AMNOTEC INTERNATIONAL MEDICAL
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Surgical Hand instruments

CE

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General

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With the purchase of this instrument, you receive a high-quality product, the use and proper handling of which are described below.
To minimise potential hazards for patients and users, please read and follow the instructions for use carefully.
Use, disinfection, cleaning and sterilisation may only be carried out by trained specialists.

⚠ **Please note that our instruments are supplied non-sterile and must be sterilised before use.**
must be cleaned, disinfected and sterilised for the first use.
Scissors must not be dismantled for cleaning, disinfecting and sterilising.

Scope of application

These instructions for use apply to all surgical hand instruments of risk class I / Annex IX RL93/42/EEC of AMNOTEC International Medical GmbH. Depending on their functionality, they are assigned to one of the following product families:

1. Cutting instruments, such as scissors, scalpels, sickle knives, rongeurs, chisels, needles, etc.
2. Retaining instruments, such as specula, retractors, spatulas, etc.
3. Holding, clamping instruments, such as needle holders, vessel and tissue clamps, forceps, etc.
4. Scraping instruments, such as spoons, raspatories, rasps, snares, etc.
5. Leading instruments, such as probes, cannulas, palpation hooks, bougies, etc.
6. Diagnostic instruments, such as mirrors, tuning forks, stethoscopes, etc.
7. Accessories, such as attachments and adapters

For detailed information on the available sizes/variants and models, please refer to our current product catalogue.

Intended use / Indication

Reusable surgical instruments are used for the manual manipulation, processing and diagnosis of tissues during surgical procedures, such as the:

1. Cutting / punching out tissue (separating instruments)
2. Holding and spreading tissue (holding instruments)
3. Gripping and clamping of tissue, gripping of aids (holding, clamping instruments)
4. Removal of tissue (scraping instruments)
5. Touching, feeling tissue and anatomical structures (leading instruments)
6. Assessment of tissue and anatomical structures (diagnostic instruments)

⚠ **The surgical instruments are not intended for use in direct contact with the central nervous system or for correcting defects in the heart or central circulatory system!**

Contraindications

Patients for whom, in the opinion of the attending physician, there is a general surgical risk or the instrument cannot be used without endangering the patient.

The instrument is used exclusively by medical staff specially trained in the surgical technique.

The attending physician is also responsible for ensuring that the operating theatre staff and their colleagues have sufficient knowledge of the
and handling of the instruments.

⚠ **The selection of the appropriate surgical instrument is the responsibility of the experienced user.**

There are no other known specific contraindications.

Application and safety instructions

Failure to observe these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents.
⚠ All types of reusable surgical instruments must be completely cleaned, disinfected and sterilised before they are used for the first time and before each subsequent use.

⚠ Before each use, the instruments must be checked for correct function and visible damage as well as possible signs of wear, such as cracks, fractures, loose components and blunt cutting edges. The patency of instruments with lumens must be ensured before each use.

⚠ The packaging (including protective covers) in which the instrument was supplied is unsuitable for reprocessing (cleaning, disinfection and sterilisation) and is not approved. They must therefore be discarded before the first reprocessing and replaced with suitable containers or devices.

⚠ Do not overload the instruments at any time. Overloading due to excessive force can lead to breakage, bending and malfunction of the medical device and to injury to the patient or user. Do not bend bent instruments back into their original position, as there is a risk of breakage. This applies not only to use, but also to handling during reprocessing, care, storage and transport of the instruments.

⚠ Do not use a damaged or defective product. Sort out the damaged product immediately, label it and ensure that it cannot be used again.

⚠ Ensure that accessories or detachable components are securely attached throughout the entire use of the product.

⚠ When using instruments with cutting edges, sharp edges and points, be aware of the potential risk of injury, especially when picking up and handing over the instruments and during transport and reprocessing.

⚠ When inserting cutting edges or blades into the corresponding instrument, ensure that they are correctly positioned and firmly seated so that they cannot come loose during use.

⚠ Only use original accessories from AMNOTEC International Medical GmbH for the respective instruments. The use of accessories from other manufacturers that do not originate from AMNOTEC International Medical GmbH or have not been expressly recommended may result in a breach of warranty.

⚠ Surgical hand instruments are not suitable for combined use with laser systems, HF devices or other energy-generating procedures and devices. The instructions of the respective manufacturers for these systems must be observed.

Reportable events with AMNOTEC products

⚠ **Please note:**
The laws in your country may require you to report any serious incidents that occur in connection with the use of our products directly to us as the manufacturer or to our authorised dealer and the relevant government authority immediately after they occur.

Operation

The function of surgical hand instruments is self-explanatory. They are generally not suitable for connection to active medical devices and may only be used for the specified intended purpose. See also chapter Intended use/indication.

After use

Reprocess the surgical instruments immediately after use. If this is not guaranteed, the instruments must be placed in cleaning solution to prevent them from drying out and clogging any lumens and cavities. If necessary, use a suitable stylet to prevent clogging

Handling of surgical hand instruments

⚠ Be aware of the possible risk of injury when using instruments with cutting edges, sharp edges and points.

All surgical instruments should always be handled with the utmost care during transport, cleaning, care, sterilisation and storage. This applies in particular to fine micro instruments and instruments with delicate working ends.
Containers or devices for transporting, storing or reprocessing instruments must be of sufficient size to ensure that instruments are stored safely and are not damaged.
New instruments should have undergone three machine cleaning cycles before the first sterilisation. This leads to the formation of a passive layer on the surface, which protects the instrument from discolouration and corrosion.
New instruments should be stored without protective packaging, in a closed cabinet/drawer, in room air. Care must be taken to ensure that the applicable hygiene regulations are observed.
For new instruments that are to be stored for a longer period of time, we recommend removing them from the sealed plastic bag and treating them with a medical oil approved for sterilisation
(e.g. paraffins according to Ph. Eur.).

General information on reprocessing

- Responsibility for professional reprocessing lies with the operator of the respective central sterile supply department and its employees.
- The reprocessing of medical devices to be used in low-germ or sterile conditions must be carried out using suitable validated procedures, taking into account the manufacturer's specifications, in such a way that the success of this procedure can be clearly guaranteed and the safety and health of patients, users or third parties is not jeopardised. Evidence of the reprocessing must be kept.
- The manufacturer's instructions regarding the concentration, temperature, exposure time, etc. of the cleaning agents and disinfectants used for reprocessing must be observed.
- Excessive concentrations of chemicals can damage the instrument and make the laser or electrolytic labelling illegible**.**
- To prevent damage to the instruments, they should be reprocessed as soon as possible after use.
- Professional reprocessing of surgical instruments starts at the operating table.
- New and repaired instruments must pass through the complete reprocessing cycle before being put into operation!
- Instruments that show visible signs of damage must be discarded immediately and/or professionally repaired by the manufacturer.
- Damaged instruments can jeopardise the success of an operation!

Procedure for reprocessing surgical instruments

Preparation at the point of use

Immediately after use, remove coarse dirt from the instruments by immersing them in cold tap water (< 40°C). Do not use fixing agents or hot water (> 40°C), as this leads to the fixation of residues and can have a negative effect on the cleaning success. In addition, clogging of the cannula must be prevented by rinsing the cavities with a syringe.

Transport

The instruments must be stored in a closed and sufficiently dimensioned container for safe transport. This is to prevent any damage to the instrument.

A. Pre-cleaning

- Disassemble the instruments as far as possible and immerse the components in cold tap water for 10 minutes, ensuring that any lumens and cavities are filled with water.
- Scissors must not be dismantled for cleaning, disinfecting and sterilising.
- Thoroughly clean all components of the instruments individually under cold running tap water using a soft brush until all visible dirt has been removed.
- Then clean all hard-to-reach areas such as hinges, contact surfaces, internal lumens, cavities, drill holes and threads with a water gun (water jet gun, with a static water pressure).
  of > 2 bar) for at least 20 seconds.
- Repeat the process until all visible soiling has been removed.

For heavy soiling or incrustations, pre-cleaning in the US bath with the following parameters is recommended:

- Place the instruments in the metal sieve so that they do not touch each other.
- Completely immerse in a 0.8% Cidezyme solution.
- All cavities must be filled with the solution; if necessary, fill the lumens with a syringe.
- Clean for > 10 minutes at room temperature and 35 kHz.
- After ultrasonic pre-cleaning, the instruments are removed and the cavities, bores and threads are rinsed with cold tap water from the water gun for at least 20 seconds in pulse mode.

B. Manual cleaning

⚠ **Manual cleaning can only be recommended if automated reprocessing in the washer-disinfector is not possible or the instruments do not have joints, cavities, crevices and lumens that are difficult to access.**

- Place the instruments in the metal sieve so that they do not touch each other.
- Completely immerse in a 0.8% Cidezym/Enzol or Mucadont Zymaktiv cleaning solution.
- All lumens must be filled with the solution; if necessary, fill the lumens with a syringe.
- Clean at 45°C and 35 kHz for > 10 minutes.
- After ultrasonic cleaning, the instruments are removed and the cavities, bores and threads are rinsed with cold tap water from the water gun for at least 20 seconds in pulse mode.
- Finally, the instruments are rinsed with cold, demineralised water (demineralised water).

C. Manual disinfection

⚠ **Manual disinfection can only be recommended if automated reprocessing in the washer-disinfector is not possible, or the instruments do not have joints, cavities, crevices and lumens that are difficult to access.**

The instruments are completely immersed in a 4% Mucocit-T solution and left at room temperature between Disinfected for 5-10 minutes.

After removing the instruments from the disinfection bath, place them in deionised water and rinse thoroughly. After rinsing, dry and sterilise with moist heat.

D. Machine cleaning, thermal disinfection and drying

The automated processes were validated using a washer-disinfector, Miele brand, model 7836CD

Place the disassembled instruments in a sieve tray on the trolley. If possible, connect the instruments with lumen directly to the rinsing nozzles of the washer-disinfector using a hose.

Start the cleaning process with the following minimum settings:

1. Pre-clean for 2 minutes with cold tap water (16°C ±2°C)
2. emptying
3. 5 minutes cleaning at 55°C, dosage 0.5% MediClean forte with tap water
4. emptying
5. 3 minutes neutralisation with cold deionised water (20°C ±2°C)
6. emptying
7. Rinse for 2 minutes with cold deionised water (20°C ±2°C)
8. emptying

Settings for thermal disinfection

Start the automated thermal disinfection in accordance with the national requirements regarding the A0 value (see ISO 15883).

9. Rinse for 2 min with warm demineralised water (> 40°C)
10. heating up to disinfection temperature ≥ 93°C*
11. holding time at > 90°C* for ≥ 10 minutes

*The disinfection temperatures refer to the upper and lower switching points of the washer-disinfector thermostat.

Drying

12. The washer-disinfector programme must ensure a drying time of at least 20 minutes at a maximum of 93°C.
13. The instruments are removed from the washer-disinfector immediately after the drying time has elapsed.

Manual drying
If necessary, additional manual drying can be achieved
using a lint-free cloth. If necessary, dry cavities with sterile compressed air.

E. Care, functional testing and packaging

After the cleaning and disinfection process, the instruments are carefully visually inspected for cleanliness. If residual soiling can still be detected, the entire cleaning and disinfection process must be repeated until residue-free cleaning can be confirmed.

⚠ **If cleaning is not possible, the instrument must be discarded and excluded from further use. In this case, the instrument must be disposed of.**

The instruments and their components must then be checked for possible damage such as cracks, bent and loose or missing parts and then all components must be reassembled and the instrument checked for function.

Treat threads and hinges with an approved medical care oil. The oil used
(e.g. paraffins according to Ph. Eur.) must not influence the success of the subsequent sterilisation.

⚠ **Sort out and label defective instruments and exclude them from further use.**
Be aware of the risk of injury when handling sharp-edged or pointed instruments.

Packaging

Only standardised and approved packaging materials and systems may be used (EN 868 Part 2-10, ISO 11607 Part 1 + 2, DIN 58953).

The instruments must be packaged in such a way that damage to the sterile barrier can be ruled out.

⚠ **The instruments must not be reprocessed in the protective and transport packaging supplied.**

F. Service life

The service life of surgical instruments is only insignificantly influenced by the number of reprocessing cycles performed if they are carried out according to the validated procedures described here. Rather, it depends on the careful and careful handling of the instruments in all phases of use, reprocessing, transport and storage. The end of the service life is reached when the prescribed visual and functional inspection reveals signs of wear or defects that restrict the functionality of the product. In this case, the instruments must be labelled and excluded from further use and replaced with functional instruments. Furthermore, the end of the usage cycle is reached when the instruments can no longer be clearly identified due to the lack of labelling.

Instruments that show visible signs of damage must be discarded immediately and/or professionally repaired by the manufacturer.

Please note: If single-use instruments are reprocessed with reusable surgical instruments, the entire contents of the washer-disinfector or the entire surgical tray in the steam steriliser may rust. AMNOTEC International Medical GmbH accepts no liability for this.

⚠ **We generally recommend machine cleaning and thermal disinfection of surgical instruments prior to sterilisation with moist heat**.

G. Sterilisation with moist heat

The products are preferably sterilised using the fractionated pre-vacuum process with saturated steam
(in accordance with ISO 13060 / ISO 17665 or EN ISO 285), taking into account the respective national requirements.

- 3 pre-vacuum phases with at least 60 millibar pressure
- Heating to a sterilisation temperature of typically 134°C
- Holding time: typically 5 minutes
- Drying time: at least 10 minutes

The above specifications are recommendations of the RKI/KRINKO for sterilisation with moist heat. This information was verified for our surgical hand instruments with the study SMP No. 23616 at reduced settings.
(132°C, 4 minutes holding time).

⚠ **However, other regional and national regulations and directives may also apply.**

⚠ **With regard to the reprocessing of medical devices that are to be used on patients suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) or suspected cases of the disease, a special reprocessing procedure must be followed or the device must be disposed of immediately after use.**

Storage

The packaging manufacturer's storage conditions for maintaining an effective sterile barrier apply to the storage of sterilised instruments. The instruments themselves do not require any special storage conditions.

Repairs

Do not carry out repairs yourself. Service and repairs may only be carried out by appropriately trained and qualified persons. Contact the manufacturer or your medical technology department if you have any questions in this regard.

⚠ **Defective products must have undergone the entire reprocessing process before being returned for repair. Furthermore, the hygiene clearance certificate from AMNOTEC International Medical GmbH must be enclosed with every return.**
This can be found on our homepage (www.amnotec.de) in the download centre. If it is a reportable incident, you must report it using the following link https://www.amnotec.de/de/downloadcenter.

Waste disposal

No special measures are required regarding disposal. Observe the applicable local and national laws and regulations when disposing of the product.

Preparation validation, studies, information

The following materials and machines were used to validate the individual reprocessing steps. Information on this can be requested from the manufacturer.

Manual cleaning:
Cleaning agents: ASP: Cidezyme/Enzol
Merz Hygiene GmbH: Mucadont Zymaktiv

Ultrasonic bath: Bandelin Sonorex RK 1028H

Manual disinfection:
Disinfectant: Merz Hygiene GmbH: Mucocit-T

Machine cleaning:
Cleaning agent: Neodisher MediClean forte
(Chemische Fabrik Dr. Weigert GmbH & Co. KG, REF 405033)

Washer-disinfector: Miele 7836CD
Slide-in trolley: Miele E 327
MIC trolley: Miele E 429

Validation reports:
Manual cleaning: SMP No. 15812
Manual disinfection: SMP No. 26913
Machine cleaning: SMP No. 16016
Sterilisation: SMP No. 23616

⚠ **If the chemicals and machines described above are not available, it is the responsibility of the user to validate his process accordingly.**

It is the user's duty to ensure that the reprocessing process, including all necessary equipment, materials and personnel, is suitable to achieve the required results.

The state of the art and national laws require that these processes and the equipment they use are kept in a validated and maintained condition.

Explanation of symbols used

LOT	Batch designation of the medical device
REF	Order/catalogue number of the medical device
	Attention, safety instructions
	Follow the instructions for use
CE	CE mark for medical devices in risk class I
	Manufacturer
MD	Medical device

Disclaimer

AMNOTEC International Medical GmbH only delivers tested and faultless products to its customers. All our products are designed and manufactured to meet the highest quality standards. No liability is accepted for products that have been modified, misused or improperly handled or used compared to the original.

AMNOTEC International Medical GmbH accepts no liability for direct damage or consequential damage caused by improper use, handling or improper preparation, sterilisation and maintenance. Non-observance of the instructions, improper handling or improper use of the products supplied by AMNOTEC International Medical GmbH will result in the exclusion of any warranty claims. AMNOTEC International Medical GmbH cannot be held liable for any resulting damage.