## FEHLING MICS IMA intercostal retractor:

**Retractor:**

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|---|---|
| MQC-1 | MICS IMA retractor |

**IMA blades:**

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|---|---|
| MQC-2I | 70 x 40 mm |
| MQC-3I | 90 x 40 mm |
| MQC-4I | 110 x 40 mm |
| MQC-6I | 70 x 30 mm |
| MQC-7I | 90 x 30 mm |
| MQC-8I | 110 x 30 mm |
| MQC-9I | 130 x 30 mm |

**Counter blades:**

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|---|---|
| MQF-1 | 40x35x60mm |
| MQF-2 | 50x35x60mm |

**Xiphoid blades:**

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|---|---|
| MQE-1I | 40x60x20mm |
| MQE-2I | 40x45x20mm |
| MQE-3I | 40x30x20mm |

**Accessories:**

| | |
|---|---|
| NVG-9 | Hexagonal wrench (CERAMO®) |
| LMT-4 | Cardan screwdriver |

**THOREXPO:**

| | |
|---|---|
| EEJ-1 | OR-table adapting clamp |
| EEJ-2 (a, b, c) | Angulated rod |
| EEP-0 | Coupling rider |
| EEL-4F | Blade guide |

**Warning:** Do not use Orthovario or Oxivario procedures to clean CERAMO® instruments (which have a blackish-brown surface) or titanium instruments. Using these procedures will destroy the titanium instruments or the CERAMO® coating that contains titanium over time due to their oxidative processes (corrosion of titanium due to $H_2O_2$).
The instrument must undergo risk assessment prior to reprocessing.

**Only trained medical personnel may use, reprocess or dispose of retractor systems.**
**The retractor system is intended for temporary use only.**

### Intended use:

The **MICS IMA intercostal retractor** is intended for exposure of the surgical field for minimally invasive, intercostal approaches. Depending on requirements, the retractor can be configured and used for simultaneous IMA exposure.

### Indications and contraindications:

Indications:
Surgery that is performed via minimally invasive, intercostal approaches
LIMA preparation
RIMA preparation

Contraindications:
Osteoporosis
Diseases that have a negative impact on the structure and stability of bone
Surgery in children and persons with unsuitable anatomy

Possible side effects:
Damage to soft tissue
Rib fracture

## Components:

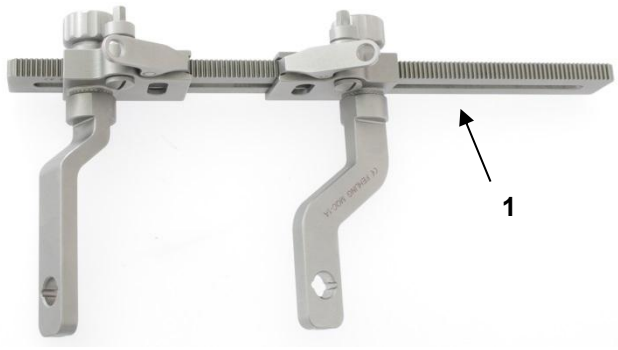
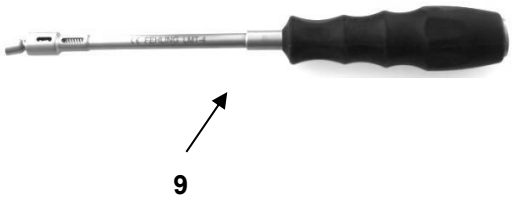



Figure 1

| | Article no. | Description |
|---|---|---|
| 1 | MQC-1 | MICS IMA retractor complete |
| 2 | MQC-2I…9I | IMA blades |
| 3 | MQF 1/2 | Counter blades |
| 4 | MQE-1I...3I | Xiphoid blades |
| 5 | EEJ-1<br>EEJ-2 (a,b,c) | OR-table adapting clamp with angulated rod |
| 6 | EEP-0 | Coupling rider |
| 7 | EEL-4F | Blade guide |
| 8 | NVG-9 | Hexagonal wrench (CERAMO®) |
| 9 | LMT-4 | Cardan screwdriver |





The MICS IMA intercostal retractor is a U-shaped bar retractor with Z-shaped retractor arms (Fig. 1).

The two retractor arms can be rotated 360° and can be moved freely on the toothed rack.

The movable retractor arms are moved by means of a gear control using the NVG-9 hexagonal wrench or the LMT-4 cardan screwdriver.

For IMA exposure, retraction elements in the form of xiphoid blades, counter plates, and IMA blades are used that are connected with the THOREXPO system by means of the blade guide. (Fig. 2)

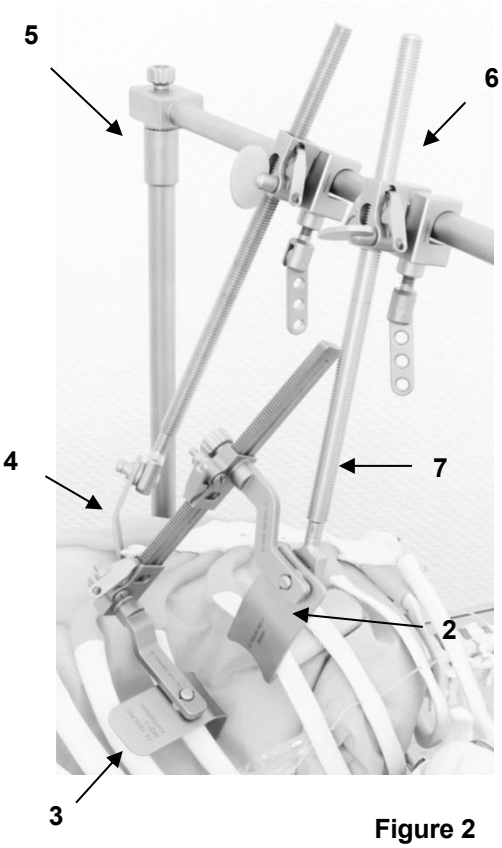



Figure 2

## Prior to use:

FEHLING INSTRUMENTS retractor systems are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see Reprocessing).

Retractors must be handled with care during storage, transportation and cleaning. Avoid striking the instrument or applying pressure to only parts of it. Perform a safety check prior to each use.

When doing so, check for cracks, fractures and mechanical malfunctions (see Maintenance, Checking and Functional Testing).

**Use only sterilized products of sound quality.**

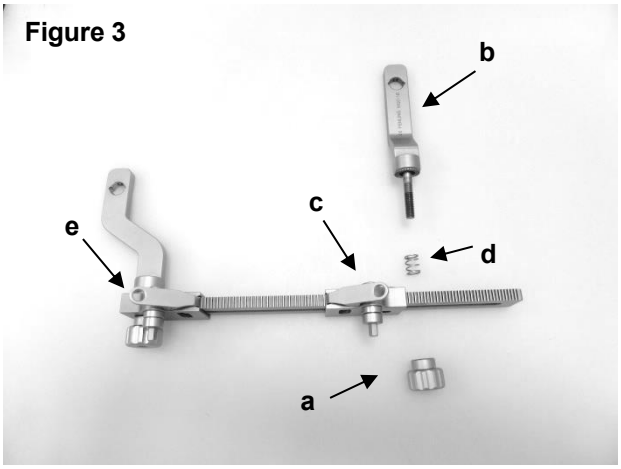
## Disassembly/Assembly:

To clean and reprocess the system, the rotatable retractor arms must be detached.

To do so, unscrew milled nut (a) completely and remove the arm with integrated threaded bolt (b) from rider element (c). The spring (d) positioned between the two sprockets is also removed. The rider element (c) can now be completely slid off the toothed rack (e).

Figure 3 shows the retractor with the retractor arm detached on one side. The other side is detached in the same way.

**Figure 3**




Please note: Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing.

**Figure 4a**

**Figure 4b**

To assemble the retractor arms, proceed as described for disassembly but in reverse order.

The rider elements must first be slid onto the toothed rack. When doing so, the locking levers are pointing toward the center of the toothed rack.

The next step is to slide the spring (d) onto the threaded bolt (b) (Figure 4a).

The threaded bolt is then placed through the hole in the sprocket of rider element (c) and thus simultaneously through the slit of the toothed rack (Figure 4b).

The retractor arm is locked in place by screwing on the milled nut (a).

## Use:

**Use as an intercostal retractor:**

At the distal end of the two retractor arms, various sizes of MICS counter blades can be inserted for use as an intercostal retractor.

The retractor arms are set so that the distal ends of the arms (Figure 5a) are approximately parallel to the surface of the patient.

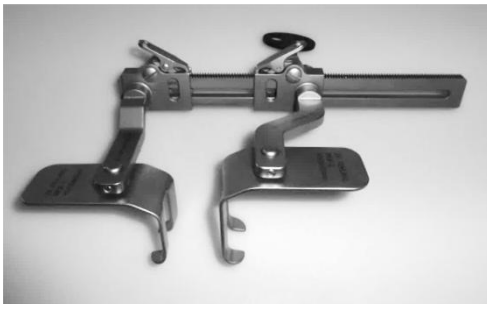


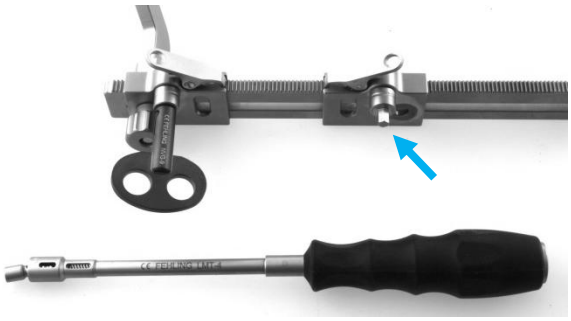
**Figure 5a**

For this purpose, loosen the milled nut until the teeth of the two sprockets are pushed apart by the spring (Fig. 5b). The arm can now be rotated 360°. Once the desired position has been reached, use the milled nut to lock the arm in place.

**Figure 5b**

**Please note:** The toothing of the toothed rack should always face away from the patient in order to prevent the locking levers from disengaging inadvertently. Do not completely unscrew the milled nut, in order to prevent individual parts (e.g. spring) from dropping into the surgical field. Before spreading, make sure the two lock washers interlock properly and completely and the milled nut is tightened.

**Figure 6**



Bring the two retractor arms close enough to allow the blades to be inserted into the incision easily. Then spread the two retractor arms far enough apart for the MICS retractor blades to become anchored in the tissue.

The movable arms are moved by means of a gear control using the NVG-9 hexagonal wrench or the LMT-4 cardan screwdriver, which is placed on the hexagonal attachment of the gear wheel (see arrow in Figure 6).

**Please note:** Only the aforementioned accessories (LMT-4 or NVG-9) may be used to move the gear control.

The retractor may only be spread with pressure applied if the retractor arms (sprockets) are correctly attached and are completely locked in place.

**Use for IMA exposure:**

When using the retractor system for IMA exposure (see Fig. 2), the THOREXPO components are first assembled.

The three-part EEJ-2 angulated rod (a, b, c) is attached to the EEJ-1 table adapting clamp mounted on the OR table. The EEP-0 coupling rider, which receives the EEL-4F blade guide, is placed on the horizontal rod. (Figure 7a). When doing so, make sure the two sprockets are connected to each other properly and completely. To make sure, raise the distal end of the horizontal bar when tightening the screw.

The next step is to connect the bolt (D10 blue arrow Fig. 7b) of the IMA blade to the blade guide and slide it under the ribs.

The correct alignment and locking of the elements depends on the particular anatomy of the patient. The IMA blade can now be retracted. That raises the ribs slightly. In some cases, retraction also causes the gallows to be elastically bent toward the patient. This bending is canceled out later by using the IMA retractor.

**Figure 7b**

**Figure 7a**

The retractor arm (I) is positioned so that the rider is located at the end of the toothed rack and the angulated, distal end projects beyond the toothed rack. (see Figure 8a). The second rider with the retractor arm (II) is moved as close to the first rider as possible. Depending on the patient's anatomy, the arm can be arranged parallel to the lower retractor arm (I) or moving away from it in the opposite direction.

Orientation of the arms toward the toothed rack (view from the side, Fig. 8b) is dictated by the patient's anatomy. In general, a parallel position of the long blade sides when the retractor is assembled is ideal. The toothed rack is positioned at an angle whose steepness is similar to that of the blade guide. To rotate the arms, the milled nut must be loosened until the teeth of the two sprockets are pushed apart by the spring (Fig. 5b). The arm can now be rotated 360°. Once the desired position has been reached, use the milled nut to lock the arm in place.

A suitable counter blade is then attached to the retractor arm (I) so that the long side of the L-shaped blade can lie on top of the patient and the short end can be inserted into the surgical site with the retractor arm (see Fig. 8b).
The second bolt (D8) of the IMA blade serves to connect it to the arm (II) of the IMA retractor.

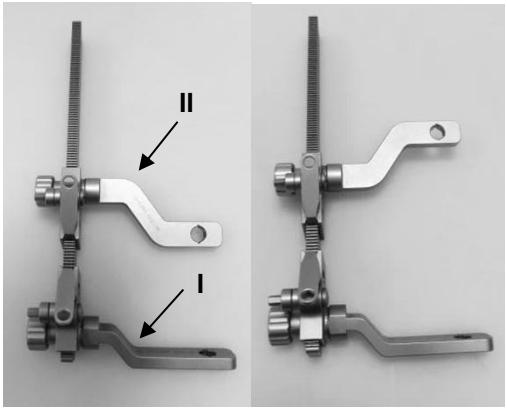



**Figure 8a**

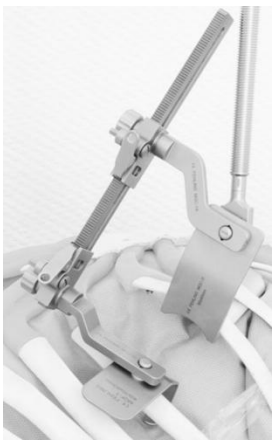
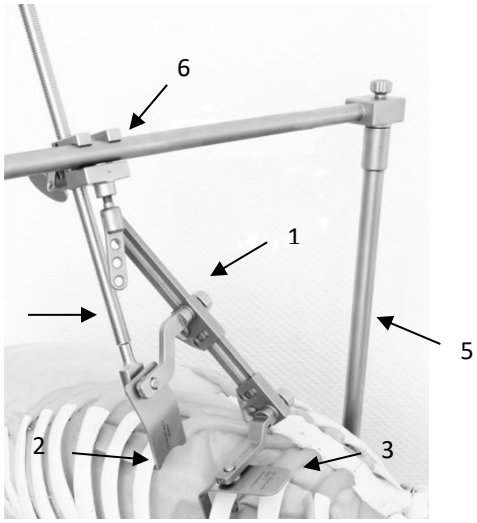
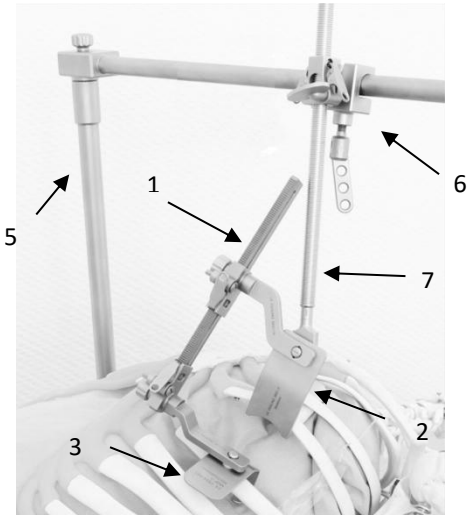
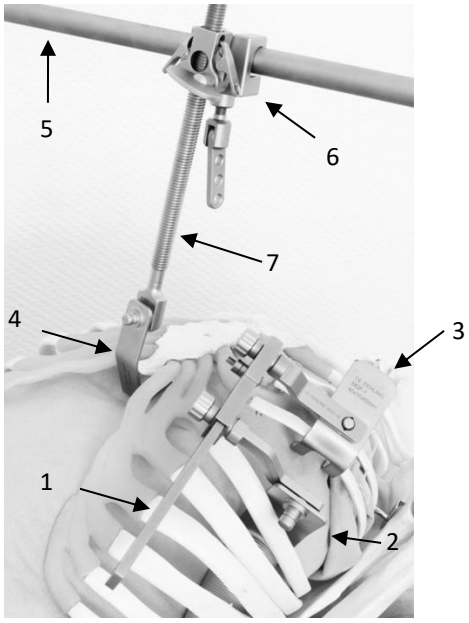
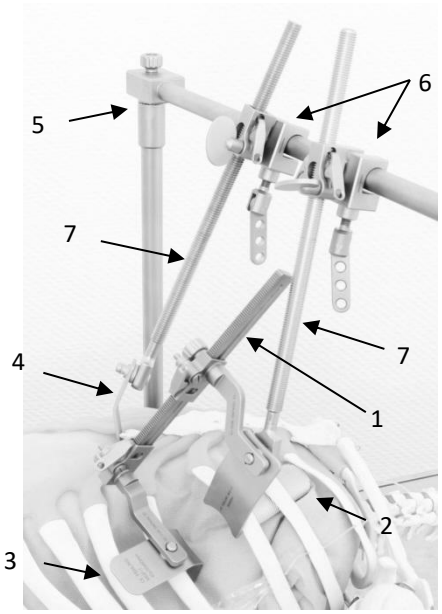


**Figure 8b**

| Potential uses of the retractor for IMA exposure: | |
|---|---|
| Preparation of the distal LIMA:<br>  <br> | Preparation of the proximal LIMA:<br>  <br> |
| Preparation of the distal RIMA:<br>  <br> | Preparation of the proximal RIMA:<br>  <br> |

**Please note:** The toothing of the toothed rack must always face away from the patient in order to prevent the locking levers from loosening inadvertently. Never completely unscrew and remove the milled nut. Be sure that the two lock washers interlock properly.

As soon as the blades are placed in the surgical site and the retractor arms are locked, the gear control can be used to move retractor arm (II) in order to spread the surgical site. The turning movement of the pinion is performed using the NVG-9 hexagonal wrench or the LMT-4 cardan screwdriver, which is placed on the hexagonal attachment of the gear wheel (see arrow in Figure 6).

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| ⚠ | **Please note:** Only the aforementioned accessories (LMT-4 or NVG-9) may be used to move the gear control.<br>The retractor may only be spread with pressure applied if the retractor arms (sprockets) are correctly attached and are completely locked in place. |

**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.

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| **Point of use:** | Use a disposable cloth/paper towel to remove surface contamination – pre-cleaning. |
| **Storage:**<br>**In accordance with § 4 of the German Medical Devices Operator Ordinance (MPBetreibV)** | Store the instruments in a dry place in order to avoid condensation.<br>It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. |
| **Cleaning preparation:**<br>Automated cleaning in accordance with Robert Koch Institute (RKI) guidelines. Automated cleaning is preferable to manual cleaning. | Ensure that blood, tissue and drug residues are removed from the instruments immediately after completion of the procedure and that they undergo automated cleaning immediately. For this purpose, use suitable soft brushes to clean the instruments under running water until no residues are visible.<br>Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking).<br>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).<br>Avoid overfilling instrument trays and washing trays. Use only suitable instrument holders.<br>When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh.<br>Disassemble take-apart instruments in accordance with the relevant disassembly/assembly instructions (page 3). |
| **Cleaning/Disinfection**<br>In accordance with DIN EN ISO 15883-1:2009 | 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, applications times and temperatures will be complied with. |

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| **Cleaning: Automated**<br>In accordance with<br>DIN EN ISO 15883-1:2009 | Validated procedure:<br>Washer-disinfector G 7836 CD (Miele)<br>2-component process alkaline/enzymatic<br>deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland)<br>Preparation:<br>Ensure that the inside of all cavities is also completely rinsed.<br>Ensure that no unwashed areas are left.<br>Parameters:<br>Pre-wash for 3 minutes with cold water.<br>Empty.<br>Wash for 10 minutes with tap water with 0.3% TWIN PH10 at 35 °C and 0.2% TWINZYME at 40 °C.<br>Empty.<br>Rinse for 2 minutes with fully deionized water at at least 30 °C.<br>Empty.<br>Rinse for 1 minute with fully deionized cold water.<br>Empty.<br>Perform thermodisinfection for at least 5 minutes at 93 °C.<br>After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually. |
| **Cleaning/Disinfection: Manual** | Validated procedure<br>Equipment: Bandelin Sonorex RK 1028 H<br>Detergent: Cidezyme/Enzol (ASP) or<br>Mucadont Zymaktiv (Merz Hygiene GmbH)<br>Pre-cleaning<br>• Place instruments in cold water for 10 minutes.<br>• Move any movable parts back and forth.<br>• Use a soft brush to clean the instruments until no more contamination is visible.<br>• Rinse the instruments for at least 20 seconds with a water spray gun.<br>Ultrasonic cleaning<br>• Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz.<br>After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds.<br>Rinse the instruments with tap water.<br>Deionized water must be used for the final rinse. Ensure that no residues remain on the products.<br>Disinfection:<br>Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). In automatic cleaning, thermodisinfection can be performed to complete the process (at 93 °C for at least 5 minutes). (For thermodisinfector see device manufacturer's information.)<br>Deionized water must be used for the final rinse. Ensure that no residues remain on the products. |

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| **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 assembly instructions. Apply a small amount of high-quality, water-soluble instrument spray to the threaded bolts and gear control. |
| **Checking and functional testing:** | Check instruments for smooth operation (avoid excessive play). Check locking mechanisms.<br>Use a magnifying lamp to visually inspect the components for damage and wear and tear.<br>In particular, inspect the critical points on moving parts and in the working area.<br>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:** | Single: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.<br>Sets: Sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately. |
| **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!<br>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.<br><u>Validated procedure:</u><br>Equipment: Selectomat HP (MMM)<br>3 pre-vacuum phases<br>Sterilization temperature 134 °C<br>Holding time: 5 minutes<br>Drying time: at least 10 minutes |
| **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 and any deviation from these Instructions for Use will result in exclusion of liability!**
**Subject to change without notice.**

| Storage / Symbols | | | | |
|---|---|---|---|---|
|  Store in a dry place! |  Protect from excessive heat! |  Follow the Instructions for Use |  Article number |  Lot number |
|  Manufacturer |  CE mark |  Warning | | |
| Kontakt zum Hersteller | | | | |
|  | FEHLING INSTRUMENTS GmbH<br>Seligenstädter Str. 100<br>63791 Karlstein/Germany<br>Tel.: +49 (0) 6188-9574-40<br>Fax: +49 (0) 6188-9574-45<br>E-Mail: info@fehling-instruments.de<br>www.fehling-instruments.de | |  | |