All FEHLING Rongeurs	**Accessories:** For GRUMME and LOVE GRUENWALD X Rongeurs: TXW-1X..... Screw driver for Allen screw TXW-2X..... Screw driver for Allen screw, sterilizable For FERRIS-SMITH X and large-jaw X Rongeurs: TXX-0X..... Screw driver for Allen screw TXW-9X..... Screw driver for Allen screw, sterilizable

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).
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Dismountable rongeurs with GRUMME X, LOVE GRUENWALD X or FERRIS-SMITH X/large-jaw X disassembling mechanism can be identified by the arrow mark next to the Allen screw at the end of the instrument.
For disassembling RICHTER X-modells, no tools are needed.
For assembly and disassembly please refer to the appropriate assembly instructions.
The same models of rongeurs without 'X' are not dismountable!

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

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

FEHLING rongeurs are intended for transient use only (< 60 minutes).

Intended use:

Rongeurs are intended for grasping soft tissue (e.g. resected parts of an intervertebral disk).

Only FERRIS SMITH rongeurs and large-jaw-rongeurs can also be used to cut tissue.

Indications / Contraindications

Indications:	**Contraindications:**
Primarily spinal operations: Grasping soft tissue parts (e. g. previously separated parts of an intervertebral disk) or (FERRIS-SMITH / large-jaw rongeurs) cutting thin tissue layers.	Not known.

Possible adverse effects associated with procedures in the lumbar spine region

In the medical literature, the following adverse effects are described that can possibly occur despite the correct use of the FEHLING rongeurs during or after performing specific techniques (method-specific complications):

Injury to neighboring - abdominal vessels - ureter - kidneys - intestine	Lesions of - nerves/roots - dura	- AV fistula - (pseudo) aneurisms epidural hematomas - impaired wound healing - infections

Before use:	
FEHLING INSTRUMENTS rongeurs are delivered non-sterile and must be cleaned and sterilized by the user before their first and any further use (see reprocessing). **Risk of infection!** Rongeurs must be handled with care during storage, transportation and cleaning! Avoid striking the instrument or applying pressure to its parts! **Risk of injury!** Prior to each application of the rongeur, a safety inspection should be performed. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing). **Use only sterilized products of sound quality!**	
During use:	
⚠	Rongeurs are intended for **grasping** soft tissue, **not** for cutting (except for FERRIS SMITH and large-jaw rongeurs only)! Risk of damage due to overload; **risk of injury!** Only grasp completely resected tissue parts to avoid distortion and overstressing of the instrument. If the anatomy allows for, the considerably more rugged FERRIS SMITH or large-jaw rongeurs can be used, which can cut soft tissue even without prior resection.
⚠	Only grasp completely resected tissue parts. Avoid distortion, tilting and overstressing of the instrument, especially when using titanium rongeurs. **Risk of injury!**
⚠	Important rule of thumb: overload can be detected visually by the bulge of the slide above the level of the shaft. If this happens, stop the gripping process and - either free the gripped tissue completely with a suitable sharp instrument or - use a FERRIS-SMITH or large-jaw rongeur of a suitable size. Continuing the grip and removal process in spite of obvious overload may result in breakage of the joint that connects the movable jaw with the pusher and shaft. Risk of breakage; **risk of injury!**
⚠	The instrument must remain in sight during use to prevent injury to adjacent structures (see "Adverse effects"). **Risk of injury!**
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. 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.	
According to ISO 17664 a manufacturer 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.	
Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage: acc. to § 4 MPBetreibV (regulation on the operation of medical devices)	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 acc. to RKI directives. 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. To do so, clean these instruments with soft brushes under running water until all visible contaminatin 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 trays 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 screen baskets. Disassemble dismountable instruments (identifiable by the arrow mark next to the Allen screw at the joint of the instrument) according to the appropriate assembly instructions. Please refer to the appropriate assembly instructions, if necessary! CERAMO® rongeurs with GRUMME X and LOVE-GRUENWALD X disassembling mechanism ..... M18 CERAMO® FERRIS-SMITH X/large jaw X rongeurs..... M23 CERAMO® RICHTER rongeurs..... M24 Always open joint instruments before processing. Release the springs, if necessary.
Cleaning/ Disinfection acc. to DIN EN ISO 1588 3-1:2009	It is assumed that the products used for cleaning and disinfection are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.
Automated Cleaning acc. to EN ISO 1588 3-1:2009	Validated procedure: **Manual precleaning** Equipment: ..... Basin, soft brushes 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. Soak the devices in the detergent solution. Remove gross soil using soft -bristled brush. Actuate mobile parts of device minimum 5 times. Rinse each device with cold deionized water for 1 min. Remove gross soil using a soft-bristled brush. Actuate mobile parts of the device minimum 5 times. **Automated Cleaning** Equipment: ..... Miele PG 8536 Detergent: ..... neodisher® MediClean forte (Dr. Weigert) Parameters 1. 3 min pre-cleaning with tap water (< 45 °C) 2. 10 min cleaning with a solution of 0,5 - 2 % neodisher® in tap water at 55 °C 3. 2 min rinsing with cold tap water (< 45 °C) 4. 5 min rinsing with deionized water (90 °C) 5. 25 min drying (> 50 °C)

Manual Cleaning	Validated procedure Equipment: ..... Bandelin Sonorex RK 1028 H Detergent: ..... Cidezyme/Enzol (ASP) oder Mucadont Zymaktiv (Merz Hygiene GmbH) Precleaning • Soak instruments in cold water for 10 min. • Activate mobile parts of the instrument • Clean instruments using soft brushes until all visible contamination is removed. • Rinse instruments at least 20 s using a water-spray pistol. Ultrasonic Cleaning • Sonicate 10 min at 45° C with a solution of 0.8 % detergent at 35 kHz Following sonication, rinse instruments for at least 20 s with a water-jet pistol. Rinse instruments with tap water. Demineralized water must be used for the final rinsing. Make sure that no residues remain on the products.
Disinfection: Manual	Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). 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 edges of the jaw close completely over the entire length. If not the instrument cannot or only in a limited way achieve its function. The rongeur 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. Instruments that cannot be repaired have to be deposed in the usual hospital waste disposal system. It is important to ensure safe storage in an unbreakable disposable container, especially for surgical instruments with pointed or sharp edges. Do not use damaged instruments!
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:	Do not sterilize CERAMO® instruments (identifiable by the brownish black surface) and titanium instruments with processes using peroxide/peroxide plasma processes (e.g. STERRAD®! These processes are based on using hydrogen peroxide (H_2O_2) which can lead to the destruction of the titanium instruments or the titanic CERAMO® coating.

	Steam-sterilize using the fractional vacuum process at 134 °C (min. 5 minutes holding time) with equipment acc. to DIN EN 285, validated sterilization processes! To avoid 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: .....GETINGE HS55 autoclave Type of Cyclus: .Prevacuum Temperature:.....134 °C Cycle time: .....5 min. at least Drying time: 20 min. at least
Storage:	Acc. to DIN EN 868, DIN EN ISO 11607.
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 reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.

⚠	Any modification to the device or deviation from these instructions for use will result in exclusion of liability. Subject to change without notice.

Symbols

Manufacturer	Article number	Lot number	Follow the instructions for use.	CE marking	Warning

FEHLING INSTRUMENTS GmbH & Co. KG
Hanauer Landstr. 7A
63791 Karlstein/Germany
Tel.: +49 (0) 6188-957440
Fax: +49 (0) 6188-957445
E-Mail: info@fehling-instruments.de