FEHLING cannulas and suction devices	
Accessories	
MNO-7	Mandrin für MNO-6 suction device
MRK-6	Counter wrench for MRK-5 (optional)

⚠	For cannulas and suction devices with a removable basket or with a removable Luer-lock connection (LL connection), please observe assembly and disassembly (see sections 9 and 10). Suction devices with the suffix "G" are closed at the distal end of the suction tube and therefore do not have a hole for false air. Therefore, please observe the corresponding warnings (see section 7 under "During application", page 9).

⚠	This instrument resp. 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. Cannulas and suction devices may only be used, reprocessed and disposed of by qualified medical personnel! Cannulas and suction devices are intended for re-use.

1) Intended purpose

Cannulas and suction devices are intended to aspirate as well as to deliver and remove endogenous and exogenous fluids or gases, if necessary into drainage or suction systems, to remove calcium deposits and soft tissue, for blunt preparation and to retain tissue.

Additional information regarding the intended purpose

Duration of application: cannulas and suction devices are intended for temporary use.

Field of application: cannulas and suction devices are used in all patients where endogenous and exogenous fluids or gases need to be delivered and removed, where soft tissue and calcium deposits need to be removed, blunt preparations need to be performed, and where tissue needs to be retained.

User profile: cannulas and suction devices may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: cannulas and suction devices are only to be used in controlled environments (e.g. OR).

2) Indications

Every surgical intervention where endogenous or exogenous fluids or gases need to be delivered/or removed, or where calcium deposits or soft tissue need to be removed, or where blunt preparations of tissue need to be performed, or where tissue needs to be retained.

3) Contraindication
All applications that run counter to the physical and/or mechanical properties of the individual models of cannulas and suction devices are contraindicated. There are no generally applicable contraindications for the use of cannulas and suction devices. 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 cannulas and suction devices: - Infections - Impaired wound healing - Lesions of structures (tissues, nerves, vessels) - Necroses - Ischemia	
⚠	Medical devices may, for example, contain chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
FEHLING INSTRUMENTS cannulas and suction devices 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 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Cannulas and suction devices must be handled with care during storage, transportation and cleaning! Avoid striking the cannulas and suction devices or applying pressure to their parts so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	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.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.

⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	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.
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization should be used to activate the shape memory. The following should be observed here: • SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e.g., other instruments or restricted 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 approx. 40 °C.

Limitations on reprocessing	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 (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. 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.

Initial treatment at the 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. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	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). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
Manual Pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • 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 solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, 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. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (potable water quality) at 55 °C • Emptying • Rinse for 2 minutes with water (potable water quality, <40 °C) • Emptying • Rinse for 1 minute with cold deionized water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: Manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert)

	Procedure/Parameters: • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). Ultrasonic cleaning: • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • 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 applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • 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.
Assembly	See 9) Assembly

Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. 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. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by 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 closed, 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, DIN 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.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. 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. <u>Validated procedure:</u> Equipment: 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 min. Drying time: 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	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium alloy. These are 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 pointed tips or sharp 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) Configuration and application

Cannulas and suction devices have become standard instruments in the OR. Their purpose is the delivery and removal of endogenous and exogenous fluids or gases. For this reason, appropriate drainage or delivery systems, such as flexible tubes with or without Luer or Luer lock connection, must be adapted to the cannulas and suction devices.
Due to the variety of anatomical and physiological conditions, the cannulas and suction devices differ in their design and specific characteristics, such as the length of the instruments or the design of their handles.
Unlike suction devices, cannulas may have an oblique cut at their distal end to allow penetration of tissue through a small incision.

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the cannula or the suction device, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of cannula or suction device depends on the anatomical and physiological conditions as well as the field of application. Here, care should be exercised to ensure that the cannulas or suction devices used are of the correct size and have adequate stability.

During use
In the case of suction devices with suction power control on the handle, the suction power can be controlled via the suction interruptor. There are different variants of suction interrupters (see Fig. 1). If the suction interrupter remains completely open, the suction device also draws in air through the suction interrupter and reduces suction power at the distal end. For stronger suction power, cover the suction interrupter with a finger. This closes the suction interrupter and increases suction power at the distal end.

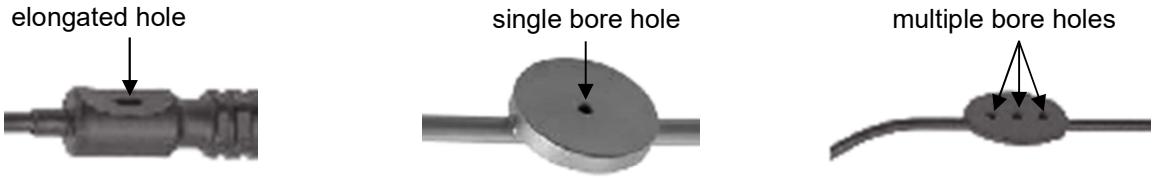

Fig. 1: Examples of variants for suction interrupters

Suction devices are available in variants with or without a hole for false air at the distal end of the suction tube (see Figs. 2 and 3). In the case of suction devices with a hole for false air, it is possible to regulate suction power both via the suction interrupter as well as the hole for false air.

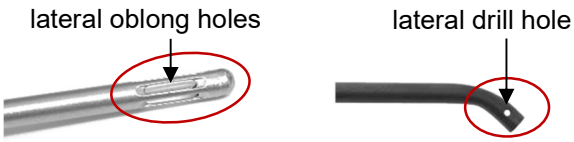

Fig. 2: Suction device with hole for false air (exemplary)

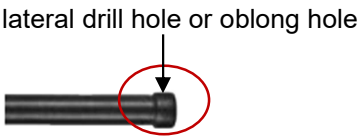

Fig. 3: Suction device without hole for false air (exemplary)

⚠	Suction devices without a hole for false air can become stuck to the tissue when the suction interrupter is fully closed. Risk of injury! Unlike for suction devices with a hole for false air, there is less risk of sticking to the tissue. However, there is a risk that the suction device will be held too deep in the tissue, the holes for false air will become blocked by the tissue and thus the suction device is sucked onto the tissue. Risk of injury!
⚠	Suction devices without a suction interrupter can become stuck to the tissue when the suction opening and the hole for false air are completely closed. Risk of injury!
⚠	The choice for a suction device with or without a hole for false air depends on whether or not full control over suction power is required. To obtain complete control of the suction power, use a suction device without a hole for false air at the distal end of the suction tube. However, it should be noted that if used incorrectly, the suction device may become stuck to the tissue. Risk of injury!

8) Required accessories

A MNO-7 mandrin can be used for the application of the MNO-6 suction device. A mandrin is a guide wire for reusable medical suction devices. Among other things, mandrins are pulled through the lumen of reusable suction devices to check for patency. They can also be used as a cleaning wire after use of the suction device.

Two 8 mm open-end wrenches (e.g. counter wrench MRK-6 (Fig. 4)) are required to remove the LL connection when using the SUPERPLAST MICS sump suction device MRK-5.

No accessories are required for all other variants of cannulas and suction devices.

Fig. 4: Counter wrench for MRK-6 and for MRK-5

9) Assembly

To assemble the cannula and the suction device with removable basket or removable LL connection, please follow the corresponding assembly instructions.

List of assembly instructions

Suction device with removable Luer-lock connection (LL connection).....M19
Cannulas and suction devices with removable basket M34

No assembly is necessary for cannulas and suction devices which do not feature a removable basket or removable LL connection.

10) Disassembly

To disassemble the cannula and suction device with removable basket or with removable LL connection, please follow the corresponding assembly instructions (see 9) Assembly).

No disassembly is necessary for cannulas and suction devices which do not feature a removable basket or removable LL connection.

⚠	Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing!

11) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

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	 Instructions for Use are to be observed	 Warning
 Article number	 Batch code	 Serial number
 CE labeling	 CE labeling	 Oil can for points to be lubricated

To contact the manufacturer:		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de