

## Instruction for Use

### Sterile Disposable Instruments Steel

#### 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 also of the AKI) are known (see under "Standards/references") and therefore limit ourselves to the instructions and information to be observed by the user for each product, which are of importance for our products. Reasons for these instructions and the hazards arising from 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 instruments intended for single use. The products are medical devices in the sense of the national and international laws for products in human medicine.

#### 4. ARTICLES

Surgical scissors	Dressing forceps	Bone curettes	Sponge/Swab forceps
Enucleation scissors	Needle holder	Tenaculum forceps	KOCHER-forceps
Forceps	Magill forceps	Wound retractor	Scissors gynaecology
Vaginal specula	Tracheal hook	Self retaining retractor	Foreign body gouge
Tissue grasping forceps	Foreign body needle	Tube forceps	Curette
Towel clamp	Spring scissors	Polyps forceps	Fixation ring
PEAN-forceps	Tendons-scissors	Dressing forceps	Manipulator
Bone curettes	Iris-scissors	Hemostatic forceps	

#### 5. INTENDED USE

Instruments and accessories are intended for single use. The instruments can be used individually for surgical use or as part of a surgical set. It must be ensured that the intended use of the SCILO instructions is observed.

#### 6. PRODUCT GROUP (KLEMMEN)

- PEAN-forceps
- Hemostatic forceps
- Kocher forceps
- Forceps Diefenbach

6.1 *Intended use:* Instruments for clamping and grasping vessels and compressing smaller vessels.

#### 7. PRODUCT GROUP (NEEDLE HOLDER)

- Needle holder

- 7.1 *Intended use:* Instruments for performing a manual suture. Ophthalmic needle holders have the same function but are much finer in their design.
- 8. PRODUCT GROUP (INSTRUMENTS FOR HOLDING AIDS)**
- Sponge/Swab forceps
  - Dressing forceps
  - Tube forceps
  - Dressing forceps
  - Towel clamp
- 8.1 *Intended use:* Instruments for holding and fixing aids in the surgical area such as cloths, swabs, sponges, tubes and tamponages.
- 9. PRODUCT GROUP (FORCEPS, SURGICALLY-INVASIVE)**
- Tissue grasping forceps
- 9.1 *Intended use:* Instruments for grasping tissue and pulling out the grasped organ part using hooked forceps.
- Tenaculum forceps
- 9.2 *Intended use:* The tenaculum forceps is a gynaecological instrument for grasping and holding tissue. Through the locking function, a fixation of the held tissue can be achieved in order to perform the surgical procedure during this time. .
- Polyps forceps
- 9.3 *Intended use:* Instrument for removing a polyp.
- Magill forceps
- 9.4 *Intended use:* The Magill forceps are medical forceps that are angled. The gripping jaws are also roughened and widened. This makes the Magill forceps particularly suitable for use in the mouth/throat area. They are often used in combination with laryngoscopy to remove foreign bodies from the upper airways, to position the tube for nasal intubation and to insert stomach tubes into the oesophagus.
- 10. PRODUCT GROUP (CURETTES)**
- Bone curettes
  - Schiller spoon (Bone curettes)
- 10.1 *Intended use:* Instruments with sharp or blunted spoon shape for tissue ablation.
- 11. PRODUCT GROUP (RETRACTORS)**
- Self retaining retractor
  - Retractors
- 11.1 *Intended use:* Instrument with pointed and blunt hooks for keeping the surgical field open. This makes the wound area visible and accessible. Performing the spreading can also be made self-retaining with a lock.
- Tracheal hook
- 11.2 *Intended use:* Instrument with pointed and blunt hooks for keeping the surgical field open. With tracheal hooks mostly in the tracheotomy. This makes the wound area visible and accessible.
- Nasal speculum
- 11.3 *Intended use:* Application in rhinoscopy. In anterior rhinoscopy, the examination is performed using a nasal speculum to hold the nasal passage open and a light source, either under indirect illumination with a forehead mirror or with a headlamp.
- 12. PRODUCT GROUP (SCISSORS, SURGERY)**
- Surgical scissors
  - Enucleation scissors
- 12.1 *Intended use:* Scissors are used as tissue-cutting instruments, including the removal and cutting of suture material.
- Umbilical cord scissors
- 12.2 *Intended use:* Used to cut the umbilical cord after the birth of an infant.
- Episiotomy scissors
- 12.3 *Intended use:* In order to spare the woman giving birth a perineal tear or to shorten the birth process, one cuts into the genital area with perineal scissors during the birth of her child. This is called an episiotomy.
- There are two methods of episiotomy. The median episiotomy is cut along the midline, the raphe perinei towards the anus. The mediolateral episiotomy is made starting from the centre at an angle of 45° and can be made longer due to the lack of a boundary through the anus, resulting in a greater gain of space.
- 13. PRODUCT GROUP (TWEEZERS)**
- Tweezer
- 13.1 *Intended use:* Instrument for gripping smaller objects.
- 14. PRODUCT GROUP (SPECULAE)**
- Vaginal specula
- 14.1 *Intended use:* Instruments are inserted into the vagina during gynaecological examinations. Many specula then allow the two blades to spread so that the vagina can be unfolded. This makes the vaginal skin as well as the cervix visible and accessible. Specula make it possible to take smears from the cervix or to insert other instruments into the uterus via the cervix. After the examination, the blades are closed again and the speculum removed.
- 15. PRODUCT GROUP (OPHTHALMIC SPOONS)**
- Curette

15.1 *Intended use:* Instrument used to remove a chalazion. The chalazion is cut open on the inside of the eyelid under local anaesthesia and the sebaceous contents are generously removed with a sharp curette.

### 16. PRODUCT GROUP (OPHTHALMIC)

➤ Iris Scissors

16.1 *Intended use:* Scissors with pointed or blunt ends, straight or curved are used for removing and cutting suture material and small cuts at the wound edge or for surgical procedures on the eye.

➤ Spring scissors

16.2 *Intended use:* The spring scissors are a disposable instrument made of brushed steel that can be used without glare. The spring scissors are suitable for fine applications in iridectomy. This is a surgical procedure in which a piece of the iris (iris skin) is removed. First, it is necessary to open the cornea in a very small area. Since the scissors are operated against a spring pressure, they open again automatically when the pressure around the handle is reduced

### 17. PRODUCT GROUP (OPHTHALMIC RETRACTORS)

➤ Fixation Ring

➤ Manipulator Strabismus hook

➤ Manipulator Iris hook

➤ Manipulator claw phaco chopper

➤ Skin retractor

17.1 *Intended use:* The iris hooks are used to hold back the iris during eye surgery. The fixation ring fixes the eyeball during eye surgery, e.g. corneal surgery using laser technology.

The Strabismus hooks are used to grasp muscles. All manipulators are used for grasping in the respective applications.

Eye hooks are used for holding or retracting during operations on or in the eye. Fine hook.

### 18. PRODUCT GROUP (OPHTHALMIC INSTRUMENTS OTHERS)

➤ Foreign body needle

18.1 *Intended use:* A foreign body in the cornea is removed using a magnifying glass with the blunt tip of a foreign body needle.

➤ Foreign body gouge

18.2 *Intended use:* A foreign body in the cornea is removed using a magnifying glass with the blunt tip of a foreign body gouge.

### 19. USED MATERIALS

Surgical instruments are made of stainless steels according to ISO 7153-1 and EN 10088-3

### 20. CONTRAINDICATIONS

The use of the instruments is generally contraindicated when the use of other surgical techniques is indicated

- in the case of general inoperability,
- if the patient is not willing,
- if the technical requirements are not met.
- Not for use on the central circulatory and nervous system as defined in the regulation..

### 21. APPLICATION RISKS

Risks from the application of the instruments exist due to

- local infections due to poor soft tissue conditions,
- increased fibrous tissue around the surgical site.
- 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 application due to insufficient healing phase before stress,
- destabilisation of the cornea,
- temporary opacity.

Nerve damage is possible as a result 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 material used must always be checked before use.

**The instruments may only be used by trained personnel.**

### 22. TARGET GROUP (INTENDED USERS)

The instruments may only be used for their intended purpose in medical specialties, in medical facilities and by trained and qualified medical personnel (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 operative use, for appropriate training and information and for sufficient experience in handling the instruments.

The reprocessing and sterilisation of the instruments and accessories is only allowed by qualified personnel with qualified training.

### 23. INTENDED PATIENT POPULATION

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

### 24. BASIC WARNINGS AND PRECAUTIONS

The products are delivered **STERILE!** The packaged 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 patients, users or third parties.

Sources of information on the products are the relevant product catalogues, videos, technical specifications, instructions from medical device advisors, working groups, seminars, technical courses, publications, etc. Appropriate product training - including 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 me-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 control.

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

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 intended use of the product may lead to the following, among other things

- contamination of the product that can no longer be safely controlled,
- material fatigue and material changes,
- non-visible damage, e.g. in the form of micro-cracks,
- wear on functional features which are necessary for the safe use of the product,
- missing or incomplete function, which precludes reuse and can lead to, among other things, the following hazards for patients, users and third parties
- 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.

### 25. 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.

### 26. PACKING

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

### 27. STORAGE

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

### 28. OPERATING, STORAGE AND TRANSPORT CONDITIONS

Prerequisite: proper storage

Sterile: 3 years from date of manufacture

Sterile products must be stored in a dry and dust-free place.

In principle, however, the instruments must be inspected for visual defects (damage, corrosion, etc.) and, in the case of sterile instruments, for packaging damage before use.

### 29. 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.

### 30. 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.

### 31. 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 caused by:

- misappropriation
- improper maintenance and repair
- improper use, application or handling
- Failure to observe the instructions for use
- Preparation and sterilisation

**32. STANDARDS – REFERENCES**

- DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 to -10 Packaging materials
- DIN EN ISO 17664 / ANSI AAMI ST81 Sterilization - Information from the manufacturer
- DIN EN ISO 11135 Sterilization of health care products - Ethylene oxide

**SCILO Vertriebs GmbH**