Instruction for Use
Disposable Instruments Class I

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. If required, we can offer you user training on the safe use of medical devices.
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

	Manufacturer	CH REP	Swiss Representative (SWISS AR Services, Industriestraße 47, 6300 Zug (Switzerland))
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	Community European
MD	Medical device		Manufacturing date
NON STERILE	Indication for NOT sterile product		Do not use if the packaging is damaged,

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

Abortion Forceps	Cloth clamp plastic / BACK-HAUS	Tweezers mini disposable plastic	Probes
Tweezer, satined	Hose/dialysis clamp	Sponge clamp	Nasal and vaginal specula
Tweezers Disposable, Plastic	Fixation forceps	Micro-forceps (spring-type)	Chalazion tweezers
Clamps Kocher-/PEAN	Universal clamp	Bulb syringe	Bandage scissors
Wire cutters	Micro-tweezers	Suturet weezers	Cilia-tweezers
Eye speculum	Iris-tweezers	Folding forceps	Punctal dilator
Lid retractor	Eye-marker	Eyelid plate	Incision plate
Eye protection shield	Medical plastic drain	Eye hollow needle with tube extension	Neonate scleral depressor
Lenticule extraction forceps	IOL lens loading tweezers	Gypsum Scissors with micro-serration	Eye tweezers
Tweezers surgical			

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. PRODUCT GROUPS

6.1 ABORTION FORCEPS

Intended use: Abortion forceps or afterbirth forceps are inserted into the uterus in order to grasp the detached parts and remove them.

6.2 TWEEZERS

- Tweezers satin finish
- Tweezers disposable plastic
- Tweezers mini disposable plastic

Intended use: Forceps are holding, clamping and gripping instruments for gripping, temporarily holding and removing various materials in different areas of application, e.g. also for removing foreign bodies.

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6.3 TWEEZERS (OPHTHALMOLOGY)

- Micro-tweezers/micro-tweezers
- Iris tweezers
- Fixation forceps
- Micro-forceps (spring-type)
- Suture tweezers
- Cilia tweezers
- Folding forceps
- Chalazion tweezers
- Eye tweezers
- Surgical tweezers

Intended Use: Tweezers in ophthalmology are used to hold the conjunctiva; to grasp and pull forward the iris and remove foreign bodies, to securely grasp fine hairs directly on the skin or when treating a chalazion. In ophthalmology, suture forceps are often used to place fine sutures during eye operations. The special shape enables precise handling in the sensitive eye area.

6.4 CLAMPS

- KOCHER/PEAN clamp
- Cloth clamp plastic/BACKHAUS
- Hose dialysis clamp
- Universal clamp
- Sponge/swab clamp

Intended use: The Kocher/PEAN clamp is intended for gripping and holding surgical material in SCILO. The appearance is similar to the PEAN stove clamp. Cloth clamps are used to hold or fix surgical cloths or surgical material. Hose/dialysis clamps are used to hold or fix surgical drapes or surgical material. The universal clamp is used to hold and fix aids in the operating theater, such as cloths, swabs, sponges and tubes. Sponge/swab clamps, on the other hand, are used to hold or fix surgical drapes or surgical material.

6.5 BALLOON SYRINGE

Intended use: The balloon syringe is used to “suck out” foreign bodies, e.g. from the ears. This balloon syringe is also frequently used for rinsing.

6.6 PROBES

- Hysterometer
- Button probe

Intended use: The hysterometer is an instrument .for determining the length of the uterus. The button probe is used to palpate and trace tissue ducts.

6.7 SPEKULA

- Nasal speculum
- Vaginal speculum

Intended use: The nasal speculum is used in rhinoscopy. The examination is performed during anterior rhinoscopy using a nasal speculum to hold the nasal entrance open and a light source, either under indirect illumination with a forehead mirror or with a forehead lamp. The vaginal speculum is inserted into the vagina during gynecological examinations. Many specula then allow the two blades to be spread apart so that the vagina can be unfolded. This makes the vaginal skin and the cervix visible and accessible. Specula make it possible to take swabs 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.

6.8 EYE SPECULUM

Intended use: In ophthalmology, eye speculum prevent the eye from closing unintentionally during an operation or treatment. The instruments are used for myopia (short-sightedness) of less than -10 diopters, astigmatism (curvature of the cornea) and mydriasis (long-sightedness) of less than +3 diopters.

6.9 LID RETRACTOR

Intended use: Lid retractors are mainly used in ophthalmology to examine the upper envelope fold.

6.10 SCISSORS

- Bandage scissors
- Wire cutters
- Gypsum Scissors with micro-serration

Intended use: Bandage scissors are used to cut through bandage material. Wire scissors are used to cut through wire. The Gypsum Scissors with micro-serration are used to cut through plaster.

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6.11 PUNCTAL DILATOR

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

6.12 EYE MARKERS

Intended use: Eye markers are instruments for intravitreal injections. For fixing or marking the surgical area.

6.13 EYELID PLATE

Intended use: An eyelid plate is a surgical instrument used to protect the superficial structures of the eye.

6.14 INCISION PLATE

Intended use: The incision plate is another form of eye marker. Instead of the two tips, a round plate is pressed onto the eye to hold it in place.

6.15 EYE PROTECTION SHIELD

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

6.16 MEDICAL PLASTIC DRAIN

Intended use Medical Plastic Drains are used to drain tear fluid.

6.17 EYE HOLLOW NEEDLE WITH TUBE EXTENSION

Intended use: Eye hollow needles with tube extension are used for rinsing the tear ducts.

6.18 NEONATE SCLERAL DEPRESSOR

Intended use: Neonate scleral depressors are used to displace tissue in order to facilitate the examination of the surrounding area in the eye socket during eye surgery.

6.19 LENS EXTRACTION FORCEPS

Intended use: The lens extraction forceps are used to detach lenses.

6.20 IOL LENS LOADING TWEEZERS

Intended use: IOL lens loading tweezers are used to insert intraocular lenses during cataract surgery.

7. MATERIALS USED

Table 1: List of raw materials and materials currently used (excluding operating materials and packaging materials):

Register	Materialbezeichnung
1	1.4006 (X12Cr13), AISI 410
2	1.4021 (X20Cr13), AISI 420A
3	1.4306 (X2CrNi19), AISI 304
4	1.4404, ASTM A240/A240M (316L)
5	Stainless steel SUS 304
6	Polyamid
7	PA6 TP-4208
8	KR03NW Styrene Butadiene Copol
9	Polycarbonate
10	Methyl-vinyl silica rubber Po

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Register	Materialbezeichnung
11	Polyethylene LLDPE
12	LDPE 2426K
13	General Grade ABS AC-800
14	ABS (Acrylnitril-Butadien-Styrol)
15	TPE
16	PP GF30
17	PA GF30
18	PA6 G30

Chirurgische Instrumente werden aus rostfreien Stählen gemäß ISO 7153-1 und EN 10088-3 hergestellt.
Die Instrumente mit Kunststoffelementen beinhalten einen oder mehrere der oben genannten Materialien. Die oben gelisteten Kunststoffe sind biokompatibel und für den Einsatz in der Medizintechnik geprüft und genehmigt. Die Bewertung der verwendeten Materialien im Patientenkontakt erfolgt im Rahmen der Biokompatibilitätsbewertung (siehe 06 Verifizierung Validierung- 06-1 BIOLOGISCHE BEURTEILUNG).

8. CONTRAINDICATIONS

The use of the instruments is generally contraindicated when the use of other surgical techniques is indicated.
Contraindications are generally present,

1. in case of general inoperability.
2. if the patient is not ready.
3. if the technical requirements are not met.
4. not for use on the central circulatory and nervous systems as defined in the regulation.
5. destabilization of the cornea.
6. temporary opacity.

9. APPLICATION RISKS

Risks arising from the use of the instruments exist due to
- Local infections due to poor soft tissue conditions,
- increased occurrence of fibrous tissue around the surgical site,
- early or late deep and / or surface infections.

Any complications that may occur are in most cases not directly related to the use of an instrument, but are rather caused by incorrect patient selection, inadequate training and imprecise handling. If excessive force is applied, unintentional injury to the tissue or bone can lead to impairment or even breakage of the instruments. Careful use of the instruments is therefore 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.

10. TARGET GROUP (INTENDED USERS)

The instruments may only be used for their intended purpose in medical specialties. The instruments may only be used in medical facilities and by trained and qualified medical personnel (physician, medical assistants under the supervision of a physician).
The attending physician and/or the user/operator is responsible for the selection of the instruments for applications and/or operative use, adequate training and information and sufficient experience for handling the instruments.
The reprocessing and sterilization of instruments and accessories may only be performed by qualified personnel.

11. 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 attending physician or the user/operator is responsible for the selection of the instrument set for specific applications or operative use, appropriate training and information, and sufficient experience for handling the instrument set.

12. BASIC WARNINGS AND PRECAUTIONS

The products are delivered NON-STERILE! The packed products are marked accordingly.
Upon receipt of the products, check the identity, completeness, integrity and function.

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

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The attending physician and all other persons involved in the handling of the products are responsible, within the scope of their activities, for having the 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.
The sources of information for the products are the relevant product catalogs, videos, technical specifications, instructions from medical device consultants, working groups, seminars, professional courses, publications and so on. 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 attending physician is responsible for the proper selection of patients, evaluation of the indication and selection of the instrument.
The treating doctor should discuss the result of treatment expected with the use of the products with the patient in detail. Special attention should be paid to 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 stability of a product.

The patient must be instructed in proper postoperative hygiene and should be instructed to notify 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 situations

- contamination of the product that can no longer be safely controlled
- material fatigue and/or material changes
- non-visible damage, for example in the form of microcracks
- wear of functional features which are necessary for the safe use of the product
- missing or no longer complete function.

These things can preclude 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 surgery
- delayed recovery or prolonged treatment time
- 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.

13. PRODUCT RETURN

Any return of products may only be sent back to us after disinfection/sterilization has been carried out and clearly visible (appropriate packaging with sterile indicators, decontamination certificate, etc.).
The relevant hygiene and plant regulations must be complied with.

14. 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 sterilization of the steel instruments.
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 sterilization. The devices used (Cleaning-Desinfection-Machine, sterilizer) must be regularly maintained and checked. The validated parameters must be adhered to for each cycle.

Please also observe the legal regulations applicable in your country and the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements regarding effective prion inactivation.
A mechanical process (washer-disinfector/disinfector) is used to clean and disinfect the instruments.
Proof of the basic suitability of the process (in the washer-disinfector from BHT, model Innova M 5 using Neodisher Mediclean forte from Dr. Weigert) for effective automated cleaning and thermal disinfection of the instruments was provided by process validation. In addition, the instruments were checked for residues after cleaning and disinfection by a test laboratory.

15. MACHINE CLEANING/DISINFECTION

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

- that the washer-disinfector has been tested for effectiveness (e.g. DGHM or FDA approval or CE marking in accordance with DIN EN ISO 15883),
- that, if possible, a tested program for thermal disinfection (at least 5 min at 90 °C or A^0- Wert > 3000) is used,
- that the program 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, furthermore that the air used for drying is filtered and thus the hygiene status is not reduced at this point,
- that the WD is regularly maintained and checked.

When selecting the cleaning agent system to be used, it is important to ensure that,

- that this is basically suitable for cleaning the instruments,
- that - if thermal disinfection is not used - a suitable disinfectant with tested efficacy (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 "Materials used" section).

The concentrations specified by the manufacturer of the cleaning agent and, if applicable, 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.

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16. CONTROLS

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

17. 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)

18. STERILISATION

Only the sterilization methods listed below may be used for sterilization; other sterilization methods are not permitted.
ETO sterilization:
- 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 sterilization temperature and duration depends on the ethylene oxide mixture according to DIN EN ISO 11135-1 / DIN EN 1422

19. STORAGE

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

20. OPERATING, STORAGE AND TRANSPORT CONDITIONS

Prerequisite: proper storage in a dry place, free of frost and dust, without direct sunlight
Temperature conditions: All non-sterile disposable instruments -5°C to +45°C;
Balloon syringe +5°C to +35°C
Non-sterile: 10 years
In principle, however, the instruments must be checked for visual defects (damage, corrosion, etc.) before use.

21. REUSABILITY

SCILO instruments are intended for single use. The service 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.

22. 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.

23. 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

24. 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.

25. STANDARDS - REFERENCES

- AKI guide “Instrument reprocessing done right”
- RKI recommendation: “Hygiene requirements for the reprocessing of medical devices”
- DIN EN ISO 11135 Sterilization of healthcare products-ethylene oxide
- DIN EN ISO 15883-1-3 Washer-disinfectors
- DIN EN ISO 17664 Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices

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