CEBOTARI Universal Sternal Retractor

REF: MQL-1, CEBOTARI universal sternal retractor, body

Sternotomy blades		**Accessories:**
MQL-4..... 34x50mm (pair)	MQL-9..... 34x120mm (pair)	MZZ-1Q.....Clamping element
MQL-5..... 43x50mm (pair)	MQM-1..... 43x120mm (pair)	MZZ-2.....Clamping element
MQL-6..... 34x100mm (pair)	MQM-2..... 50x120mm (pair)	MZZ-3.....Clamping element
MQL-2..... 43x100mm (pair)	MQM-3..... 63x120mm (pair)	- Ball joint adapter
MQL-7..... 50x100mm (pair)		- IMA retractor blades
MQL-8..... 63x100mm (pair)	MQL-3..... CEBOTARI IMA blade	- Atrial retractor

⚠ Only trained medical personnel may use, reprocess or dispose of retractor systems!
The FEHLING CEBOTARI universal sternal retractor is intended for temporary use only (< 60 minutes)!

Intended use:

The CEBOTARI universal sternal retractor is intended for exposure of the thorax via total and partial sternotomy approaches, including the exposure of IMA and mitral valves.

Indications and contraindications

Indications	**Contraindications**
Every surgical intervention requiring sternotomy access in patients with appropriate anatomy.	Patients with an anatomy unsuited for use of the retractor.

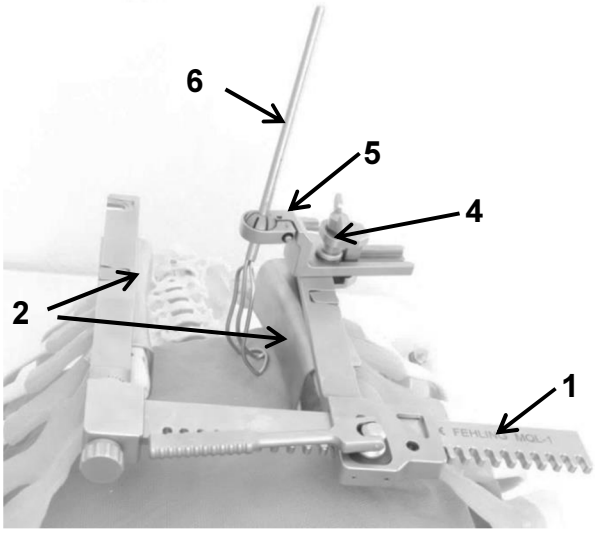
Possible side effects of a sternotomy

In the medical literature, the following adverse effects are described for a sternotomy that can also occur during the intended use of the CEBOTARI universal sternal retractor:

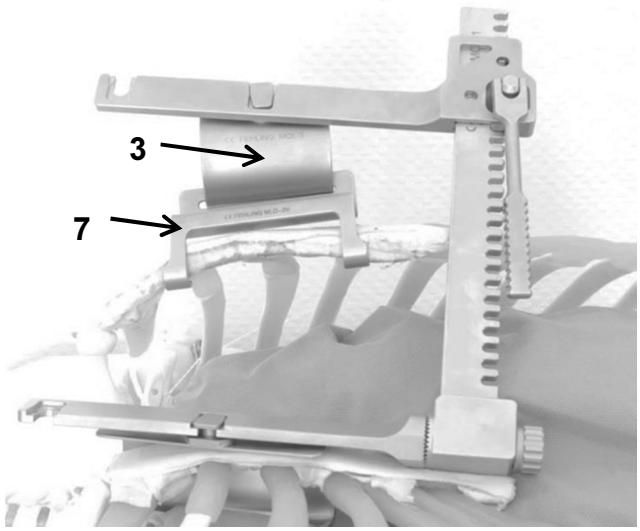
- Infections including mediastinitis
- Instability of the sternum and the thorax
- Impaired wound healing
- Bruising of anterior and posterior sternum structures
- Fractures of the sternum, sternocostal joints and costal cartilage
- Necrosis

Components

Examples of configurations:



with atrial retractor



with IMA blade

Kugeladapter **Befestigungselemente**

5a **5b** **5c** **4a** **4b** **4c**

MRV-0F MRV-0J MRV-0R

MZZ-1Q MZZ-2 MZZ-3

	Description	REF
1	CEBOTARI universal sternal retractor body (see components listed under Assembly)	MQL-1
2	Sternotomy blades	
	Sternotomy blades 43x100mm	MQL-2
	Sternotomy blades 34x50mm	MQL-4
	Sternotomy blades 43x50mm	MQL-5
	Sternotomy blades 34x100mm	MQL-6
	Sternotomy blades 50x100mm	MQL-7
	Sternotomy blades 63x100mm	MQL-8
	Sternotomy blades 34x120mm	MQL-9
	Sternotomy blades 43x120mm	MQM-1
	Sternotomy blades 50x120mm	MQM-2
	Sternotomy blades 63x120mm	MQM-3
3	IMA blade	MQL-3
Accessories		
4	Clamping element	
4a	with wing screw	MZZ-1Q
4b	with gear wheel	MZZ-2
4c	with gear wheel and lip	MZZ-3
5	Ball joint adapter D 6.35mm	MRV-0J
5a	Bayonet	MRV-0F
5b	with joint, hexagon bolts	MRV-0J
5c	with joint, wing bolts	MRV-0R
6	Atrial retractor	
	Tricuspid 45/45/150 mm	MRV-2H
	Tricuspid 45/45/200 mm	MRV-2L
	Atrial retractor 65/30/150 mm	MRV-3H
	Atrial retractor 65/30/200 mm	MRV-3L
	Atrial retractor 65/20/150 mm	MRV-4H
	Atrial retractor 65/20/200 mm	MRV-4L
	Atrial retractor 65/40/200 mm	MPF-1H
7	IMA retracting blade	MLC-2V
	Hexagon cardan screwdriver (not illustrated)	LMT-4

Prior to use:

⚠ The FEHLING INSTRUMENTS CEBATORI universal sternal retractor is non-sterile when delivered and must be cleaned and sterilized by the user prior to initial use and prior to all other further uses (see reprocessing). **Risk of infection!**

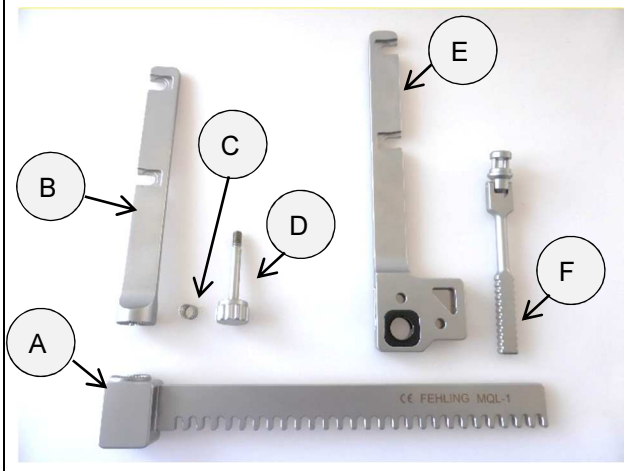
Retractor components must be handled with care during storage, transportation and cleaning! Avoid striking the instrument or applying pressure to its parts! **Risk of injury!**

Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions (see also Maintenance, Checking and functional testing).

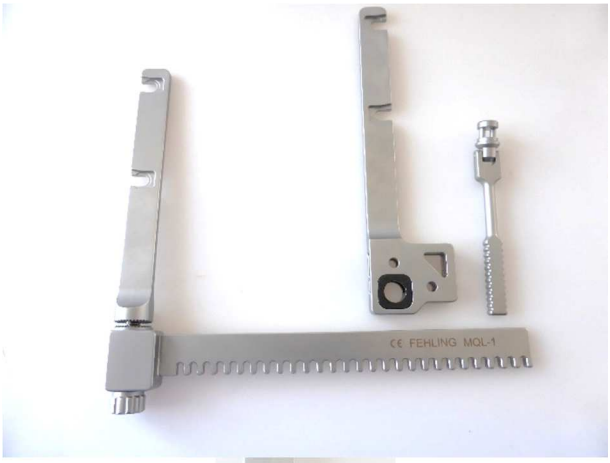
Use only sterilized products of sound quality!

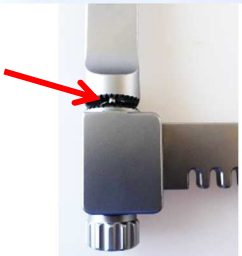
Assembly:

The CEBOTARI universal sternal retractor must be disassembled for processing (see "Reprocessing").
For this reason, assembly prior to use is necessary.



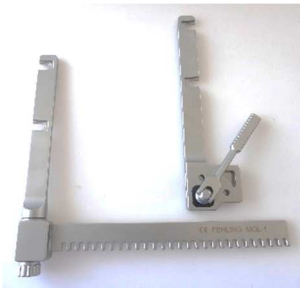
Sternal retractor (body)	
A	Gear Rack
B	Rotating retractor arm
C	Spring
D	Clamping screw
E	Linear movable retractor arm
F	Drive lever

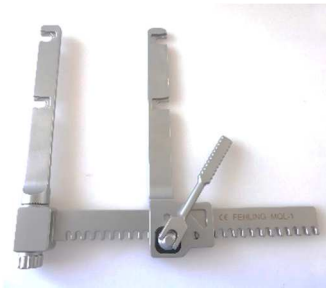




To mount the rotating retractor arm to the gear rack, first push the clamping screw through the drill hole in the body as illustrated.
Push the spring over the protruding thread of the screw.
Then mate the rotating retractor arm and the clamping screw and screw them together.

⚠ The face of the rotating retractor arm is fitted with a pin which restricts the rotation of the rotating retractor arm. This pin (arrow) must engage with the corresponding groove on the body.





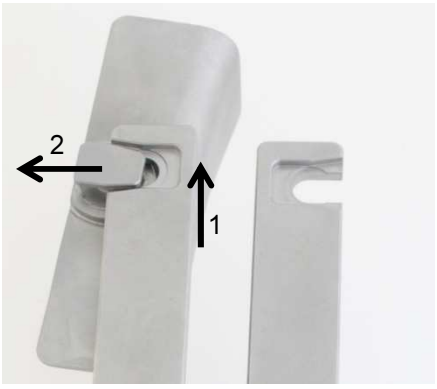
To mount the linear movable retractor arm, insert the drive lever into the retractor arm as illustrated on the left.
Then push the retractor arm laterally onto the gear rack and move it completely onto the retractor body by turning the drive lever clockwise.

During use:

⚠ Avoid striking the instrument or applying pressure to its parts! **Risk of injury!**

⚠ Only use small sternotomy blades for **partial sternotomy**. **Risk of injury!**
In **Z-sternotomy**, ensure that the retractor is not twisted. **Risk of injury!**

Insertion of the sternotomy blades



⚠ **Observe the direction of the clamping profile!**

The blade suspension must be inserted with the narrow side first.
Slight engagement of the cylindrical cone on the bottom of the blade suspension signals the correct final position of the blade.

If the blade is suspended incorrectly, the angular rotation of the sternotomy blades is no longer given.

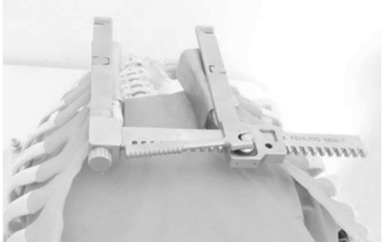
To suspend the blades, slight pressure toward the distal end of the retractor arm is necessary to overcome the blade safety (arrow 1). Then the blades can be removed laterally (arrow 2).

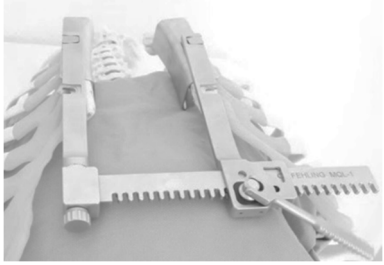
⚠ **Observe correct orientation of the sternotomy and IMA blades! Risk of injury!**

Depending on the surgical purpose and space available for assembly, the sternotomy blades can be connected to the retractor either before (A) or after (B) introduction to the sternal incision.

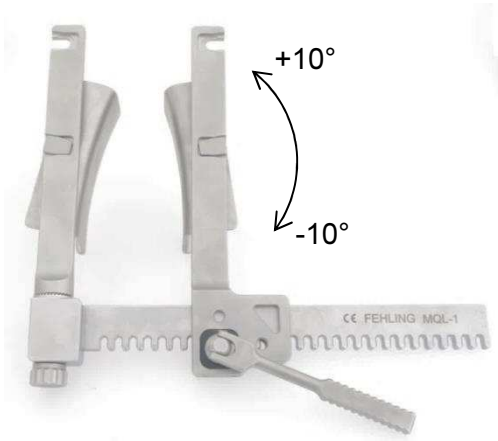
A) The blades are first mounted in the slots of the retractor arms by inserting the cylindrical pins and then into the sternal incision.

B) The blades are first inserted into the sternal incision. Then insert the two retractor arms between the blade pins. (This can be performed with the retractor either closed or slightly open.) Open the retractor arms by winding the drive lever and the slots on the retractor arms will engage with the pins on the blades and retract the cut edges of the sternum.





Depending on requirements of the surgical field, the sternotomy blades can be positioned on either of the two slots on the retractor arms.



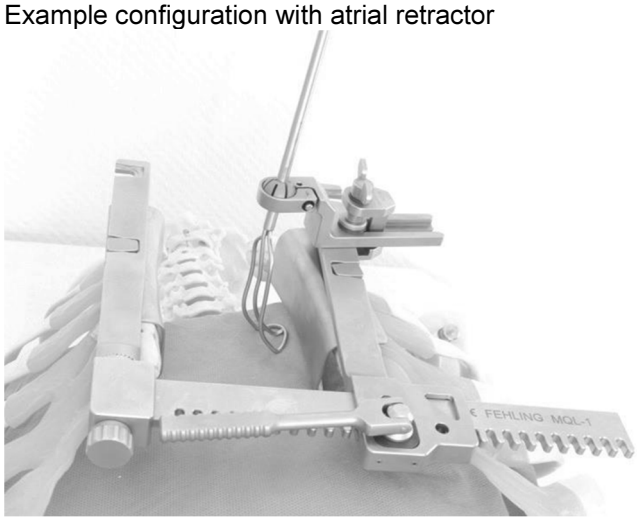
Angular rotation of the sternotomy and IMA blades:

The design of the blade attachment allows an angle rotation of the blades of up to ±10°. The sternotomy blade can thus lie against the edge of the sternum during retraction (better load distribution than with rigid attachment) and distend the sternum safely.

Attention: If the blade is attached incorrectly, the angular rotation of the sternotomy blades is no longer possible.

For exposure of the thorax, open the retractor as far as necessary using the drive lever.

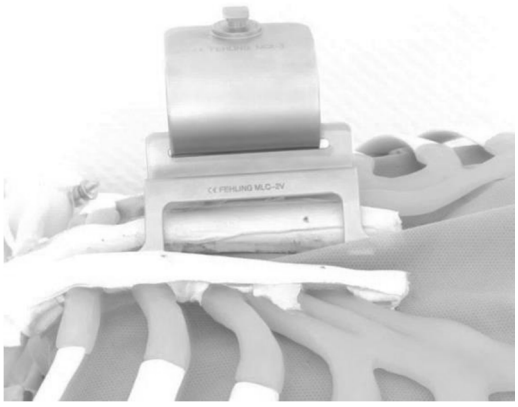
Example configuration with atrial retractor



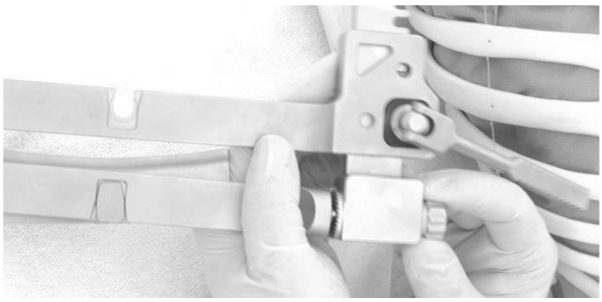
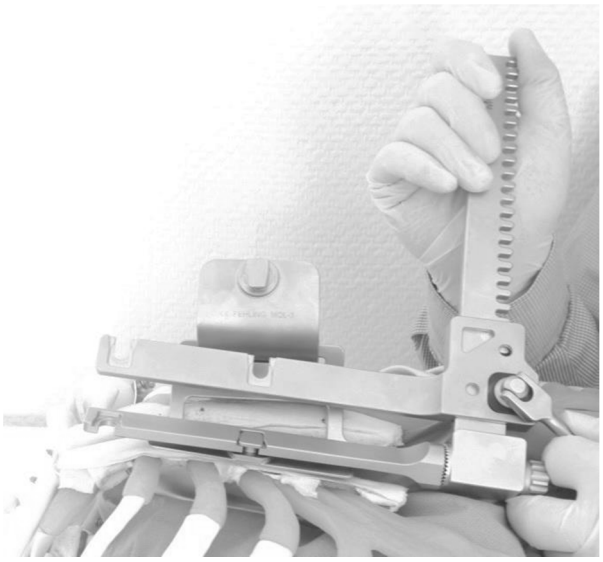
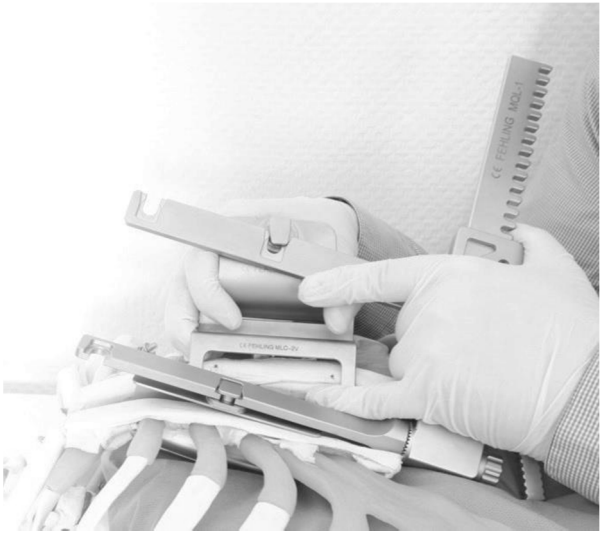
Atrial retractors (see list of components and accessories on page 2) can be attached anywhere on the retractor arms (including the area of the blades) using clamping element MZZ-1Q with a suitable ball joint adapter.
Mounting of the clamping element and the ball joint adapter is described in IFU G071.

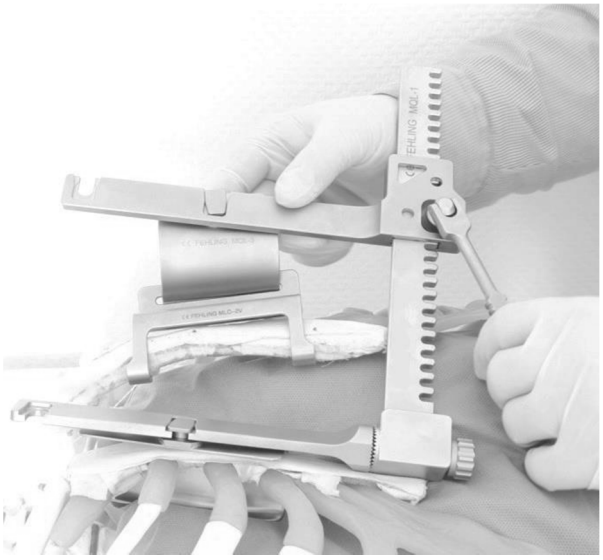
Use in sternotomy for IMA exposure

To use the CEBOTARI universal sternal retractor for total sternotomy during exposure and preparation of the internal mammary arteries (IMA), the following configuration of the retractor system is recommended:
CEBOTARI universal sternal retractor.....MQL-1
Sternotomy blade, ...e.g. MQL-2
IMA blade MQL-3
IMA retracting blade MLC-2V



1. Introduction of the IMA blade in conjunction with the IMA retracting blade into the sternal incision.

	2. Turn the rotary clamping arm by loosening the clamping screw until the gears no longer engage. Turn the clamping arm anticlockwise up the stop (the gearing also allows less rotation). Tighten the clamping screw by hand. ⚠ **The profiles of the gears must be engaged securely and may not be canted! Risk of injury!**
	3. Introduce the sternal retractor with the mounted sternotomy blade into the sternal incision and position at the desired retraction site.
	4. Use the drive lever to open the retractor arms until the IMA retracting blade engages correctly with the sternal edge. ⚠ **Ensure secure mounting of the blade! Risk of injury!**



5. Continue to widen the retractor to achieve the desired exposure of the thorax.

Design for exposure and preparation of the LIMA:
The gear rack is located caudal.

Design for exposure and preparation of the RIMA:
The gear rack is located cranial.

Reprocessing:

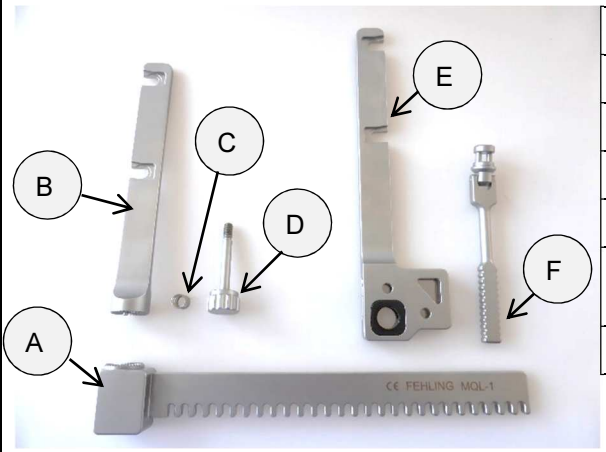
Reprocessing restrictions:
Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use.
According to ISO 17664 manufacturers must provide one method for the cleaning and sterilisation of reusable instruments. This does not mean that other methods may not be used. Any method, appropriately validated for the cleaning and sterilisation of these surgical instruments, may be used.

The instrument must undergo risk assessment prior to reprocessing.

⚠ Retractors must be handled with care during storage, transportation and cleaning!
Avoid striking the instrument or applying pressure to its parts! **Risk of injury!**

Place of use:	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately.
Storage: in accordance with § 4 of the	Store the instruments in a dry place in order to avoid condensation. It is recommended to reprocess the instruments immediately after use because it is

Medical Devices Operator Ordinance (MPBetreibV)	very difficult to remove dried residues from instrument parts that are difficult to access.
Cleaning preparation: mechanical cleaning in accordance with Robert Koch Institute (RKI) guidelines. Mechanical cleaning is preferable to manual cleaning.	**Disassembly**



Sternal retractor	
A	Gear Rack
B	Rotating retractor arm
C	Spring
D	Clamping screw
E	Linear movable retractor arm
F	Drive lever

The clamping screw D must be unscrewed completely from the retractor frame A. The rotating retractor arm B and spring C are thus released.
The linear movable retractor arm E is retracted completely from frame A using the drive lever. The drive lever F can be detached easily from the linear movable retractor arm E.

⚠ Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing!

Clean the instruments under running water with suitable soft brushes until no residues are visible.
Do not immerse in normal saline solutions (risk of pitting or stress corrosion).
Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemical manufacturer's recommendation for the mixture).
Avoid overfilling instrument trays and washing trays. Use only suitable instrument holders.
When placing and removing the instruments, take special precautions to ensure that they do not become stuck in the basket mesh.

Cleaning/disinfection in accordance with EN ISO 15883-1	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, exposure times and temperatures will be complied with.
Cleaning: Automated in accordance with DIN EN 15883-1	Validated procedures:

Manual pre-cleaning

Equipment:.....Basin, soft brush
Detergent: .....Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner (Steris®)
Mixing ratio:.....0.5 – 2 % Prolystica® in tap water
Temperature: .....40 °C
Exposure time:10 – 30 min

During the exposure time, use appropriate brushes to remove coarse contamination.

Rinse the instruments for one minute in cold deionized water.

	Mechanical cleaning Equipment:.....Miele PG 8536 Detergent: .....neodisher® MediClean forte (Dr. Weigert) Procedure: 1. Pre-wash for 2 minutes with cold tap water (< 45 °C) 2. Clean for 10 minutes with a solution of 0.5 - 2% neodisher® in tap water at 55 °C 3. Rinse for 2 minutes with cold tap water (< 45 °C) 4. Rinse for 5 minutes with deionized water (90 °C) 5. Dry for 25 minutes (> 50 °C)
Cleaning: Manual	Validated procedure Equipment:.....Bandelin Sonorex RK 1028 H Detergents: .....Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth over the entire range of movement. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Disinfection: Manual	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Drying:	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Maintenance:	Assemble instruments in accordance with the section on "Assembly". Apply a small amount of high-quality, water-soluble lubricant to the gear control. Test functionality.
Checking and functional testing:	Check instruments for smooth operation (avoid excessive play). Use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Remove damaged instruments and send them to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.
Packaging:	Singly: In accordance with the standard series EN 868, EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilization trays. Blades must be protected. Pack the trays appropriately using a suitable procedure.

Sterilization:	Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. Validated procedure: Equipment:.....GETINGE HS55 sterilizer Cycle type: .....Pre-vacuum Temperature: ....134 °C Holding time:.....at least 5 min Drying time:.....at least 20 min
Storage:	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.

! Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability!
Subject to change without notice.

Storage / Symbols

Manufacturer	Article number	Batch code	Follow the Instructions for Use	CE labeling	Warning

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