FEHLING Scissors with tube shafts

Note: This IFU only applies to FEHLING scissors with tube shafts (common and micro scissors: see IFU G106EN).

⚠ Do not use Orthovario or Oxivario procedures to clean CERAMO® instruments (those which have a black surface). Using these procedures will gradually destroy the CERAMO® coating that contains titanium due to their oxidative processes (corrosion of titanium by H_2O_2).

⚠ Only trained medical personnel may use, reprocess or dispose of FEHLING scissors!

Intended use:

Scissors are intended for sharp and blunt separation of tissue or auxiliary materials.

Indications and contraindications:

Indications:	**Contraindications:**
Treatment methods requiring (blunt or sharp) separation of tissue or auxiliary materials.	Not known

Possible adverse effects

Not known

Prior to use::

FEHLING scissors are non-sterile when delivered and must be cleaned and sterilized by the user before initial use and all subsequent uses (see Reprocessing).→ Risk of infection.

Perform a safety check prior to each use. When doing so, check for cracks, fractures and mechanical malfunctions (see Maintenance, Checking and Functional Testing) otherwise there is a risk of injury

⚠ **Use only sterilized products which are in perfect working order!**

Use:

⚠ Avoid striking the instrument or applying pressure to only parts of it! **Risk of injury!**

⚠ Use only for separating tissue or material/auxiliary materials whose volume and firmness is suitable for the construction of the scissors. Avoid overloading the instrument. Overloading the instrument can cause plastic deformation of blades and therefore prevent the closure necessary for cutting. **Risk of injury!**

Note: CERAMO® surfaces protect from abrasion but not from plastic deformation. Separating hard materials always causes indentations to appear. The laterally displaced material of the notch acts like a spacer between cutting edges and prevents the closure necessary for cutting.

Guide the cutting edges so that they are positioned as vertically as possible to the material to be cut.

Use only to separate. Both sharp (cutting blades) and blunt (back of cutting blades) cutting is permitted.

Do not cut materials (e.g. thread)!

During the surgical procedure, rinse repeatedly via the Luer lock connection to prevent residues from drying onto the scissors.

Reprocessing instructions:	
Reprocessing restrictions: Frequent reprocessing has only minor effects on these instruments. Usually the end of the product service life is determined by wear and damage from use	
The instrument must undergo risk assessment prior to reprocessing.	
⚠ Scissors must be handled with care during storage, transportation and cleaning! Avoid striking the instrument or applying pressure to only parts of it! **Risk of injury!** Keep **scissors with tube shafts** separate from general instrument sets if possible.	
Place of application:	Use a disposable cloth/paper towel to remove surface contamination – pre-cleaning.
Storage: in accordance with § 4 of the Medical Devices Operator Ordinance (MPBetreibV)	Store instruments in a dry place to avoid condensation. 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.
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	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. Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not immerse in normal saline (NaCl) solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemicals manufacturer's recommendation for the mixture). Avoid overfilling instrument trays and washing trays – use only suitable instrument holders. When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck anywhere. Always open and/or disassemble joint instruments for processing.
Cleaning/Disinfection according to DIN EN ISO 15883-1:2009	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with. If available, the use of a washer/disinfector unit which uses thermal disinfection is recommended.
Cleaning mechanically acc. to standard EN ISO 15883-1:2009	**Validated procedure** <u>Pre-cleaning</u> Equipment: Basin, soft brush Detergents: Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner (Steris®) Mixing proportion: 0,5 – 2 % Prolystica® in tap water Temperature: 40 °C Application time: 10 – 30 minutes Process: Remove all visible contamination with a suitable soft brush during application time and move the instruments in the basin while actuating mobile parts of device minimum 5 times. Rinse each device under cold high purity water for 1 minute while actuating mobile parts of device minimum 5 times.

	Mechanically cleaning: Equipment: Miele PG 8536 Detergents: neodisher® MediClean forte (Dr. Weigert) Process: 1. 2 min. prewash with cold 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)
Cleaning manually	Validated procedure Equipment: Bandelin Sonorex RK 1028 H Detergents: Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz. After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Desinfection: Manuell	Consult the instructions on the label when selecting a disinfectant (see information on chemical manufacturers). Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Drying:	If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Maintenance:	Apply a small amount of high-grade, water-soluble instrument spray on the hinges. Sort out blunt or damaged instruments (check for cracks or damage). Verify usability.
Control and function test:	Check joint instruments for easy operation (avoid too much play). Check locking mechanisms. Use a magnifying lamp to visually inspect the components for damage and wear and tear. Edges should not show nicks and should be even. In particular, inspect the critical points on moving parts and in the working area. Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.
Packaging:	Single: in accordance with the standard series EN 868 and EN ISO . Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately..

Sterilisation:	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 sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! 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: .....GETINGE HS55 Sterilisator Cycle: .....Pre-vakuum Temperature:.....134 °C Holding time: .....at least 5 Min. Drying time: .....at least 20 Min.
Storage:	In accordance with EN 868 and EN ISO 11607.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences. Additional national standards like AAMI TIR-12-2004 may be applicable.

	Any modification to the device or deviation from these instructions for use will result in exclusion of liability. Subject to change without notice.

Storage / Symbols

 Manufacturer	 Article number	 Lot-number	 Follow the instructions for use	 CE marking	 Warning

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