| **SUPERFLEX Soft Tissue Retractor, spatulated** | |
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| MTI-0 | SUPERFLEX Soft Tissue Retractor, spatula-shaped, 25x200 mm (Material thickness 0.13 mm) |
| MTK-1 | SUPERFLEX Soft Tissue Retractor, spatula-shaped, 25x200 mm (Material thickness 0.25 mm) |
| MTK-2 | SUPERFLEX Soft Tissue Retractor, spatula-shaped, 25x200 mm (Material thickness 0.35 mm) |
| MTK-3 | SUPERFLEX Soft Tissue Retractor, spatula-shaped, 25x200 mm (Material thickness 0.45 mm) |
| **Accessories** | |
| MTK-0 | Sterilizing and storage tray |

This 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.
Only trained medical personnel may use, reprocess or dispose of the SUPERFLEX soft tissue retractor! The SUPERFLEX soft tissue retractor is only intended for short-term use.

## 1) Intended purpose

Retractors and retractor components, which are used invasively and for short periods in surgery, serve to separate or hold back various tissue structures, such as skin, bone, muscles and organs. The spatula-shaped SUPERFLEX soft tissue retractor in particular is intended for self-retaining concentric spreading and temporary retraction of soft tissue.

## 2) Indications

Surgical procedures that require the temporary spreading and holding of various tissue structures, such as skin, bones, muscles and organs, to reach the body structure requiring treatment. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the retractors or retractor blades used are of the correct size and have adequate stability.

The SUPERFLEX soft tissue retractor in particular is intended for

- concentric spreading of soft tissue, for use in abdominal or cardiac surgery
- temporary retraction of soft tissue, for use in abdominal or cardiac surgery

## 3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no generally applicable contraindications for the use of the SUPERFLEX soft tissue retractor.
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

The following adverse effects have been described in the medical literature during the intended use of retractors.

- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses

In particular, when using the SUPERFLEX soft tissue retractor as intended during or after performing minimally invasive techniques on the heart the following (method-specific complications) can occur:

- postoperative atrial fibrillation
- postoperative cardiac arrhythmias
- tissue trauma
  and in rare cases
- infections
- strokes

## 5) Prior to use

The SUPERFLEX soft tissue retractor is non-sterile when delivered and must be cleaned and sterilized by the user before initial use and every time before being used thereafter (see Reprocessing).

⚠ The SUPERFLEX soft tissue retractor must be handled with care during storage, transportation and cleaning!
Avoid striking or applying pressure to the SUPERFLEX soft tissue retractor so as not to cause any consequential damage!
SUPERFLEX soft tissue retractors consist of an austenite nickel-titanium shape memory alloy. They can be flexibly deformed at room temperature and (instantly) regain their initial shape after removal of the deforming force.
When deforming the retractor during use, do not bend and do not go below the permissible minimum bending radius of 15 mm. Bending the retractor too sharply can result in permanent deformation or irreparable kinks in the material that compromise the retractor's function.
Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and Functional testing).
Use only sterilized products of sound quality!
Prior to inserting the retractor, ensure that the surgical field has been prepared accordingly beforehand.

## 6) 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 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.

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| ⚠ | The SUPERFLEX soft tissue retractor must be handled with care during storage, transportation and cleaning!<br>Avoid striking or applying pressure to the SUPERFLEX soft tissue retractor so as not to cause any consequential damage! |
| ⚠ | 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.<br>Similarly, instruments with Propylux plastic handles should not be cleaned 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. |

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| 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. |
| Storage:<br>in accordance with § 4 of the Medical Devices Operator Ordinance (MPBetreibV) | The SUPERFLEX soft tissue retractor must be stored dry, at room temperature, clean, protected from damage and mechanical influences.<br>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 cracking). |
| Disassembly | See 7) Configuration and application |
| Manual pre-cleaning | Rinse instruments under running cold mains supply water of drinking quality (<40 °C) until all visible contamination has been removed. Remove stubborn dirt with a soft brush (not a wire brush). Cavities, crevices and slits must be rinsed intensively (>10 seconds) with cold town water of drinking water quality (<40 °C) using a water pressure gun (or similar). Place the products in a combined detergent bath. 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 detergent. If necessary, the moving parts of the instrument are to be moved back and forth.<br><br><u>Validated procedures:</u><br>**Manual pre-cleaning**<br>Equipment: Basin, soft brush<br>Detergents: neodisher® MediClean forte<br>Mixing ratio: 0.5 – 2 % in tap water<br>Temperature: Room temperature (23°C)<br>Exposure time: 10 – 30 minutes<br>During the exposure time, use appropriate brushes to remove coarse contamination.<br>Rinse the instruments for one minute in cold deionized water |

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| Cleaning/Disinfection | 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.<br>If possible, a washer/disinfector which uses thermal disinfection is to be preferred. |
| Cleaning: Automated | Avoid overfilling instrument trays and washing trays - use only suitable instrument holders.<br>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.<br>Always reprocess joint instruments open and/or disassembled.<br>If applicable, loosen springs.<br><br><u>Validated procedure:</u><br>Equipment: washer-disinfector G 7835 CD (Miele)<br>Detergent: neodisher® MediClean forte (Dr. Weigert)<br><br><u>Preparation:</u><br>• The joint instruments are to be placed in the device such, that the joints are opened and that the water can flow from the cavities and blind holes.<br>• Ensure that the inside of all cavities is also completely rinsed.<br>• Ensure that no areas are left unwashed.<br><br><u>Parameters:</u><br>• Pre-wash for 3 minutes with cold water (< 40 °C)<br>• Emptying<br>• Clean for 10 minutes with a solution of 0.5 - 1 % neodisher® MediClean forte in tap water at 55 °C<br>• Emptying<br>• Rinse for 2 minutes with tap water (< 40 °C)<br>• Emptying<br>• Rinse for 1 minute with fully deionized cold water (< 30 °C)<br>• Emptying<br>• Thermodisinfection for 5 minutes with deionized water (>90 °C)<br>• Dry for 30 minutes (> 50 °C)<br>After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually. |

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| Cleaning: Manual | <u>Validated procedure</u><br>Equipment: Bandelin Sonorex Digitec<br>Detergent: neodisher® MediClean forte (Dr. Weigert)<br>Disinfectant: Korsolex® med AF<br><br><u>Pre-cleaning</u><br>• Place instruments in cold water for 10 minutes.<br>• Move any movable parts back and forth over the entire range of movement.<br>• Use a soft brush to clean the instruments until no more contamination is visible.<br>• Rinse the instruments for at least 20 seconds with a water spray gun.<br><br><u>Ultrasonic cleaning</u><br>• Expose for 10 minutes at < 40°C with 0.5 – 3 % cleaning solution at 35kHz<br>After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds.<br>Rinse the instruments with tap water for 10 seconds.<br>Deionized water must be used for the final rinse. Ensure that no residues remain on the products. Rinse the instruments with deionized water for at least 30 seconds. |
| Disinfection manually | Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).<br>Deionized water must be used for the final rinse. Ensure that no residues remain on the products. 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 necessary, move the moving parts in the disinfection bath.<br>After disinfection, rinse all products thoroughly with deionized water (> 1 minute) to remove the disinfectant |
| 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 7) Configuration and application |
| Maintenance: | For instruments with movable components that are exposed to friction (e.g. joints), a high-quality water-soluble instrument spray is to be applied. Such places are additionally marked by an oil can.  symbol |

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| Checking and functional testing | 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.<br><br>Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms.<br>All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points in the working area, such as the integrity of the mesh bars.<br>Defective or damaged instruments must be sorted out and cleaned and disinfected before being returned to the manufacturer. A verification form for this process is available from the manufacturer.<br>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 puncture and break-proof disposable container must be ensured. Do not use damaged instruments! |
| Packaging: | Singly: in accordance with the standard series EN 868, EN ISO 11607 and DIN 58953.<br>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 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.<br><br><u>Validated procedure:</u><br>Equipment: Selectomat HP (MMM)<br>1. 3 pre-vacuum phases<br>2. Sterilization temperature 132 °C<br>3. Holding time: 4 minutes<br>4. Drying time: at least 20 minutes |
| Storage: | In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868,<br>DIN EN ISO 11607, and DIN 58953 |
| Disposal: | This product is made of NiTi. 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). |

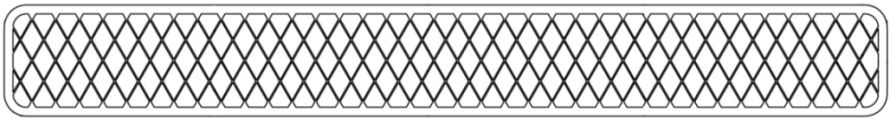
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing carried out achieves the desired results with the actual equipment, materials, and personnel in the reprocessing facility. 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.

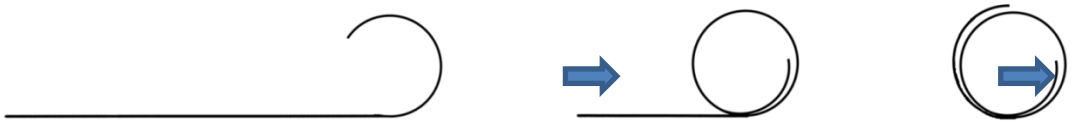
## 7) Configuration and application

### During use

During use, do not place more pressure on the tissue being retracted than absolutely necessary for the surgical purpose.



Carefully roll up the spatula-shaped SUPERFLEX soft tissue retractor prior to insertion. Depending on thickness, this will yield a cylinder with a minimum diameter of 15 mm.



**Warning:** The SUPERFLEX soft tissue retractors are manufactured from austenitic NiTi material and have a shape memory. They can be flexibly deformed at room temperature and instantly regain their initial shape after removal of the deforming force.
When deforming the retractor during use, do not bend and do not go below the permissible minimum bending radius of 15 mm. Bending the retractor too sharply can result in permanent deformation or irreparable kinks in the material that compromise the retractor's function!

To secure the shape of the rolled retractor, use a gentle clamp or grasping forceps. For example:

Position the rolled-up SUPERFLEX soft tissue retractor in the soft tissue to be retracted and detach the clamp / grasping forceps.

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| ⚠ | **Warning: Risk of injury!** After removal of the holding instrument, the SUPERFLEX soft tissue retractor immediately regains its initial shape. Do not open the clamp or grasping forceps until the retractor has been correctly placed in the soft tissue. |

To remove the SUPERFLEX soft tissue retractor with a clamp or grasping forceps, grasp both the overlapping ends and **carefully** withdraw the retractor from the operating site.

**Sterilizing and storage tray MTK-0**

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|  | Sterilizing and storage tray MTK-0 is required for safe storage of the flexible soft tissue retractor during reprocessing and storage. |
|  | The flexible soft tissue retractor is mounted on the retaining pins with the retaining covers open. The mounting pins of the retaining plates protrude through the mesh profile of the retractor. |
|  | The two safety covers prevent the retractor from being loosened from the retaining plates when closed and locked. This prevents loss. |
|  | **Warning:**<br>If the retaining plates are not in a vertical position, the flexible soft tissue retractor may be bent or damaged. The retaining plates must always be in a vertical position. |

| Symbols | | | |
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| In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning: | | | |
|  Manufacturer |  Article number |  Batch code |  Serial number |
|  Instructions for Use are to be observed |  0297 CE labeling |  Warning |  Oil can for points to be lubricated |

| To contact the manufacturer: | |
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|  | FEHLING INSTRUMENTS GmbH & Co. KG<br>Hanauer Landstr. 7A<br>63791 Karlstein, Germany<br>Tel.: +49 (0) 6188 - 957440<br>Fax: +49 (0) 6188 - 957445<br>E-mail: info@fehling-instruments.de |