pH 10) cleaning agents.
- Never clean any instrument with metal brushes or steel wool.
- Instruments must never be exposed to temperatures higher than 141°C (286°F)!

5.11 Reusability – Warranty
The instruments can be used for either up to 2 years or 400 cycles, whichever occurs first, if corresponding care is taken and they are not damaged. After this period, they must be sent back to the manufacturer for testing and inspection. Please note that the user must accept responsibility for each further use extending beyond this period or the use of damaged and contaminated parts.

The manufacturer is not liable in any way in the event of failure to observe the above.

6.0 Approval

CE

The instruments correspond to the fundamental requirements of the European **Council Directive 93/42/EEC and the Harmonized Standards concerning Medical Devices.** The **HV Heart Retractor®** meets the essential requirements of Annex VII as a Class I medical device.

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