FEHLING retracting system for elastic retraction elements

Holding system

EEJ-4	Galea table adapting clamp with ball joint
EEJ-5	Galea holding arm left
EEJ-6	Galea holding arm right

Components

MANNHEIM galea hooks

EEF-7	MANNHEIM galea hook 2-prong, 0.8 x 10 x 10 mm (PU 20 pieces)
EEF-7S	MANNHEIM galea hook 2-prong, 1.0 x 10 x 12 mm (PU 20 pieces)
EEF-7F	MANNHEIM galea hook 2-prong, 1.2 x 12 x 12 mm (PU 20 pieces)

Silicone cord

EEF-8F	Silicone cord for MANNHEIM galea hook, Ø 3.0 mm, 2.5 m roll

Hygiene protection shield

EEG-7	Hygiene protection shield 200 x 18 x 3 mm, silicone sterilizable (optional)

Accessories

Clamp, e.g. PEAN (optional)

This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.

The holding system for elastic retraction elements may only be used, reprocessed or disposed of by trained medical personnel!

The holding system for elastic retraction elements is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The holding system for elastic retraction elements is intended for short-term application.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

In medical literature, the following adverse effects are described that can possibly occur during the intended use of a holding system for elastic retraction elements:

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses

⚠	Medical devices may, for example, contain chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use

The FEHLING INSTRUMENTS holding system for elastic retraction elements is non-sterile when delivered and must be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see 6) Reprocessing).

⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	The holding system for elastic retraction elements must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to the holding system for elastic retraction elements, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing

⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.

⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!

Limitations on reprocessing	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 (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
Initial treatment at the 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. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	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. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly

Manual Pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. 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. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed.

	• Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. Procedure/Parameters: • Pre-wash for 3 minutes with cold water (potable water quality, <40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (potable water quality) at 55 °C • Emptying • Rinse for 2 minutes with water (potable water quality, <40 °C) • Emptying • Rinse for 1 minute with cold deionized water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: Manually	Validated procedure: Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) Procedure/Parameters: • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). Ultrasonic cleaning: • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.

Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly
Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: 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. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!

Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. 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. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.

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.

7) Configuration and application

This holding system is to be used for elastic retraction elements and serves to hold and position the silicone cord as well as the MANNHEIM galea hook.

Figure 1 depicts a configuration example for the holding system for elastic retraction elements. Table 1 lists the corresponding components.

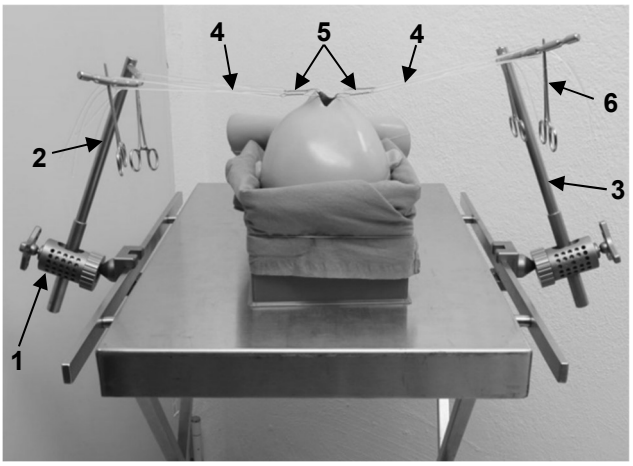


Fig. 1: Configuration example for the holding system for elastic retraction elements

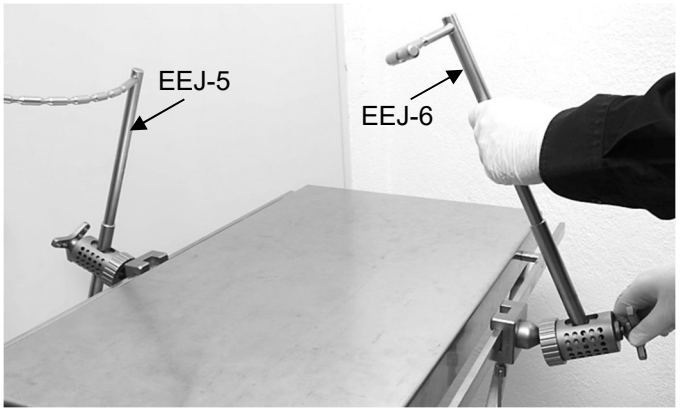
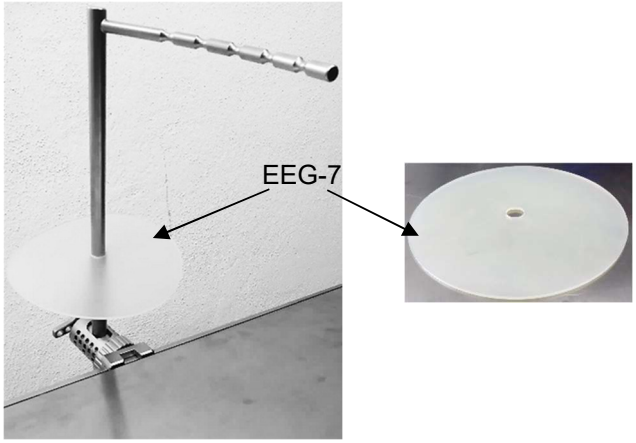
Table 1: List of the corresponding components

	Article no.	Description
1	EEJ-4	Galea table adapting clamp with ball joint
2	EEJ-5	Holding system galea arm left
3	EEJ-6	Holding system galea arm right
4	EEF-8F	Silicone cord for MANNHEIM galea hook
5	EEF-7/7S/7F	MANNHEIM galea hook 2-prong
6	None Special	PEAN clamp (exemplary)

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the holding system for elastic retraction elements, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of component depends on the anatomical and physiological conditions as well as the field of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

During use

Assembly of the holding system for elastic retraction elements can be carried out easily and without requiring additional tools.
However, the following applies to all manipulations of the holding system for elastic retraction elements:
As little force as possible, as much force as necessary!

Attach the fully assembled table adapting clamp to the rail of the operating table (Fig. 2). The position of the table adapting clamps on the operating table depends on the head area to be displayed.	 Fig. 2
Left (EEJ-5) and right (EEJ-6) 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 (Fig. 3). The position of the holding arms can be changed by screwing on the star grip of the table adapting clamp.	 Fig. 3
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. Figure 4 only shows the positioning of the hygiene protection shield on the holding arm and is to be interpreted as an illustration of the principle.	 Fig. 4

Place the galea hook (a) in the appropriate place of the incision and anchor it in the skin tissue. Attach the silicone cords (b) to the most convenient position on the EEJ-5 and EEJ-6 holding arms and secure using a clamp (c) (e.g. Pean clamp) (Fig. 5).

Please follow the Instructions for Use G207 for the silicone cords and galea hooks!

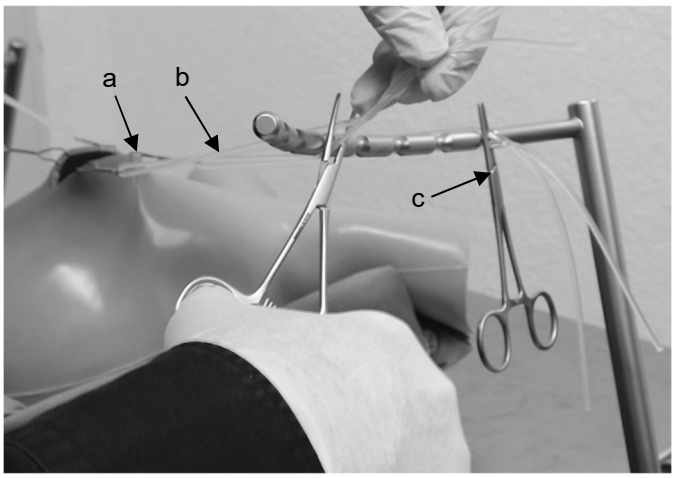


Fig. 5

During use, do not place more pressure on the tissue being retracted than absolutely necessary for the surgical purpose (Fig. 6).

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

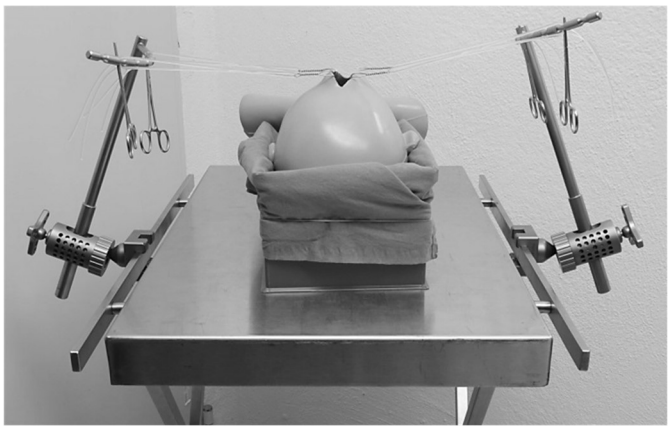


Fig. 6

8) Required accessories

No accessories are required for using the holding system for elastic retraction elements.

9) Assembly

To assemble the holding arms EEJ-5 and EEJ-6, please observe 7) Configuration and Application - during application.

To assemble the table adapting clamp EEJ-4 please observe the following assembly instructions.

Figure 7 illustrates the individual parts of the table adapting clamp which are required for assembly. Table 2 lists the corresponding designations of the individual parts.

Table 2: Designation of the individual parts

	Designation of the individual parts
A	Adapting clamp with ball
B	Union nut
C	Washer
D	Outer clamping jaw
E	Inner clamping jaw (with spherical indentation)
F	Clamping cylinder

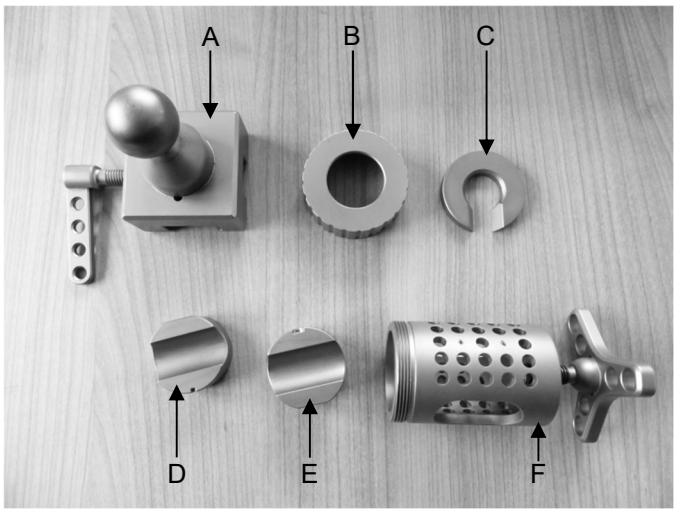


Fig. 7

First insert the outer (D) and then the inner (E) clamping jaw into the clamping cylinder (Fig. 8). 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 (F). These serve as anti-rotation protection.
Then the inner clamping jaw (E) is pushed into the clamping cylinder (F).

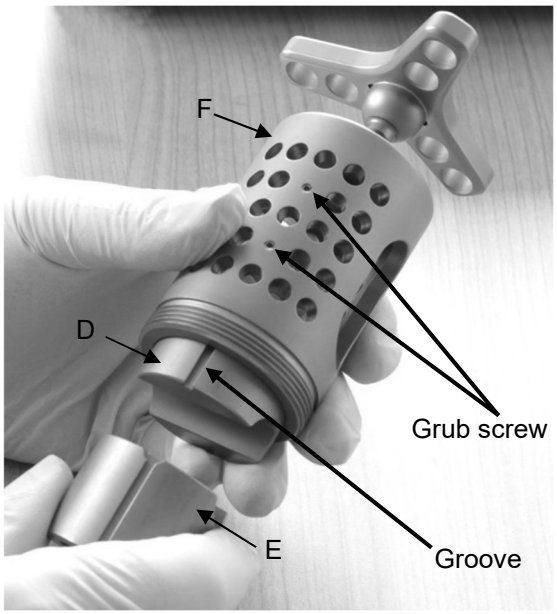


Fig. 8

Slide the union nut (B) over the ball of the adapting clamp (A), slide the washer (C) with its recess around the ball neck so that it lies on the inner base of the union nut (B) (Fig. 9). The small bevel of the washer points towards the ball. Then screw the 3-part assembly with the union nut (B) onto the clamping cylinder (F) (Fig. 10).

Following a functional test, the assembled instrument is now ready for use again.

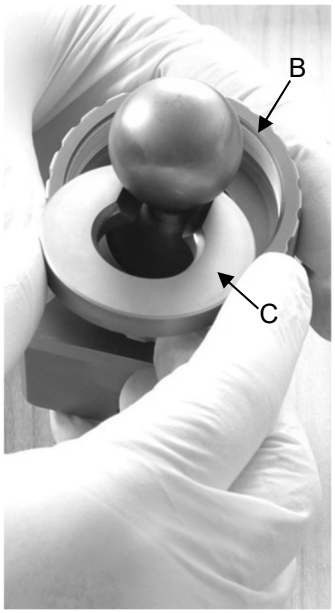


Fig. 9

Fig. 10

10) Disassembly

To disassemble the holding arms EEJ-5 and EEJ-6, please observe 7) Configuration and Application - during application.

The table adapting clamp EEJ-4 must be disassembled as follows for reprocessing.

To clean and reprocess the system, the table adapting clamp must be disassembled again. To do this, unscrew the union nut (B) (Fig. 11) and remove the two clamping jaws (D and E) (Fig. 12). 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) (Fig. 13) and then pull out the union nut (B) over the ball.

Fig. 11

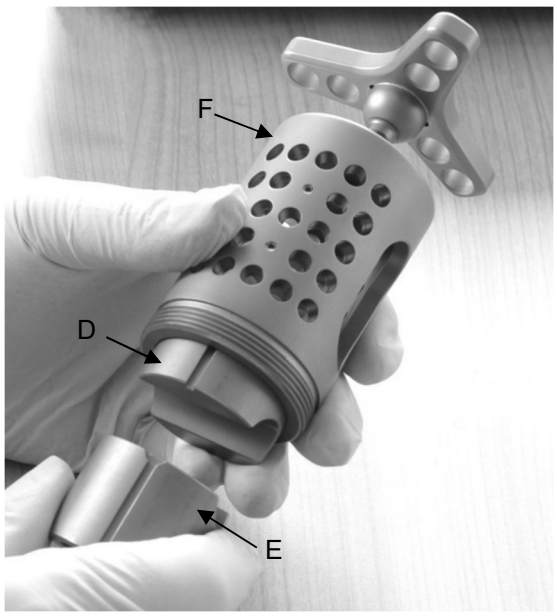


Fig. 12

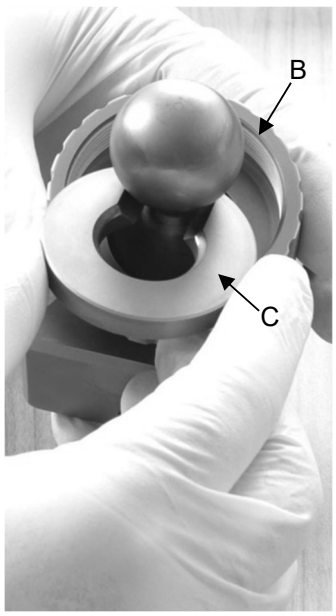


Fig. 13

The instrument is now disassembled into its separate parts (Fig. 14) and can be reprocessed.

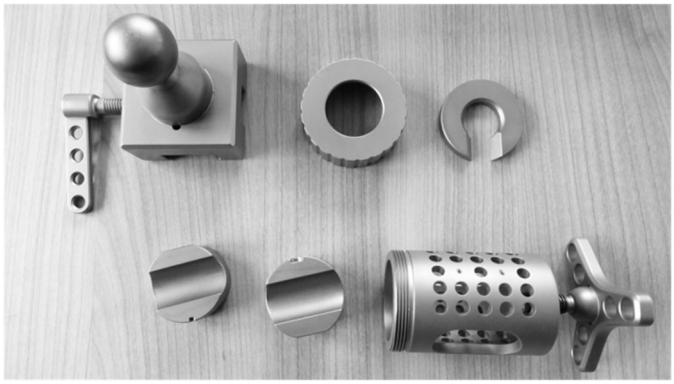


Fig. 14

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

11) Obligation to report serious incidents
The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:		
Manufacturer	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

To contact the manufacturer	
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de