All FEHLING Aortic Punches	

Warnings: Do not clean CERAMO® instruments (identifiable by the brownish black surface) and titanium instruments using the Orthovario and Oxivario process: Using the two processes will result in the destruction of titanium instruments or the titanic CERAMO® coating after some time due to oxidative processes (titanium is dissolved out by H_2O_2).

Prior to processing a risk assessment on the instrument must be performed.

Aortic punches may only be used, processed and disposed of by competent medical personal!

Intended use:

Aortic punches are used for circular excision off vessel walls for anastomosis.

Before use:

FEHLING INSTRUMENTS aortic punches are delivered non-sterile and have to be cleaned and sterilized by the user before their first and any further use (see reprocessing).

⚠ Handle punches with care on storage, transport and cleaning!
Avoid impacts and selective loads!

⚠ Perform a safety check before each use of the punch. Check for cracks, breaks or mechanical malfunctions. This check is performed by closing and opening the punch outside the patient.

During use:

⚠ Avoid overstressing in order to minimize the risk of breakage!

The conical shearing head of the punch is introduced into the vascular incision. By compressing the handle, the ring knife at the distal end of the slider (upper part of the instrument) is moved over the shearing head and thereby cuts the tissue.

⚠ While still in the closed position, remove the punch from the patient and harvest the tissue to avoid the risk of embolism.

It may occur that single thin tissue fibres are not cut completely. In those cases final cutting should be performed with an appropriate instrument i.e. scissors or knife.

Reprocessing:

Restriction for reprocessing:
Frequent reprocessing has only minor effects on these instruments.
Usually the end of the product service life is determined by wear and damage due to utilization.

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage:	Store instruments in dry rooms to avoid condensation. It is recommended to start reprocessing the instruments directly after use, as dried residues located in areas with limited access are quite difficult to remove.

Preparation of cleaning: Mechanical processing should be preferred over manual processing.	Make sure that traces of blood, tissue and medication are removed from the instruments directly after termination of the surgery and that they are immediately forwarded to mechanical cleaning. Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use an approved solution of a combined cleaning and disinfecting agent without protein fixing effect (observe the recommendation of the chemicals producer when mixing the solution). Avoid overfilling of instrument sets and washing trays – use appropriate instrument carriers only. Be particularly careful that the mouths/points do not get stuck in the mesh when placing and removing the instruments into/from the set baskets. Disassemble dismountable instruments according to the appropriate assembly instructions. Please refer to the appropriate assembly instructions, if necessary! CERAMO® aortic punches.....M09 Aortic punches with T-handle .....M25 Always open joint instruments before processing. Release the springs, if necessary.
Cleaning/Disinfection acc. to EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfecting are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.
Cleaning: mechanically acc. to EN ISO 15883-1:2009	<u>Validated procedure:</u> Equipment: Washer/disinfector G 7836 CD (Miele) Process: 2-component process alkaline/enzymatic Detergent: deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland) <u>Preparation:</u> • Joint instruments are to be placed in the device such that the hinges are open and the water can flow off cavities and blind holes. • Make sure that all cavities are completely flushed on the inside as well. • Make sure that no flushing shadows arise. <u>Parameters:</u> • 3 min pre-cleaning with tap water • Drain • 10 min cleaning with tap water and 0.3 % TWIN PH10 at 35 °C (95°F) and 0.2 % TWINZYME at 40 °C (104°F) • Drain • 2 min rinsing with deionized water > 30 °C (86°F) • Drain • 1 min rinsing with deionized cold water • Drain • 5 min thermal disinfection at 93 °C (200°F) • After mechanical cleaning check cavities, blind holes, etc. in particular for visible dirt. Repeat cycle or clean manually, if required.
Cleaning/Disinfection: Manually Manual cleaning should be avoided as it cannot be validated.	<u>Equipment:</u> Detergent (active and non protein-fixing cleaner, with or without anti-microbial effect and/or enzymes), compressed-air cleaning gun, soft cloths/sponges, running water. 1. Thoroughly rinse dirt from the surface of the instrument. 2. Apply detergent solution on all surfaces using a soft cloth or sponge. Make sure that joint instruments are cleaned in open as well as in closed position. 3. Thoroughly rinse all cavities and blind holes with a sufficient amount of detergent solution (min. 200 ml) using a syringe. Take special care that enough solution flows to the distal end. 4. Hold the instrument under running water. The running water must flow through the cavities, and blind holes must be filled and emptied several times. Use deionized water for the final rinsing.

	For manual cleaning the detergent solution should not be warmer than room temperature. Disinfection: Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (min. 5 minutes at 93 °C / 200°F). (Thermal disinfector, see indications of the device manufacturer.) Demineralized water must be used for the final rinsing. Make sure that no residues remain on the products.
Drying:	If drying is achieved as part of the cleaning/disinfection cycle, 120 °C (248°F) should not be exceeded.
Maintenance:	Assemble the instruments according to the assembly instructions. Apply a small amount of high-grade, water-soluble instrument spray on the hinges.
Control and function test:	Check instruments for easy operation (avoid too much play). Check locking mechanisms. Using a magnifying lamp visually inspect for damage and wear. Edges should not show nicks and should be even. Pay special attention to the critical points on movable parts and in the working area. Check if the two opposing cutting edges of slider and foot close completely over the entire length of the cutting edge. If not the instrument cannot or only in a limited way achieve its function. The punch must be taken to be repaired. Sort out defective, blunt or damaged instruments and send them to the manufacturer for repair. Clean and disinfect instruments before sending them to be repaired. A confirmation form for this procedure can be obtained from the manufacturer.
Packaging:	Separate: acc. to standards of the EN 868 and EN ISO 11607. Sets: Sort instruments in trays provided for that purpose or place them on universal sterilization trays. The edges must be protected. Use an appropriate procedure to pack the trays.
Sterilization:	Steam-sterilize using the fractional vacuum process at 134 °C / 273°F (min. 5 minutes holding time) with equipment acc. to EN 285, validated sterilization processes! To avoid formation of stains and corrosion, the steam must be free of components. The recommended limit values of the components for feed-water and steam condensation are defined in EN 285. Validated process: Equipment: Selectomat HP (MMM) 1. Three times pre-vacuum 2. Sterilization temperature 134 °C (273°F) 3. Holding time: 5 minutes 4. Drying time: min. 10 minutes
Storage:	Acc. to EN 868 and EN ISO 11607.
Additional information:	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer). Additional national standards like AAMI TIR-12-2004 may be applicable.
Contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: +49 (0) 6188-957440 Fax: +49 (0) 6188-957445 E-mail: info@fehling-instruments.de

Storage / Symbols

Protect from excessive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Observe instructions for use	Article number	Attention	

! Each modification to the product or deviation from these instructions of use results in exclusion of liability!
Subject to change without notice.

Manufacturer:
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The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.