FEHLING cannulas and aspirators
Accessories MNO-7 ..... Mandrin for aspirators MNO-6 MRK-6..... Counter key for MRK-5 (optional)

	For cannulas and aspirators with removable basket or with removable Luer-Lock connection (LL connection), please observe assembly and disassembly (see chap. *9) Assembly* and *(10) Disassembly*). Aspirators with the suffix "G" are closed at the distal end of the suction pipe and therefore do not have a false air bore. Therefore, please observe the corresponding warnings (see chap. *7) Configuration and use* under *"During use"*, page 8).

	This instrument or medical device is supplied non-sterile. It must be prepared before use. Before reprocessing, the instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C). The cannulas and aspirators may only be used, prepared and disposed of by qualified medical personnel! The cannulas and aspirators are intended for reuse.

(1) Intended purpose

The purpose of cannulas and aspirators is to absorb, introduce and remove endogenous and exogenous fluids or gases, if necessary into drainage or suction systems, to remove calcium deposits and soft tissue, for blunt dissection and to hold tissue away.

Supplementary information on the intended purpose

Duration of application: Cannulas and aspirators are intended for temporary use.

Field of application: Cannulas and aspirators are used for all patients where endogenous and exogenous fluids or gases need to be introduced and removed, soft tissue and calcium deposits removed, blunt dissections performed and tissue held away.

User profile: Cannulas and aspirators may only be used by medically trained specialists (e.g. medical specialists).

Application environment: Cannulas and aspirators are only used under controlled environmental conditions (e.g. operating theater).

Anticipated patient population: No restrictions

2) Indications

Any surgical procedure in which the body's own or foreign fluids or gases are introduced and/or removed, or in which calcium deposits or soft tissue must be removed, or in which tissue must be bluntly dissected or held aside.

3) Contraindication

Any application that runs counter to the physical and/or mechanical properties of the individual cannula or aspirator model is contraindicated. There are no generally valid contraindications for the use of cannulas and aspirators.
Nevertheless, attention must be paid to increased risks that could arise from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible side effects
The following side effects are described in the medical literature, which may also occur during the intended purpose of cannulas and aspirators: - Infections - Wound healing disorder - Lesions of structures (tissue, nerves, vessels) - Necrosis - Ischemia.

⚠	Medical devices may contain chromium, nickel and/or titanium, for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use	
The cannulas and aspirators are supplied non-sterile and must be cleaned and sterilized by the user before first use and before each subsequent use (see chap. *6) Reprocessing*).	
⚠	A safety inspection must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see chap. *6) Reprocessing* under *"Maintenance, inspection and testing"*).
⚠	Handle the cannulas and aspirators with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the cannulas and aspirators to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!

6) Reprocessing	
⚠	The medical device must be prepared before use. Before reprocessing, it must be risk-assessed according to the RKI guidelines (non-critical/semicritical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing must be complied with.
⚠	The respective national regulations for the reprocessing of instruments that have been used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants must be observed.
⚠	The instruments may only be used, prepared and disposed of by qualified medical personnel.
⚠	Handle the instruments with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the instruments in order not to cause any possible consequential damage! Do not overload functional parts!
⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative methods (methods with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time due to the dissolution of titanium.

⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization are used to activate the shape memory. Please note the following: • SUPERPLAST instruments must be stored in such a way that the recovery of the straight shape is not impaired by environmental influences (e.g. other instruments or limited space). • After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. Bending the instruments at temperatures above approx. 40 °C can impair their function.
Limitations during reprocessing	Frequent reprocessing has little effect on the label of the instruments and does not impair the function of the instruments. The end of the product's life is normally determined by wear and damage caused by use (e.g. damage, illegible label, functional failure - see also "Maintenance, inspection and testing"). When used and reprocessed properly, the instruments have been shown to withstand at least 500 processing cycles.
General information on reprocessing	The reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". For validation, the recommended reprocessing agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); Disinfectant: Korsolex® med AF (Bode Chemie GmbH)) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning because it provides a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical 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 with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for machine cleaning. Once the instruments have been pre-treated, visual inspections must be carried out to ensure that they are complete. The instruments must be transported from the place 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 (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation before cleaning	It is recommended that the instruments be reprocessed immediately after use, as dried residues are difficult to remove from hard-to-reach places. Do not place in NaCl solutions (otherwise risk of pitting 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> Equipment: Basin Soft brush Water pressure gun (or similar) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse the instrument in disassembled condition under cold running water (drinking water quality, < 40 °C) until all visible soiling has been removed. Use a soft brush (not a wire brush!) to remove stubborn dirt. • Cavities, gaps, slits and lumen must be rinsed intensively (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Soak the products for 10 – 30 minutes in a solution containing 0.5 – 2 % Neodisher® MediClean forte with water (drinking water quality, < 40 °C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be observed. • Make sure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). • Rinse the instrument for 1 minute under cold demineralized water (see *"General information on reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ disinfection	If possible, a washer-disinfector that uses thermal disinfection and complies with DIN EN ISO 15883 is preferable.
Cleaning: Machine	Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. • If applicable, relax springs • Make sure that all cavities are completely flushed out, including the inside. • Make sure that no areas are left unwashed. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector.

	Procedure/parameters: • 3 minutes pre-rinse with cold water (drinking water quality, < 40 °C) • Emptying • 10 minutes cleaning with a solution of 0.5 – 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C • Emptying • 2 minutes rinsing with water (drinking water quality, < 40 °C) • Emptying • 1 minute rinse with cold demineralized water (< 30 °C) • Emptying • 5 minutes thermal disinfection with demineralized water (> 90 °C) • 30 minutes drying (90 °C) After machine cleaning, cavities, blind holes, etc. in particular are inspected for visible dirt. If necessary, repeat the cycle or clean manually.
Cleaning: Manual	Validated procedure: Equipment: Basin Soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) Procedure/parameters: • If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. • Operate moving parts, if any, through their full range of movement. • Clean the instruments with a soft brush (not a wire brush!) until no visible contamination remains. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). Ultrasonic cleaning: • 10 minutes sonication at < 40 °C with 0.5 – 2% detergent solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments with water (drinking water quality, < 40 °C) for at least 10 seconds. • Deionized water (< 40 °C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH)

	Procedure/parameters: • After cleaning, immerse the products for 5 minutes in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5% Korsolex® med AF). Ensure that all surfaces are wetted with the disinfectant. If necessary, move mobile 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 necessary, move mobile parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Then dry with suitable compressed air in accordance with RKI recommendations. Pay particular attention to drying areas that are difficult to access.
Assembly	See chap. *9) Assembly*
Maintenance, inspection and testing	For instruments with moving components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such points may also be indicated by an oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to sluggishness and jeopardize the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). Check the locking mechanisms. All instruments: Visually inspect for damage and wear using a magnifying lamp. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments whose label is no longer legible must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or workshops authorized by the manufacturer. A confirmation form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of in the standard hospital scrap metal disposal system. In this case, especially for surgical instruments with pointed or sharp edges, it is important to ensure safe storage in a closed, puncture- and break-proof disposable container. 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 trays provided for this purpose or place them on all-purpose sterilization trays. A suitable method must be used to pack the trays.

Sterilization	Steam sterilization in a fractionated vacuum process in an appliance according to DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended limit values for the ingredients of feed water and steam condensate are defined in DIN EN 285. Validated procedure: Equipment: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert Procedure/parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 - 134 °C Holding time: 4 - 5 minutes Drying time: 20 minutes When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see appliance manufacturer's instructions).
Storage	In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage). If applicable, always store instruments in a tension-free state. This helps to prevent premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are mainly made of steel or titanium alloy. These must be cleaned before disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care should be taken to ensure that any pointed or sharp edges are protected.

The instructions listed above have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The person carrying out the reprocessing is responsible for ensuring 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 and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for effectiveness and possible adverse consequences.

Any modification to the product or deviation from these instructions for use will result in exclusion of liability!
Subject to change without notice.

7) Configuration and application

The cannulas and aspirators have become standard instruments in the operating theater. They are used to introduce and drain the body's own and foreign fluids and/or gases. For this reason, appropriate outlet and inlet systems, such as flexible tubing with or without a Luer or Luer lock connection, must be adapted to the cannulas and aspirators.
Due to the variety of anatomical and physiological conditions, cannulas and aspirators differ in their schematic design and their specific properties, such as instrument length or handle design.
In contrast to the aspirators, cannulas can have a beveled edge at their distal end to allow penetration into tissue through a small incision.

Only use flawless and sterilized products!

⚠	Before inserting the cannula or aspirator, ensure that the surgical field has been prepared accordingly.
⚠	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 be exposed to a power source or external electrical influences.
⚠	The choice of cannula or aspirator depends on the anatomical and physiological conditions and the area of application. It is important to ensure that the cannula and/or aspirator used is the correct size and has sufficient stability.

During the application

In aspirators with aspirator power control on the handle, the aspiration power can be regulated by means of aspirator interruption. There are different variants of aspirator interruptions (see Fig. 1).

If the aspirator interruption remains completely open, the aspirator also draws air through the aspirator interruption and the suction power at the distal end is reduced.

For a stronger suction power, cover the aspirator interruption with your finger. This closes the aspirator interruption and increases the suction power at the distal end.

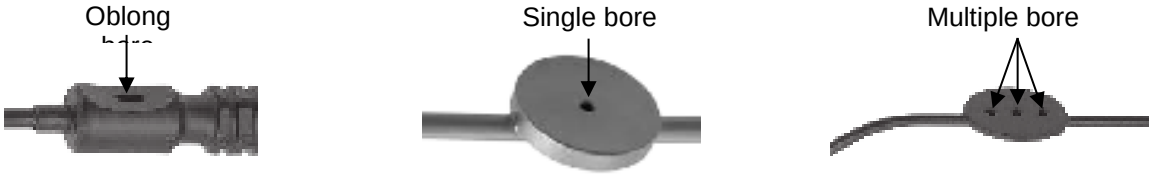

Fig. 1: Examples of variants for aspirator interruptions

Aspirators are available with or without a false air bore at the distal end of the suction tube (see Fig. 2 and 3). Aspirators with a false air bore offer the option of regulating the suction power not only by aspirator interruption, but also by the false air bore.

Fig. 2: Aspirator with false air bore
(by way of example)

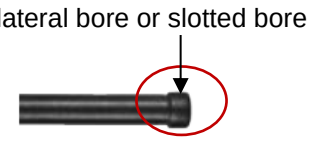

Fig. 3: Aspirator without false air bore
(by way of example)

⚠	Aspirators without a false air bore can cling to the fabric when the aspirator interruption is completely closed. Risk of injury! In contrast to aspirators with a false air bore, there is less risk of suction to the fabric. However, there is a risk that the aspirator will be held too deep into the tissue, the false air bores will be closed by the tissue and the aspirator may become stuck to the tissue. Risk of injury!
⚠	Aspirators without aspirator interruption can suck onto the fabric when the suction opening and false air bore are completely closed. Risk of injury!
⚠	The choice between an aspirator with or without a false air bore depends on whether full control over the suction power is required or not. To obtain complete control of the suction power, use an aspirator without a false air bore at the distal end of the suction tube. However, be aware that if used incorrectly, the aspirator can stick to the tissue. Risk of injury!

⚠	Cannulas and aspirators must not be used as levers. Excessive pressure can cause plastic deformation or breakage of cannulas and aspirators!
⚠	Rinse the instruments repeatedly during the operation to prevent residues from drying.

8) Required accessories

An MNO-7 stylet can be used with the MNO-6 aspirator. A mandrin is a guide wire for reusable medical aspirators. Mandrins are drawn through the lumen of reusable aspirators to test patency, among other things. They can also be used as a cleaning wire after the aspirator has been used.

To use the SUPERPLAST MICS sump aspirator MRK-5, two 8 mm open-end wrenches (e.g. counter wrench MRK-6 (Fig. 4)) is required to remove the LL connection.

No accessories are required for the use of all other types of cannulas and aspirators.

Fig. 4: Counter key MRK-6 for MRK-5

9) Assembly

To install the cannula and the aspirator with removable basket or removable LL connection, please follow the corresponding assembly instructions.

Listing of the assembly instructions:

Aspirator with removable Luer-Lock connection (LL connection)..... M19
Cannulas and aspirators with removable basket..... M34

No assembly is required for cannulas and aspirators that do not have a removable basket or removable LL connection.

10) Disassembly

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

No disassembly is necessary for cannulas and aspirators that do not have a removable basket or removable LL connection.

⚠	Place small parts in suitable containers (e.g. needle box) for storage and reprocessing!

11) Obligation to report serious incidents

The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.

Symbols		
If displayed on the medical device, the label of the medical device or the instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meaning:		
Manufacturer	Follow the instructions for use or use electronic follow the electronic instructions for use	Caution
REF Catalog number	LOT Batch designation	SN Serial number
MD Medical device	UDI Unique Device Identifier	CE 0297 CE marking
Oil can for points that require lubrication	CE CE marking	

Contact the manufacturer		
	FEHLING INSTRUMENTS GmbH Hanauer Landstrasse 7A D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 Email: info@fehling-instruments.de www.fehling-instruments.de	CE