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Instructions for use

Re-usable surgical instruments / Scissors in class I

NON STERILE

Information and directions for use of re-usable surgical scissors / instruments in class I

READ THIS INSTRUCTION MANUAL VERY CAREFULLY BEFORE PREPARING AND USING THE PRODUCT FOR THE FIRST TIME

Part I: General specifications:

Area of application:
Surgical Scissors / Instruments

Basic information:
This product satisfies ordinance (EU) 2017/745 on medical products.
You have chosen a product from SIEMA. Thank you for your trust.
You have purchased a high-quality product for which the correct handling and use are described below.
In order to minimise hazards for patients and users, we request careful observance of the instruction manual. Use, disinfection, cleaning and sterilisation of the instruments must only be carried out by trained, qualified personnel.

Intended use / misuse:
The instruments must only be used according to their intended use in medical fields by appropriately trained and qualified personnel. The doctor administering treatment and/or the user is responsible for the choice of instruments for specific applications and/or the use in operation, the appropriate training and information and the adequate experience in the handling of said instruments. Misuse, inadequate care and preparation, improper handling, misuse and modifications of the instrument can severely impair its serviceability, cause damage and create a source of serious injuries of the patient and user alike.

Area of application:
We produce our instruments as standard instruments for use in operation in general surgery. The doctor administering treatment is responsible for the choice of instruments for intended applications or use in operation. The doctor is also responsible for reasonable training and adequate information for the surgical staff and for adequate experience with the handling of the instruments.

Handling:
The instruments must not be overstressed by twisting or leverage, because this can damage or break parts of the instruments.

Indication / intended purpose:
Use of the products described below must only be carried out by personnel trained and qualified for this purpose. This instruction manual cannot replace the user's training, caution or the state of the art. Instruments and accessories are intended for repeated use. The instruments can be used individually for surgical applications or as a component in an operation kit. It must be ensured that the use of the instrument intended by **siema** is observed.

EMDN no.: L01040102
Scissors, bandage
Bandage scissors (also known as Lister scissors) are used for professional cutting of bandages. It is a special scissors of which the front part mostly angled. Therefore it is possible to even push it underneath a tight bandage. The top of the lower blade is often prolonged and laterally flattened to avoid injuries while cutting a bandage. They are not suitable for surgical procedure as cutting of tissue and vessels or dissection of various types of tissue.

EMDN no.: L010402
Scissors, suture
These scissors are used for cutting of suture material and compresses of fleece or for. professional cutting of bandages. They are not suitable for surgical procedure as cutting of tissue and vessels or dissection of various types of tissue.

Contraindications:
1. Working on tissue that cannot be cut with scissors (bone, chalk, liquefied tissue as in the case of an abscess, etc.)
2. Increased appearance of fibrous tissue around the operation area.
3. Early or late internal and/or surface infection.

Complications:
1. Nerve damage is possible as a consequence of a surgical procedure.
2. Failure of the procedure due to an inadequate healing phase prior to stress.
Any complications which occur are usually unrelated to the use of an instrument. They are generally caused by the incorrect choice of patient, inadequate training or imprecise handling. With the exertion of great forces, undesired injuries to the tissue or bones can cause damage or even break the instruments. Therefore, careful use of the instruments is mandatory.
In order to eliminate complications due to damage to the instruments, the product to be used must always be inspected prior to use. Use of the instruments must be carried out by trained staff only.

Combination with other products / instruments:
Products from **siema** must never be combined with products and components of other manufacturers. Combination with products of other manufacturers can negatively influence the result of the procedure and is not permitted, because the components may not be intended for use together.

Limitations:
Frequent refurbishing has a minor influence on the service life, which is determined by wear, damage during use and misuse.

Warning notices
In general, the instruments are delivered **NON-STERILE**!
After receiving the products, check the identity, completeness, intactness and function before the instruments are handed over for preparation.

Materials
The materials use for production are non-rusting steals in accordance with DIN EN ISO 7153-1.

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Material resistance

Cleaning and disinfectants must not contain the following components:

- organic, mineral and oxidising acids,
- strong alkalis (> pH 11, mild alkaline cleansers are recommended),
- halogenated hydrocarbons, chlorine, iodine,
- organic solvents (alcohols, acetone, etc.),
- ammonia.

The products are thermally stable, but must not be exposed to temperatures higher than 141 °C (286 °F)!

Proper disposal of the instruments:

If the instruments can no longer be used due to wear or damage, they must be disposed of properly. This means that the instruments must be dismantled (if possible), cleaned and sterilised again prior to disposal. (refer to the instructions for preparation).

Warranty

The products are manufactured from high-quality materials and subject to a quality control prior to delivery. Nevertheless, should defects or errors appear, please contact our customer service.
However, we cannot assume any guarantee whether the products are suitable for the respective procedure. This must be determined by the user.
siema assumes no liability if it can be substantiated that this instruction manual was disregarded.
Safety notice: The operator / product user is responsible for the proper cleaning, disinfection and sterilisation of instruments. National regulations and limitations in this respect must be observed.

siema exclusively delivers inspected and fault-free products to their customers. All of our products are designed and produced so that they satisfy the highest quality demands.

siema, the manufacturer of the products, rejects any warranty claims and assumes no liability for indirect or consequential damage resulting from the following:

- unintended use
- improper use or handling
- improper preparation and sterilisation
- improper maintenance and repairs
- disregard of this instruction manual

Repairs must only be carried out by companies or persons authorised by **siema**. Violations render any warranty claims void.

Manufacturer service contract:

Inadequate understanding of this instruction manual can have the following consequence:

- death or injury of the patient
- severe injury of the user
- damage to the equipment

In case of uncertainty, discrepancies or questions, please contact us before the product is (re-) used or prepared.

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Reporting of serious incidents

All serious incidents resulting in the death of a patient or the serious deterioration of a patient's state of health must be reported immediately to the manufacturer and to the authorities of the country in which the incident occurred.

Meaning of symbols:

REF	Article no.
LOT	Batch no.
	Attention! Observe notices
NON STERILE	Product is delivered non-sterile
	See the electronic instructions for use at www.siema.de/downloads
	Manufacturer
CE 0483	Mark of conformity with ordinance (EU) 2017/745 for medical products
MD	Label for medical product
	Label for hazardous materials, as we use cobalt

Part II: Information on preparation:

STERILISATION DOES NOT REPLACE CLEANLINESS!

Inspection:

The instruments must be inspected for proper function prior to each use.
Damage on the surface, such as scratches, cracks, notches, nicks, etc., as well as bent parts, means that the instrument must not be used. The products must be repaired or disposed of in the appropriate manner. Do not use damaged products!

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Preparation at the place of use:

Never **set down open** hinged instruments under tension; ensure that the instruments are handled and set down appropriately!
The instruments should be disinfected and cleaned immediately after use, insofar as possible. Remove heavy contamination from the instruments immediately after use. Contaminants should not dry on the objects, which also complicates disinfection and cleaning. Do not use securing means or hot water (> 40°C), because this causes residue to adhere and can impede the cleaning success.
Instruments must never be placed in physiological saline solution, because extensive contact will lead to pitting and rust.

Manual cleaning process

1. **Pre-cleaning:**
   Place the instruments in cold tap water (< 40°C) for at least 5 min. Clean the instruments under cold tap water with a soft brush until there is no longer any visible residue.
2. **Cleaning:**
   If possible, ultrasound-assisted cleaning is recommended here.
   Place the instruments in an ultrasonic bath with demineralised water (40°C) and 0.5% alkaline cleaner (neodisher ® MediClean forte is recommended) and treat with ultrasound for 15 min. Minimum ultrasonic frequency 35 kHz. (Recommended 45kHz).
3. **Intermediate rinsing:**
   Subsequently remove the instruments from the cleaning bath and rinse them thoroughly for at least 1 minute under flowing demineralised water.
4. **Manual disinfection process:**
   Place the cleaned instruments in a disinfection bath for 15 minutes (it is recommended to soak the instruments in 1% Bomix plus) so that the scissors are sufficiently covered. In the process, ensure that the instruments are not touched. Move moving parts back and forth a minimum of five times at the beginning and end of the exposure time.
5. **Final rinsing:**
   Subsequently remove the instruments from the disinfecting bath and rinse them thoroughly for at least 1 minute under flowing demineralised water.
6. **Drying:**
   Adequate drying must be ensured by the cleaning and disinfecting device or other suitable measures such as the drying by blasting with filtered compressed air.

Mechanical cleaning process

1. **Pre-cleaning:**
   Place the instruments in cold tap water for at least 5 min. Clean the instruments under cold tap water with a soft brush until there is no longer any visible residue.
   Place the instruments in an ultrasonic bath with demineralised water at 40°C with 0.5% alkaline cleaner (neodisher ® MediClean forte is recommended) and treat with ultrasound for 15 min. Minimum ultrasonic frequency 35 kHz. (Recommended 45kHz). Remove instruments and rinse off with cold tap water.
2. **Cleaning:**
   Pre-rinse the instruments with cold tap water for 1 minute.
   Clean at 55°C ± 2°C for at least 5 minutes (RKI recommendation of 10 minutes). For machine cleaning of thermostable and thermolabile instruments, use a 0.5% alkaline cleaner (neodisher ® MediClean forte is recommended) in the machine (pH value of approx. 10 measured in the rinsing liquid). If there is an elevated chloride concentration in the water, pitting and stress crack corrosion can appear on the instruments. Such corrosions can be minimised with the use of alkaline cleaners or use of fully desalinated water. The cleaning result must be inspected visually. The instruments must also be optically clean; repeat the process, if necessary.
3. **Intermediate rinsing (neutralisation):**
   Use of an acid-based neutralising agent facilitates the rinsing off of alkaline cleaning agent residue. With use of neutral cleansers, use of a neutraliser is recommended for unfavourable water qualities with excessive salt content, etc. in order to prevent scaling.
   Neutralise with a 0.1% mild alkaline detergent pH 9 to 11 (neodisher ® Z is recommended) in cold demineralised water for 2 minutes.
4. **Re-rinsing:**
   Subsequently re-rinse the instruments with cold demineralised water for at least 2 minutes.
5. **Thermal disinfection:**
   Perform thermal disinfection at 90°C ± 2°C for at least 5 min (A0 value of 3000).
6. **Drying**
   Adequate drying must be ensured by the cleaning and disinfecting device or other suitable measures. Perform the drying at 55-60°C for about 30 minutes. Any residual moisture can be removed in a drying cabinet at 60°C. However, the drying time depends on the loading and the wash item.

Sterilisation process

STERILISER: Steam autoclave:

Temperature: 132° Celsius, pressure: 2-3 bar (20 to 30 psi) with an exposure time of 3 minutes (RKI recommendation: 134°C, 5 minutes).

Drying time: Minimum 20 minutes.

When choosing the cleaning agent and the disinfectant, it must be ensured:

- that they are suitable for the cleaning and disinfection of instruments made of metal and plastic,
- that the cleaning agent - if applicable - is suitable for ultrasonic cleaning (no foam development).
- that an enzymatic aldehyde-free disinfectant is used for the manual pre-cleaning of medical instruments.
- that the chemicals which are used are compatible with the instruments (refer to the section "Material resistance").

Combined cleanser/disinfectants should not be used, insofar as possible. Combined cleanser/disinfectants are only permitted in cases of very low contamination (no visible contamination). The concentrations and exposure times specified by the cleanser and disinfectant manufacturers must be observed.

Other notices:

The basic suitability of the instruments for an effective manual or machine preparation process was certified by the accredited testing laboratory Clean Controlling. The method described above was applied in this connection.

Use of other of cleaning and disinfecting methods is not the responsibility of the manufacturer. The recommendations of the cleaning agent manufacturers must be observed.

The person preparing the instruments is responsible for ensuring that the preparation which is actually conducted (manually or by machine) with the equipment, materials and staff in the preparation facility achieves the desired results. For this purpose, validation and routine monitoring of the procedure are normally required.

If the user applies a different method, the chosen method must be validated by the user. Fresh disinfectant and cleaning solutions must be used each day. The following problems can occur in case of extended use: Danger of corrosion with increased concentration as a consequence of evaporation and reduced disinfecting effect due to heavy contamination. The residue from the cleaning process must be removed reliably; otherwise, spots and/or discolourations appear on the instruments.

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Shipment to siema for repairs

Instruments are only accepted for repairs and/or service if they have been cleaned, disinfected and sterilised as specified in the preparation instructions above. A corresponding declaration or verification must be included with the return shipment.

Inspection and maintenance

Perform an inspection before and after each use. Products that are damaged, incomplete or have loose parts must no longer be used. Send in damaged products with loose parts for repair. Do not carry out any repairs on your own authority.

- Inspect products for damage, sharp edges, loose or missing parts and rough surfaces.
- Opening and closing must be smooth with easy operation.
- Instruments must be cooled to room temperature!
- Treat hinges, threads and sliding surfaces with a suitable oil spray after the cleaning/disinfection, but before the final inspection and sterilisation. Paraffin/white-oil-based care agents must be silicone-free and approved for steam sterilisation and tested for biocompatibility.
- Sort out damaged instruments, inspect to ensure successful cleaning and disinfection (repeat if necessary), send to **siema** with a decontamination certificate.

Information on expected clinical benefit and brief report on safety and clinical performance

The reusable surgical scissors manufactured by siema Siegfried Martin GmbH are used to cut through various tissues and other materials during medical procedures. These scissors can be reused after appropriate treatment.
However, there are some risks associated with re-use, which can be minimised by knowing the materials and design and by following the treatment instructions contained in these instructions for use carefully.
The indications, contraindications and potential complications of the use of surgical scissors and reusable surgical instruments in general were reviewed based on the available literature, as part of the clinical evaluation.
This test and the market surveillance by the manufacturer have shown that the use of the reusable surgical scissors as manufactured by siema Siegfried Martin GmbH are safe for the intended purpose and that no further unacceptable risks are to be expected.

As siema Siegfried Martin GmbH only manufactures reusable surgical instruments in class I and Ir, a summary report on safety and clinical performance does not need to be prepared in accordance with Regulation (EU) 2017/745. This only applies to implantable medical devices and class III medical devices.
The Post Market Surveillance - Report (PMS Report), which has to be prepared for class I and Ir instruments, is part of our technical documentation and can be viewed upon request of the authorities.

Packaging:

- No special requirement.
- Packages can be sent in accordance with DIN EN 868/ ANSI AAMI ISO 11607.

Storage and transport:

- Dry, splash-proof, dust-proof and not in the immediate vicinity of aggressive media.
- Avoid direct sunlight
- Permissible temperature range: 5°C to 40°C
- Storage and transport in trays, containers and cabinets is expedient.
- Relative air humidity: 0 - 75%, non-condensing

Otherwise, there are no special or additional requirements.

Service life:

For the optimum safety of patients, do not exceed a total of 200 preparation cycles.

Index of changes:

Version	Date	Description of the change	Change by	Training requirement
A	24/08/2022	First created	K. Schmid, QMO	YES
B	07/06/2023	Product groups adjusted and EMDN numbers added. Furthermore, the MD symbol for medical products and the danger symbol regarding cobalt were added to the symbols.	K. Schmid, QMO	NO