FEHLING Needle Holder

	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 needle holders may only be used, processed and disposed of by qualified medical personnel! The needle holders are intended for reuse.

1) Intended purpose

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

Supplementary information on the intended purpose

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

Field of application: Needle holders are used on all patients in instances where needles have to be temporarily held and manipulated during surgical suturing.

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

Application environment: Needle holders are only used under controlled environmental conditions (e.g. operating theatre).

Expected patient population: No restrictions

2) Indications

Surgical interventions that involve surgical suturing of tissue structures. The choice of needle holder is contingent on the anatomical and physiological conditions as well as the area of application. It is important to ensure that the needle holders used are the right size and have sufficient stability.

3) Contraindication

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

4) Possible side effects	
The following side effects are described in the medical literature, ones that may also occur during the intended use of the instrument: - Infections - Wound healing disturbances	
⚠	Medical devices may contain chromium, nickel and/or titanium, for example. The materials used are biocompatible yet they can induce allergic reactions or intolerances.

5) Before use	
The needle holders 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 needle holders carefully during storage, transport and cleaning! Avoid impacts and targeted loads on the needle holders to prevent possible consequential damage! Do not overload functional parts!
⚠	Always store needle holders with the locking mechanism in an unengaged state. This has a counteracting effect on premature fatigue of the spring tension.
⚠	Microneedle holders must only be stored and transported in custom-made containers for this purpose.
⚠	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 reprocessing must be complied with.
⚠	The relevant national regulations must be adhered to when instruments are reprocessed that have been used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or any possible variants.
⚠	The instruments may only be used, processed and disposed of by qualified medical personnel.
⚠	Handle the instruments carefully during storage, transport and cleaning! Avoid impacts and targeted loads on the instruments to prevent possible consequential damage! Do not overload functional parts!

⚠	Microneedle holders must only be stored and transported in custom-made containers for this purpose.
⚠	Always keep the needle holders separated from the general instrument set.
⚠	Do not clean CERAMO instruments (distinguishable by the black-brown surface) using oxidative processes (process with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these processes leads to the destruction of the CERAMO coating containing titanium after some time due to the dissolution of titanium. Instruments with plastic components should also not be cleaned using oxidative processes. These processes result in oxidative ageing of the material, which may well not be recognizable by visible discoloration or embrittlement.

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

Preparation before cleaning	The general recommendation is to reprocess the instruments immediately after use, since dried residues in hard-to-reach areas are difficult to remove. Do not place in NaCl solutions (otherwise risk of cavitation erosion or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See section *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Supplied with: Basin Soft brush Water pressure gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, flush the disassembled instruments under cold running water (of drinking water quality, < 40 °C) until all visible contaminants have been removed. Stubborn debris should be removed using a soft brush (not a wire brush!). • Cavities, gaps, slits and openings must be intensively flushed (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Immerse the products in a solution containing 0.5 - 2 % Neodisher MediClean forte with water (with drinking water quality, < 40 °C) for 10 - 30 minutes. • Only use an approved solution made of a cleaning agent that does not have an effect that fixes protein. In this case, the instructions of the cleaning agent and disinfectant manufacturer must be followed. • Ensure that all areas of the instrument come into contact with the solution. • It might be necessary to sway moving parts on the instrument back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the interaction time. • Rinse the instruments for 1 minute under cold deionized water (see *"General information about reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ Disinfection	A cleaning/disinfection device in accordance with DIN EN ISO 15883 that uses thermal disinfection is preferable where possible.
Cleaning: Automated	Avoid overfilling instrument sieves and wash trays - only use suitable instrument holders. It is especially important to ensure that the tips do not get stuck in the mesh when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Supplied with: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergents: Neodisher® MediClean forte (Dr. Weigert)

	Preparation: • Jointed instruments must be inserted into the device as such, that the joints are open or disjoined, if possible, and the water can drain out of cavities and blind holes. • If needed, relax springs • Ensure that all cavities are also completely flushed through the inside. • Ensure that no flushing shadows are created. • Connect the Luer connections of the instruments, if present, to the Luer lock flushing attachment of the cleaner-disinfector. Procedure/parameters: • 3 minutes pre-flush using cold water (drinking water quality, < 40 °C) • Drain • 10 minutes cleaning using a solution of 0.5 - 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C • Drain • 2 minutes flushing using water (drinking water quality, < 40 °C) • Drain • 1 minute flushing with cold deionized water (< 30 °C) • Drain • 5 minutes thermal disinfection with deionized water (> 90 °C) • 30 minutes drying (90 °C) Once automated cleaning is complete, cavities, blind holes, etc. in particular are examined for visible dirt. Repeat cycle or clean manually if necessary.
Cleaning: Manual	Validated procedure: Supplied with: Basin Soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Detergents: Neodisher® MediClean forte (Dr. Weigert) Procedure/parameters: • If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. • Actuate moving parts, if present, over the entire range of movement. • Use a soft brush (not a wire brush!) to clean the instruments until there is no visible contamination. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). Ultrasound cleaning: • 10 minutes ultrasonic treatment at < 40 °C with 0.5 - 2 % detergent solution at 35 kHz • After ultrasonic treatment, rinse the instruments for at least 20 seconds using a water pressure gun (or similar).

	• Rinse the instruments using water (with drinking water quality, < 40 °C) for at least 10 seconds. • Deionized water (< 40 °C) must be used for the final flush. The instruments are flushed through with deionized water for at least 30 seconds. It must be ensured that no residues are left behind on the products.
Disinfection: Manual	Disinfectant solutions can be used in conformity to what is stated on the label (see chemical manufacturer's instructions). <u>Validated procedure:</u> Supplied with: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • The products should be placed in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med AF) for 5 minutes 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. • Following disinfection, thoroughly flush all products with deionized water (< 40 °C) for at least 1 minute to ensure that the disinfectant is removed and, if necessary, sway moving parts back and forth on the instrument. • It must be ensured that no residues are left behind on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as a part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Drying should then be carried out with suitable compressed air in accordance with RKI recommendations. It is especially important to dry areas that are difficult to access.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	Instruments with moving components that are exposed to frictional wear (e.g. joints) must be treated with a paraffin/white oil-based instrument oil (in accordance with the currently valid European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable before sterilization. Such points may also be marked with a corresponding oil can symbol. Instruments must not be treated with care products containing silicone. These can prompt sluggishness and impair the effectiveness of steam sterilization. A safety inspection of the instruments must be performed before each use. In this case, sharp edges, cracks, fractures, mechanical malfunctions and missing components must be checked. Check instruments with moving parts for ease of movement (avoid excessive play). Check the locking mechanisms if applicable. All instruments: Perform a visual inspection with a magnifying lamp to check for damage and wear. Particular attention should be paid to critical points on moving parts and in the working area. Defective, damaged instruments or those, the labelling of which is no longer legible, must be separated, cleaned and disinfected before being returned to the manufacturer. Only the manufacturer or workshops authorized by the

	manufacturer may undertake repairs. A confirmation form related to this process can be obtained from the manufacturer. Instruments that can no longer be repaired must be disposed of in the standard hospital scrap metal disposal system. Cautious handling must be taken to ensure safe storage in a closed, puncture and break-proof disposable container, notably for surgical instruments with points or sharp edges. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into dedicated trays for this purpose or place them on all-purpose sterilization trays. A suitable procedure must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in 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. <u>Validated procedure:</u> Supplied with: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 - 5 minutes Drying time: 20 minutes The maximum load of the sterilizer must not be exceeded when sterilizing several instruments in one sterilization cycle (see device manufacturer's instructions).
Storage	In accordance with § 4 Medical Device Operator Ordinance (MPBetreibV) and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments must be stored dry, at room temperature, clean and protected against damage and mechanical influences (avoid condensation, damage). Always store instruments in an unengaged state, where applicable. This has a counteracting effect on premature fatigue of the spring tension. Instruments must be transported to the point of use in a closed, puncture-proof sterile container.
Disposal	These products are primarily made of steel or titanium. These should be cleaned before disposal. Disposal at a scrap metal recycling center is possible. Ensure that any tips and sharp edges are protected to safeguard employees.

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

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

7) Configuration and application

The needle holders typically consist of two branches that are connected via a linkage. The two branches are pressed together via the proximal handles/grip surface to create the clamping effect for holding at the distal jaw. The two jaw parts are moved towards each other via a hypomochlion by pressing together.

The jaws of models with a locking mechanism are locked using the mechanism.

Needle holders differ in their specific characteristics, such as the length of the branch or the design of the handles, due to the variety of possible anatomical and physiological conditions.

Needle holders are classified according to their needle holder shape into ring grip, spring grip, pincer grip and tubular shaft needle holders.

Needle holders with a ring grip are the most commonly used needle holder type these days. Pincers are typical for strong needle holders. The spring grip needle holders dominate the field of microsurgery due to their delicate shape and tubular shaft needle holders are tailored for endoscopic procedures.

It is possible to combine the needle holders with the different thread variants. The user selects the right combination product based on their individual requirements.

⚠	The following fundamental rules must be abided by to prevent premature damage: - Guide the needles in the direction of the longitudinal axis when suturing, if possible. This reduces torques and shear forces. - Only change the position of the needle when the needle holder is open (disengaged). - Do not use PLASMA needle holders for needles longer than 30 mm. Rule of thumb for PLASMA needle holders: The length of the needle should not exceed ten times the width of the gripping surface in the gripping area. - Do not use PLASMA needle holders for needles intended for penetrating bone (e.g. sternal wire needles). - We recommend our TC needle holders for these needles. - Always use matching needle holder models and threads (see following table).

Needle holder variants	Gripping surface material	Needle holder model (Example)	Width of the gripping surface at the tip	Recommended thread thickness
Needle holder general	PLASMA (Spray ceramics)	MAYO-HEGAR	> 3 mm	4x0 and greater
		DeBAKEY, RYDER	1.5 – 2.5 mm	6x0 – 4x0
		EUPHRATE, RYDER	1.0 – 1.5 mm	7x0 – 6x0
	PLASMA TCM (Hard metal melting)	VASCULAR	1.0 – 1.2 mm	7x0 – 6x0
Microneedle holder	TCM	CERAMO Rondo CERAMO Plano CERAMO Plano S	0.5 mm	8x0 and less
			1.0 mm	7x0 and 8x0
			1.5 mm	6x0
			2.0 mm	5x0
Microneedle holder strong model	TCM	CERAMO Rondo CERAMO Plano	2.0 – 2.5 mm	Max. 3x0

⚠	Always store needle holders with the locking mechanism in an unengaged state. This has a counteracting effect on premature fatigue of the spring tension.
⚠	Only use flaw-free products that have been sterilized!
⚠	It must be ensured that the surgical field has been prepared accordingly before inserting the needle holder.
⚠	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not come into contact with a power source or external electrical influences.
⚠	The choice of needle holder 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 needle holders used possess the correct size and geometry as well as sufficient stability.
During application	
⚠	Always keep the microneedle holder separate from the general instruments - even at the operating table!
⚠	Avoid impacts and targeted loads on the needle holders to prevent possible consequential damage! Do not overload functional parts!
⚠	Make sure that the instruments are always rinsed through the Luer lock connection, if present, during the operation to prevent residues from drying.

8) Necessary accessories
No accessories are required when using the needle holder.

9) Assembly
The needle holder does not need to be assembled.

10) Disassembly
The needle holder does not need to be disassembled.

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 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 instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer contact	
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