All FEHLING rongeurs

Accessories

For CERAMO® rongeurs – Ring handle with screw:
TXW-1X ..... Screwdriver for X rongeurs, hexagon socket 2 mm
TXW-2X ..... Screwdriver for X rongeurs, hexagon socket 2 mm, 75 mm, sterilizable

For CERAMO® rongeurs – Pliers handle with screw:
TXX-0X ..... Screwdriver for X rongeurs, hexagon socket 3 mm
TXW-9X ..... Screwdriver for X rongeurs, hexagon socket 3 mm, 75 mm, sterilizable

Rongeurs with ring handle/pliers handle with screw can be taken apart and are recognizable by the arrow mark next to the hexagon socket screw at the end of the instrument.

No tools are required to disassemble the rongeurs with ring handle with peacock eye, either with or without locking bars.

Rongeurs of the same model group that do not have an added "X" cannot be disassembled!

For assembly and disassembly, please follow the corresponding instructions.

This instrument or medical device is delivered non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed according to the RKI guidelines (non-critical/semi-critical/critical A/B/C).

Rongeurs may only be used, reprocessed and disposed of by competent medical personnel!

Rongeurs are intended for reuse.

1) Intended Purpose

Rongeurs and forceps are medical devices with the following purposes:
- to grasp soft tissues such as already severed parts of an intervertebral disc (rongeurs)
- to separate tissue (FERRIS-SMITH, large-jaw and BRODNER rongeurs)
- to grip, hold and move organs and other tissue (grasping forceps in rongeur design)
- to separate hard tissue such as bone (cutting forceps)

Supplementary information on the intended purpose

Duration of use: Rongeurs are intended for temporary use.

Field of application: Rongeurs and forceps are used in all procedures where soft or hard tissue needs to be grasped or separated, and organs and other tissue needs to be grasped, held and moved.

User profile: Rongeurs and forceps may only be used by medically trained specialists (e.g. specialists).

Use environments: Rongeurs and forceps are only used under controlled environmental conditions (e.g. surgery).

2) Indications

Surgical procedures where tissue needs to be grasped, held, mobilized and/or separated or hard tissue such as bone needs to be separated.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual rongeur or forceps model are contraindicated. There are no generally valid contraindications for the use of rongeurs and forceps.
Nevertheless, attention must be paid to increased risks that could arise from the anatomical and physiological conditions as well as the medical condition of the patient.

4) Possible side effects

The following side effects are described in the medical literature, which may occur during or after the implementation of special techniques, despite using the FEHLING rongeurs as intended (method-specific complications):

Damage to neighboring - abdominal vessels - ureter - kidneys - intestine(s)	Lesions of - nerves/roots - dura	- AV fistulae - (Pseudo)aneurysms, Epidural hematomas - Impaired wound healing - Infections - Possible carryover of tumor cells

⚠	Medical devices may contain, for example, chromium and/or nickel. The materials used are biocompatible, but they can cause allergic reactions or intolerances.

5) Before use

FEHLING INSTRUMENTS rongeurs are delivered non-sterile and must be cleaned and sterilized by the user before first use and before each further use (see section *6) Reprocessing*).

⚠	A safety check must be carried out before each use. Attention must be paid to sharp-edged points, cracks, breaks, mechanical malfunctions and missing components (see section *6) Reprocessing* under *"Maintenance, inspection and testing"*).
⚠	Handle rongeurs carefully during storage, transport and cleaning! Avoid blows and punctual loads on the rongeur so as not to cause any possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!

6) Reprocessing

⚠	The medical device must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed according to the RKI guidelines (non-critical/semi-critical/critical A/B/C).
⚠	National legal regulations, national and international standards and guidelines as well as own hygiene regulations for reprocessing must be observed.

⚠	For the reprocessing of the instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants, the applicable national regulations must be observed.
⚠	The instruments may only be used, reprocessed and disposed of by competent medical personnel.
⚠	Handle instruments carefully during storage, transport and cleaning! Avoid blows and punctual loads on instruments so as not to cause any possible consequential damage! Do not overload functional parts!
⚠	Do not clean CERAMO® instruments (recognizable by the black-brown surface) or titanium instruments with oxidative methods (method with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). Using these methods will eventually lead to the destruction of titanium instruments or the titanium-containing CERAMO® coating, due to the titanium being dissolved.

Limitations on processing	Frequent reprocessing has little effect on the labeling of the instruments and does not impair the function of the instruments. The end of the product life is usually determined by wear and damage due to use (e.g. damage, unreadable marking, functional failure – see also *"Maintenance, inspection and testing"*). With proper application and reprocessing, the instruments can go through up to 500 reprocessing cycles.
General information on reprocessing	The reprocessing is based on a validated procedure. All mentioned cleaning steps (manual pre-cleaning, machine/manual cleaning, manual disinfection and sterilization) were validated with the respective specified parameters and listed under "Validated procedure". For validation, the recommended treatment agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); Disinfectant: Korsolex® med AF (Bode Chemie GmbH)) have been used. Water of drinking water quality as well as fully deionized water (DI water; demineralized, microbiologically at least drinking water quality) are used for cleaning. Machine reprocessing is preferable to manual cleaning due to a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions for concentration, exposure time, temperature and renewal of the cleaning and disinfecting agents. All application specifications of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical material changes or to material damage, such as corrosion, fractures or premature aging.
Pre-treatment at the place of use	Pre-cleaning: It must be ensured that residues of blood, tissue and medicines are removed from the instruments with a disposable cloth/paper towel immediately after the end of the procedure, and that the instruments are immediately sent for machine cleaning. After completion of the pre-treatment of the instruments, visual inspections must be carried out for the completeness of the instruments. The instruments must be transported from the place of use to the place of processing in such a way that neither users, third parties, the environment nor medical devices are endangered or damaged (placement in closed, puncture-proof containers and – if necessary – use of protective caps).

Preparation before cleaning	It is recommended to reprocess the instruments immediately after use, as dried-on residues are difficult to remove in hard-to-reach areas. Do not deposit in NaCl solutions (for risk of pitting or stress cracking corrosion). Instruments that have been connected to each other during use must be disassembled back to their original state before cleaning.
Disassembly	See section *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Pressurized water cleaning gun (or similar) Cleaning agent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse instruments in disassembled state under running, cold water (drinking water quality, <40°C) until all visible contamination has been removed. Remove any stuck grime with a soft brush (never a wire brush!). • Cavities, gaps, slits and lumens must each be rinsed intensively (>10 seconds) with cold water (drinking water quality, <40°C) using a pressurized water cleaning gun (or similar). • Insert the products into a solution containing 0.5 – 2% Neodisher® MediClean forte with water (drinking water quality, <40°C) for 10 - 30 minutes. • Use only an approved solution of a detergent that does not have a protein-fixing effect. The instructions of the cleaning and disinfectant manufacturer must be followed. • Make sure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • Remove any coarse grime during the exposure time with a suitable brush (never a wire brush!). • Rinse the instruments for 1 minute under cold DI water (see *"General information on reprocessing"*) and, if necessary, move moving parts on the instrument back and forth.
Cleaning/ disinfection	If possible, a cleaning/disinfection device according to DIN EN ISO 15883, which uses thermal disinfection, is preferred.
Cleaning: Automated	Avoid overfilling instrument screens and washing trays – use only suitable instrument carriers. Make sure that when inserting and removing the instruments into/from the sieve baskets, the tips do not jam in the grid. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agent: Neodisher® MediClean forte (Dr. Weigert)

	<u>Preparation:</u> • Hinged instruments must be inserted into the device in such a way that the hinges are opened or disassembled, if possible, and the water can drain from cavities and blind holes. • If necessary, relax springs. • Make sure that all cavities are completely flushed through. • It must be ensured that no area is unexposed. • Connect the Luer connections of the instruments, if present, to the Luer-Lock flushing attachment of the washer-disinfector. <u>Procedure/parameters:</u> • 3 minutes pre-rinse with cold water (drinking water quality, <40°C) • Drain empty • 10 minutes cleaning with a solution of 0.5 – 2% Neodisher® MediClean forte in water (drinking water quality) at 55°C • Drain empty • 2 minutes rinse with water (drinking water quality, <40°C) • Drain empty • 1 minute rinse with cold DI water (<30°C) • Drain empty • 5 minutes thermal disinfection with DI water (>90°C) • 30 minutes drying (90°C) After machine cleaning, cavities, blind holes, etc. in particular are examined for visible grime. If necessary, repeat cycle or clean manually.
Cleaning: Manual	<u>Validated procedure:</u> Equipment: Basin Soft brush Pressurized water cleaning gun (or similar) Bandelin Sonorex Digitec Cleaning agent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, place instruments in disassembled state in cold water (drinking water quality, <40°C) for 10 minutes. • Actuate moving parts, if present, over the entire range of movement. • Clean the instruments with a soft brush (never a wire brush!) until there is no longer any visible contamination. • Rinse the instruments for at least 20 seconds using a pressurized water cleaning gun (or similar). <u>Ultrasonic cleaning:</u> • 10 minutes sonication at <40°C with 0.5 – 2% cleaning solution at 35 kHz • After the sonication, rinse the instruments for at least 20 seconds using a pressurized water cleaning gun (or similar). • Rinse the instruments with water (drinking water quality, <40°C) for at least 10 seconds.

	• DI water (<40°C) must be used for the final rinse. The instruments are rinsed with DI water for at least 30 seconds. It must be ensured that no residue remains on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see information provided by the chemical manufacturer). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectants: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, <40°C) for 5 minutes, with a suitable disinfectant (e.g. 0.5% Korsolex® med AF). It must be ensured that all surfaces are wetted with the disinfectant. If necessary, move moving parts in the disinfection bath before switching on the ultrasonic device. • After disinfection, rinse all products thoroughly with DI water (<40°C) for at least 1 minute to remove the disinfectant and, if necessary, move moving parts on the instrument back and forth. • It must be ensured that no residue remains on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is part of the cleaning/disinfection cycle, 120°C should not be exceeded. Dry with suitable compressed air according to RKI recommendation. Pay particular attention to the drying of hard-to-reach areas.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing:	For instruments with movable components that are exposed to friction (e.g. hinges), an instrument oil based on paraffin/white oil (according to the valid European or United States pharmacopoeia), which is biocompatible, steam-sterilizable and steam-permeable, must be applied before sterilization. Such locations may additionally be identified by an oil can symbol. Instruments may not be treated with silicone-containing care products. These can lead to sluggishness and may invalidate the effect of steam sterilization. A safety check must be carried out before each use. Attention must be paid to sharp-edged points, cracks, breaks, mechanical malfunctions and missing components. Check the ease of operation of instruments with moving parts (avoid too much play). Check locking mechanisms. All Instruments: Carry out a visual inspection with a magnifying lamp for damage and wear. Pay particular attention to the critical points on moving parts and in the work area. Defective or damaged instruments, or instruments whose labeling is no longer legible, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs are to be carried out exclusively by the manufacturer or by workshops authorized by the manufacturer. A confirmation form about this process is available from the manufacturer. Instruments that can no longer be repaired must be sent to hospital waste metal disposal. Particularly in the case of surgical instruments with tips or

	sharp edges, care must be taken to ensure safe storage in a closed, puncture-proof and break-proof disposable container. Do not use damaged instruments!
Packaging	Individually: According to standards of the series DIN EN 868, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into designated trays or place them on all-purpose sterilization trays. A suitable method must be used to pack the trays.
Sterilization	Steam sterilization in the fractionated vacuum process in a device according to DIN EN 285 and DIN EN ISO 17665 (Parts 1 and 2). In order to prevent staining and corrosion, the steam must be free of ingredients. The recommended limit values of the ingredients for feedwater and steam condensate are set 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 several instruments in a sterilization cycle, the maximum load of the sterilizer must not be exceeded (see information provided by the device manufacturer).
Storage	According to § 4 MPBetreibV and standards of the 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 (avoidance of condensation, damage). If applicable, always keep instruments in a relaxed state. This counteracts premature fatigue of the spring tension. Instruments are to be transported to the place of use in a closed, puncture-proof sterile container.
Disposal	These products are mainly made of steel. Products must be cleaned before disposal. Disposal can take place at a scrap metal recycling site. To protect employees, it must be ensured that any tips and sharp edges are protected.
The instructions listed above have been validated by the medical device manufacturer as suitable for preparing a medical device for reuse. The processor is responsible for ensuring that the processing actually carried out, with the equipment, materials and personnel used, achieves the desired result in the processing facility. This requires verification and/or validation and routine monitoring of the procedure. Likewise, any deviation from the provided instructions should be carefully evaluated by the processor for their effectiveness and possible adverse consequences.	
⚠	Any change to the product or deviation from these instructions for use leads to exclusion of liability! Subject to change without notice.

7) Configuration and application	
Due to the variety of possible anatomical and physiological conditions, rongeurs differ in their specific properties, such as limb length or design of the handles.	
Performance Characteristics:	
Rongeurs	Rongeurs can grip soft tissue in the front quarter up to a thickness of 20% opening width
Separating rongeurs	Rongeurs can separate soft tissue in the front quarter up to a thickness of 20% opening width
⚠	Only use flawless and sterilized products!
⚠	Before inserting the rongeur, it must be ensured that the surgical field has been prepared accordingly.
⚠	Medical devices made of ferromagnetic substances 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 rongeur depends on the anatomical and physiological conditions as well as the field of application. In doing so, it must be ensured that the rongeurs used are the right size and have sufficient stability.
During use	
⚠	Richter X rongeurs without safety latch, recognizable by the additional letter "X", can come loose during use if too much pressure is applied to the slider. The peacock eye of the movable handle part can detach from its receptacle in the slider and the rongeur falls apart. To avoid this, the Richter X rongeur with locking bar, recognizable by the additional letter "Y", can be used. The locking bar prevents unintentional detachment of the peacock eye from its receptacle in the slider.
⚠	Rongeurs are intended for **grasping** soft tissue, **not** for separation (exceptions here are only FERRIS-SMITH-, large-jaw and BRODNER rongeurs)! Risk of breakage due to overload possible; risk of injury! If anatomy permits, the considerably more robust FERRIS-SMITH, large-jaw or BRODNER rongeurs can be used, which can cut soft tissues even without prior separation.
⚠	Only grab completely separated tissue parts. Avoid twisting, tilting and overloading the instrument, especially in the case of titanium rongeurs. Risk of injury!

⚠	Important rule of thumb: Overload can be visually recognized by the curvature of the slider above the shaft level. If this occurs, interrupt the grabbing process and - either completely free the grasped piece of tissue with a suitable sharp instrument or - use a suitably sized FERRIS-SMITH or large-jaw rongeur or the BRODNER rongeur. Continuation of the gripping and removal process despite recognizable overload may destroy the hinge that connects the movable jaw part to the slider and shaft. Risk of breakage; Risk of injury!
⚠	The application must be carried out under visual control in order to avoid injury to adjacent structures (see section *4) Possible side effects*). Risk of injury!

8) Required accessories

A screwdriver is required for the assembly/disassembly of rongeurs with ring handle/pliers handle with screw. For CERAMO® rongeurs with ring handle with screw, for example, the TXW-1X or TXW-2X screwdriver (sterilizable) can be used. For assembly/disassembly of CERAMO® rongeurs with pliers handle and screw the TXX-0X or TXW-9X screwdriver (sterilizable) is suitable.

No tools are required to disassemble the CERAMO® rongeurs with ring handle with peacock eye, but please follow the corresponding assembly instructions (see section *9) Assembly*).

Rongeurs are stand-alone instruments. Therefore, no combination with other products is provisioned.

9) Assembly

For assembly of the modular rongeurs, please follow the corresponding instructions.

List of assembly instructions:

CERAMO® Rongeurs – Ring handle with screw M118
CERAMO® Rongeurs – Pliers handle with screw M123
CERAMO® Rongeurs – Ring handle with peacock eye M124

10) Disassembly

For disassembly of the modular rongeurs, please follow the corresponding instructions (see section *9) Assembly*).

⚠	Place small parts in suitable containers (e.g. needle box) for storage and reprocessing!

11) Duty to report serious incidents

The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer either 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 established.

Symbols		
Insofar as depicted on the medical device or medical device label or instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meanings:		
 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Warning
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 0297 CE marking
 Oil can for lubricating points	 CE marking	

Manufacturer contact		
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