

Instructions for use for medical needle holders from Scholz Medical GmbH

Manufacturer

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This instruction manual applies to the following products

Description	Product no.	Basic UDI-DI	Category	Rule
Mayo-Hegar needle holder 160 mm	TABM2200	426052621TABM01YK	Is	5
Mayo-Hegar needle holder 180 mm	TABM0666	426052621TABM01YK	Is	5
Mayo-Hegar needle holder, 120 mm	TA07-110	426052621TABM01YK	Is	5
Mayo-Hegar needle holder, 140 mm	TA07-111	426052621TABM01YK	Is	5
Mayo-Hegar needle holder, fine, 160mm	TABM2355	426052621TABM01YK	Is	5
Micro needle holder straight without lock 160mm	TAFD0766	426052621TABM01YK	Is	5
Crile-Wood needle holder 200mm	TABM0199	426052621TABM01YK	Is	5
Olsen-Hegar needle holder 140 mm	TABM2900	426052621TABM01YK	Is	5

Warnings/Precautions

If you are sensitive to ethylene oxide or stainless steel, consult the medical staff before using the product.

The product must not be used on the central circulatory system and the central nervous system.

The needle holders can only be used for their intended purpose in medical disciplines by trained, medically qualified staff.

Improper storage or handling that deviates from the intended purpose may result in injury to the patient.

Store at **room temperature** and in a place protected from moisture, heat and direct sunlight, otherwise the sterility of the product cannot be guaranteed.



Always keep the needle holders out of the reach of children and other unauthorised persons.

The specified usage times must always be observed. Expired products must be disposed of.

Excessive mechanical forces from the user may cause damage to the product, which may result in injury to the patient.

Moving parts and their unintentional movement can cause injury to the user.

Reusing the needle holders can lead to bio-contamination and an increase in the bacterial load. The same applies if the instruments are used despite the packaging being damaged.



This is a clamping tool; if handled improperly or if the sharp ends are touched, the user may cut themselves or otherwise injure themselves.

Improper disposal of instruments leads to environmental pollution. Please refer to the section on proper disposal.

#### Intended use

Needle holders are important tools with great benefits that have many applications in the health and medical fields. The needle holders are surgical manual instruments for grasping surgical needles during wound suture in order to guide the needle and suture material through tissue. They have a short serrated jaw to allow for improved needle grip. Due to the numerous possible applications, many different forms of needle holders are available.

A needle holder is a hand-held manual surgical instrument used to grasp a sewing needle as it is pushed/pulled through tissue with the attached suture material during suturing. The present needle holders consist of two parts, finger rings, working areas with beards or grooves and, in certain cases, a groove in the centre of the holding/clamping area.

Essentially, these needle holders differ

- in shape (straight, curved, wide, fine, micro)
- in the needle clamp length, width,
- in the design and arrangement of the grooves, beards
- in the design of the tip (broad, fine, very fine, micro)

The respective versions of the products can be seen in the product description in the product list.

**Indication:** Use in routine surgical procedures in hospitals or medical practices.

**Contraindication:** The use is contraindicated in cases of general inoperability, previously mentioned intolerances or applications to the central circulatory and nervous systems.

**Target patient group:** All patient groups can be treated with sterile needle holders

**Intended users:** The needle holders are intended for use only by trained, medically qualified staff.

#### Features

There is a sterile barrier for the needle holders.

#### Correct application

The needle holders can only be used for their intended purpose in medical disciplines by trained,

medically qualified staff. The needle holders are only used for a short time, i.e. for a period of up to several hours.

### Sterility

If the sterile packaging is damaged, the needle holder must no longer be used. The sterile packaging can only be opened immediately before use. If the sterile packaging is accidentally opened or damaged, please use another product with intact sterile packaging. The product is sterilised using the ethylene oxide process.



### Reuse of the product

The needle holders are designed for single use. Re-sterilisation is prohibited because there is no validated procedure for this process.

### Disposal

When disposing of potentially contaminated products, regulations for preventing infection and dealing with microbiological hazards must be observed. This particularly applies to needle holders that have come into contact with tissue or body fluids. For disposal, country-specific legislation and regulations must be observed. Our instruments are licensed for disposal via the Scholz Recycling System ( SReS®).

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Notice: All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located