

Instruction for use

Sterile disposable instruments class Is

1. BASIC

















It is absolutely necessary that all prerequisites and special information described in this instruction are fulfilled or taken into account. Otherwise, the products must not be used for clinical applications. In addition, the specific instructions for use that may be enclosed with the products must be observed.

Therefore, if any uncertainties or questions arise, please contact us before using the products. If required, we can offer you user training on the safe use of the medical products.

These instructions for use cannot replace the training, care and state of the art of the user. We therefore assume that the relevant legal regulations, standards and recommendations (e.g. of the RKI or the AKI) are known (see under "Standards/references") and therefore limit ourselves to the instructions and information to be complied with by the user for each product, which are of importance for our products. The reasons for these instructions and the hazards that arise in the event of non-compliance are listed in the legal regulations and recommendations.

READ ALL APPLICABLE USAGE INFORMATION VERY CAREFULLY BEFORE USING A PRODUCT FOR THE FIRST TIME!

2. INDICATIONS AND SYMBOLS ON LABELS

	Manufacturer		Temperature limit
	Ref.-Number and Order-Number		Product for single use only
	Quantity indication in the packaging		Notice instructions for use
	Batch number		Community European (European over-the-counter mark) CE with the identification number "0044" of the notified body "TÜV NORD CERT GmbH" in D-45307 Essen, Germany
	Medical device		Do not sterilise again
	Indication for sterile product		Store dry
	Usable until		Protect from sunlight
	Do not use if packaging is damaged!		
	Swiss Representative (SWISS AR Services Industriestraße 47, 6300 Zug (Switzerland))		

3. DESCRIPTION AND PRODUCT-SPECIFIC NOTES

Our products can be a single instrument or a set of instruments. They are sterile instruments intended for single use. The products are medical devices in the sense of national and international laws for products in human medicine.

4. ARTICLES

Abort forceps	Wire scissors, Ligature scissors	Uterine probes	Blunt probe
Bandage scissors	forceps, Anatomic tweezer	Eye probe	Eye-speculae
Eye marker	Bulb syringe	Medical plastic drain	Eye protection shield
Sponge/Swab forceps	Stapel remover	Tube forceps	Needle holder

5. INDICATIONS

Instruments and accessories are intended for single use. The instruments can be used individually for surgical use or as part of a surgical set. Care must be taken to ensure that the intended use of the SCILO instrument is observed.

6. MATERIALS USED

Surgical instruments are made of stainless steels according to ISO 7153-1 and EN 10088-3 or plastics suitable for medical instruments.

7. PRODUCT GROUP (EYE-SPECULUM)

- Eye-speculum
- Lid retractor

This product group includes the eye-speculae product family. The instruments are used in ophthalmology. The task of the instruments is to keep the eye wide open during the examination or operation.

Intended use

In ophthalmology, eye-speculae prevent the unintentional closing of the eye during an operation or treatment. The instruments are used, among other things, for myopia (short-sightedness) of less than -10 diopters, astigmatism (astigmatism of the cornea) and mydriasis (long-sightedness) of less than +3 diopters.

Lid retractors are mainly used to examine the upper fold in ophthalmology.

8. PRODUCT GROUP (FORCEPS)

- Abort forceps
- Kocher-/PEAN-forceps
- Tube/dialysis clamp
- Skin stapel remover
- Sponge/Swab forceps
- Towel clamp
- Medical forceps scissors

Intended use

Abort forceps or postpartum forceps are inserted into the uterus to grasp the loosened parts there and transport them out.

Medical forceps are versatile surgical instruments that can be used to hold or fix surgical drapes or surgical material in place.

Kocher-/PEAN forceps are intended for grasping and holding surgical material; this is made clear in the product description. The appearance is similar to the PEAN-/ Kocher forceps.

9. PRODUCT GROUP (INSTRUMENTS FOR CUTTING AIDS)

- Wire scissors
- Universal Scissors
- Bandage scissors
- Ligature scissors

Intended use

An instrument for cutting wire or bandages

10. PRODUCT GROUP (PROBES)

- Uterine probes
- Eye probe
- Blunt probe

Intended use

Instrument for measuring the length of the uterus, Blunt probe for palpation and tracing of tissue ducts.

Eye probe for tear duct irrigation. For this purpose, the upper and lower lacrimal puncta must be dilated with the dilator. The tear duct is then probed with a tear duct probe through the lacrimal punctum, first vertically and then parallel to the edge of the eyelid, according to the anatomy. The probe is advanced as far as possible and then irrigation fluid is injected.

11. PRODUCT GROUP (OPHTHALMIC TWEEZERS)

- Chalazion clamp
- Micro tweezers
- Fixation tweezers
- Spring tweezers
- Forceps, Tweezers plastic
- Iris-tweezers
- Folding tweezers / tweezer

Intended use

Tweezers are used to hold the conjunctiva and eyelids and also to grasp and pull forward the iris and remove foreign bodies.

12. PRODUCT GROUP (EYE MARKER)

- Eye marker
- Incision instrument

Intended use

Eye markers are instruments for intravitreal injection. Used to fix or mark the surgical area.

Incision instrument is another form of eye marker.

Instead of the two tips, a round plate is pressed onto the eye to hold it in place.

13. PRODUCT GROUP (OTHERS)

- Eye protection shield
- Bulb syringe
- Medical plastic drain

Intended use

Eye protection shield is used to protect the eyeball during treatment or examination.

Medical plastic drains are used to drain the tear fluid.

Bulb syringes are used to "suck" foreign bodies out of the eye and ears. This bulb syringe is also frequently used for rinsing.

14. PRODUCT GROUP (NEEDLE HOLDER)

- Needle holder Castroviejo

Intended use

Needle holders are used to hold needles and suture material securely during treatment.

15. CONTRAINDICATIONS

Contraindications are present,

- general inoperability;
- if the patient is not willing to undergo the procedure;
- if the technical requirements are not met.
- The instruments are not for use in the central circulatory system and the central nervous system according to Regulation (EU) 2017/745.

16. APPLICATIONS RISKS

Risks from the use of the instruments are due to

- local infections due to poor soft tissue conditions,
- increased fibrous tissue around the surgical site,
- early or late deep and/or surface infections.

In the case of ophthalmological instruments, there is a risk of use due to

- local infections,
- early or late deep and/or surface infections,
- Failure of the application due to insufficient healing phase before loading,
- destabilisation of the cornea,
- temporary opacity.
- Nerve damage is possible as a consequence of surgical intervention.

In most cases, complications that may occur are not directly related to the use of an instrument, but are rather caused by the wrong choice of patient, inadequate training and imprecise handling. If too much force is applied, unintentional injuries to the tissue or bones can lead to impairment or even breakage of the instruments. Careful use of the instruments is therefore absolutely necessary.

To avoid complications due to damage to the instruments, the instrument used must always be checked before use.

The instruments may only be used by trained and qualified personnel.

17. TARGET GROUP (INTENDED USERS)

The sterile disposable instruments may only be used in medical facilities and by trained and qualified medical staff (doctor, medical assistants under the supervision of a doctor). The attending physician or the user/operator is responsible for the selection of the instruments for specific applications or surgical use, for appropriate training and information and for sufficient experience in handling the instruments.

18. INTENDED PATIENT POPULATION

With regard to sterile disposable instruments, there are no restrictions and limitations to the patient population, unless there is at least one contraindication. The attending physician or the user/operator is responsible for the selection of the instruments for specific applications or surgical use, for adequate training and information and for sufficient experience in handling the instruments.

19. BASIC WARNINGS AND PRECAUTIONS

The products are delivered STERILE! The packed products are marked accordingly.

After receiving the products, check the identity, completeness, integrity of the packaging

Before each use of instruments, inspect them for breaks, cracks, deformation, damage and proper functioning. Particular care should be taken with areas such as blades, tips, locks, catches and all moving parts. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

The attending physician and all other persons involved in the handling of the products are responsible, within their scope of practice, to have appropriate product knowledge based on the latest technology standard. This enables the correct handling of the products and prevents health or safety risks for the patient, user or third parties.

Sources of information on the products are the relevant product catalogues, videos, technical specifications, instructions from medical device consultants, working groups, seminars, technical courses, publications, etc. Appropriate product training - including the handling of the products - must be carried out before clinical use.

The indications for use of the products represent a set of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The treating physician is responsible for the correct selection of patients, the assessment of the indication and the selection of the instrument.

The treating physician should discuss in detail with the patient the treatment outcome expected with the use of the products. Special attention should be paid to a postoperative discussion and the need for regular medical check-ups.

Products must be handled and stored with care. Damage or scratches to instrument can significantly affect the strength and fatigue resistance of a product.

The patient must be instructed in proper post-operative hygiene and should be instructed to inform the attending physician immediately of any unusual changes in the surgical area. The patient should be permanently monitored if any change is noticed in the surgical area.

Reuse of the instruments is not permitted. Depending on the type of product, the first use of the product for its intended purpose may lead to, among other things

- contamination of the product that can no longer be controlled safely
- material fatigue and material changes,
- non-apparent damage, e.g. in the form of micro-cracks
- wear and tear of functional features which are necessary for the safe use of the product,
- missing or incomplete function, which precludes reuse and can lead to the following hazards for patients, users and third parties, among others:
 - life-threatening infections
 - failure of clinical treatment
 - discontinuation and repetition of operations
 - delayed recovery or prolonged treatment times
 - permanent injury, disability or death of the patient
 - with resulting claims for damages and criminal prosecution

We disclaim any responsibility for consequences and claims of any kind due to the reuse of a single-use product.

20. PRODUCT RETURN

Any return of products may only be sent back to us after they have been disinfected/sterilised (appropriate packaging with sterile indicators, decontamination certificate, etc.).

The corresponding hygiene and business premises regulations must be complied with.

21. PACKAGING

The packaging must be undamaged. Please check for damage before using the instruments.

22. STORAGE

After sterilisation, the instruments must be stored in the sterilisation packaging in a dry and dust-free place.

23. OPERATING, STORAGE AND TRANSPORT CONDITIONS

Temperature conditions	All sterile disposable instruments -5°C to +35°C;
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Shelf life of the unused product

Prerequisite: proper storage

Sterile: 3 years from date of manufacture

As a general rule, however, the instruments must be inspected for visual defects (damage, corrosion, etc.) before use.



Instruments with damaged sterile packaging must not be used!

24. REUSABILITY

The instruments from SCILO Vertriebs GmbH are intended for single use.

The shelf life of the Sterile Barrier System is 3 years! In case of disregard, any liability is excluded.

25. INCIDENT REPORTING

In the event of a serious incident occurring in relation to the device, the user and/or the patient shall immediately report it to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

26. WARRANTY

SCILO Vertriebs GmbH only delivers tested products to its customers. All our products are designed and manufactured to meet the highest quality standards.

SCILO Vertriebs GmbH, as the distributor of the products, excludes all warranty claims and accepts no liability for direct or consequential damage resulting from:

- use for purposes other than intended
- improper maintenance and repair
- improper use, application or handling
- non-observance of the instructions for use
- reprocessing and sterilisation

27. STANDARDS-REFERENCES

DIN EN ISO 11607 and EN 868-2 bis -10 Packaging materials

DIN EN ISO 17664 Information to be provided by the medical device manufacturer

DIN EN ISO 11135 Sterilisation of healthcare products - ethylene oxide

SCILO Vertriebs GmbH

