# Retracting System for elastic retraction elements

| Components | REF: | Optional components | REF |
|---|---|---|---|
| Table Adapting Clamp with ball and socket joint | EEJ-4 | | |
| Galea Holding System left arm | EEJ-5 | Hygiene Protection Shield 200x18x3mm, Silicone sterilizable | EEG-7 |
| Galea Holding System right arm | EEJ-6 | | |

**Not sterile.** Clean and sterilize prior to first use and before all further use!

⚠ **The holding system for elastic retraction elements may only be used, reprocessed or disposed of by trained medical personnel!**
**The holding system is intended for short-term use!**

## Intended use:

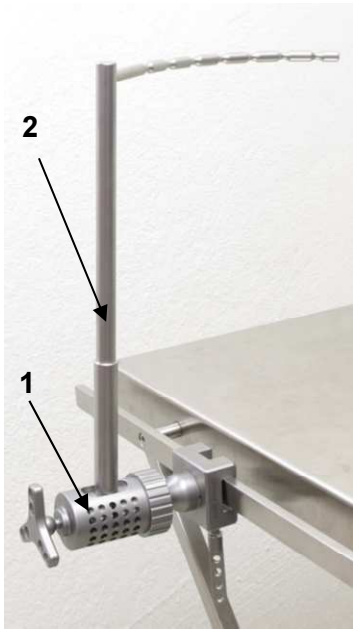
The holding system for elastic retraction elements is used to hold elastic retraction elements with distal soft tissue blades.

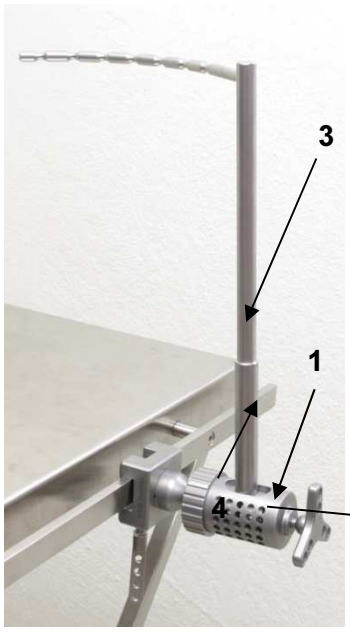
## Indications and contraindications:

Indications:
+ All applications where gimbaled mobility of the retracting elements is required

Contraindications:
- None known

## Components:

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|---|---|---|
| 1 | Operating Table Adapting Clamp | EEJ-4 |
| 2 | Galea Holding system left arm | EEJ-5 |
| 3 | Galea Holding system right arm | EEJ-6 |
| Optional: | | |
| 4 | Hygiene Protection Shield 200x18x3mm, silicone, sterilizable | EEG-7 |

## Prior to use:

Adapting Clamps are supplied non-sterile and must be cleaned and sterilized by the user before first use and before each further use (see reprocessing).

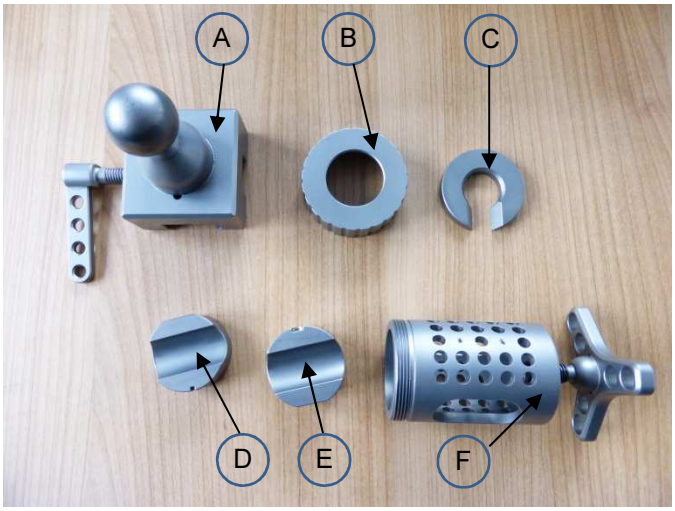
Adapting Clamps must be handled with care during storage, transportation and cleaning! Avoid striking the instrument or applying pressure to its parts!

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:

For reprocessing (see "Reprocessing") the union nut (B), the clamping jaws (D and E), the adapting clamp (A) and the washer (C) must be removed.
For this reason, assembly prior to use is necessary.
The assembly of the set can be carried out easily and without requiring additional tools. However, the following applies to all manipulations on the set:
Use as little force as possible and only as much force as necessary!

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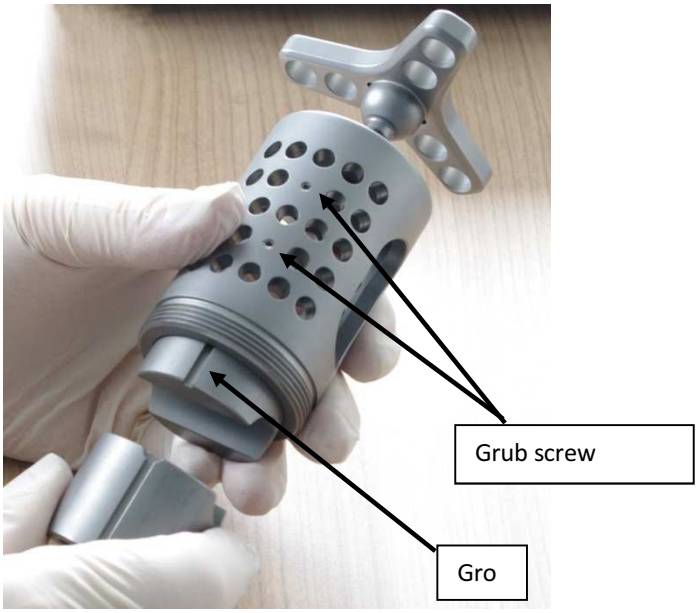
|---|---|
| A | Adapting clamp with ball |
| B | Union nut |
| C | Washer |
| D | Outer clamping jaw |
| E | Inner clamping jaw (with spherical indentation) |
| F | Clamping cylinder with Star Knob |




First insert the outer and then the inner clamping jaw into the clamping cylinder. Ensure that the groove of the clamping jaws is pushed over the two small grub screws protruding from the inner wall of the clamping cylinder. These serve as anti-rotation protection.

Then the inner clamping jaw is pushed into the cylinder.

Slide the union nut over the ball, slide the washer with its recess around the ball neck so that it lies on the inner base of the union nut. The small bevel of the washer points towards the ball. Then screw the 3-part assembly with the union nut onto the clamping cylinder.

**Use:**

Attach the fully assembled Adapting Clamp to the rail of the operating table. The position of the Adapting Clamps on the operating table depends on the head area to be displayed.

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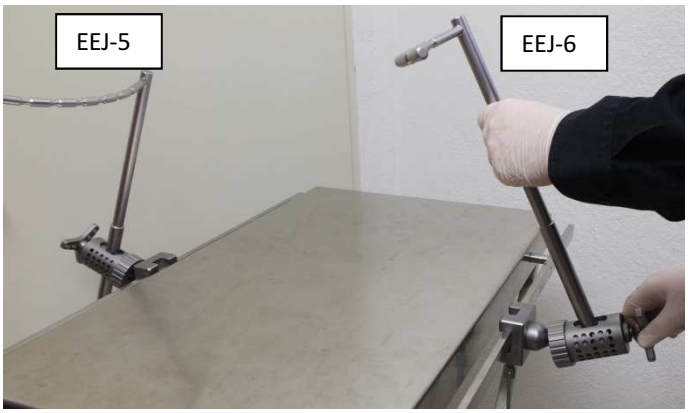
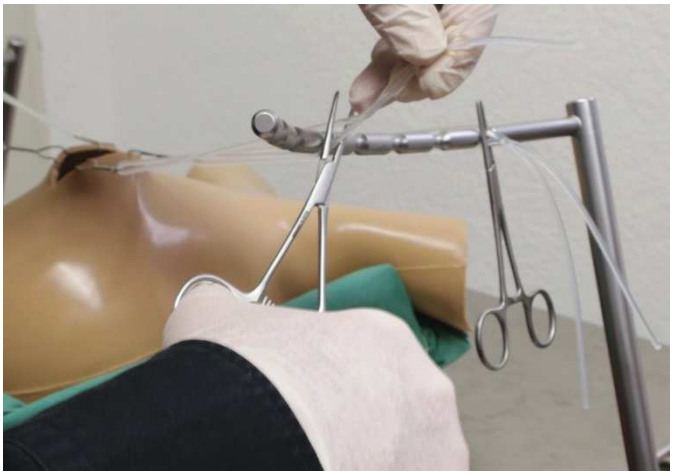
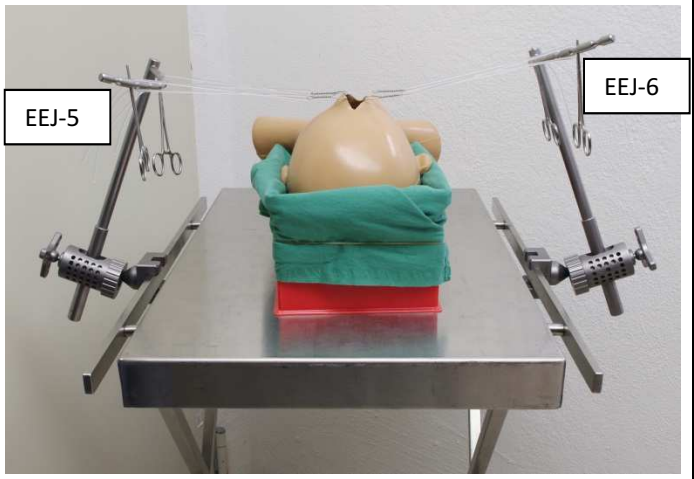
|  | Left and right Holding Arms are radially and angle-height-adjustable (max.ca.27°). The profiled cross rods are to be arranged with their convex side facing the operating field. The position of the Holding Arms can be changed by turning the star knob of the Adapting Clamp. |
|  | The optionally available Hygiene Protection Shield made of silicone (EEG-7) serves as a sterile barrier and is mounted on the holding arm. Specifically, this serves to separate sterile from non-sterile areas in the operating field and is positioned over the surgical drape.<br>(The illustration on the left only shows the positioning of the hygiene protection shield on the holding arm and is to be interpreted as an illustration of the principle) |
|  | Place the Galea hooks in the appropriate place of the incision and anchor them in the skin tissue. Attach the silicone cords to the most convenient position on the EEJ-5 and EEJ-6 holding arms and secure using a clamp (e.g. Pean clamp). |




During use, do not place more pressure on the tissue being retracted than is absolutely necessary for the surgical purpose.

**WARNING:**

**Overstretching and excessive compression of the silicone cord with the clamp can cause tearing and thus injury to patient and user.**

## 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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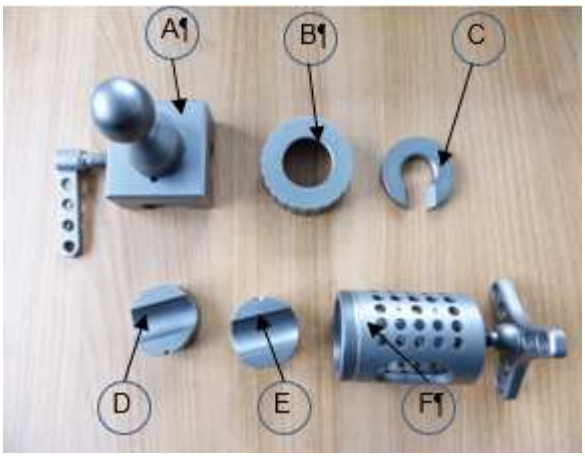
| **Place of use:** | Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. |
| **Storage:**<br>in accordance with § 4 of the Medical 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>mechanical cleaning in accordance with Robert Koch Institute (RKI) guidelines. Automated cleaning is preferable to manual cleaning. | Disassemble the instrument for reprocessing.<br>**Disassembly:**<br>The adapting clamp must be removed again for cleaning and reprocessing of the system. To do this, unscrew the union nut (B) and remove the two clamping jaws (D and E). Press the union nut (B) towards the adapting clamp and hold it such that the washer (C) protrudes from the nut. Then pull out the washer (C) and then pull out the union nut (B) over the ball. The assembly of the adapting clamp is explained in more detail in the section Assembly. |

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| A | Adapting clamp with ball |
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| D | Outer clamping jaw |
| E | Inner clamping jaw (with spherical indentation) |
| F | Clamping cylinder and Star Knob |

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| | ⚠ **Please note:** Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing!<br><br>Clean the instruments under running water with suitable soft brushes until no residues are visible. Do not place in NaCl solutions. 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 baskets and washing trays - use only suitable instrument carriers. When placing and removing instruments into/from the perforated baskets, take special precautions to ensure that tips/teeth do not become stuck in the mesh. Disassemble separable instruments according to the corresponding assembly instructions. |
| **Cleaning/Disinfection** | It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. Also ensure that the recommended concentrations, exposure times and temperatures are observed. If possible, a washer/disinfector which uses thermal disinfection is to be preferred. |
| **Cleaning: Automated** | **Validated procedure**<br><u>Pre-cleaning</u><br>Equipment: Basin, soft brush<br>Detergent: Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner (Steris®)<br>Mixing ratio: 0.5 – 2 % Prolystica® in tap water<br>Temperature: 40 °C<br>Exposure time: 10 – 30 minutes<br>Execution: During the exposure time, use appropriate brushes to remove coarse contamination and move the instruments around in the bath.<br>Rinse the instruments for one minute in cold deionized water and move them around during the process. |
| | <u>Automated cleaning</u><br>Equipment: Miele PG 8536<br>Detergent: Neodisher® MediClean forte (Dr. Weigert)<br>Execution:<br>1. Pre-rinse for 2 minutes with cold tap water (< 45 °C)<br>2. Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® in tap water at 55 °C<br>3. Rinse for 2 minutes with cold tap water (< 45 °C)<br>4. Rinse for 5 minutes with deionized water (90 °C)<br>5. Dry for 25 minutes (> 50 °C) |

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| **Cleaning: Manual** | Validated procedure<br>Equipment: Bandelin Sonorex RK 1028 H<br>Detergents: 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 over the entire range of movement.<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. |
| **Disinfection: Manual** | Disinfection:<br>Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).<br>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 good-quality, water-soluble instrument spray to the points identified by the  symbol. |
| **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:** | Singly: 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 using a suitable procedure. |

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| **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>Validated procedure:<br>Equipment: Selectomat HP (MMM)<br>3 pre-vacuum phases<br>1. Sterilization temperature 134 °C<br>2. Holding time: 5 minutes<br>3. 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.

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

## Symbols

In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:

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| Manufacturer | REF<br>Article number | LOT<br>Batch code | SN<br>Serial number |
| Instructions for Use are to be observed | CE labeling | Warning | Oil can for points to be lubricated |

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