FEHLING SUPERPLAST and SUPERFLEX probes

SUPERPLAST linear vascular probe

MIH-1 to MIH-9	MIH-1N to MIH-9N
MNG-0 to MNG-9	MNG-0N to MNG-9N
MNH-0 to MNH-9	MNH-0N to MNH-9N
MNK-3 to MNK-9	MNK-3N to MNK-9N

SUPERFLEX linear vascular probe

MNA-1 to MNA-5	MNA-1N to MNA-5N
MNC-1 to MNC-5	MNC-1N to MNC-5N

BOULITO SUPERPLAST tubular probe

MSF-0 to MSF-9	MSF-0N to MSF-9N
MSG-1 to MSG-9	MSG-1N to MSG-9N
MSH-1 to MSH-9	MSH-1N to MSH-9N

SUPERFLEX retrograde vascular probe

MNB-1 to MNB-5	MNB-1N to MNB-5N
MND-1 to MND-5	MND-1N to MND-5N

SUPERPLAST long olive-shaped vascular probe

MNY-2 to MNY-4

SUPERPLAST double-ended occluder

MNK-0 to MNK-2

Table 1: List of accessories for the probes

Accessories

MSG-0 ..... Storage and sterilization container, sterilization and storage sieve for BOULITO probes, 160 x 210 x 26 mm, (max. Ø Olive 17 mm)
MSH-0..... Storage and sterilization container for BOULITO probes, 160 x 210 x 30 mm (max. Ø Olive 22 mm)
MSG-0N..... Sterilization and storage sieve for BOULITO probes, 243 x 253 x 47 mm

SUPERPLAST and SUPERFLEX instruments are made of shape-memory metal (titanium alloy). Their properties differ depending on thermal conditions.
At standard 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.
SUPERFLEX instruments are super-elastic at standard surgical temperatures. Their shape follows the external pressure applied and they regain their initial shape when this pressure is cancelled, thus causing no permanent deformation.

This instrument / medical device is supplied unsterilized. It must be processed before use. Before Reprocessing, the instrument must be subjected to a risk assessment in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).
The probes may only be used, processed and disposed of by qualified medical personnel.
The probes are intended for reuse.

1) Intended purpose

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

Additional information regarding the intended purpose

Duration of application: Probes are intended for temporary use.

Field of application: Probes are used in all patients where cavities that are not visible and/or cannot be adequately assessed geometrically need to be probed and occluded.

User profile: Probes must only be used by medically trained specialists (e.g., healthcare specialists).

Application environment: Probes are only used under controlled ambient conditions (e.g., operating room).

Target patient population: No restrictions

2) Indications

Treatment methods in which hollow organs, body orifices, body cavities, natural or disease- or injury-related cavities or pockets in tissue layers can be explored and examined:

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual probe model are contraindicated. There are no generally valid contraindications for the use of probes.
In spite of that, attention must be paid to increased risks that could result from the anatomical and physiological circumstances as well as the patient's clinical state.

4) Possible side effects

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

- Infections
- Lesions of structures (tissue, organs, nerves, vessels)
- Necroses
- Wound healing disorders

⚠	Medical devices may contain, for example, PEEK, chromium, nickel and/or titanium. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.

5) Before use	
The probes are supplied unsterilized and have to be cleaned and sterilized by the user before first use and before each subsequent use (see section *6) Reprocessing*).	
⚠	A safety inspection must be performed before each use. In this case, sharp edges, cracks, fractures, mechanical malfunctions and missing components must be checked (see section *6) Reprocessing* under *"Maintenance, inspection and testing"*).
⚠	Probes must be handled with care during storage, transportation and cleaning! Avoid impacts and targeted loads on the probes to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flaw-free products that have been sterilized!

6) Reprocessing	
⚠	The medical device must be processed before use. Before processing, it must be subjected to a risk assessment in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).
⚠	The national legal directives, national and international standards and guidelines as well as our own hygiene regulations for processing must be complied with.
⚠	The relevant national regulations must be adhered to when instruments are reprocessed that have been used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or any possible variants.
⚠	The instruments may only be used, processed and disposed of by qualified medical personnel.
⚠	Handle the instruments carefully during storage, transport and cleaning! Avoid impacts and targeted loads on the instruments to prevent possible consequential damage! Do not overload functional parts!
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization are recommended for activation of the shape memory. When doing so, the following shall be taken into account: • SUPERPLAST instruments must be stored in such a way that the restoration of their linear shape is not impeded by environmental influences (e.g., other instruments or limited space). • After disinfection/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.

Limitations during reprocessing	Frequent reprocessing doesn't have much effect on the labelling of the instruments and does not impair the function of the instruments. The end of the product's service life is typically determined by wear and damage caused by use (e.g., damage, illegible labelling, functional failure – see also *"Maintenance, inspection and testing"*). It has been proven that the instruments can undergo at least 500 reprocessing cycles if used and reprocessed correctly.
General Information about Reprocessing	Reprocessing is based on a validated procedure. All cleaning steps specified (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) have been validated with the parameters specified in each case and listed under "Validated process." For validation, the recommended reprocessing agents (cleaning agent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) have been used. Both water of drinking water quality as well as fully deionized water (deionized water; demineralized, microbiologically with at least drinking water quality) is used for cleaning. It is preferable to use automated reprocessing rather than manual cleaning due to the cleaning results being better and safer. Our instruments can also be cleaned with other tested and approved chemicals that have been recommended by the chemical manufacturer in relation to their material compatibility. Please always observe the manufacturer's specifications regarding concentration, contact time, temperature and replenishing of the cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly observed. Failing to do so may result in visual material changes or material damage, such as corrosion, fractures or premature ageing.
Pre-treatment at the point of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and medication residues are removed from the instruments using a disposable cloth/paper towel immediately following the end of the procedure and that they are immediately sent for automated cleaning. Visual inspections must be conducted to ensure that the instruments are complete once pre-treatment has been finished. The instruments must be transported from the point of use to the place of reprocessing in such a way that neither users, third parties, the environment nor the medical devices are endangered or damaged (placed in closed, puncture-proof containers and, where required, use of protective caps).
Preparation before cleaning	The general recommendation is to reprocess the instruments immediately after use, since dried residues in hard-to-reach areas are difficult to remove. Do not place in NaCl solutions (otherwise risk of cavitation erosion or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See section *10) Disassembly*

Manual Pre-cleaning	<u>Validated procedure:</u> Supplied with: Basin Soft brush Water pressure gun (or the like) Detergents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, flush the disassembled instruments under cold running water (of drinking water quality, < 40°C) until all visible contaminants have been removed. Stubborn debris should be removed using a soft brush (not a wire brush!). • Cavities, gaps, slits and openings must be intensively flushed (> 10 seconds) with cold water (drinking water quality, < 40°C) using a water pressure gun (or the like). • Immerse the products in a solution containing 0.5-2% Neodisher® MediClean forte with water (with drinking water quality, < 40°C) for 10-30 minutes. • Only use an approved solution made of a cleaning agent that does not have an effect that fixes protein. In this case, the instructions of the cleaning agent and disinfectant manufacturer must be followed. • Ensure that all areas of the instrument come into contact with the solution. • It might be necessary to sway moving parts on the instrument back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the interaction time. • Rinse the instruments for 1 minute under cold deionized water (see *"General information about reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ Disinfection	A cleaning/disinfection device in accordance with DIN EN ISO 15883 that uses thermal disinfection is preferable where possible.
Cleaning: Automated	Avoid overfilling instrument sieves and wash trays – only use suitable instrument holders. It is especially important to ensure that the tips do not get stuck in the mesh when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Supplied with: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Jointed instruments must be inserted into the device as such, that the joints are open or disjoined, if possible, and the water can drain out of cavities and blind holes. • If applicable Relax springs • Ensure that all cavities are also completely flushed through the inside.

	• Ensure that no flushing shadows are created. • Connect the Luer connections of the instruments, if present, to the Luer lock flushing attachment of the cleaner-disinfector. <u>Procedure/parameters:</u> • 3 Minutes pre-flush using cold water (drinking water quality, < 40°C) • Drain • Clean for 10 minutes with a solution of 0.5-2% Neodisher® MediClean forte in water (potable water quality) at 55°C • Drain • 2 Minutes flushing using water (drinking water quality, < 40°C) • Drain • 1 Minute flushing with cold deionized water (< 30°C) • Drain • 5 Minutes thermal disinfection with deionized water (> 90°C) • 30 Minutes drying (90°C) Once automated cleaning is complete, cavities, blind holes, etc. in particular are examined for visible dirt. Repeat cycle or clean manually if necessary.
Cleaning: Manual	<u>Validated procedure:</u> Supplied with: Basin Soft brush Water pressure gun (or the like) Bandelin Sonorex Digitec Detergents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, place the disassembled instruments in cold water (of drinking water quality, < 40°C) for 10 minutes. • Actuate moving parts, if present, over the entire range of movement. • Use a soft brush (not a wire brush!) to clean the instruments until there is no visible contamination. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). <u>Ultrasonic cleaning:</u> • 10 Minutes ultrasonic treatment at < 40°C with 0.5-2% detergent solution at 35 kHz • After ultrasonic treatment, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments using water (with drinking water quality, < 40°C) for at least 10 seconds. • Deionized water (< 40°C) must be used for the final flush. The instruments are flushed through with deionized water for at least 30 seconds. It must be ensured that no residues are left behind on the products.

Disinfection: Manual	Disinfectant solutions can be used in conformity to what is stated on the label (see chemical manufacturer's instructions). <u>Validated procedure:</u> Supplied with: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • The products should be placed in an ultrasonic bath (35 kHz, < 40°C) with a suitable disinfectant (e.g., 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are dampened with the disinfectant. Sway moving parts in the disinfection bath before switching on the ultrasonic device if necessary. • Following disinfection, thoroughly flush all products with deionized water (< 40°C) for at least 1 minute to ensure that the disinfectant is removed and, if necessary, sway moving parts back and forth on the instrument. • It must be ensured that no residues are left behind on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as a part of the cleaning/disinfection cycle, 120°C should not be exceeded. Drying should then be carried out with suitable compressed air in accordance with RKI recommendations. It is especially important to dry areas that are difficult to access.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	Instruments with moving components that are exposed to frictional wear (e.g., joints) must be treated with a paraffin/white oil-based instrument oil (in accordance with the currently valid European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable before sterilization. Such points may also be marked with a corresponding oil can symbol. Instruments must not be treated with care products containing silicone.These can lead to stiffness and impair the effectiveness of steam sterilisation.. A safety inspection of the instruments must be performed before each use. In this case, sharp edges, cracks, fractures, mechanical malfunctions and missing components must be checked. Check instruments with moving parts for ease of movement (avoid excessive play). Check locking mechanisms, if applicable. All instruments: Perform a visual inspection with a magnifying lamp to check for damage and wear. Particular attention should be paid to critical points on moving parts and in the working area. Defective, damaged instruments or those, the labelling of which is no longer legible, must be separated, cleaned and disinfected before being returned to the manufacturer. Only the manufacturer or workshops authorized by the manufacturer may undertake repairs. A confirmation form related to this process can be obtained from the manufacturer. Instruments that can no longer be repaired must be disposed of in the standard hospital scrap metal disposal system. Cautious handling must be taken to ensure safe storage in a closed, puncture and break-proof disposable

	container, notably for surgical instruments with points or sharp edges. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into dedicated trays for this purpose or place them on all-purpose sterilization trays. A suitable procedure must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance in accordance with DIN EN 285 and DIN EN ISO 17665. The steam must be free of any particles to prevent staining and corrosion. The recommended limit values for the constituents of feed water and vapor condensate are defined in DIN EN 285. <u>Validated procedure:</u> Supplied with: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134°C Holding time: 4 – 5 minutes Drying time: 20 minutes The maximum load of the sterilizer must not be exceeded when sterilizing several instruments in one sterilization cycle (see device manufacturer's instructions).
Storage	In accordance with § 4 Medical Device Operator Ordinance (MPBetreibV) and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments must be stored dry, at room temperature, clean and protected against damage and mechanical influences (avoid condensation, damage). Always store instruments in an unengaged state, where applicable. This has a counteracting effect on premature fatigue of the spring tension. Instruments must be transported to the point of use in a closed, puncture-proof sterile container.
Disposal	These products are made of titanium and nitinol. These should be cleaned before disposal. Disposal at a scrap metal recycling center is possible. Ensure that any tips and sharp edges are protected to safeguard employees.

The instructions listed above have been validated as suitable for the preparation of a medical device for reuse by the medical device manufacturer. It is the responsibility of the reprocessor to ensure that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation together with routine monitoring of the process. In a similar vein, the reprocessor should carefully assess any deviation from the instructions provided for effectiveness and possible adverse consequences.

⚠	Any modification to the product or deviation from these instructions for use will culminate in exclusion of liability! Subject to change.

7) Configuration and application	
The probes consist of a handle, a shaft and a working part or head. The working part can vary in size and shape. Olive-shaped, cylindrical and round are the most common shapes. Depending on the material used, the shape of the shaft can be elastically (SUPERFLEX) or plastically (SUPERPLAST) modified. Probes differ in their specific characteristics, such as the head shape or special shape, due to the variety of possible anatomical and physiological conditions.	
⚠	Only use flaw-free products that have been sterilized!
⚠	Before using the probe, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not come into contact with a power source or external electrical influences.
⚠	The choice of the probe is contingent on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the probes used are of the correct size and shape, and have adequate stability.
During application	
⚠	Modify the shape of probes with martensitic shaft (SUPERPLAST probes) by firstly manipulating the shaft area in such a way that the probe is perfectly suited for its intended scanning purpose.
⚠	Probes with an austenitic shaft (SUPERFLEX probes) cannot be pre-shaped.
⚠	When examining tissue resistance, retract the probe and replace it with a smaller probe.
⚠	The SUPERPLAST probes are made of martensitic NiTi material with shape memory. They are pliable at room temperature and regain their initial shape during processing due to the heat applied. Do not bend when shaping the probe during use. Rule of thumb: Always bend the probes around two thumbs.

8) Necessary accessories	
No accessories are required for using the probe. A suitable storage and sterilization container (see Table 1, page 1) can be used for sterilization and storage. The storage and sterilization containers are not intended for use in the washer/disinfector. Figure 1 shows an example of a storage and sterilization container. The probes are stand-alone instruments. Therefore a combination with other products is not intended.	 Fig. 1: Storage and sterilization container for BOULITO probes MSG-0 (example)

9) Assembly
Assembly of the probe is not necessary.

10) Disassembly
Disassembly of the probe is not necessary.

11) Obligation to report serious incidents
The user is obliged to report serious incidents relating to the medical device to the manufacturer by email vigilance@fehling-instruments.de or via the report form at https://www.fehling-instruments.de/en/complaint/ and the competent authority of the Member State where the user is registered.

Symbols		
The symbols shown on the medical device or medical device label or instructions for use convey the following meaning in accordance with DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or electronic Instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE marking	

Manufacturer contact		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 63791 Karlstein/Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 Email: info@fehling-instruments.de www.fehling-instruments.de	CE