



All FEHLING needle holders



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.
Only trained medical personnel may use, reprocess or dispose of needle holders!
Needle holders are intended for re-use.

1) Intended purpose

Needle holders are used to hold and manipulate needles during surgical suturing.

Additional information regarding the intended purpose

Duration of application: needle holders are intended for temporary use.

Area of application: needle holders are used for all patients where needles have to be temporarily held and manipulated during surgical suturing.

User profile: needle holders may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: needle holders are only to be used in controlled environments (e.g. OR).

2) Indications

Surgical procedures that require the suturing of tissue structures. The choice of needle holder depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the needle holders used are of the correct size and have adequate stability.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual needle holder model are contraindicated. There are no generally applicable contraindications for the use of needle holders.

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 the instruments.

- Infections
- Impaired wound healing



5) Prior to use	
<p>FEHLING INSTRUMENTS needle holders 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).</p>	
	<p>Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and Testing).</p>
	<p>Needle holders must be handled with care during storage, transportation and cleaning! Avoid striking the needle holder or applying pressure to its parts so as not to cause any consequential damage! Do not overstrain functional parts!</p>
	<p>Always keep the needle holder with lock in a released state. This counteracts premature fatigue of the spring tension.</p>
	<p>Micro needle holders are only to be stored and transported in specially designed containers.</p>
	<p>Use only sterilized products of sound quality!</p>

6) Reprocessing	
	<p>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.</p>
	<p>The instruments may only be used, reprocessed and disposed of by qualified medical personnel.</p>
	<p>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!</p>
	<p>Micro needle holders are only to be stored and transported in specially designed containers.</p>
	<p>Always keep needle holders separate from general instrument sets if possible.</p>
	<p>Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes using hydrogen peroxide H₂O₂, 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.</p> <p>Similarly, instruments with Propylux plastic handles should not be cleaned with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.</p>



<p>Limitations on re-processing</p>	<p>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").</p>
<p>Initial treatment at the place of use</p>	<p>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).</p>
<p>Preparation prior to cleaning</p>	<p>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 cracking). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.</p>
<p>Disassembly</p>	<p>See 10) Disassembly</p>
<p>Manual pre-cleaning</p>	<p><u>Validated procedure:</u></p> <p>Equipment: Basin Soft brush Water spray gun (or similar)</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/Parameters</u></p> <ul style="list-style-type: none"> • Rinse instruments, if possible in disassembled condition, under running cold tap water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn dirt with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold town water of drinking 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 tap 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. • During the exposure time, use appropriate brushes to remove coarse contamination.



	<ul style="list-style-type: none"> Rinse the instruments for one minute in cold deionized water (see "Additional Information") and, if applicable, move movable parts back and forth.
Cleaning / Disinfection	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. Compliance with the recommended concentrations, application times and temperatures is also assumed. 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> <ul style="list-style-type: none"> The joint instruments 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 connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. <u>Procedure/Parameters:</u> <ul style="list-style-type: none"> Pre-wash for 3 minutes with cold tap water (potable water quality, < 40 °C) Emptying Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® MediClean forte in tap water (potable water quality) at 55°C Emptying Rinse for 2 minutes with tap 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.



<p>Cleaning: Manually</p>	<p><u>Validated procedure</u></p> <p>Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/Parameters</u></p> <ul style="list-style-type: none"> • Place instruments, if possible in disassembled condition, in cold tap 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 with a water spray gun (or similar). <p><u>Ultrasonic cleaning</u></p> <ul style="list-style-type: none"> • Clean for 10 minutes at < 40 °C with 0.5 – 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments with a water spray gun (or similar) for at least 20 seconds. • Rinse the instruments for at least 10 seconds with tap water (potable water quality, <40°C). • Deionized water (<40 °C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.
<p>Disinfection: Manually</p>	<p>Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).</p> <p><u>Validated procedure:</u></p> <p>Equipment: Basin Bandelin Sonorex Digitec</p> <p>Disinfectant: Korsolex® med AF</p> <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Assembly	<p>See 9) Assembly</p>
Maintenance, checking and testing	<p>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.</p> <p>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.</p> <p>Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms.</p> <p>All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear.</p> <p>In particular, inspect the critical points on moving parts and in the working area.</p> <p>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.</p> <p>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!</p>
Packaging	<p>Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.</p> <p>Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.</p>
Sterilization	<p>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.</p> <p><u>Validated procedure:</u></p> <p>Equipment: 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 min.</p> <p>Drying time: 20 min.</p>
Storage	<p>In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.</p> <p>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.</p> <p>Instruments must be transported to their place of use in a closed, puncture-proof sterile container.</p>
Disposal	<p>These products largely consist of steel or titanium. 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 sharp or pointed edges are protected.</p>
Additional information	<p>Both potable quality tap water as well as deionized tap water (deionized water) are used for cleaning.</p> <p>When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).</p>
<p>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.</p>	
	<p>Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability!</p> <p>Subject to change without notice.</p>

7) Configuration and application

As a rule, needle holders consist of two branches, which are connected by a closure. To create the clamping effect for holding at the distal jaw, the two branches are pressed together via the proximal handles/handle surface. Using a hypomochlion, the two jaws are moved towards each other by pressing them together.

On models with a catch, the jaws are locked with the catch.

According to the variety of possible anatomical and physiological conditions, the needle holders differ in their specific characteristics, such as length of the branches, length and design of the working end and design of the handles.

Due to their different needle holder shapes, the needle holders are divided into ring grip, spring grip, pincer grip and tube shaft needle holders.

Needle holders with a ring handle are the most commonly used needle holder form these days. Pincer handles are typical for strong needle holders. The spring handle needle holders dominate in the field of microsurgery due to their delicate shape and tube shaft needle holders are designed for endoscopic procedures.

The combination between the needle holders and the different suture variants is provided for. The user selects the appropriate combination product according to his/her individual requirements.



The following basic rules must be observed to prevent premature damage:

- If possible, guide the needles in direction of the longitudinal axis during suturing. This reduces torque and shearing forces.
- Only change the position of the needle when the needle holder is open (released).
- Do not use PLASMA needle holders for needles longer than 30 mm and not for sternum needles.
- For these needles we recommend our TC needle holders.
- Always use matching needle holder models and sutures (see table).

Variants of needle holders	Surface material of grip	Needle holder model (example)	Width of the grip surface at the tip	Recommended suture strength
Needle holders in general	PLASMA (sprayed ceramics)	MAYO-HEGAR	> 3 mm	4x0 and larger
		DeBAKEY, RYDER	1.5 – 2.5 mm	6x0 – 4x0
		EUPHRATE, RYDER	1.0 – 1.5 mm	7x0 – 6x0
	PLASMA TCM (carbide melt)	VASCULAR	1.0 – 1.2 mm	7x0 – 6x0
Micro needle holder	TCM	CERAMO Rondo CERAMO Plano CERAMO Plano S	0.5 mm	8x0 and smaller
			1.0 mm	7x0 and 8x0
			1.5 mm	6x0
			2.0 mm	5x0
Micro needle holder, strong model	TCM	CERAMO Rondo CERAMO Plano	2.0 – 2.5 mm	Max. 3x0



Always keep the needle holder with lock in a released state. This counteracts premature fatigue of the spring tension.



Use only sterilized products of sound quality!



Prior to inserting the needle holder, ensure that the surgical field has been prepared accordingly beforehand.

During use



Always keep micro needle holders in a separate location from other instruments – including while they are on the operating table!



Avoid striking the needle holder or applying pressure to its parts so as not to cause any consequential damage! Do not overstrain functional parts!

8) Required accessories

No accessories are required for using the needle holders.



9) Assembly

Assembly of the needle holder is not necessary.

10) Disassembly

Disassembly of the needle holder 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 and the competent authority of the Member State where the user is registered.

Symbols

In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent 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:

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