FEHLING SUPERFLEX and SUPERPLAST-Probes

REF:

MIH-1 to MIH-9	MIH-1N to MIH-9N	MNG-0 to MNG-9	MNG-0N to MNG-9N
MNA-1 to MNA-5	MNA-1N to MNA-5N	MNH-0 to MNH-9	MNH-0N to MNH-9N
MNB-1 to MNB-5	MNB-1N to MNB-5N	MNK-0 to MNK-9	MNK-3N to MNK-9N
MNC-1 to MNC-5	MNC-1N to MNC-5N	MSF-0 to MSF-9	MSF-0N to MSF-9N
MND-1 to MND-5	MND-1N to MND-5N	MSG-1 to MSG-9	MSG-1N to MSG-9N
		MSH-1 to MSH-9	MSH-1N to MSH-9N

SUPERPLAST and SUPERFLEX instruments are made of shape-memory metal (titanium alloy). Their properties differ depending on thermal conditions.

SUPERPLAST instruments are pliable and can be gently bent into the desired shape. At normal surgical temperatures at higher temperatures, such as for sterilization, they return to their original shape.

SUPERFLEX instruments are super-elastic at regular operation room temperature. Their shape follows the pressure applied from outside and they regain their initial shape when this pressure is cancelled; thus no permanent deformation is caused.

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 probes! The probes are intended for temporary use.

1) Intended purpose

The instruments are designed for the probing, dilating and occluding of, for example, cavities that are not visible and/or cannot be adequately assessed geometrically.

2) Indications

- Exploring and examining hollow organs, body orifices, body cavities, natural or disease- or injury-related cavities or pockets in tissue layers.
- Detecting foreign objects

3) Contraindication

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

In medical literature, the following adverse effects are described that can possibly occur during the intended use of probes:

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

5) Prior to use	
FEHLING INSTRUMENTS probes 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).	
⚠	Probes must be handled with care during storage, transportation and cleaning! Perform a safety check prior to each use. Check for sharp edges, cracks, fractures and missing components (see also Maintenance, Checking and Functional Testing). Use only sterilized products of sound quality!

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. It should further be noted that the SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape due to environmental influences. After thermal disinfection and sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of 40 °C.	
⚠	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.
⚠	Probes must be handled with care during storage, transportation and cleaning! Avoid striking the probe or applying pressure to its parts so as not to cause any consequential damage!
⚠	Do not clean titanium instruments (SUPERPLAST, SUPERFLEX) 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 nickel-titanium instruments.
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: In accordance with § 4 of the German Medical Devices Operator Ordinance (MPBetreibV)	Probes must be stored dry, at room temperature, clean, protected from damage and mechanical influences. It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking).

Manual pre-cleaning	Validated procedure: Equipment: Basin, soft brush Detergent: Neodisher® MediClean forte Procedure/Parameters • Rinse instruments under running town water of drinking water quality (<40 °C) until all visible contamination has been removed. Remove stubborn dirt with a soft brush (not a wire brush!). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with tap water. Ensure that all areas of the instrument come into contact with the solution. If necessary, the moving parts of the instrument are moved back and forth. During the exposure time, use appropriate brushes to remove coarse contamination • Rinse the instruments for one minute in deionized water (<40°C)
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. 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. 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. Validated procedure: Equipment: washer-disinfector G 7835 CD (Miele) Detergent: neodisher® MediClean forte (Dr. Weigert) Preparation: • Ensure that no areas are missed (for example, by overloading the baskets). Parameters: • Pre-wash for 3 minutes with cold water (< 40 °C) • Empty • Clean for 10 minutes with a solution of 0.5 - 2 % • Neodisher® MediClean forte in tap water at 55 °C • Empty • Rinse for 2 minutes with tap water (< 40 °C) • Empty • Rinse for 1 minute with fully deionized cold water (< 30 °C) • Empty • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (> 90 °C) After mechanical cleaning, the transitions from the working end/shaft/handle are inspected for visible dirt. If necessary, repeat the cycle or clean manually.

Cleaning: Manual	Validated procedure Equipment: basin Bandelin Sonorex Digitec Detergent: neodisher® MediClean forte (Dr. Weigert) Pre-cleaning • Use a soft brush to clean the instruments under running tap water (< 40°C) until no more coarse contamination is visible. Ultrasonic cleaning • Expose for 10 minutes at < 40°C with 0.5 – 2 % cleaning solution at 35kHz • Use a soft brush to clean the instruments under running tap water (< 40°C). Ensure that no residues remain on the products • Deionized water (<40 °C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds.
Disinfection: Manual	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Immersion bath Disinfectant Korsolex® med AF Procedure/Parameters: • After cleaning, place the products in an immersion bath with deionized water (<40 °C and 0.25% disinfectant solution) for 15 minutes. Ensure that all surfaces are wetted with the disinfectant. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant. • Dry with sterile, oil-free compressed air
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.
Checking and functional testing:	Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures as well as missing components. Return the SUPERPLAST instruments manually to their original shape as far as possible so that they can be placed in the intended sterilization containers. – Their final straight shape is obtained through the sterilization temperature. Use a magnifying lamp to visually inspect the components for damage and wear and tear. 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. 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 DIN EN 868, EN ISO 11607, and DIN 58953 Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure (e.g. wrapping in fleece or insertion into containers).
Sterilization:	Do not use peroxide/peroxide-plasma methods (e.g., STERRAD®) to sterilize nickel-titanium instruments! These sterilization systems work with hydrogen peroxide (H_2O_2), which can cause nickel-titanium instruments to be destroyed. Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285. 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: Tuttnauer EHS 3870 Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 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 consists of titanium (alloyed/unalloyed) and nitinol. 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.

⚠	Jede Veränderung am Produkt oder Abweichung von dieser Gebrauchsanweisung führt zum Haftungsausschluss! Änderungen vorbehalten.

7) During use	
	Modify the shape of a probe with martensitic shaft (SUPERPLAST probes) by firstly manipulating the shaft in such a way that it is shaped perfectly for its intended purpose. Probes with an austenitic shaft (SUPERFLEX probes) cannot be preshaped. When examining tissue resistance, retract the probe and replace it with a smaller probe - except when performing dilatation. The SUPERPLAST probes are made of martensitic NiTi material with shape memory. They are pliable at room temperature and regain their initial shape during reprocessing due to the heat applied. Do not bend when shaping the instrument during use, but leave a minimum radius of approx. 10 mm.

Symbols			
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	 CE labeling	 Warning	 Oil can for points to be lubricated

To contact the manufacturer:	
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