FEHLING SUPERPLAST probes
Article numbers
MIH-1U to MIH-9U; MNG-0U to MNG-9U; MNH-0U to MNH-9U; MNK-0U to MNK-2U; MNK-3U to MNK-9U

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

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

	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 single reuse only.

1) Intended purpose

The instruments are intended to be used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures.

2) Indications for Use

The Fehling SUPERPLAST Probes are intended to be used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

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 before they are used thereafter (see Reprocessing). The device is a single reuse device; it is limited to initial cleaning and sterilization processing followed by one (1) reprocessing cycle and reuse. The device must be disposed of or returned to the manufacturer following the first reuse.	
⚠	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 Checking and Functional Testing). Use only sterilized products of sound quality!

6) Reprocessing	
Reprocessing restrictions: The device is a single reuse device; it is limited to initial cleaning and sterilization processing followed by one (1) reprocessing cycle and reuse. The device must be disposed of or returned to the manufacturer following the first reuse. The end of product life can also be determined by wear and tear and damage occurring following first 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) 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.
General information on reprocessing:	There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
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 (not applicable to the United States): 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	<u>Procedure:</u> Equipment: Basin, soft brush Detergent: 0.5 - 0.8 % Neutral pH Enzymatic Detergent with tap water <u>Procedure/Parameters:</u> • Rinse instruments under running town water of drinking water quality (<40 °C) until all visible contamination has been removed. Use a soft brush (not a wire brush!) to thoroughly clean the instruments and remove stubborn dirt. • Place the products for 10 - 30 minutes in a solution with 0.5 - 0.8 % neutral pH enzymatic detergent with tap water. Ensure that all areas of the instrument come into contact with the solution. 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.
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. <u>Procedure:</u> Equipment: Washer-disinfector Detergent: 0.5 - 0.8 % Neutral pH Enzymatic Detergent with tap water <u>Preparation:</u> • Ensure that no areas are missed (for example, by overloading the baskets). <u>Parameters:</u> • Pre-wash for 3 minutes with cold water (<40 °C) • Empty • Clean for 10 minutes with a solution of 0.5 - 0.8 % neutral pH enzymatic detergent with 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.
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 (or ISO 17665-1). 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 (or ISO 17665-1). Products shall be placed in an FDA cleared-wrap prior to sterilization.

	Procedure/Parameters: Equipment: Sterilizer Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 °C Holding time: 4 min. Drying time: at least 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage (United States):	In accordance with ISO 11607
Storage (outside of the United States):	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.
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.

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. 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.

8) Storage

Store in a cool, dry place. Do not expose to direct sunlight.

9) Symbols	
CE	CE sign, indicates that the medical device complies with MDD 93/42/EEC

Symbols standard of origin: ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:

NON STERILE (5.2.7)	Non-sterile; indicates a medical device has not been subjected to a sterilization process.	(5.4.3)	Consult instructions for use; indicates the need for the user to consult the instructions for use.
LOT (5.1.5)	Batch code; indicates the manufacturer's batch code so that the batch or lot can be identified.	REF (5.1.6)	Catalog number; indicates the manufacturer's catalog number so that the medical device can be identified.
(5.4.4)	Caution; indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot for a variety of reasons be presented on the medical device itself.	SN (5.1.7)	Serial number; indicates the manufacturer's serial number so that the unique medical product can be identified.
(5.1.1)	Manufacturer; indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. FEHLING INSTRUMENTS **GmbH & Co. KG** Hanauer Landstr. 7A, 63791 Karlstein, Germany Tel.: +49 (0) 6188 - 957440 Fax: +49 (0) 6188 - 957445 www.fehling-instruments.de		