



<b>FEHLING hook for endoscopic vessel harvesting with tailored suction tube</b>	
EVH-1 ..... Hook for endoscopic vessel harvesting, with side walls, 275x22mm EVH-2 ..... Hook for endoscopic vessel harvesting, without side walls, 275x22mm	
<b>Components</b>	
EVH-3 ..... Suction tube for EVH-1 and EVH-2, D = 3.0 mm, 265 mm	
	The hooks EVH-1 and EVH-2 may, if required, <b>only be used in combination</b> with the suction tube EVH-3! Any combination with other suction tubes is not permitted!
	The suction tube EVH-3 is <b>only to be used in combination</b> with the hooks EVH-1 and EVH-2!
	Only endoscopes featuring a diameter of 5 mm, a length of 287 mm and a locking pin with a diameter of 3 mm and a length of up to 15 mm may be used! The EVH-1 and EVH-2 hooks are suitable for endoscopes that also have a guiding pin with a diameter of 3.3 mm and a length of up to 15 mm.
	This instrument / medical device is supplied non-sterile. It must be processed before use. Before processing, the instrument must be subjected to a risk assessment in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C). The hook and suction tube may only be used, processed and disposed of by qualified medical personnel! The hook and the suction tube are intended for re-use.
<b>1.1) Intended purpose of the hook</b>	
Spreaders (retractors) that are intended either for the surgically invasive and temporary manual spreading or retracting of various tissue structures such as skin, bones, muscles or organs or for the invasive and short-term self-retaining spreading or retracting of various tissue structures such as the oral cavity or nasal cavity.	
<u>Supplementary information on the intended purpose</u>	
<b>Duration of application:</b> Spreaders (retractors) are intended for temporary use.	
<b>Field of application:</b> Spreaders (retractors) are used on all patients where tissue structures such as skin, bones, muscles or organs are required to be temporarily spread open or retracted manually or where tissue structures such as the oral or nasal cavity need to be temporarily spread open or retracted.	
<b>User profile:</b> Spreaders (retractors) must only be used by medically trained specialists (e.g. healthcare specialists).	
<b>Application environment:</b> Spreaders (retractors) are only used under controlled environmental conditions (e.g. operating theatre).	
<b>Target patient population:</b> EVH-1 and EVH-2 may only be used for adults.	



1.2) Intended purpose for the suction tube

Cannulas and suction devices are used to absorb, introduce and remove endogenous and exogenous fluids and gases, if required into drainage or suction systems, to remove calcium deposits and soft tissue, for blunt dissection and to retract tissue.

Supplementary information on 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 introduced and removed, soft tissue and calcium deposits removed, blunt dissections performed and tissue retracted.

**User profile:** Cannulas and suction devices may only be used by healthcare trained specialists (e.g. healthcare specialists).

**Application environment:** Cannulas and suction devices are only used under controlled environmental conditions (e.g. operating theatre).

**Target patient population:** EVH-3 may only be used for adults.

2.1) Indications for the hook

Surgical interventions that entail the temporary, manual spreading or retracting of various tissue structures, such as skin, bones, muscles and organs, or the short-term, self-retaining spreading or retracting of various tissue structures, such as the oral cavity or nasal cavity, to reach the body structure to be treated. The choice of spreader and accessory components is contingent on the anatomical and physiological conditions as well as the area of application.

2.2) Indications for the suction tube

Any surgical intervention that's performed in which the body's own or external fluids or gases are introduced and/or drained, calcium deposits or soft tissue are removed or tissue is bluntly dissected or retracted.

3.1) Contraindication for the hook

All applications which could be considered to run counter to the physical and/or mechanical properties of the individual spreader model are contraindicated. There are no generally valid contraindications for the use of spreaders (retractors).

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.

3.2) Contraindication for the suction tube

All applications which could be considered to run counter to the physical and/or mechanical properties of the individual cannula or suction model are contraindicated. There are no generally valid contraindications for the use of cannulas and suction devices.

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.



**4.1) Possible side effects of using the hook**

The following side effects are described in the medical literature, ones that may also occur during the intended use of the hook:

- Infections
- Wound healing disturbance
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischemia
- Hematomas



Medical devices may contain chromium and nickel, for example. The materials used are biocompatible, but they may cause allergic reactions or intolerances.

**4.2) Possible side effects of using the suction tube**

The following side effects are described in the medical literature, ones that may also occur during the intended use of the cannulas and suction devices:

- Infections
- Wound healing disturbance
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischemia



Medical devices may contain chromium and nickel, for example. The materials used are biocompatible yet they can induce allergic reactions or intolerances.

**5) Before use**

The hook and suction tube are supplied non-sterile and have to be cleaned and sterilized by the user prior to 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*").



Handle the hook and the suction tube carefully during storage, transport and cleaning!  
Avoid impacts and targeted loads on the hook and the suction tube 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 reprocessing, 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.



	<p>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.</p>
	<p>The instruments may only be used, processed and disposed of by qualified medical personnel.</p>
	<p>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!</p>
	<p>Do not clean instruments with components made of plastic using oxidative processes (processes with hydrogen peroxide H<sub>2</sub>O<sub>2</sub>, e.g. Orthovario or Oxivario from Miele). These processes result in oxidative ageing of the material, which may well not be recognizable by visible discoloration or embrittlement.</p>
<p>Limitations during re-processing</p>	<p>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 "<i>Maintenance, inspection and testing</i>"). It has been proven that the instruments can undergo at least 500 reprocessing cycles if used and reprocessed correctly.</p>
<p>General Information about re-processing</p>	<p>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: Korsorex® 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.</p> <p>It is preferable to use automated reprocessing rather than manual cleaning due to the cleaning results being better and safer.</p> <p>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.</p>
<p>Pre-treatment at the point of use</p>	<p>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.</p> <p>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).</p>
<p>Preparation prior to cleaning</p>	<p>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).</p> <p>Instruments that have been joined together during use must be disassembled back to their original state before cleaning.</p>
<p>Disassembly</p>	<p>See section 10) <i>Disassembly</i></p>



<p>Manual Pre-cleaning</p>	<p><u>Validated procedure:</u> Supplied with:           Basin                                       Soft brush                                       Water pressure gun (or similar)</p> <p>Detergents:                Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/parameters:</u></p> <ul style="list-style-type: none"> <li>• If possible, flush the disassembled instruments under cold running water (drinking water quality, &lt; 40 °C) until all visible contaminants have been removed. Stubborn debris should be removed using a soft brush (not a wire brush!).</li> <li>• Cavities, gaps, slits and openings must be intensively flushed (&gt; 10 seconds) with cold water (drinking water quality, &lt; 40 °C) using a water pressure gun (or similar).</li> <li>• Immerse the products in a solution containing 0.5 - 2 % Neodisher MediClean forte with water (with drinking water quality, &lt; 40 °C) for 10 - 30 minutes.</li> <li>• 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.</li> <li>• Ensure that all areas of the instrument come into contact with the solution.</li> <li>• It might be necessary to sway moving parts on the instrument back and forth in the cleaning bath.</li> <li>• Remove coarse contamination using a suitable brush (not a wire brush!) during the interaction time.</li> <li>• Rinse the instruments for 1 minute under cold deionized water (see "<i>General information about reprocessing</i>") and move any moving parts on the instrument back and forth.</li> </ul>
<p>Cleaning/ Disinfection</p>	<p>A cleaning/disinfection device in accordance with DIN EN ISO 15883 that uses thermal disinfection is preferable where possible.</p>
<p>Cleaning: Automated</p>	<p>Avoid overfilling instrument sieves and wash trays - only use suitable instrument holders.</p> <p>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.</p> <p><u>Validated procedure:</u> Supplied with:           Cleaning and disinfection machine                                       G 7835 CD (Miele) / PG 8535 (Miele)</p> <p>Cleaning program:       Des-Var-TD (G 7835 CD)</p> <p>Detergents:                Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Preparation:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• If needed, Relax springs</li> <li>• Ensure that all cavities are also completely flushed through the inside.</li> <li>• Ensure that no flushing shadows are created.</li> <li>• Connect the Luer connections of the instruments, if present, to the Luer lock flushing attachment of the cleaner-disinfector.</li> </ul> <p><u>Procedure/parameters:</u></p> <ul style="list-style-type: none"> <li>• 3 Minutes pre-flush using cold water (drinking water quality, &lt; 40 °C)</li> <li>• Drain</li> </ul>



	<ul style="list-style-type: none"> <li>• 10 Minutes cleaning using a solution of 0.5 - 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C</li> <li>• Drain</li> <li>• 2 Minutes flushing using water (drinking water quality, &lt; 40 °C)</li> <li>• Drain</li> <li>• 1 Minute flushing with cold deionized water (&lt; 30 °C)</li> <li>• Drain</li> <li>• 5 Minutes thermal disinfection with deionized water (&gt; 90 °C)</li> <li>• 30 Minutes drying (90 °C)</li> </ul> <p>Once automated cleaning is complete, cavities, blind holes, etc. in particular are examined for visible dirt. Repeat cycle or clean manually if necessary.</p>
<p>Cleaning: Manual</p>	<p><u>Validated procedure:</u> Supplied with:           Basin                                   Soft brush                                   Water pressure gun (or similar)                                   Bandelin Sonorex Digitec</p> <p>Detergents:                Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/parameters:</u></p> <ul style="list-style-type: none"> <li>• If possible, place the disassembled instruments in cold water (drinking water quality, &lt; 40 °C) for 10 minutes.</li> <li>• Actuate moving parts, if present, over the entire range of movement.</li> <li>• Use a soft brush (not a wire brush!) to clean the instruments until there is no visible contamination.</li> <li>• Rinse the instruments for at least 20 seconds using a water pressure gun (or similar).</li> </ul> <p><u>Ultrasound cleaning:</u></p> <ul style="list-style-type: none"> <li>• 10 Minutes ultrasonic treatment at &lt; 40 °C with 0.5 - 2 % detergent solution at 35 kHz</li> <li>• After ultrasonic treatment, rinse the instruments for at least 20 seconds using a water pressure gun (or similar).</li> <li>• Rinse the instruments using water (with drinking water quality, &lt; 40 °C) for at least 10 seconds.</li> <li>• Deionized water (&lt; 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.</li> </ul>
<p>Disinfection: Manual</p>	<p>Disinfectant solutions can be used in conformity to what is stated on the label (see chemical manufacturer's instructions).</p> <p><u>Validated procedure:</u> Supplied with:           Basin                                   Bandelin Sonorex Digitec</p> <p>Disinfectant:             Korsolex® med AF (Bode Chemie GmbH)</p> <p><u>Procedure/parameters:</u></p> <ul style="list-style-type: none"> <li>• The products should be placed in an ultrasonic bath (35 kHz, &lt; 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med AF) for 5 minutes after cleaning. Ensure that all surfaces are dampened with the disinfectant. Sway moving parts in the disinfection bath before switching on the ultrasonic device if necessary.</li> </ul>



	<ul style="list-style-type: none"> <li>Following disinfection, thoroughly flush all products with deionized water (&lt; 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.</li> <li>It must be ensured that no residues are left behind on the products.</li> <li>Drying with sterile, oil-free compressed air.</li> </ul>
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) <i>Assembly</i>
Maintenance, inspection and testing	<p>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 prompt sluggishness and impair the effectiveness of steam sterilization.</p> <p>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.</p> <p>Check instruments with moving parts for ease of movement (avoid excessive play). Check the locking mechanisms if applicable.</p> <p>All instruments: Perform a visual inspection with a magnifying lamp to check for damage and wear.</p> <p>Particular attention should be paid to critical points on moving parts and in the working area.</p> <p>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.</p> <p>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!</p>
Packaging	<p>Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.</p> <p>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.</p>
Sterilization	<p>Steam sterilization in a fractionated vacuum process in a appliance in accordance with DIN EN 285 and DIN EN ISO 17665 (parts 1 and 2). 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.</p> <p><u>Validated procedure:</u></p> <p>Supplied with: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert</p> <p><u>Procedure/parameters:</u></p> <p>Cycle type: 3 pre-vacuum phases</p> <p>Sterilization temperature: 132 – 134 °C</p> <p>Holding time: 4 - 5 Minutes</p>



	<p>Drying time: 20 Minutes</p> <p>The maximum load of the sterilizer must not be exceeded when sterilizing several instruments in one sterilization cycle (see device manufacturer's instructions).</p>
Storage	<p>In accordance with § 4 Medical Device Operator Ordinance (MPBetreibV) and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.</p> <p>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.</p> <p>Instruments must be transported to the point of use in a closed, puncture-proof sterile container.</p>
Disposal	<p>The hook is made of steel and plastic (PPSU) and the suction tube is made of steel. 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.</p>
<p>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.</p>	
	<p>Any modification to the product or deviation from these instructions for use will culminate in exclusion of liability!</p> <p>Subject to change without notice.</p>

## 7) Configuration and application

The hook is used to spread the tissue during vessel harvesting, e.g. of the radial artery (forearm artery) or saphenous vein (leg vein). The hook can be fitted prior to the intended application. A recess for an endoscope is provided in the middle. Separate recesses are provided on the left and right for one suction tube each.

The hook for endoscopic vessel harvesting can be supplied with side walls EVH-1 and without side walls EVH-2 (Fig. 1). The handle of the hook features a recess for holding the endoscope's fiber optic cable during use (Fig. 4c).

The special suction tube EVH-3 (Fig. 2) is designed to be used as a component of the hooks EVH-1 and EVH-2. The suction tube EVH-3 can be positioned in two different configurations within EVH-1 or EVH-2. The tube can be used on both the left (Fig. 3a) and the right side (Fig. 3b) of the hook.

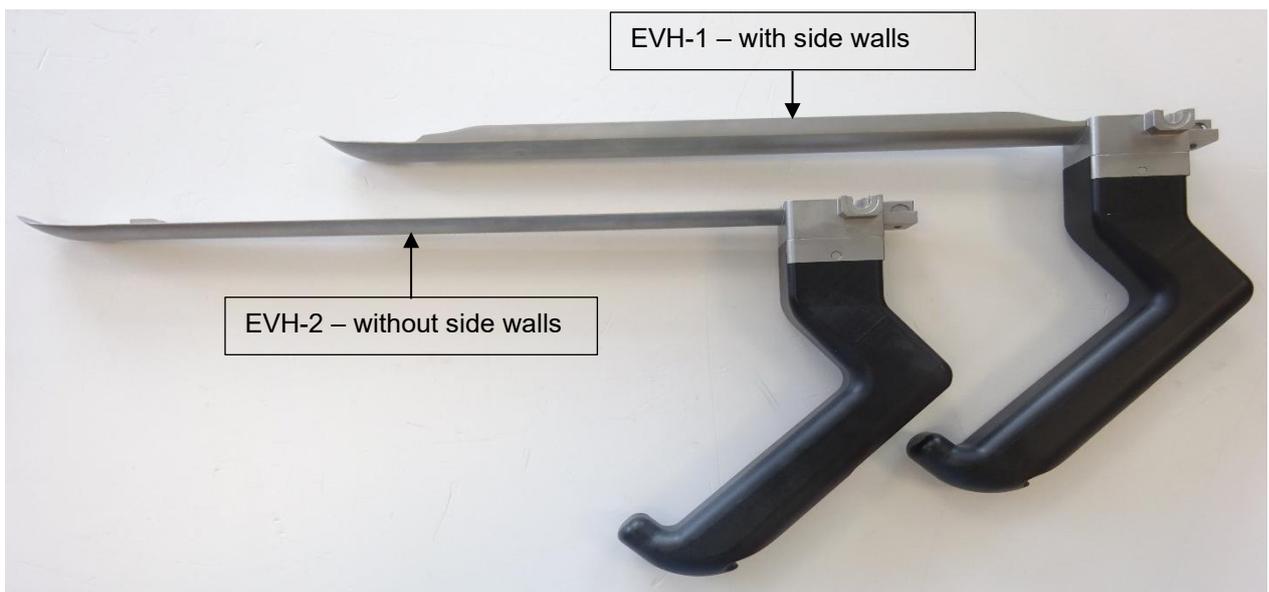


Fig. 1: Hook for endoscopic vessel harvesting, with side walls EVH-1 and without side walls EVH-2



Fig. 2: Suction tube EVH-3



Fig. 3a: EVH-3 inserted in the left position of the EVH-1



Fig. 3b: EVH-3 inserted in the right position of the EVH-1

The individual components of the hook are listed in the following table.

	Designation of the components of the hook
<b>a</b>	Hook
<b>b</b>	Profile support for EVH-3 left
<b>c</b>	Support hole for EVH-3 left
<b>d</b>	Profile support for EVH-3 right
<b>e</b>	Support hole for EVH-3 right
<b>f</b>	Push-button endoscope lock
<b>g</b>	Support hole for endoscope distally
<b>h</b>	Support hole for endoscope proximally
<b>i</b>	Support hole for locking pin
<b>j</b>	Support hole for guiding pin
<b>k</b>	Handle
<b>l</b>	Handle recess for fiber optic cable

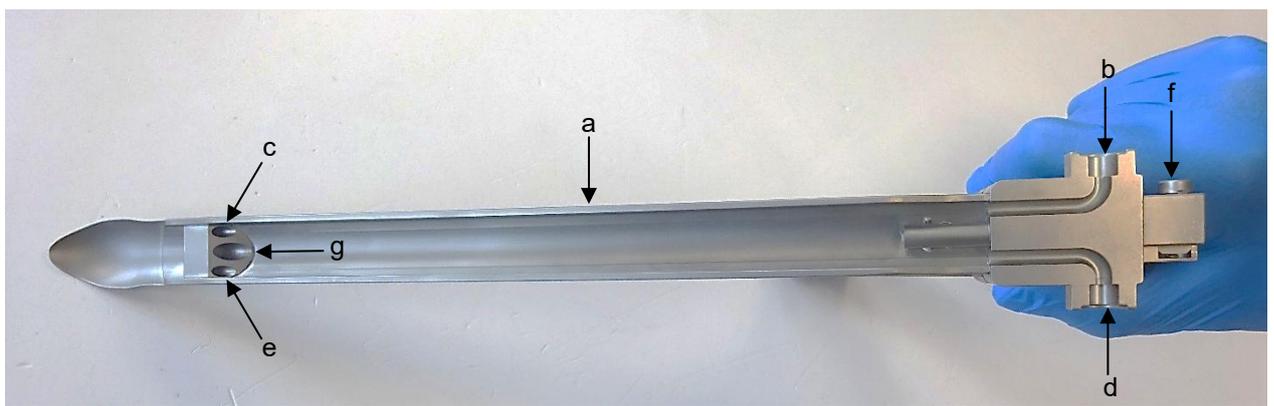


Fig. 4a

Fig. 4b

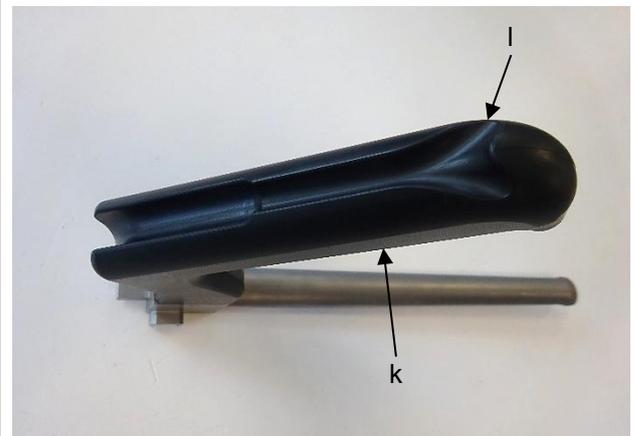


Fig. 4c

The individual components of the suction tube are listed in the following table.

	Designation of the components of the suction tube
<b>m</b>	Suction tube
<b>n</b>	Luer lock connection



Fig. 5

	Only use flaw-free products that have been sterilized!
	It must be ensured that the surgical field has been prepared accordingly before inserting the hook.
	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.



	<p>The choice of configuration is contingent on the anatomical and physiological conditions as well as the area of application. In this case, care must be taken to ensure that the components used possess the correct size and geometry as well as sufficient stability and function and are fixed in accordance with the suction tube application specifications.</p>
<p>Preparation for using the hook</p>	
	<p>It must be ensured before inserting the hook that the hook is fitted according to the intended engagement.</p>
<p>1. The endoscope (o) must first be inserted proximally (h) into the support hole provided for the endoscope (Fig. 6a). To do this, press the push button (f) to release the locking mechanism (Fig. 6a) and in doing so, guide the endoscope (o) through the proximal endoscope support hole (h) (Fig. 6b). For endoscopes with an additional guiding pin, insert this into the designated mounting hole (j).</p>	
<p>Abb. 6a</p>	<p>Abb. 6b</p>
<p>2. The endoscope (o) needs to be guided as such that it passes through the distal endoscope support hole (g) (Fig. 7a). The endoscope must be inserted as far as it will go.</p>	
	<p>Ensure when inserting the endoscope (o) that the locking pin of the endoscope (o) is inserted into the support hole (i) provided for this purpose.</p>
<p>3. To do this, press the push button (f) to release the locking mechanism (Fig. 7b).</p>	
<p>Fig. 7a</p>	<p>Fig. 7b</p>
<p>4. The suction tube (m) is first passed through the support hole for EVH-3 on the right (e) for the purpose of positioning the suction tube on the right (Fig. 8a and Fig. 8b). The proximal end of the suction tube (m) is then placed in the profile support for EVH-3 right (d) (Fig. 8c and Fig. 8d).</p>	



The suction tube (m) for the left positioning is passed through the support hole for EVH-3 left (c) in the same way and then the proximal end of the suction tube (m) is placed in the profile support for EVH-3 left (b).  
The following figures show the insertion of the suction tube (m) as an example for the right positioning.



When inserting the suction tube into the hook, ensure that it has not been deformed plastically.

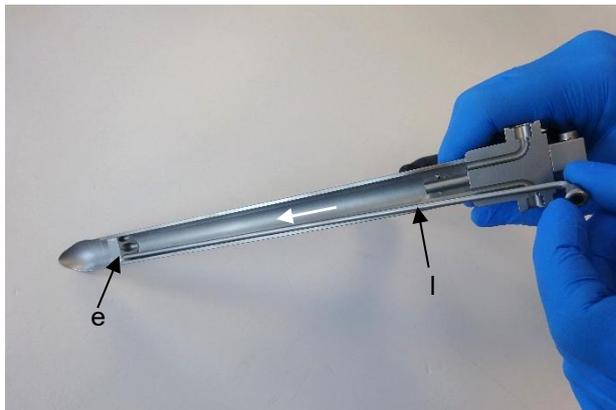


Fig. 8a

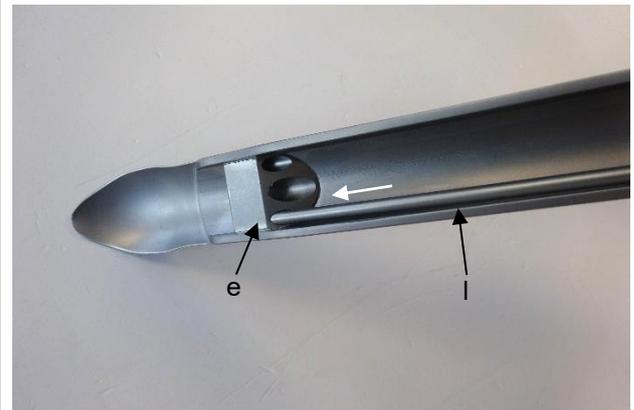


Fig. 8b

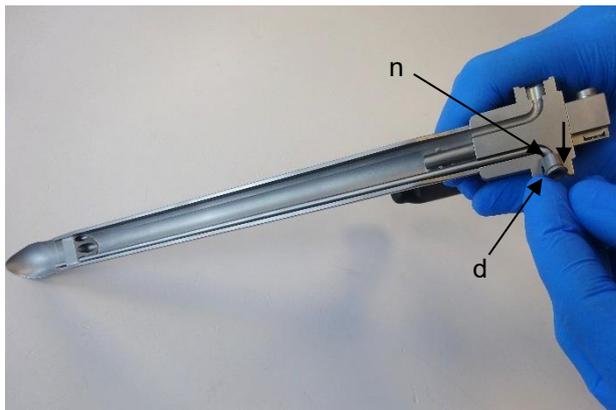


Fig. 8c



Fig. 8d



Only a Luer lock connection with union nut should be used when fixing the suction tube EVH-3 to the hooks EVH-1 or EVH-2!

- The Luer lock connection with union nut (p) must be placed on the thread of the Luer lock connection of the suction tube (n) when fixing (Fig. 9a) and tightened clockwise with moderate manual force (Fig. 9b).

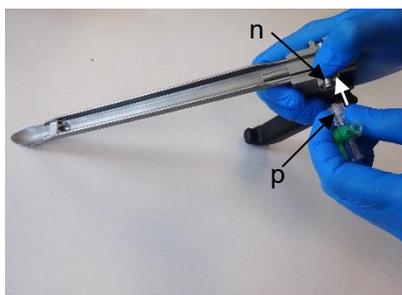


Fig. 9a

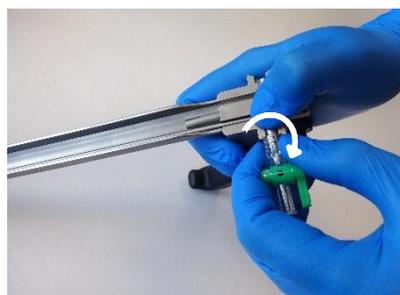


Fig. 9b



Fig. 9c



6. When checking that the suction tube is secured to the hook, hold the hook as shown in Figure 10.



Fig. 10



The hook fitted with the relevant components must be checked prior to use to ensure that all fitted components are securely fixed to the hook.

During application



Make sure that the instruments are always rinsed through the Luer lock connection, if present, during the operation to prevent residues from drying.

The handle (k) (Fig. 11a) contains a recess (l) through which the fiber optic cable (q) of the endoscope can be guided (Fig. 11b).

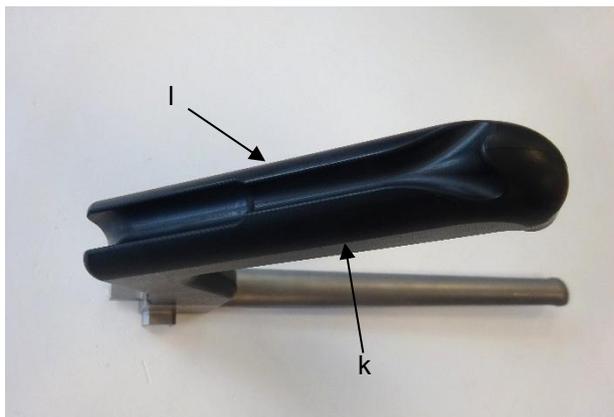


Fig. 11a

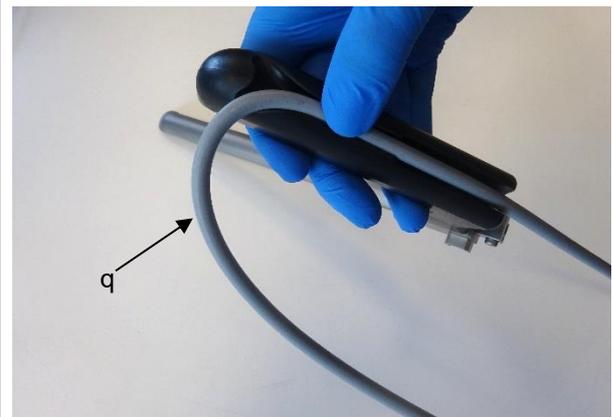


Fig. 11b

Removal of the fitted components of the hook after use

7. Press the push button (f) to unlock the locking mechanism to remove the endoscope (o) (Fig. 12b) and pull the endoscope (o) out of the distal endoscope support hole (g) (Fig. 12c). The endoscope must then be pulled out proximally from the endoscope support hole (h) (Fig. 12d). As soon as the endoscope has been completely removed from the hook, the push button (f) for unlocking the locking mechanism can be released.

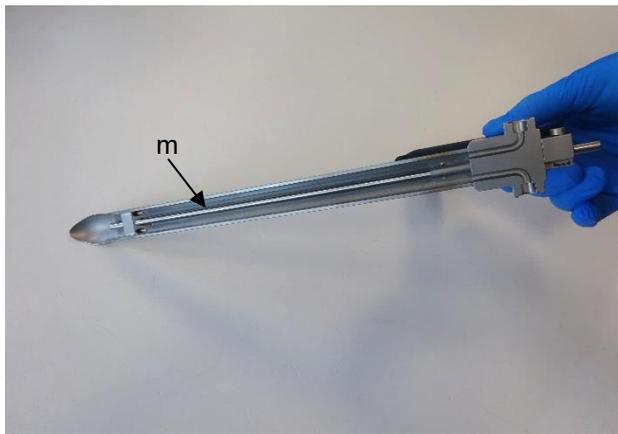


Fig. 12a

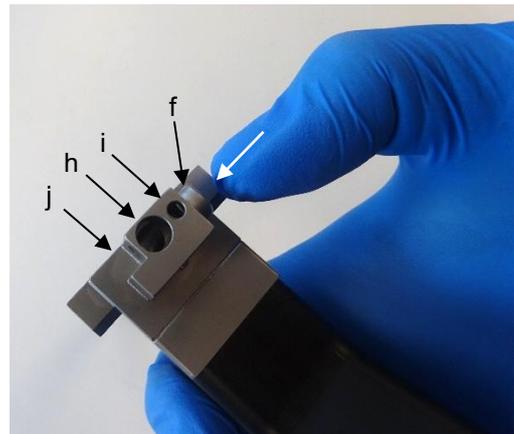


Fig. 12b

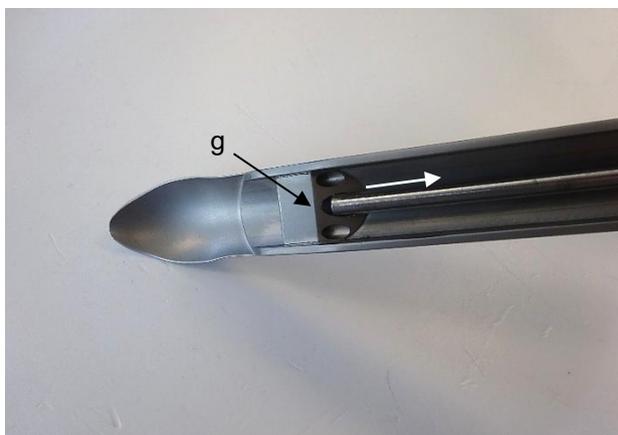


Fig. 12c

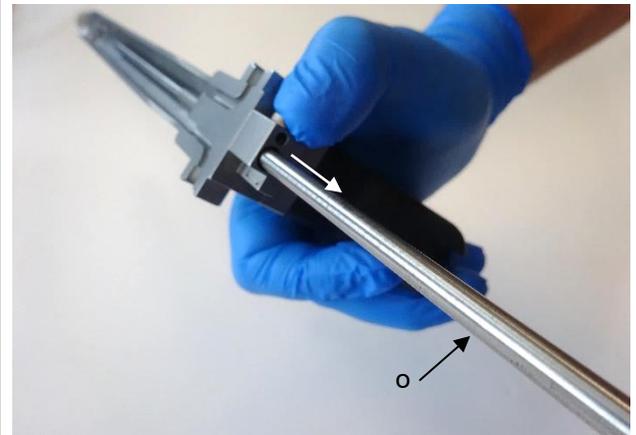


Fig. 12d

- When removing the suction tube, first unscrew the Luer lock connection with union nut (p) (Fig. 13a). To do this, unscrew the Luer lock connection with union nut (p) by turning it anti-clockwise using moderate manual force (Fig. 13b) and remove it from the thread of the Luer lock connection of the suction tube (p) (Fig. 13c).

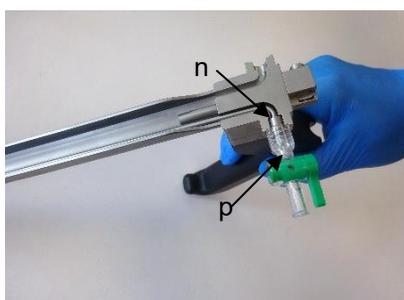


Fig. 13a



Fig. 13b

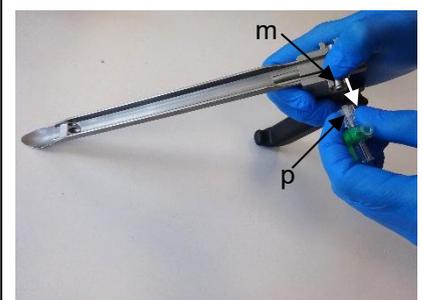


Fig. 13c

- Remove the suction tube (m) after loosening the Luer lock connection with union nut (p). To do this, first remove the Luer lock connection (n) of the suction tube from the profile support for EVH-3 right (d) (Fig. 14b) and then pull the distal end of the suction tube (m) out of the support hole for EVH-3 right (e) (Fig. 14c) and remove (Fig. 14d).  
The suction tube (m) for the left positioning must be removed from the profile support for EVH-3 left (c) in the same way, whereupon the distal end of the suction tube (m) must be removed from the support hole for EVH-3 left (b).  
The following figures show the removal of the suction tube (m) as an example for the right positioning.



When removing the suction tube out of the hook, ensure that it has not been deformed plastically.



Fig. 14a

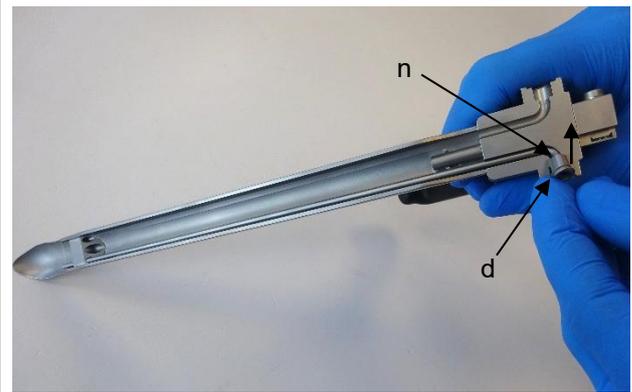


Fig. 14b

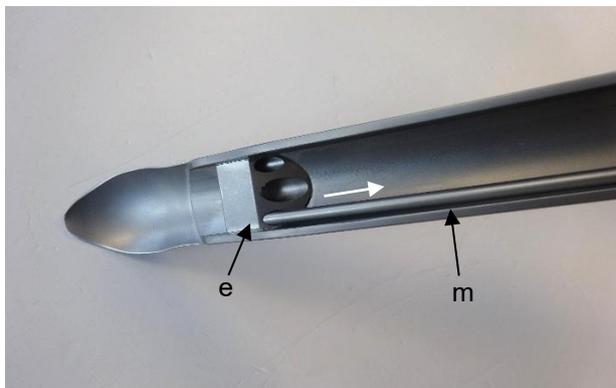


Fig. 14c

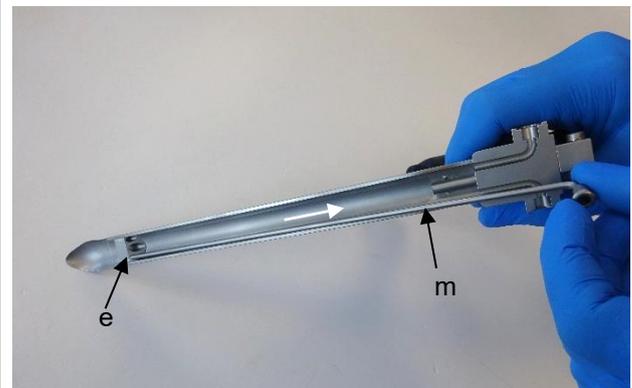


Fig. 14d

10. As soon as all fitted components have been removed from the hook, they must be processed in accordance with the relevant processing instructions.

#### 8) Necessary accessories

There is no need for accessories when using the hook and the suction tube.

#### 9) Assembly

No assembly of the hook and suction tube necessary.

#### 10) Disassembly

No disassembly of the hook and suction tube necessary.

#### 11) Obligation to report serious incidents

The user is under an obligation to report serious incidents that might have occurred in connection with the medical device to the manufacturer either by e-mail to [vigilance@fehling-instruments.de](mailto:vigilance@fehling-instruments.de) or via the complaint form at <https://www.fehling-instruments.de/en/complaint/> and to the designated authority of the Member State in which the user is headquartered.



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 the instructions for use or consult electronic Instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 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: <a href="mailto:info@fehling-instruments.de">info@fehling-instruments.de</a> <a href="http://www.fehling-instruments.de">www.fehling-instruments.de</a>	