FEHLING bone punches

Accessories

TXX-0X	Hexagon screwdriver, 3 mm
TXW-9X	Screwdriver Allen, 3 mm, sterilizable
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
UCA-3	Container for 10 spinal punches 515 x 250 x 150 mm

Note: these Instructions for Use do **not** apply to FEHLING TURNUS bone punches (see 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 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.
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 where bone, cartilage and tissue must be removed from the skull and in particular from the spine.

User profile: here, bone punches may only be used by medically trained personnel.

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

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 adverse 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 during or after performing specific techniques (method-specific complications):

- Compression or lesions of the nerve roots
- Injuries to the nerves or dura during lamina undercutting

⚠	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

FEHLING bone punches are non-sterile when delivered so they have to 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").
⚠	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 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!

⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments 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 titanium instruments or the titanium-containing CERAMO® coating after some time. In the same meaning, do not clean instruments containing plastic components with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.
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. <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 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	<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 no more contamination is 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). • 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	
Bone punches with ejectors have the special feature that the ejector prevents the separated bone material from getting caught between the shaft and the slider and thus 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 counterclockwise to tighten it.	
⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the bone punch, 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. Here care should be exercised to ensure that the bone punches used are of the correct size and have adequate stability.
During use	
⚠	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: the possible broken flank piece disappears 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 another 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 assembleded APART punch can be recognised in that the golden locking button on the labeled 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).

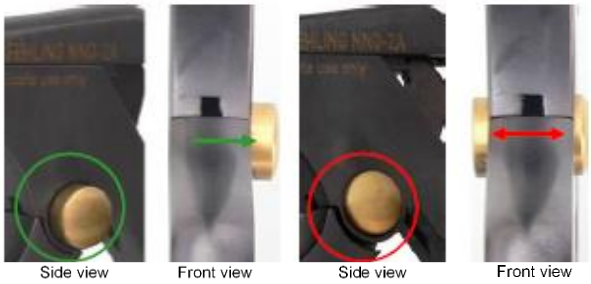

Fig. 1

8) Required accessories

An Allen screwdriver, 3 mm, e.g. TXX-0X or TXW-9X (sterilizable), 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) or for 10 spinal punches (UCA-3) can be used for sterilisation or storage.

Bone punches are stand-alone instruments and therefore a combination with other products is 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. 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 represent the following meaning:		
 Manufacturer	 Instructions for Use are to be observed	 Warning
 Article number	 Batch code	 Serial number
 CE labeling	 0297 CE labeling	 Oil can for points to be lubricated

To contact the manufacturer:		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 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