

TD01: Surgical Instruments, Class I

00_A09x01_GebrauchsanweisungEN_v1.3



Instructions for Use

Manufacturer

Carl Teufel GmbH & Co. KG · Tuttlinger Straße 30 · D- 78576 Emmingen- Liptingen
Tel.: +49 (0) 7465-1022 · Fax: +49 (0) 7465-1024 · www.carl-teufel.de · office@carl-teufel.de

Products

These Instructions for Use apply to the products listed below.

Important note

 Read these instructions for use carefully before each use and keep them easily accessible for the users or the relevant specialists. Please refer to the abbreviation behind this symbol before application, and refer to the item specific information on intended purpose, indication and contra-indication.

 Carefully read the warnings indicated by this symbol. Improper use of the products may result in serious injury to the patient, the user or third parties.

1. Scope of application

The listed products may be used only by properly trained and qualified staff. The products are intended exclusively for the medical field described below and must therefore be used in a suitable operating environment. It is mandatory that the user and the relevant specialist staff become familiar with the instruments before applying them.

1. Intended purpose / Indication / Contraindication

1.1. Intended purpose: General surgical instruments

The instruments are intended for general surgical use.

1.2. Indication

1.2.1. A (12-235 Knife handle)

Hand-held manual surgical instrument for interchangeable scalpel blades, used by the surgeon to manually cut or dissect tissue.

1.2.2. B (12-421 Hammer)

A surgical hammer is a manually powered instrument, which is used together e.g. with a chisel for contouring, ablation, or the like, of bone. Here the hammer is used, depending on the location of the application, to apply heavy strokes e.g. to the chisel.

1.2.3. C (12-726 Needle holder)

Hand-held manual surgical instrument for grasping a suture needle when the same is pushed/pulled, together with the attached suturing material, through tissue during suturing.

1.2.4. D (13-228 Rongeur)

Manual surgical universal instrument for removal of soft tissue or bone samples during surgical procedures.

1.2.5. E (13-480 Scissors; 13-493 Scissors, gynecology ; 13-495 Scissors, nasal; 13-496 Scissors, neurosurgery ; 15-977 Scissors, fistula ; 16-520 Scissors, tonsil)

The instruments are hand-held, manual surgical instruments for cutting, holding, scraping or ablating body tissue, sutures or other surgical material.

1.2.6. F (13-996 Hook)

Hand-held, manually operated surgical instrument for lifting, positioning or pushing up anatomical structures or surgical materials.

1.2.7. G (14-257 Forceps)

General surgery instrument for grasping, holding or manipulating anatomical structures, a bleeding vessel (with spring mechanism), or for applying or assisting the handling of dressings on tissue during a surgical procedure.

1.2.8. H (15-211 Chisel, others)

Surgical instrument with a single blade for cutting or contouring of bone.

1.2.9. X (11-504 Elevator)

Hand-held, manually operated surgical instrument for elevation / separation / distention / dilation (elevation) in ophthalmological surgery.

1.3. Contraindication

The reusable surgical instruments listed must not be reused or processed after contact with patients suffering from a Creutzfeldt-Jakob condition (CJD or vCJD). The reusable surgical instruments of general surgery are contraindicated for any type of use beyond their intended uses. Use on the central cardiovascular system is contraindicated. The instruments may be used only by trained and qualified staff.

2. Intended purpose: Surgical instruments, ophthalmology

The instruments are intended for examination and ophthalmological-surgical use.

2.1. Indication

2.1.1. I (10-573 Cannula, eye)

Tube to deliver or aspirate liquids or air to the eye.

2.1.2. J (12-252 Knife, Scalpel; 12-241 Knife, cataract)

Ophthalmological-surgical knives / instruments for excision and removal of tissue.

2.1.3. K (12-302 Rinsing unit, corneal)

Handle for various irrigation cannulas, using which, as already described, the inside of the eye is supplied with fluid during a procedure in order to ensure preservation of the structural integrity of the eye.

2.1.4. L (12-442 Marker, ocular)

Manual instrument for marking by embossing, indenting and or incising of corneal tissue in ophthalmological surgery or in perioperative treatment.

2.1.5. M (13-119 Probe, eye; 13-120 Probe, eye lacrimal)

Hand-held rod-shaped thin surgical instrument made of flexible metal with a blunt tip for examination or manipulation of eye tissue during an ophthalmological procedure.

2.1.6. N (13-381 Retractor, eye)

Ophthalmological-surgical instrument for spreading apart the edges of an incision in the eye and its adjacent structures during a surgical procedure.

2.1.7. E (13-480 Scissors; 13-487 Scissors, eye, enucleation)

The instruments are hand-held, manual ophthalmological-surgical instruments for cutting, holding, scraping or ablating body tissue, sutures or other surgical material.

2.1.8. O (13-485 Scissors, eye; 13-486 Scissors, eye corneal; 13-488 Scissors, eye, iris; 13-490 Scissors, eye, tenotomy)

Hand-held ophthalmological-surgical instrument for transection of tissue during surgery on the iris of the eye (iris scissors), for transection of corneal tissue in operative cataract extraction, for dissection and/or separation of tendinous tissue in the eye, or for transection of tissue of the anterior or posterior portion during an intervention on the eye.

2.1.9. P (13-630 Loop instrument)

Hand-held ophthalmological-surgical instrument, inter alia for removing the lens during enucleation surgery.

2.1.10. Q (13-648 Spatula, eye)

Hand-held ophthalmological instrument to apply pressure on the eye.

2.1.11. R (13-663 Speculum, eye)

Surgical instrument for retraction of the eyelids or other eye tissue during ophthalmological examination, treatment or surgery.

2.1.12. F (13-996 Hook)

Hand-held, manually operated ophthalmological-surgical instrument for lifting, positioning or pushing up certain areas of the eye, such as eyelid, iris, etc.

2.1.13. S (14-148 Trephine, corneal)

Ophthalmological-surgical knife for excision and removal of round pieces of corneal tissue (corneal discs) and or sclera from patients in preparation for transplantation, or from donor corpses for obtaining implant material.

2.1.14. G (14-257 Forceps)

Ophthalmological Instrument for grasping and holding tissue and other material.

2.1.15. H (15-211 Chisel, others)

Ophthalmological-surgical instrument with a single blade for cutting or contouring bone.

2.1.16. T (16-415 Calliper, ophthalmological)

Surgical instrument used to measure distances during an ophthalmological procedure or in perioperative treatment.

2.1.17. U (10-861 Clamp; 16-450 Clamp, ophthalmological)

Surgical instrument for temporary atraumatic compression of an artery for the purpose of haemostasis (suppression or stopping of bleeding) during an intervention.

2.2. Contraindication

The ocular fundus is considered a high-risk tissue with regard to the possibility of containing prions of Creutzfeldt-Jakob's disease or a variant thereof (CJK or vCJK). The reusable ophthalmological-surgical instruments listed must not be reused or processed after exposure to patients suffering from a Creutzfeldt-Jakob condition (CJD or vCJD). If the patient suffers from an active infection, the reusable surgical instruments are contraindicated for enucleation of the eye.

The reusable surgical instruments of ophthalmology are furthermore contraindicated for any type of application beyond their intended uses.

Use on the central cardiovascular system is contraindicated.

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

3. Intended purpose: Microsurgery instruments

The instruments are intended for use in microsurgery / minimally invasive surgery.

3.1. Indication

3.1.1. W (11-254 Dilator)

The vascular dilator is a microsurgery instrument for controlled intraluminal vascular dilation. The special spherical shape of the tips ensures uniform distribution of the dilatation pressure over the entire surface of the vessel.

3.1.2. C (12-726 Needle holder)

Hand-held manual surgical instrument of microsurgery for grasping a suture needle when the same is pushed/pulled, together with the attached suturing material, through tissue during suturing.

3.1.3. E (13-480 Scissors; E13-496 Scissors, neurosurgery)

The instruments are hand-held, manual microsurgery instruments for cutting, holding, scraping or ablating body tissue, sutures or other surgical material.

3.1.4. G (14-257 Forceps)

Surgical instrument of microsurgery for grasping, holding or manipulating anatomical structures.

3.2. Contraindication

If immediately before or during surgery the technical requirements for microsurgical intervention are not fulfilled, the reusable microsurgical medical devices listed here must not be used. The term "technical requirements" is used here to refer to, among other things, poor or inadequate lighting conditions. The reusable surgical instruments listed must not be reused or processed after contact with patients suffering from a Creutzfeldt-Jakob condition (CJD or vCJD). The reusable surgical instruments of microsurgery are contraindicated for any type of application beyond their intended uses. Use on the central cardiovascular system is contraindicated.

Due to the complexity of microsurgical procedures, the instruments may be used only by appropriately trained and qualified staff.

4. Intended purpose: accessories

The sterile accessories are used for storage, fixation and stabilisation of the corresponding components during processing and sterilisation.

4.1. Indication

4.1.1. Y (16-349 Container system for surgical instruments)

The sterile accessories are used for cleaning and processing of surgical instruments from transport through storage to operational use.

4.2. Contraindication

Improper use can lead to premature wear or destruction of the sterilisation containers and their accessories. This results in an indirect hazard to the patient or third parties. The sterilisation accessories may be used only for their intended use and by trained and qualified staff.

5. Precautions and warnings

Please note:

The instruments by Carl Teufel GmbH Co. KG are designed for surgical use only and may not be used for any other purpose. Improper handling and care as well as use for any other than the intended purpose may lead to premature wear of the products.

Material incompatibility

The medical devices must not be used under any circumstances if the user or the specialist staff is aware that the patient has material incompatibilities.

Functional impairment

Surgical instruments will corrode and be functionally impaired when they come into contact with aggressive substances. For this reason, it is indispensable to follow the processing and sterilisation instructions.

Operating conditions

To ensure safe operation of the aforementioned products, proper maintenance and care of the products are essential. In addition, a functional or visual check should be carried out before each application. For this reason, we refer to the relevant sections in this manual.

Storage

We recommend storing the medical devices in a clean and dry environment.

6. Liability and warranty

Carl Teufel GmbH Co. KG as the manufacturer assumes no liability for any consequential damage caused by improper use or handling. This applies particularly in case of any use that does not comply with the intended use, or disregard of the processing and sterilisation instructions. This also applies to repairs or changes to the product not made by authorised staff of the manufacturer. These disclaimers likewise apply to warranty services.

7. Sterility



Delivery condition

The medical devices are shipped in non-sterile condition and must be processed and sterilised by the user in accordance with the instructions below before the first as well as before any further application.

8. Product service life

The service life of the products essentially depends on the careful handling during application and processing of the products by the user. Carl Teufel GmbH & Co. KG guarantees a service life of 2 years in case of careful use and appropriate processing.

 If the user decides that the medical device no longer functions reliably, he has to make sure that they are no longer used.

9. Processing

Warnings

- Frequent reprocessing affects the quality of the products.
- The water to be used must comply with Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- This processing instruction specifies the cleaning and disinfecting agents used for the validation. When using an alternative cleaning agent and disinfectant (RKI- or VAH-listed), responsibility rests with the processor.
- Reassemble disassembled products before sterilisation.

Place of use

The first steps of proper processing start already in the operating theatre.

Heavy contamination, residues of e.g. haemostatics, skin disinfectants and lubricants, as well as caustic drugs, should be removed, if possible, before the instruments are laid aside.

Wherever possible, preference should be given to dry disposal (closed system). Drying of residues is to be avoided!

Long waiting times until processing, e.g. overnight or over the weekend, are to be avoided during both types of disposal (<6 hours).

Transport

The products must be disposed of by the dry method immediately after application. This means that the products are to be transported moist in a closed container from the place of application to the processing facility so that no drying of the products takes place.

Reprocessing of the instruments

According to EN / ISO 17664, the manufacturer of a medical device is obliged to describe at least one automated method for its cleaning. The following mechanical cleaning process was validated using the radionuclide method in a Miele GD 7735CD with the chemistry Deconex 28 AlkaOne (Zugwil / Switzerland). Of course, other cleaners or other machines can be used for processing as well. In this case, ask your chemicals supplier or machine manufacturer if their products deliver the same performance as the products with which the process was validated.

Preparation for decontamination

If possible, the products should be dismantled before the subsequent processing steps, or fed into the further processing steps in opened state, respectively. "Rinsing shadows", i.e. areas not cleansed due to surface coverage during the treatment process, are to be avoided. The products must be prepared in suitable tray baskets or rinsing bowls (select size to match the product). The products should be fixated at a minimum distance from each other in the cleaning basket. Mutual overlapping is to be avoided in order to prevent damage to the products from the cleaning process.

Pre-cleaning

Pre-clean the products in an ultrasonic bath for 5 minutes using 0.5 % Neodisher Medizym. Rinse devices under cold tap water of drinking water quality (< 40 °C / 104 °F) until all visible dirt has been removed. Remove hardened dirt using a soft brush or the enclosed cleaning mandrel. Cavities and lumina are to be rinsed intensely (> 30 sec) with cold tap water of drinking water quality (<40 °C / < 104 °F), using a water jet gun (or similar). Movable parts must be moved.

Cleaning / disinfection

(Washing machine, WD):

- Pre-clean for 1 minute with cold tap water of drinking water quality < 40 °C / < 104 °F
- Drain the water
- Pre-clean for 3 minutes with cold tap water of drinking water quality < 40 °C / < 104 °F
- Drain the water
- Clean for 5 minutes at 55 ± 5 °C / 131 ± 9 °F using 0.4 % alkaline cleaning agent (Neodisher MediClean)
- Drain the water
- Neutralise for 3 minutes (0.1 % Neodisher® Z) with cold tap water of drinking water quality < 40 °C / < 104 °F
- Drain the water
- Rinse for 2 minutes with demineralised water < 40 °C / < 104 °F

The specific instructions by the manufacturer of the automatic cleaning machine must be observed.

Automatic disinfection

Automatic thermal disinfection in washer disinfector, taking into account the national requirements for the A₀ value; e.g. A₀ value 3000:

> 5 minutes at 93 ± 2 °C / 199 ± 3 °F with deionised water.

Automatic drying

Automatic drying according to the automatic drying process of the washer disinfector for at least 30 minutes (at 60 ± 5°C / 140 ± 9 °F in the rinsing room). If necessary, subsequent manual drying with lint-free cloth and blowing dry of lumina using sterile, oil free compressed air.

Sterilisation

Sterilisation of the products using the fractionated pre vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilised in suitable sterilisation packaging.

The sterilisation is to be carried out using a fractionated pre vacuum method with the following parameters:

- 134 °C / 273.2 °F
- ≥ 5 minutes holding time,
- 3 pre-vacuum cycles
- Drying in vacuum for at least 20 minutes.

Flash sterilisation is not suitable for products with lumina!

The instructions for use by the autoclave manufacturer and the recommended guidelines for maximum loading with sterilisation material must be observed. The autoclave must be properly installed, maintained, validated and calibrated.

Additional information

The person processing the instrument bears the responsibility that the processing actually performed with the equipment, materials and staff at the processing facility achieves the desired results. This usually requires validation and routine monitoring of the process and the equipment used.

10. Function test

Check the products after processing and before sterilisation for the following aspects:

- Cleanliness
- Damage, including signs of corrosion (rust, pitting), discoloration, deep scratches, peeling, cracks and abrasion.
- Proper functioning, including sharpness of the cutting tools, pliancy of flexible products, mobility of hinges / joints / box locks and moving parts, such as handles and ratchets.
- Missing or removed (abraded) part numbers.
- Do not use improperly functioning, defective or excessively worn products, nor products with illegible markings or missing or removed (abraded) part numbers.

Check the products for flawless surfaces, correct assembly and full functionality. Do not use heavily damaged products or products with illegible markings, signs of corrosion, or blunt cutting edges.

Reassemble disassembled products before sterilisation.

11. Service and repair

Service and repair

Do not carry out any repairs or changes to the product on your own. For this purpose, only authorised staff of the manufacturer are responsible and assigned. If you have any questions, complaints or comments regarding our products, please contact us.

Return

Defective or non-compliant products must undergo the entire reprocessing procedure.

Instruments sent to us for repair must be cleaned and sterilized.

12. Packaging, storage and disposal

Standard-compliant packaging of the products for sterilisation according to ISO 11607.

Store sterile products in a dry, clean and dust-free environment, protected from damage and at moderate temperatures.

The manufacturer's medical devices should be stored and warehoused in individual packages, boxes or protective containers. Please treat the instruments with utmost care during transport, storage and processing. Maintenance of the sterile state after the sterilisation process is to be ensured by the user or specialist staff assigned to this purpose.

Disposal of the products, the packaging material and the accessories must be carried out in accordance with the nationally applicable regulations and laws. No specific instructions for this are provided by the manufacturer.

13. Description of symbols used

 WARNING ("Warning: Please consult the accompanying documents")

 Observe Instructions for Use

 Item number

 Batch designation

 CE mark, conformity to EC Directive 93/42

 Non-sterile product

 Name and address of the manufacturer