

Instructions for use of medical speculum from Scholz Medical GmbH

Manufacturer

Scholz Medical GmbH
Robert-Bosch-Strasse 1
83052 Bruckmühl
Germany
<https://www.scholz-instruments.com/>
info@scholz-medical.de
+49 8062 8070801



This instruction manual applies to the following products

Description	Product no.	Basic UDI-DI	Category	Rule
Cusco speculum, 100x25-27mm	SIOK4270	426052621SIOK015J	Is	5
Cusco speculum, 110x37mm	SIOK4269	426052621SIOK015J	Is	5
Cusco speculum, 92x23-25mm	SIOK4268	426052621SIOK015J	Is	5
Kristeller speculum, size 0, 2 pcs	SIOK4244	426052621SIOK015J	Is	5
Kristeller speculum, size 1, 2 pcs	SIOK4255	426052621SIOK015J	Is	5
Kristeller speculum, size 2, 2 pcs	SIOK4266	426052621SIOK015J	Is	5
Kilian speculum, 20mm shaft	SIOK0820	426052621SIOK015J	Is	5
Kilian speculum, 30mm shaft	SIOK0811	426052621SIOK015J	Is	5
Kilian speculum, 50mm shaft	SIOK0850	426052621SIOK015J	Is	5
Kilian speculum, 70mm shaft	SIOK0870	426052621SIOK015J	Is	5
Hartmann-Halle speculum, 30mm shaft	SIOK0630	426052621SIOK015J	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 speculum 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 speculum 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 speculum 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 spreading tool; if handled improperly or the spreading jaws are touched, the user may be crushed or otherwise injured.

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

Intended use

Depending on the model, specula are used to look into body cavities, either for diagnostic and/or treatment reasons. The tissue is spread and held in the spread position for a short time.

These specula consist of a handle, an optional locking mechanism and a spreading area for viewing and working.

Essentially, these specula differ

- In the handle shape
- in the type of spread – insight and working area
- in the form of the specula

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 specula

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

Features

There is a sterile barrier for the specula.

Correct application

The speculum can only be used for their intended purpose in medical disciplines by trained, medically qualified staff. The specula are only used temporarily, i.e. for a period of less than one hour.

Sterility

If the sterile packaging is damaged, the speculum 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 specula 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 specula 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©).

Date of issue of the instructions for use 20/05/2025

Version: 3.0

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