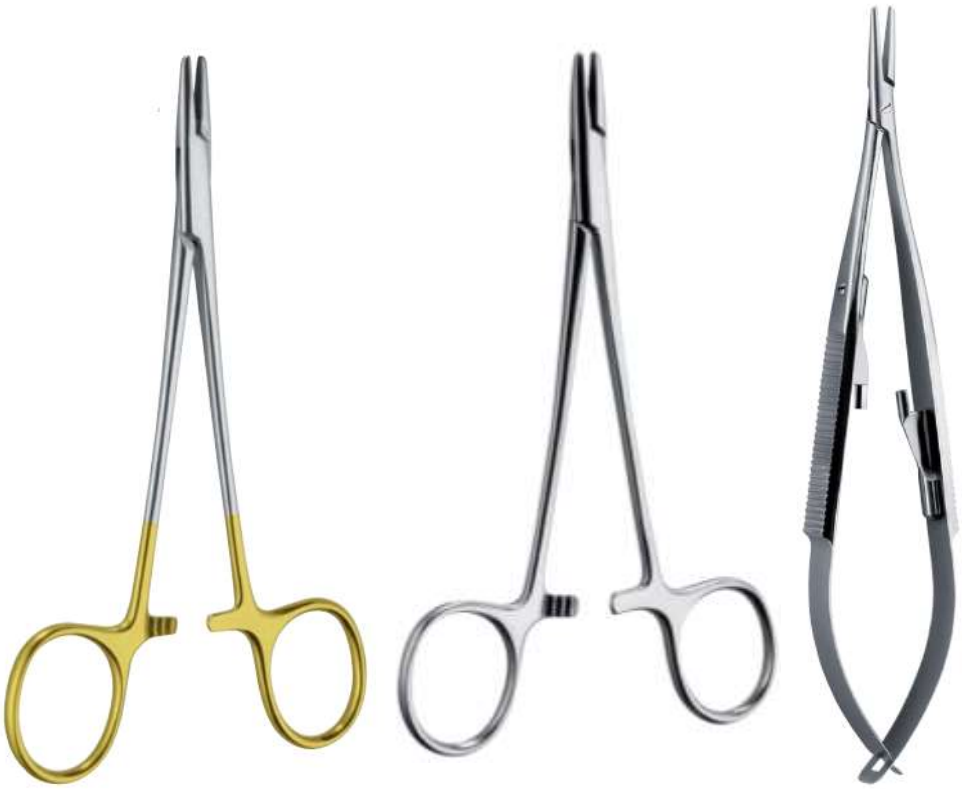
» NEEDLE HOLDER «



TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483

TEKNO-Medical Optik-Chirurgie GmbH
Sattlerstr. 11
D-78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Phone: +49 7461 17 01 0
Fax: +49 7461 17 01 50
Mail: mail@tekno-medical.com
Web: www.tekno-medical.com

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483

Content

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483

In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, preparation and testing of the instruments may only be carried out by trained specialists. Unless otherwise stated, reusable surgical instruments from Tekno-Medical are delivered non-sterile and must go through the complete cleaning and sterilization cycle before the first and every subsequent use.

1 SCOPE

MD The scope of this instruction manual refers to the following products: Needle holders.
(See product list in the last section).

2 EXAMS

Prior to each use, the needle holders must be inspected for breaks, cracks, deformations, damage and functionality. Areas such as locks, joints and working ends must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The attending physician or user is responsible for selecting the instruments for specific applications or surgical use, the appropriate training of the personnel and the experience in handling the products. All surgical instruments should always be handled with the utmost care when transporting, cleaning, caring for, sterilizing and storing. This applies in particular to fine tips and other sensitive areas.

4 NEEDLE HOLDER WITH TC-INSERTS

Needle holders with a jaw diameter of 5mm have a TC plate pitch of 0.4mm and are suitable for fine needles and suture material in sizes 5-0 and 6-0.
Needle holders with a jaw diameter of 3mm have a TC plate pitch of 0.3mm and are suitable for extra-fine needles and suture material in sizes 7-0 and up to 10-0.

5 INTENDED PURPOSE

Surgical instrument used to grasp needles during wound suture to guide needles and suture material through tissue.

6 INDICATIONS

Instruments in this product group are used in all types of surgical procedures, for example:

- endoscopic sutures such as peritonealization, end-to-end anastomosis, ligatures, etc. in laparoscopic surgery,
- Sutures in open surgery,
- Sutures during general surgical or dermatological procedures.

The products with different working lengths are to be used as follows:

- Ø2.3mm, Ø3mm and Ø5mm needle holders with a working length of 210mm to 250mm are normally used in pediatrics.
- Ø2.3mm, Ø3mm and Ø5mm needle holders with a working length of >250mm to 330mm are normally used in normal weight patients.
- Ø2.3mm, Ø3mm and Ø5mm needle holders with a working length of >330mm to 450mm are usually used in patients with obesity

7 CONTRAINDICATIONS

Contraindications directly related to the product are currently not known. The attending physician/surgeon must decide whether or not the planned use is possible based on the patient's general condition. For more information, please refer to current medical literature.

8 PATIENT POPULATION

Apart from contraindicated uses, there are no restrictions on the patient population.

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Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

9 COMBINATIONS

The products are not intended to be combined with or connected to other products.

10 DISPOSAL

If the instruments can no longer be repaired and reprocessed, they must be disposed of in accordance with the applicable country-specific regulations and laws.

11 REPROCESSING

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the reprocessing of surgical instruments can be found in the "**Red Brochure**" of the AKI. Under www.a-k-i.org you will also find links to laws, standards and publications of processing expert committees.
Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is determined by their function and gentle handling. Frequent reprocessing has little effect on the product. The end of product life is usually determined by wear and damage caused by use. The legibility of the marking has been verified over 200 preparations.

11.1 On-site preparation

Immediately after use, remove coarse dirt from the instruments. Do not use any fixing agents or hot water (>40°C), as this will cause residues to freeze and may affect the success of cleaning.

11.2 Transport

Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination to the environment.

11.3 Preparation for decontamination

If possible, the instruments must be disassembled or opened for reprocessing. The instruments must be stored on machine-compatible instrument carriers in a dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

11.4 Manual pre-cleaning

For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents.
Place the instruments in cold water for at least 5 minutes. If possible, disassemble the instruments and clean them under cold water with a soft brush until no residue is visible. Pressure flush cavities, holes and threads with a water gun for at least 10 seconds (pulsed method, minimum pressure 2 bar).
Place instruments in an ultrasonic bath at 40°C for 15 minutes with 0.5% alkaline or enzymatic cleaner and sonicate. Remove instruments and rinse with cold water. The cleaning solution should be changed at least once a day, more often if necessary. Too much contamination impairs the cleaning effect and increases the risk of corrosion.
National laws and guidelines must be observed.

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11.5 Automated cleaning

Place the opened instruments in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments as much as possible.

Step	Parameter	
Pre-rinsing 1	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinsing 2	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
Cleaning	Cleaning-temperature	45°C
	Water quality	Tap water
	Exposure time	300 s (worst case condition) / RKI Recommendation: 600 s
	Detergent	Neodisher Medizym
	Concentration	0,50 %
Neutralization	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
Post-rinsing	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

11.6 Automated (thermal) disinfection

Step	Parameter	
Thermal Disinfection	Disinfection-temperature	90°C (A_0 3000)
	Water quality	Deionized water
	Exposure time	300 s
Dry	Drying of the outside of the instruments by the drying cycle of the washer-disinfector. If necessary, manual drying can also be achieved with the help of a lint-free cloth.	

For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

11.7 Functional testing

Visual inspection of cleanliness; If necessary, assembly of the instruments, maintenance and functional testing.
If necessary, repeat the reprocessing process until the instrument is visually clean.
Treat instruments with moving parts with care oil, e.g.: TK95100-00. Only close instruments with locks in the first notch. Defective or damaged instruments must be discarded immediately.

11.8 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8.

11.9 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements.

Pre-vacuum	3 times
Sterilization temperature	134 °C
Sterilization time	5 min
Drying time	20 min.

The use of other sterilization methods is beyond our responsibility.

Sterilization parameters UK:
Sterilization of the instruments by applying a fractionated pre-vacuum process (according to Health Technical Memorandum 01-01 Part C):

- Heat up to a minimum sterilization temperature of 134° - 137°C (maximum temperature 137°C).
- Minimum holding time: at least 3 min.

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mail@tekno-medical.com – www.tekno-medical.com

11.10 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant level of humidity. The distance between the floor and the shelf should be at least 30cm.
The storage period is to be determined by the user himself.

11.11 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/h)
Neutralisator	Neodisher Z 0.1% (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam-autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

12 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly.
It is the responsibility of the user to ensure that the remanufacturing process, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require the following of validated processes. During reprocessing, the temperature acting on the instrument should **not** exceed **140°C**.
In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. With mechanical cleaning and disinfection, there is greater safety in the process. Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning/pre-cleaning. Strongly alkaline cleaning agents damage plastics.
The instruments must not be sterilized in hot air sterilizers. Do not use caustic cleaning agents. Do not use strong oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

13 REPORTABLE EVENTS

In accordance with the requirements of the Regulation (EU) on Medical Devices 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO.
If you cannot reach us directly for reportable events, please send an email to:
safety@tekno-medical.com
Serious incidents must also be reported to the local authority responsible.

14 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno accepts no liability for any incidental or consequential damages. Tekno assumes no liability if it can be proven that these instructions for use have been violated.

Attention: In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno declines any responsibility for reuse.

15 SERVICE AND REPAIR

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this.
Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.
Forms at: https://www.tekno-medical.com/de/service/repair service

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16 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

	Attention!		Manufacturer
MD	Medical device		Date of manufacturing
	Non-sterile		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification		
CE 0483	CE mark with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

17 PRODUCT LISTING

REF

Printed on 20.03.2025

20001-15	20210-15D	20525-23	20705-18	25624-02	25740-02	708-530
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TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 1701-0 – Fax +49 (7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

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TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 1701-0 – Fax +49 (7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

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