a1 medical

Instructions for how to use reusable surgical instruments made of steel and titanium

Please read these instructions carefully and very exactly before you prepare, apply or put the product or instrument to use for the first time!

Part I: General information

01. Scope

For reusable surgical instruments which are one-piece, have simple joints, have simple moving parts, are composed of several changeable parts, such as grip parts or other applications.

Suitable product groups

Scissors, scalpels, specula, spreaders, retractors, spatulas, sharp spoons, hooks, clamps, curettes, knives, tweezers, tongs, chisels and endoscopic instruments

Excluded are products, which

- are connected to an active device,
- are themselves operated with energy,
- are completely made of non-metallic materials

02. Guideline

These instructions for use do not replace the training, and never the care and state of the art at the user/applier. We therefore require that the user be familiar with the relevant legal regulations, standards and recommendations, such as the RKI and also the AKI, and a1 medical refers also to the standards and references under Item 23.

03. Materials

Steels meeting DIN EN ISO 7153-1 requirements for medical instruments. Plastics are approved for medical products and the biocompatibility is tested.

04. Purpose

The instruments may only be used for their intended purpose in the medical areas of expertise and by appropriately trained and qualified personnel.
The treating physician, the user or applier is responsible for the selection of the instrument for certain applications, the operative use and the appropriate training and information as well as the sufficient experience for the handling of the instruments.

14. Packaging

05. Warnings

Our instruments are generally delivered NON-STERILE! After receiving the products, check that the delivered instruments are complete, undamaged and work properly before passing them along for treatment. Before every use, examine the instruments for breaks, cracks, deformations, damage and proper function. And check against the specific requirements with regard to its purpose. Areas such as blades, points, closures, interlocks, ratchets and all moving parts are to be checked with particular care. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out immediately, without delay.

06. Identification markings

Lot number: LOT
Not sterile:
Observe the information regarding accompanying documents:
European approval: CE

Manufacturer:

07. Restrictions

Frequent retreatment has an effect on the service life, which are determined by wear, damage and misuse.
After using on patients with Creutzfeldt-Jakob's disease (CJD) or its variants, we will not accept any responsibility for their reuse!
It is absolutely imperative that these instruments be immediately destroyed. Treatment and reuse according to the RKI 2 directive are fundamentally on one's own responsibility!
Caution: Aluminium-containing instruments will be damaged by alkaline cleaning agents >pH 7!

08. Combination with other products

If instruments should be reassembled after disassembly, the components must not be exchanged with parts from other manufacturers. If, due to the product purpose, parts are exchangeable, e.g. various work inserts, no parts from other manufacturers may be used!

We also recommend that accessories, such as care products, be purchased from a1 medical.

09. Material resistance

Cleaning agents and disinfectants may not contain the listed ingredients:

- Organic, mineral and oxidizing acids
- Strong bases (> pH 12.5, mildly alkaline cleaners recommended)
- Halogen-containing hydrocarbons, chlorine, iodine
- Organic solvents: alcohols, acetone, etc. Ammonia.

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

10. Warranty

Warning:
The responsibility for the proper cleaning, disinfection and sterilization of instruments lies with the owner and/or the product user.
National regulations, including restrictions regarding these, must be absolutely observed and applied. a1 medical excludes all warranty claims and will accept no liability for direct damage and consequential damage caused by:

- unintended use
- improper use, application or handling
- improper treatment and sterilization
- improper maintenance and repairs
- nonobservance of these instructions for use

Repairs may only be carried out by companies and persons authorized by a1 medical. Nonobservance will void any warranty claims.

11. Disposal and returns

Any acceptance of returns or repairs will only occur if the products are declared "hygienically safe", cleaned and disinfected and have been marked "not decontaminated" and securely packaged with an associated hygienically safe marking.
After successful disinfection, defective or aged instruments must be properly disposed of or recycled. It is imperative that the relevant legal regulations be observed.

Part II: Information regarding treatment

Warning

No alkaline cleaning agents with >PH 7 may be used for aluminum-containing instruments!

12. General basic principles for hygiene and treatment

Factory-new instruments and instruments from repair return shipments are to be treated as used instruments before using them for the first time. The transport-protection packaging and protective caps are not suitable for sterilization.

- Only approved products (RKI /DGHM/VHA FDA etc.) may be used.
- Alkaline as well as enzymatic cleaning agents may be used.

- Water quality in acc. with DIN EN 285 Annex B
- Sterilizers in acc. with DIN EN 285 or DIN EN 13060
- Cleaning/disinfection devices in acc. with DIN EN ISO15883 Parts 1 and 2
- Only sufficiently device- and product-specific validated methods for cleaning/disinfection/sterilization may be used here.
- Manufacturer information and recommendations must always be absolutely complied with.
- In addition, the applicable legal regulations, standards and hygiene regulations for your country must be observed.

Particularly for the various requirements regarding effective prion activation.

13. Storage

- Dry,
- Protected from dust
- Without external forces acting
- Without great temperature fluctuations
- Not in the immediate vicinity of
- aggressive media
- Store in sensible containers, cabinets or trays

· Packaging in acc. with DIN EN 868 can be used.
· The packaging size is to be selected such that the instruments fit in the packaging.
· Use a sterilization indicator for the packaging, and make sure you write down the sterilization and expiration date on the packaging.

15.Transport

·Safely store and transport the instruments in a closed container to the treatment location, in order to avoid damage to the instruments and contamination vis-à-vis people and the environment .

- It is imperative that the instruments be stored and transported to the treatment location in a closed container to prevent damage to the instruments and contamination of the environment and people.

16. Check and maintenance

· Instruments must be cooled to room temperature.
· Assemble instruments for function check
· Maintain joints, threads and sliding surfaces with oil spray after cleaning/disinfection, but before the function check and sterilization . Other care products (paraffin-/white oil-based and silicone-free) only, if approved for steam sterilization and the biocompatibility has been checked.
· Damaged instruments must always be sorted out; see also Item 11.

The user must always make sure that whenever the delivered instruments are split up, that there are instructions for use available for viewing at every location where used and in every department.

17. Preparation at the location of use Preparation for cleaning/disinfection

Immediately remove residues from the application

· Do not use metal brushes or steel wool or sharp-edged materials

· Do not place in saline solution (NaCl)

· Instruments never under tension, deposit instruments with joints open, dismantle instruments which can be disassembled,
...specially pre-treat narrow-lumened instruments and places e.g. by flushing them with a rinsing gun!
· Proper instrument handling and storage
· Wet disposal: Waiting time max. 1 h until treatment!
· Dry disposal: Waiting time max. 3 h until treatment!

18. Manual cleaning and disinfection

Precleaning as well as preparation for decontamination
· Only permitted in case of non-availability and in exceptional cases.
Then, however, additional product and process-specific validation required, under responsibility of the user.

· Do not use metallic brushes or steel wool.
· Clean narrow-lumened instruments and places with great care
· Proper instrument handling
· Proper instrument storage is absolutely recommended

19. Manual cleaning with ultrasonic bath

Precleaning as well as preparation for decontamination
· Maximum temperature: 50°C.
· Frequency: 35 – 45 khz.
· Cleaning time: 4-5 minutes.
· Insert instruments with joints in open condition
· Instruments with lumen filled free of air bubbles and aligned according to the acoustic noise

20. Machine cleaning - thermal disinfection

· Machine cleaning/thermal disinfection is preferably to be applied
· Place instruments which can be opened in their open state in a sieve tray on the pushcart and start the cleaning process
· MIC instruments: Stick instruments disassembled in the inserts of the MIC cart.
Do not place insertable instruments open in a sieve tray on the MIC cart.
· Pre-rinse with cold water
· Cleaning classic steel instruments: TITANIT; alkaline up to pH 12.5, cleaning time 5 min. at 70-90°C e.g. with A-Clean AlkaClean+
· Cleaning titanium and endoscopic instruments: mild alkaline / enzymatic cleaning agent up to pH 10.5, cleaning time 10 min. at max. 55°C e.g. with A-Clean Combibasic/Combizyme+
· Rinse with VE water (when using AClean products, neutralization is not necessary)
· Thermal disinfection under the consideration of the A0 value (Duration/temperature) according to rating of the products based on the RKI guideline

IT IS ABSOLUTELY IMPERATIVE THAT THE CLEANING REGULATIONS OF THE MANUFACTURER ALSO BE OBSERVED ACCORDING TO CLEANING SCHEME INFORMATION.

21. Sterilization

· Steam sterilization!
· Other sterilization methods and the flash sterilization method are not permissible.
· Fractionated 3 pre-vacuum phase method with at least 60 millibar of pressure with sufficient product drying of at least 15 minutes.
· Maximum sterilization temperature 138°C (280°F; plus tolerance in acc. with DIN EN ISO 17665-1 or DIN EN 554)
· Sterilization time (exposure time at the sterilization temperature) min. 20 min (at 121°C (250°F) or 5 min at 132°C (270°F) / 134°C.
· According to the steam sterilizer DIN EN 13060 or DIN EN 285
· Validated in acc. with DIN EN ISO 17665-1 (or DIN EN 554)

22. Confirmation and information

The above instructions for treatment were validated as "suitable" for the preparation of a medical product for reuse. It is the responsibility of the user, the person carrying out treatment, and the user to show that the actually carried out treatment and instructions were applied with the used equipment, materials and personnel in the treatment facilities and that the desired results were obtained. The test instructions, materials and machines, which were used during validation, can be viewed in justified cases at a1 medical.
For details, see cleaning report: Project No.01707011901-4

23. Standard references

· AKI guidelines "Instrument treatment done right"
· RKI recommendation: "Hygiene requirements for treating medical products"
· DIN EN 285 Large steam sterilizers
· DIN EN 13060 Small steam sterilizers
· DIN EN ISO 15883-1-3 Washer-disinfectors
· DIN EN868 Packaging materials
· DIN EN ISO17664 Sterilization information from the manufacturer

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