CAUTION: U. S. A Federal law restricts this device to sale by or on the order of a physician

FEHLING CERAMO® rongeurs (bone punches)

INTENDED USE

FEHLING rongeurs (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

INDICATIONS

Use the product only in accordance with its intended use, see Intended Use.

CONTRAINDICATIONS

The instruments shall not be used for anything other than the Intended Use.

SAFE HANDLING AND PREPARATION

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, follow, and keep the instructions for use.
- Handle punches with care during storage, transport and cleaning!
  Avoid impacts and selective loads!
- FEHLING INSTRUMENTS bone punches are delivered non-sterile and have to be cleaned and sterilized before first and any further use. Remove the transport packaging and clean the new product, we recommend an automated cleaning, prior to its initial sterilization.
- Store any new or unused products in a clean, dry and protected from dust place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use a damaged or defect product. Send it back to the manufacturer or its representative for repair! Set a damaged product aside.
- Replace any damaged components immediately with original spare parts.
- Failure to follow these procedures may cause the instrument to fail. These cases will not be covered by the manufacturer's warranty.
- Detachable bone punches can be identified by the arrow mark next to the hex socket screw at the joint of the instrument. Do not try to dismount punches without this mark!
  For assembly and disassembly please refer to the appropriate assembly instructions (see below for a list of the referring assembly instructions).

SAFE OPERATION

Risk of injury and/or malfunction!

The bone punches must be checked thoroughly upon receipt and prior to each use, to assure proper functioning. Failure to perform this inspection may result in unsatisfactory performance, malfunction and injury!

- Check for cracks, breaks or mechanical malfunctions.
- Check the tips to ensure cutting surfaces meet evenly.
- In case of a detachable bone punch, check the screw or button which secures the instrument to avoid the loss of parts while using the instrument.
- Ensure that the ejector pin/bar is not bent (if appropriate), that the shafts are perfectly aligned and that the slider runs smoothly.
- DO NOT use instruments that fail to pass the safety check!
- DO NOT use an instrument if it does not seem to function properly!

Damage to, or destruction of the product caused by incorrect handling!

- Use the product according to its intended use.
- Avoid overstraining the device by twisting or levering the product during the punching procedure. The rule of thumb is: The volume of the cuttings must be smaller than the volume of the two cavities in punch foot and punch slider.
- Use all flat-foot punches and all punches with a useful width of 3 mm and less for soft tissue and small bone quantities only. Do not cut cortical bone!
- CAUTION: Pressing the golden button on APART models will detach the instruments.
  DO NOT press the golden button while using the instrument!

Squeeze together the handles to cut bone.

Release handles to deploy tip and eject bone tissue from shaft.

Remove gross debris from surgical instruments with a disposable towel and sterile water routinely during the procedure to prevent drying of residues.

VALIDATED REPROCESSING PROCEDURE

GENERAL SAFETY INSTRUCTIONS

NOTE: For patients with Creutzfeld-Jakob disease (CJD), suspected CJD or possible variants of CJD. If used on a patient with or suspected of having Creutzfeldt-Jakob disease (CJD), the instruments used within the treatment of the patient should not be reused and should be discarded. The instruments have not been validated to withstand procedures suitable for the eradication of prions.

GENERAL INFORMATION

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore, the time interval between the device's use and the reprocessing shall not exceed 6 hours.

The instruments shall not be exposed to temperatures > 45 °C, which could fixate the residues.

The instruments shall not be treated with disinfecting agents containing aldehydes/alcohols, which could fixate residues.

Excessive utilization of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization can cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Failure to do so may result in the following problems:

- Optical changes of materials, e.g. fading/degradation of the CERAMO® coating.
- Material damage such as corrosion, cracks, fracturing, premature ageing or swelling.
- Never use steel wool, wire brushes, scalpel blades or abrasive detergents to remove contamination. Those means might damage the CERAMO® coating and lead to corrosion!
- Keep different metal types separated, e.g. stainless steel, copper, aluminum! Galvanic reactions might lead to corrosion!

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- Use cleaning and disinfecting agents approved for high-grade steel, according to the manufacturer's use instructions.
- When using cleaning and disinfecting agents please prepare the agents according to the labeling supplied by the detergent manufacturer.
- Do not exceed the maximum allowable temperature of 60 °C.
- Do not clean instruments coated with CERAMO® (identifiable by the brownish black surface) using oxidative processes (e.g. Miele Orthovario and Oxivario process or other processes using H_2O_2). Such processes may result in the destruction (bleaching/layer loss) of the CERAMO® coating!

Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79:2010, A1:2010, A2:2009 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Instruments must be rendered safe for handling, inspection and assembly by wearing appropriate personal protection equipment (PPE) as promulgated by OSHA & AORN.

Sterilization is a two-step process involving thorough cleaning, rinsing and decontamination and terminal sterilization.

- Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to automated Cleaning and disinfection, rinse the product thoroughly with high purity water.
- Ultrasound cleaning maybe additionally used:
  – as a pre-cleaning procedure for products with encrusted residues, in preparation for automated Cleaning/disinfecting.
  – as an integrated mechanical support measure for automated Cleaning/disinfecting.

VALIDATED CLEANING AND DISINFECTION PROCEDURE

MANUAL PRE-CLEANING / AUTOMATED CLEANING/ DISINFECTION

DECONTAMINATION AND STERILIZATION PROCEDURES

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.
Limitations on reprocessing	Do not place in saline (NaCl) solution (risk of pitting or stress crack corrosion). Do not clean instruments coated with CERAMO® using oxidative processes (processes using H_2O_2). Such processes may result in the destruction (bleaching/layer loss) of the CERAMO® coating!
⚠ **Warning**	Risk of injury or malfunction! Do not modify the instrument! Never use steel wool, wire brushes, scalpel blades or abrasive detergents to remove contamination. Those means might damage the CERAMO® coating and lead to corrosion! Galvanic reactions might lead to corrosion! Use only screwdriver model TXW-9X!
Point of use	It is recommended to start reprocessing the instruments immediately after use, as otherwise, a biofilm might form or residues might dry. Both can be difficult to remove. Remove surface contamination during the procedure using a disposable towel. Where applicable, rinse non-visible surfaces preferably with deionized water, e.g. with a disposable syringe. Remove surface contamination during and after the procedure using a disposable towel. Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.
Containment and Transportation	Keep different metal types separated, e.g. stainless steel, copper, aluminum!
Preparation for cleaning	Open the instruments or disassemble the detachable ones before cleaning (hinges shall be open and the water must flow off cavities and blind holes). Specific instructions for device that require disassembly are provided in Chapter 1 of the corresponding assembly instructions. Please refer to the appropriate assembly instructions, if necessary! CERAMO CONCEPT APART punches ..... M04 CERAMO CONCEPT X punches..... M06 CERAMO GENTLE punches ..... M07 CERAMO TRADITION X punches..... M08
Manual Pre-Cleaning	Soak the devices in an alkaline, enzymatic cleaner, such as Neodisher® Mediclean Forte at 0.5-2% or Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner at 0.5-2% (about 5mL/ Liter of high purity water) at <40°C for 10-30 minutes. Remove gross soil using soft -bristled brush. Actuate mobile parts of device minimum 5 times. Rinse each device under cold high purity water for 1 minute. Remove gross soil using a soft-bristled brush. Actuate mobile parts of the device minimum 5 times.

Automated Cleaning

Load the device so that the blind holes can drain. When loading in the washer-disinfector:

1. Avoid overfilling of instrument sets and washing trays
2. Use appropriate instrument carriers only
3. 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.
4. Avoid loading heavy instruments on delicate instruments.
5. Make sure that loading doesn't prevent water jets from accessing the load directly.

Using a validated washer disinfector and an alkaline enzymatic detergent, such as Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner, intended for use in an automated cleaning process, use the minimum cycle parameter set points in Table 1.

At the end of the of the cleaning, inspect the device, in particular the joints, spring and holes, for remaining soil in a well-lit area. If there is visible contamination, repeat the entire process.

Drying

If device is still wet after automated cleaning cycle, thoroughly dry the device using a clean lint-free cloth.

Reassembly

Reassemble detachable device before sterilization.

Maintenance, Inspection and Testing

General provisions

It is of due importance to perform the maintenance on the instruments properly and effectively. Not doing so will result in a reduced life span and/or bad performance of the instrument.

Always adhere to the manufacturer's recommendations regarding the use of detergents, disinfectants and the technical equipment.

The CERAMO® coating is resistant to many chemicals commonly used in a central sterile supply department; nevertheless, avoid contact of the instruments with

- oxidizing agents (e.g. H_2O_2)
- abrasives (e.g. abrasive agents or wire brushes)
- saline solution (NaCl)

to avoid corrosion.

Remove corroding instruments from service, as corrosion damages the instrument and might lead to break. Furthermore, corroding instruments might cause the deposit of rust on other instruments.

Maintenance procedures

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's performance is impaired or impossible. The punch must be sent in for repair.

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. In case

of instruments sent for repair that lack the cleaning statement, the repair process will be delayed due to the necessary reprocessing!

In order to assure warranties and guarantees, instruments in need of repair should be sent to the manufacturer.

After maintenance, follow the instructions “Terminal sterilization”.

All punches must be lubricated before sterilization using a small amount of surgical grade, water-soluble instrument lubricant (spray) on the joints and all areas where moving parts directly meet (slider/punch body). The lubricant must be a water-soluble and compatible with steam sterilization. Lubrication will keep the instrument moving.

Packaging

The cleaned and inspected re-usable device should be packed in a peel-pouch that is FDA-cleared for the sterilization with the parameters specified in this IFU.

Terminal sterilization

Make sure that the steps “Pre-Cleaning manual”, “Automated Cleaning”, “Drying” and “Reassembly”, “Maintenance” and “Packaging” have been performed prior to sterilization.

To avoid formation of stains and corrosion, the steam must be free of components.

Pre-vacuum steam sterilization is recommended using a FDA cleared sterilizer.

The validated sterilization parameters are provided in Table 2 and will achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Table 1: Automated Cleaning cycle parameter

Cycle	Time	Minimum Temperature	Type of Detergent /Water
Pre-Cleaning	2 minutes	Cold <45°C	High purity water
Cleaning	10 minutes	Heated 55°C	Neodisher® Mediclean Forte at 0.5-2%
Rinse	2 minutes	Cold	High Purity Water
Thermal Rinse	5 minutes	Heated 90°C	High Purity Water[1]
Dry	25 minutes	Heated >50°C	Not applicable

Table 2: Steam sterilization parameter

Sterilizer	Temperature	Exposure time	Drying time (min.)
pre-vacuum	132 °C	4 min	20min

[1] Water extensively treated (usually by a multistep treatment process that may include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water

Storage	Store the sterile instruments in a germ-proof packaging protected from dust in a dry, dark and temperature-controlled area
Disposal	Adhere to national regulations when disposing of or recycling the product, its components and its packaging!

Symbols used on labeling

 Manufacturer	 Manufacturing date	 Catalog number	 Lot / Batch number	 Non-sterile - Sterilize prior to use
 Consult instruction for use	 Caution! See warning and precautions	 Complies with MDD 93/42/EEC	 CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	

Manufacturer

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

Each modification to the product or deviation from these instructions of use results in exclusion of liability!

Distributed in the U.S.A. by FEHLING SURGICAL INSTRUMENTS, INC.
509 Broadstone Ln NW
Acworth, GA 30101
(770) 794-0111
info@fehlingsurgical.com