All CERAMO® TURNUS bone punches Handles and shafts	

⚠ 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).
Before processing, the instrument must be risk-evaluated.

⚠ Bone punches may only be used, processed and disposed of by competent medical personal!

Intended Use

Bone punches are used to excise bone, cartilage and tissue at the skull and the vertebral column.

Indications / Contraindications

Indications

- Excision of bone, cartilage and tissue at the skull and the vertebral column
- Laminectomy punches are used for resection of the vertebral arch, spinous processes and to expose or releave pressure on the spinal cord, e.g. in case of a spinal disk herniation

Contraindication:
Not known

Possible adverse effects during laminectomy

The following adverse effects are described in medical technical literature, which may possibly occur in spite of using FEHLING bone punches according to their intended use, and due to practice of special surgical techniques, respectively (method specific complications):

- Compression or lesion of nerve roots
- Injury of nerves or of the Dura in case of lamina undercutting

Before Use

FEHLING INSTRUMENTS bone punches are delivered non-sterile and have to be cleaned and sterilized by the user before their first and any further use (see reprocessing).

Perform a safety check before each use of the punch. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing).

During use

⚠ CERAMO TURNUS bone punches shall only be used during surgical interventions in the area of the cervical vertebra and pituitary gland (hypophysis). When used in the lumbal area, the occuring loads can lead to malfunctions or damage to the bone punches. **Risk of injury!**

⚠ Handle punches with care on storage, transport and cleaning!
Avoid impacts and selective loads! **Risk of injury!**

Avoid overstressing! Rule of thumb: The volume of the cuttings must be smaller than the volume of the two cavities in punch foot and punch slider.

Most important rule of thumb: Overstressing can be recognized visually when the slider buldges over the shaft. In this case, stop the punching process immediately and

- try to punch a smaller amount of tissue
- use a punch with a broader foot

Continuing a punching process in spite of obvious overstressing can lead to fracture of the distal end of the slider, which can result in the loss of fragments in the operating are. **Risk of injury!**

Avoid rotative stress on the instrument while cutting bone! **Risk of injury!**

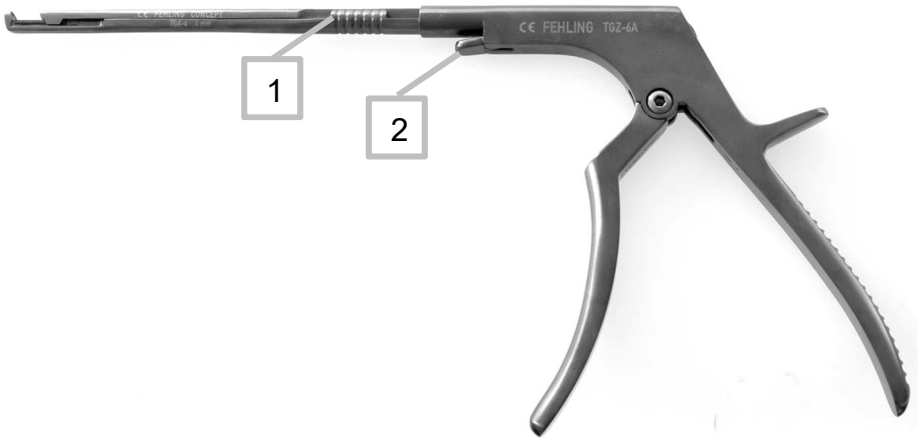
Use all flat-foot punches and all punches with a useful width of 1 mm and less for soft tissue and small bone quantities only. Do not cut cortical bones! **Risk of injury!**

Do not use the bone punches to hold or cut hard material (e.g. wire, screws)! This can lead to notches, plastic deformation or break of the instrument. **Risk of injury!**

Change of the Working Angle

a) Hold the handle in one hand and place the finger-tips of the other hand on both sides of the handle profile (1) of the shaft.

b) Keep the fingers on both sides of the handle profile and gently push the shaft as far as possible towards the handle. The shaft is released and can be turned.



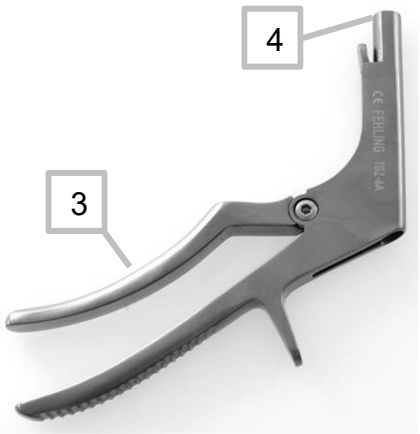
c) The shaft can be locked in 8 different angle positions: 0°, 45°, 90°, 135°, 180°, 225°, 270° und 315°.

d) Hold the shaft in the released position and turn it left or right. After reaching the desired position, release the pressure on the shaft. A clicking sound in the spring indicates that the shaft has locked into position. The punch is now ready to use.

Changing the shaft

Push the locking lever (2) upwards. Thus, the shaft is released from the handle and can easily be pulled out.

Attention: In order for the return mechanism of the TRADITION handle (TGZ-6A) to function properly, the handle element (3) must be in closed position when the shaft is inserted. To make sure that the handle element is in the correct position, hold the handle such that the handle with the shaft socket (4) shows upwards when the shaft is inserted.



Grab the assembled shaft on both sides of the handle profile (1) and push it into the handle, until a clicking sound can be heard. After a functional test, the punch is ready to use.

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.	
Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage:	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 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. Clean instruments under cold running water with a suitable soft brush until all visible contamination 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 sets 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 set baskets. Please refer to the appropriate assembly instructions for the disassembly of the respective shaft: CERAMO TURNUS punches, shafts for endoscopy ..... M16 CERAMO TURNUS punches M17
Cleaning/Disinfection acc. to EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfecting 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 15883-1:2009	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 cutting edges of slider and foot close completely over the entire length of the cutting edge. If not the instrument cannot or only in a limited way achieve its function. The punch 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.
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 EN 868 and EN ISO 11607.
Additional information	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).
Contact the manufacturer	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

Storage / Symbold

					
Manufacturer	Article number	Lot number	Observe instructions for use		Attention

! Any modification to the product or deviation from these instructions of use results in exclusion of liability!
Subject to change without notice.

Manufacturer:
FEHLING INSTRUMENTS GmbH & Co. KG, Hanauer Landstr. 7A, 63791 Karlstein/Germany, www.fehling-instruments.de

The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.