FEHLING bone punches
Accessories TXX-0X ..... Hexagon screwdriver, 3 mm TXW-9X ..... Screwdriver Allen, 3 mm, sterilisable TXW-6X ..... Assembly device for TRADITION X punches (optional) TXW-7X ..... Assembly device for CONCEPT X punches (optional) TXW-8X ..... Assembly device for GENTLE punches (optional) UCA-3S ..... Container for 5 spinal punches 385 x 150 x 150 mm
Note: These Instructions For Use do not apply to FEHLING TURNUS bone punches (sede Instructions for Use G105).

	Disassemblable bone punches can be identified by the arrow marking next to the hexagon socket screw at the end of the instrument. Bone punches without this marking cannot be disassembled. To assemble and disassemble, please follow the corresponding assembly instructions (see 9) Assembly).

	This instrument or medical device is non-sterile when delivered. It is to be processed before use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing. Bone punches may only be used, reprocessed and disposed of by qualified medical personnel! Bone punches are intended for re-use.

1) Intended purpose

Bone punches are used to remove bone, cartilage and tissue from the skull and in particular the spine.

Additional information regarding the intended purpose

Duration of application: Bone punches are intended for temporary use.

Field of application: Bone punches are used in all patients in whom bone, cartilage and tissue must be removed from the skull and in particular from the spine.

User profile: Bone punches may only be used by medically trained personnel (e.g. specialist physician).

Application environment: Bone punches are only to be used in controlled environments.

Target patient population: No restrictions.

2) Indications

Bone punches are used to remove bone, cartilage and tissue from the skull and in particular the spine.
Laminectomy punches in particular are used for the resection of vertebral arches, spinous processes and to expose or relieve the spinal cord, for example in the case of a herniated disc.

3) Contraindication
All applications that run counter to the physical and/or mechanical properties of the individual bone punch model are contraindicated. There are no generally applicable contraindications for the use of bone punches. 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 side effects in laminectomy	
In the medical literature, the following adverse effects are described that can possibly occur despite the correct use of the FEHLING bone punches / FEHLING CERAMO® TURNUS bone punches during or after performing specific techniques (method-specific complications): - Infections - Compression or lesions of the nerve roots - Lesions of structures (tissue, organs, nerves, vessels) - Injuries to the nerves or dura during lamina undercutting - Wound healing disorders	
⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Before use	
The bone punches are non-sterile when delivered, so they must be cleaned and sterilised by the user before initial use and every time before they are used thereafter (see section *6) Reprocessing*).	
⚠	Perform a safety check before each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section *6) Reprocessing* under *"Maintenance, Inspection and Testing"*).
⚠	The bone punches must be handled with care during storage, transportation and cleaning. Avoid striking the bone punches or applying pressure to their parts so as not to cause any consequential damage. Do not overstrain functional parts.
⚠	Use only sterilised products of sound quality.

6) Reprocessing	
⚠	The medical device is to be reprocessed before use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before 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.
⚠	The bone punches must be handled with care during storage, transportation and cleaning. Avoid striking and applying pressure to instruments, so as not to cause any consequential damage. Do not overstrain functional parts.
⚠	Do not clean CERAMO® instruments (recognisable by their black-brown surface) with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of the titanium-containing CERAMO® coating after some time. Similarly, do not clean instruments containing plastic components with oxidative processes. These processes lead to oxidative ageing of the material, which may under certain circumstances not be detectable by visible discolouration or embrittlement.

Limitations on reprocessing	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. 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, Inspection and Testing"*). If used and reprocessed correctly, the instruments can demonstrably undergo at least 500 reprocessing cycles.
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 sterilisation) 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 deionised water (deionised water, demineralised, 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 of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-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 before cleaning	Instruments should be reprocessed 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 that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section *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 may be 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 deionised 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 sterilisation 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 so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the 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 washer/disinfector. <u>Procedure/Parameters:</u> • 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 deionised water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionised 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	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • 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 contamination is no longer visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • 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). • Deionised water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • 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 deionised 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 section *9) Assembly*
Maintenance, Inspection 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 sterilisable and steam-permeable is to be applied before sterilisation. 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 impair the effectiveness of steam sterilisation.

	Perform a safety check of the instruments before 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 looseness). Check locking mechanisms, if applicable. 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 authorised 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	In accordance with the standard of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation 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 Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).

Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, 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. They are to be cleaned before disposal. They can be disposed of 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 result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy 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

Bone punches with ejector have a special feature where the ejector prevents the separated bone material from getting between the shaft and the slider and jeopardising functional safety.
Bone punches with an arrow marking next to the hexagon socket screw at the end of the instrument can be disassembled. The hexagon socket screw has a left-hand thread, i.e. the screwdriver must be turned clockwise to loosen the hexagon socket screw and counter-clockwise to tighten it.

⚠	Use only sterilised products of sound quality.
⚠	Before using the bone punches, 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 bone punch depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the bone punches used are of the correct size and have adequate stability.

During application

⚠	Avoid overloading the instrument.

	Rule of thumb: The volume of the cut material must be less than the volume of the two cavities in the punch foot and punch slider. **Most important rule of thumb:** Overload can be detected visually by the bulge of the slider above the level of the shaft. If this happens, stop the punching process and - either grasp a smaller amount of tissue or - use a punch with a larger working width. Continuing the punching process despite recognisable overload can lead to breakage of the flank guide at the distal end of the slider. The resulting risk is that the possible broken flank piece could disappear into the surgical field. Risk of injury. Avoid rotational loading of the shaft axis when cutting bones. Risk of injury.
⚠	Only use all flat-foot punches and all bone punches with a working width of 1 mm and less for soft tissue and small volumes of bone. Do not cut the cortex. Risk of injury.
⚠	Do not grasp or cut any hard materials (wire, screws, etc.) with the bone punches. This leads to scoring, deformation or breakage. **Risk of injury.**
⚠	**CERAMO® APART punches** When using APART punches, never press the golden locking button during use; this could cause the punch to disassemble. Risk of injury. Especially when using considerable force, make sure that the thumb or any other part of the hand does not press on the locking button. The pressure could trigger the unlocking mechanism.
	Should the APART punch catch or not run stably in the guide, immediately check whether it is has been assembled correctly. A correctly assembled APART punch can be recognised in that the golden locking button on the labelled punch side protrudes completely (Fig. 1). If this is not the case, the punch must be handed over to the surgical staff for correct assembly before further use (see 9) Assembly).

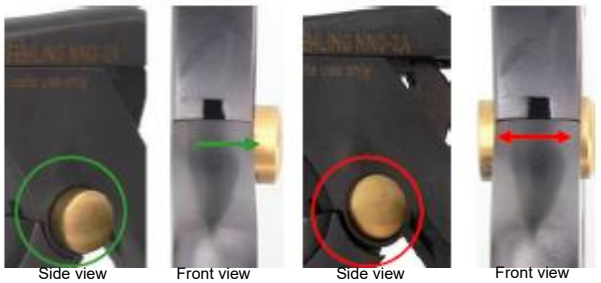


Fig. 1

8) Required accessories

An Allen screwdriver, 3 mm, e.g. TXX-0X or TXW-9X (sterilisable), is required for using the disassemblable bone punch.

The TXW-6X assembly device can be used for TRADITION X punches, the TXW-7X assembly device for CONCEPT X punches and the TXW-8X assembly device for GENTLE punches.

A container for 5 spinal punches (UCA-3S) can be used for sterilisation or storage.

Bone punches are stand-alone instruments and combination with other products is therefore not intended.

9) Assembly

To assemble the bone punch please follow the corresponding assembly instructions.
List of assembly instructions:

CERAMO® CONCEPT APART punches.....M01
CERAMO® APART punches.....M04
CERAMO® CONCEPT X punches.....M06
CERAMO® GENTLE punches.....M07
CERAMO® TRADITION X punches.....M08
CERAMO® TRADITION X punches (assembly device).....M10
CERAMO® CONCEPT X punches (assembly device).....M11
CERAMO® GENTLE punches (assembly device).....M12

10) Disassembly

To disassemble the bone punch, please follow the corresponding assembly instructions (see 9) Assembly).

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

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer's contact information		
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