Instructions for use for medical retractors 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**
Tracheal retractor, model: Laborde	SIOK1450	426052621SIBT0144	IIa	7
Retractor semi-sharp, 3x4 teeth, 195 mm	SIBV1999	426052621SIBT0144	IIa	7
Blunt retractor, 3x2 teeth, 110mm	SIBV0733	426052621SIBT0144	IIa	7
Trident hook, small, pointed 160mm	SIBT2288	426052621SIBT0144	IIa	7
Two-prong hook, blunt, 160mm,	SIBT2255	426052621SIBT0144	IIa	7
Wound and tracheal hook, 1 prong, 160mm	SISH5820	426052621SIBT0144	IIa	7
Kilner retractor, double-ended, 155mm	SIBT0055	426052621SIBT0144	IIa	7
Hook according to Desmarres Figure 1	SIOA3100	426052621SIBT0144	IIa	7
Hook according to Desmarres Figure 2	SIOA4116	426052621SIBT0144	IIa	7

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 retractors 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 retractors out of the reach of children and other unauthorized 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 retractors 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 gripping 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

Depending on their design, the retractors are used to either lift or widen existing or surgically created body openings on one side, or to open them on both sides and to temporarily close or keep them open. Furthermore, the instruments are designed to enable slow, tissue-sparing closure of the described body areas. Retractors are designed according to the tissue that needs to be held aside. The size and number of prongs depend on the size of the skin layers and the amount of tissue to be held.
Due to the numerous possible applications, many different forms of retractors are available. The respective shape and size of the instrument determine its intended use.

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 the retractors
Intended users: The retractors are intended for use only by trained, medically qualified staff.

Features

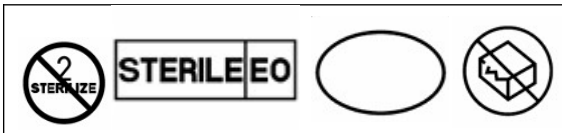
There is a sterile barrier for the retractors.

Correct application

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