Instruction for Use

Disposable Instruments Steel

1. BASIC

It is absolutely necessary that all prerequisites and special information described in these instructions 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 you have any questions or uncertainties, please contact us before using the products.
These instructions for use do not replace the training, care and state of the art of the user. We assume that the relevant legal regulations, standards and recommendations (e.g. of the RKI or also the AKI) are known (see under "Standards/references"). We limit ourselves to the instructions and information to be observed for each product which are of importance to the user for our products. Reasons for these instructions and the hazards arising 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

REF	Ref.-Number and Order-Number		Product for single use only
QTY	Quantity indication in the packaging		Notice instructions for use
LOT	Batch number	CE 0044	Community European (European over-the-counter sign) CE with the identification number "0044" of the notified body "TÜV NORD CERT GmbH" in D-45307 Essen
MD	Medical device		Do not use if the packaging is damaged.
NON STERILE	Indication for NOT sterile product		Manufacturing date
CH REP	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 national and international laws for products in human medicine.

4. ARTICLE

Surgical scissors	Dressing forceps	Bone curettes	Sponge/Swab forceps
Enucleation scissors	Needle holder	Tenaculum foreceps	KOCHER-forceps
Forceps	Magill forceps	Wound retractors	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. INDICATION

Instruments and accessories are intended for single use. The instruments can be used individually for surgical use. Or as a component in a surgical set. It must be noted that the intended use of the instrument of the company SCILO is observed.

6. PPRODUCT GROUP (FORCEPS)

- PEAN-forceps
- KOCHER-forceps
- Hemostatic forceps
- Forceps Diefenbach

6.1 Intended Use: Instruments for disconnecting and holding vessels and squeezing 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 TO HOLD AIDS)

- Sponge/Swab forceps
- Dressing forceps
- Towel clamp
- Dressing forceps
- Tube forceps

9. *Intended Use*: Instruments for holding and fixing aids in the surgical area, such as cloths, swabs, sponges, tubes and tamponages

10. PRODUCT GROUP (FORCEPS, SURGICAL-INVASIVE)

- Tissue grasping forceps

10.1 *Intended Use*: Instruments for grasping tissue and pulling out the grasped organ part using hooked forceps.

- Tenaculum forceps

10.2 *Intended Use*: The tenaculum forceps is a gynecological instrument for grasping and holding tissue. Through the locking function, a fixation of the held tissue can be achieved to perform the surgical procedure meanwhile.

- Polyps forceps

10.3 *Intended Use*: Instrument used to ablate a polyp.

- Magill forceps

10.4 *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 respiratory tract, to position the tube during nasal intubation, and to insert gastric tubes into the esophagus.

11. PRODUCT GROUP (CURETTES)

- Bone curettes
- Schiller spoon (Bone curettes)

11.1 Intended Use: Instruments with sharp or blunted spoon shape for tissue ablation.

12. PRODUCT GROUP (RETRACTORS)

- Wound restractor
- Self retaining retractor

12.1 *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

12.2 *Intended Use*: Instrument with pointed and blunt hooks for keeping the surgical field open with tracheal hooks mostly in tracheotomy. This makes the wound area visible and accessible

- Nasal speculum

12.3 *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.

13. PRODUCT GROUP (SCISSORS, SURGICAL)

- Surgical scissors
- Enucleation scissors

13.1 Intended Use: Scissors are used as a tissue cutting instrument, as well as for removing and cutting suture material.

- Umbilical cord scissors

13.2 *Intended Use*: Used to cut the umbilical cord after the birth of an infant.

- Episiotomy scissors

13.3 *Intended Use*: Along the midline, the raphe perinei, the incision is made towards the anus. The mediolateral episiotomy is performed starting from the midpoint 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.

14. PRODUCT GROUP (TWEEZERS)

- Tweezer

14.1 *Intended Úse*: Instrument for gripping smaller objects.

15. PRODUCT GROUP (SPEKULA)

- Vaginal specula

15.1 *Intended Use*: Specula allow the two blades to spread so that the vagina can be unfolded. This makes the vaginal skin and the cervix visible and accessible. With specula it becomes possible to take smears from the cervix or to insert other instruments into the uterus via the cervix.

16. PRODUCT GROUP (OPHTHALMIC SPOONS)

- Curette

16.1 *Intended Use*: Instrument used to remove a chalazion. Under local anesthesia, the chalazion is cut open on the inside of the eyelid and the sebaceous contents are generously removed with a sharp curette

17. PRODUCT GROUP (OPHTHALMIC RETRACTORS)

- Fixation ring
- Manipulator Strabismus hook
- Manipulator Iris hook
- Manipulator claw phako 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 by laser technique. 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.

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

There are contraindications,

- in case of general inoperability.
- in case of lack of willingness of the patient
- if the technical requirements are not met.
- The instruments are not intended for use in the central circulatory system and the central nervous system as defined in Regulation (EU) 2017/745.

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21. APPLIKATION RISKS

Risks from the application of the instruments exist through
- 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 ophthalmic instruments, there is a risk of applicatior due to local infections,
- early or late deep and/or surface infections,
- Failure of the application due to insufficient healing phase before the load,
- Destabilization of the cornea,
- temporary turbidity

Nerve damage is possible as a result of surgery.

In most cases, any complications that may arise are not directly related to the use of an instrument, but are rather caused by the incorrect selection of the patient, inadequate training and imprecise handling. If excessive forces are applied, unintentional injuries to tissue or bone can lead to impairment or even breakage of the instruments. Careful use of the instruments is therefore absolutely essential.
To rule out 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 disposable instruments may only be used 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 surgical use, for adequate training and information and for sufficient experience in handling the instruments.

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

23. INTENDED PATIENT POPULATION

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

24. BASIC WARNINGS AND PRECAUTIONS

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

After receiving the products, check their identity, completeness, integrity and function.

Before each use of instruments, inspect them for breaks, cracks, deformation, damage and proper functioning. Particular care should be taken to check areas such as cutting edges, 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 advisors, working groups, seminars, technical courses, publications, etc. Appropriate product training, including handling of the products, is essential 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 result to be expected with the use of the products. Special attention should be paid to a postoperative discussion and the need for regular medical check-ups.

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 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 safely controlled
- material fatigue and/or material changes
- unapparent damage, e.g. in the form of micro-cracks
- wear of functional features which are necessary for the safe use of the product
- missing or no longer complete function

which may preclude reuse and 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 injuries, disabilities 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.) and this is clearly visible.
The corresponding hygiene and operating site regulations must be observed.

26. PREPARATION, CLEANING, DISINFECTION OF INSTRUMENTS

The instruments are all delivered non-sterile. The customer must ensure that the instruments are not soiled after removing the protective transport packaging before repackaging them in the sets. Effective cleaning and disinfection is an indispensable prerequisite for efficient sterilisation of steel instruments.

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As part of your responsibility for the sterility of the instruments during use, please always ensure that only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilisation, that the devices used (WD, steriliser) are regularly maintained and checked, and that the validated parameters are adhered to for each cycle.

In addition, please observe the legal regulations valid in your country as well as the hygiene regulations of the medical practice or hospital. This applies in particular to the different specifications regarding effective prion inactivation.

For cleaning and disinfection of the instruments made of steel, a mechanical procedure (washer-disinfector / disinfector) is used.

Proof of the basic suitability of the process (in the BHT washer-disinfector, model Innova M 5, using Neodisher Mediclean forte from Dr. Weigert) for effective mechanical cleaning and thermal disinfection of the instruments made of steel was provided by process validation. In addition, the instruments were checked for residues after cleaning and disinfection by a test laboratory.

27. MACHINICAL CLEANING/DISINFECTION (CLEANING DISINFECTOR)

Products made of steel that are delivered uncleaned by SCILO must be cleaned by machine.
Machine cleaning is not used for plastic instruments.
When selecting the washer-disinfector, this must be taken into account,

- that the washer-disinfector has been tested for effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883),
- that, if possible, a tested programme for thermal disinfection (at least 5 min at 90 °C or A0 value > 3000) is used,
- that the programme used is suitable for the instruments and contains sufficient rinsing cycles,
- that suitable water (e.g. Aqua purificata/Aqua purificata valde) is used for rinsing, and that the air used for drying is filtered and thus does not reduce the hygiene status at this point,
- that the washer disinfector is regularly maintained and checked.

When selecting the cleaning agent system to be used, pay attention to this,

- that the disinfectant is suitable for cleaning the instruments,
- that - if thermal disinfection is not used - a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is also used and that this is compatible with the cleaning agent used.
- and that the chemicals used are compatible with the instruments (see chapter "Materials used").

The concentrations specified by the manufacturer of the cleaning agent and, if necessary, disinfectant must be strictly adhered to.
Proof of the basic suitability of the process (in the BHT washer-disinfector, model Innova M 5, using Neodisher Mediclean forte from Dr. Weigert) for effective mechanical cleaning and thermal disinfection of the instruments made of steel was provided by process validation. In addition, the instruments were checked for residues after cleaning and disinfection by a test laboratory.

28. CONTROLS

Check all instruments for damage and contamination and replace damaged and contaminated instruments.

29. PACKING

Pack the disposable instruments in single-use sterilization packaging that meets the following requirements:

- according to DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 to -10
- adequate protection of instruments or sterilization packaging against mechanical damage
- regularly maintained according to the manufacturer's specifications (sterilization container)

30. STERILISATION

Only the sterilisation methods listed below may be used for sterilization; other sterilization methods are not permitted.

- ETO sterilisation Sterilization process with ethylene oxide
- Low temperature sterilizers according to DIN 58948-7
- according to DIN EN ISO 11135-1 validated (valid picking and product-specific performance assessment)
- maximum sterilisation temperature and duration depends on the ethylene oxide mixture according to DIN EN ISO 11135-1 / DIN EN 1422

31. STORAGE

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

32. OPERATING, STORAGE AND TRANSPORT CONDITIONS

Prerequisite: proper storage
Non-sterile: without limitation
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 or, in the case of sterile instruments, packaging damage) before use.

33. REUSABILITY

SCILO instruments are intended for single use. The shelf life of the instruments depends on many factors, such as storage and transport of the instruments. Careful checks and functional tests before use are the best way to identify and discard an instrument that is no longer functional. In case of disregard, any liability is excluded.

34. INCIDENT REPORTING

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

35. WARRANTY

Safety note: The responsibility for the proper disinfection and sterilization of products lies with the operator / product user. National regulations, including restrictions on this, must be observed.
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 a distributor of the products excludes any warranty claims and assumes no liability for direct damage or consequential damage caused by:

- use for purposes other than intended
- improper use, application or handling
- improper reprocessing and sterilization

- improper maintenance and repair
- non-observance of the instructions for use

36. DISPOSAL

After single use the products must be disposed of in accordance with hospital practice.
The following must be observed during disposal:
- Clean instruments thoroughly before disposal.
- Dispose of packaging and used parts according to country-specific regulations.
- Protect instruments from access by unauthorised persons.

37. STANDARDS – REFERENCES

- AKI Guide "Instrument Reprocessing Done Right
- RKI recommendation: "Hygiene requirements for the reprocessing of medical devices".
- DIN EN ISO 11135 Sterilization of health care products-Ethylene oxide
- DIN EN ISO 15883-1-3 Cleaning-disinfection equipment
- DIN EN ISO 17664 Reprocessing of health care products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices

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