FEHLING micro scissors

Note: These Instructions For Use only apply to FEHLING micro-scissors
Simple scissors see IFU G106
Tubular shaft scissors see IFU G107

⚠ Do not use Orthovario or Oxivario procedures to clean CERAMO® instruments (which have a blackish-brown surface) or titanium instruments. Use of these procedures will destroy the titanium instruments or the titanium-based CERAMO® coating over time due to their oxidative processes (corrosion of titanium due to H_2O_2).

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

Intended use:

Micro scissors are intended exclusively for sharp or blunt separation of delicate tissue structures. The scissors are intended for temporary use.

Indications and contraindications:

Indications:	**Contraindications:**
Treatment methods exclusively requiring (blunt or sharp) separation of delicate tissue structures.	None known

Possible adverse effects

None known

Prior to use:

FEHLING INSTRUMENTS micro scissors 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 Reprocessing).

Perform a safety check prior to each use of the micro scissors. Check for cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and functional testing).

⚠ Only use micro scissors in perfect condition! **Risk of injury!**

During use:

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

⚠ Use only for sharp (with the cutting edges) and blunt (with the back of the cutting blade) separation of delicate tissue structures exclusively. Do not cut materials (e.g. sutures)!

The volume and strength of the tissue to be separated must be appropriate for the design 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!**

Warning! CERAMO® surfaces protect against abrasion, but not against plastic deformation. Cutting hard materials causes notches. The material displaced sideways in the notch acts as a spacer between the cutting edges and prevents closing of the scissors required for cutting.

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

Always store micro scissors separately from other instruments, including at the operating table.

To minimize the risk of breakage, avoid subjecting scissors with TC insert to striking and bending loads from the side.

Reprocessing:

Reprocessing restrictions:
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.

The instrument must undergo risk assessment prior to reprocessing.

Micro scissors must be handled with care during storage, transportation and cleaning!

Avoid striking the instrument or applying pressure to its parts! **Risk of injury!**

Always keep micro scissors separate from general instrument sets if possible.

If possible, do not clean micro scissors together with other instruments in the washer/disinfector unit.

In order to prevent deformation or breakage, protect micro scissors from spinning around in the instrument tray. **Risk of injury!**

Place of use:	Use a disposable cloth/paper towel to remove surface contamination – pre-cleaning.
Storage: In accordance with § 4 of the German Medical Devices Operator Ordinance (MPBetreibV)	Store the instruments in a dry place in order 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.
Cleaning preparation: Automated cleaning in accordance with Robert Koch Institute (RKI) guidelines. Automated cleaning is preferable to manual cleaning.	Ensure that blood, tissue and drug residues are removed from the instruments immediately after completing the procedure and that mechanical cleaning is undertaken immediately. For this purpose, use suitable soft brushes to clean the instruments under running water until no residues are visible. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemical manufacturer's recommendation for the mixture). 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 jaws/tips do not become stuck in the mesh. Always reprocess joint instruments opened. If applicable, loosen springs.
Cleaning/Disinfection In accordance with 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. Compliance with the recommended concentrations, application times and temperatures is also assumed.

Cleaning: Automated
in accordance with
DIN EN ISO 15883-1:2009

Validated procedures:

Manual pre-cleaning

Equipment:	Basin, soft brush
Detergents:	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.

During the exposure time, use appropriate brushes to remove gross contamination and activate the instruments at least five times.

Rinse the instruments for one minute in cold deionized water and activate for at least five times during the process.

Automated cleaning

Equipment:	Miele PG 8536
Detergent:	neodisher® MediClean forte (Dr. Weigert)

Procedure:

1. Pre-rinse for 2 minutes with cold tap water (< 45 °C)
2. Clean for 10 minutes with a solution of 0.5 - 2% neodisher® in tap water at 55 °C
3. Rinse for 2 minutes with cold tap water (< 45 °C)
4. Rinse for 5 minutes with deionized water (90 °C)
5. Dry for 25 minutes (> 50 °C)

Cleaning: Manual

Validated procedure

Equipment:	Bandelin Sonorex RK 1028 H
Detergent:	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 over the entire range of movement.
- 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.

Disinfection: Manual

Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).
Deionized water must be used for the final rinse. Ensure that no residues remain on the products.

Drying:

If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.

Maintenance:

Apply a small amount of good-quality, water-soluble instrument spray to the joints.
Sort out blunt or damaged instruments (check for cracks and damage).
Test functionality.

Checking and functional testing:	Perform a safety check prior to each use of the micro scissors. When doing so, check for cracks, fractures and mechanical malfunctions and missing components. Check instruments for smooth operation (avoid excessive play). Check locking mechanisms. Use a magnifying lamp to visually inspect the components for damage and wear and tear. Cutting edges should not show any nicks and should be uniform. In particular, inspect the critical points on moving parts and in the working area. Remove defective, blunt or damaged instruments and send them 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. Instruments that can no longer be repaired must be disposed of in the hospital as usual. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a puncture and break-proof disposable container must be ensured. Do not use damaged products!
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. Blades must be protected. Pack the trays appropriately using a suitable procedure.
Sterilization:	Do not sterilize CERAMO® instruments (recognizable by the black-brown surface) and titanium instruments using the peroxide/peroxide plasma process (e.g. STERRAD®)! These sterilization systems work with hydrogen peroxide (H_2O_2), which can cause titanium instruments or CERAMO® coating containing titanium to be destroyed. 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. Validated procedure:

Equipment:	GETINGE HS55 sterilizer
Cycle type:	Pre-vacuum
Temperature:	134 °C
Holding time:	at least 5 min.
Drying time:	at least 20 min.

Storage:	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953
Disposal:	This product is made of steel. It is 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 sharp or pointed edges are protected.
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 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.**

Symbols						
In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:						
Manufacturer	Article number	Batch code	Serial number	Follow the Instructions for Use	Warning	CE labeling

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