MEDICAL INSTRUMENTS GMBH

User Instructions for Manual Surgical Instruments

User Instructions

General information

CE ⚠ **Warning, safety instructions!**

In purchasing this instrument, you have acquired a superior-quality product, and information on its correct handling and use is detailed below.
Please read and observe these user instructions carefully to minimise potential hazards for both patients and users in as far as possible.
Only skilled personnel who have been appropriately trained should be entrusted with use, disinfection, cleaning and sterilisation.

Please note that our instruments are delivered in an unsterilized condition and should be cleaned, disinfected and sterilised prior to initial use.

Scope:

These user instructions apply to all manual surgical instruments in Risk Class I / Annex IX Directive 93/42/EEC. These are assigned to one of the following product families, depending on the function:

1. Cutting instruments such as scissors, scalpels, sickle knives.
2. Severing instruments such as rongeurs, chisels, needles.
3. Dilating instruments such as specula, retractors, spatulas.
4. Holding and grasping instruments such as needle holders, hemostats and tissue clamps, forceps.
5. Scraping instruments such as curettes, raspatories, rasps, loops.
6. Probing instruments such as probes, cannulae, examining hooks, bougies.
7. Diagnostic instruments such as mirrors, tuning forks, stethoscopes.
8. Accessories such as attachments and adapters.

Please refer to our current product catalogue for detailed information on available sizes/variants and models.

Purpose / Indication:

Reusable surgical instruments are used for manual manipulation, handling and diagnosis of tissue during surgical interventions such as the following:

1. Cutting of tissue (cutting instruments)
2. Cutting out of tissue (severing instruments)
3. Restraining and spreading of tissue (dilating instruments)
4. Grasping and clamping of tissue, grasping aids (holding and grasping instruments)
5. Removal of tissue (scraping instruments)
6. Touching, feeling of tissue and anatomical structures (probing instruments)
7. Assessment of tissue and anatomical structures (diagnostic instruments)

⚠ *Surgical instruments are not intended for use in direct contact with the central nervous system or the correction of defects of the heart or central circulatory system!*

Contraindications:

Patients for which, in the opinion of the attending physician, a general operating risk exists, or where the instrument cannot be used for the patient without a risk.

The instrument is used exclusively by skilled medical personnel specially trained in the operating technique.

The attending physician is also responsible for ensuring that operating personnel and his or her staff have adequate knowledge in the handling of the instruments.

⚠ *Selection of a suitable surgical instrument is incumbent upon the experienced user.*

No other specific contraindications are known.

User and safety instructions:

Failure to observe these user and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

⚠ All types of reusable surgical instruments should be cleaned, disinfected and sterilised completely prior to initial use and any other use.

⚠ Instruments must be inspected prior to every use for correct function, visible damage and any evidence of wear (e.g. cracks, fractures, loose components and blunt cutting edges). The consistency of instruments with lumens must be assured prior to every use.

⚠ The packaging (incl. protective coverings) in which the instrument was delivered is unsuitable for conditioning (cleaning, disinfection and sterilisation) and prohibited. It should therefore be disposed of prior to initial conditioning and replaced with suitable containers or devices.

- Treatment and preparation of instruments should be realised as soon as possible after use to avoid damage to the instruments.
- Professional treatment and preparation of surgical instruments begins on the operating table.
- New and repaired instruments should pass through the complete treatment and preparation cycle prior to use!
- It is imperative that instruments exhibiting visible damage be withdrawn immediately and forwarded to the manufacturer for professional repair.
- Damaged instruments can jeopardise the success of an operation!

⚠ Do not overstress instruments at any time. Overstressing due to excessive application of force can cause breakage, bending and malfunctions in medical products and lead to injuries to the patient or user. Bent instruments should not be bent back into the initial position, as there is a risk of breakage. This is not only restricted to use, but also applies to the handling during conditioning, care, storage and transportation of instruments

⚠ Do not use a damaged or defective product. Withdraw the damaged product immediately, label and exclude from any further use.

⚠ Ensure that accessories and removable components are firmly fitted during the entire period of use of the product.

⚠ In the case of instruments with cutting edges, sharp edges and points, beware of any possible risk of injury, particularly when picking up or passing the instruments and during transportation and conditioning.

⚠ When using cutting edges or blades in the appropriate instrument, ensure that they are positioned correctly and firmly so that they cannot loosen during use.

⚠ Use only original accessories from Zepf Medical Instruments GmbH for the respective instruments. There is a risk of breach of warranty if accessories from other manufacturers are used which are not from or expressly recommended by Zepf Medical Instruments GmbH.

⚠ Manual surgical instruments are not suitable for combined use with laser systems, HF equipment or other processes and devices that generate energy. It is imperative that the instructions provided for these systems by the respective manufacturers be observed.

Use:

Manual surgical instruments are self-explanatory in their function. They are not designed for connection to active medical products and should only be used for the specified purpose. See also Purpose / Indication chapter.

Following use:

Surgical instruments should be conditioned immediately after use. Where this cannot be guaranteed, instruments must be laid in a cleaning solution to prevent them drying out and any lumens and cavities becoming blocked. A suitable mandrin should be used to prevent any blockages.

Handling of manual surgical instruments:

⚠ In the case of instruments with cutting edges, sharp edges and points, beware of any possible risk of injury.

All surgical instruments should in all cases be handled with extreme care during transportation, cleaning, care, sterilisation and storage. This applies in particular to fine micro instruments and instruments with delicate working ends.

Ensure that containers or devices used for the transportation, storage or conditioning of instruments are of an adequate size so that instruments are safely stored and protected against damage.

New instruments should undergo at least three machine cleaning cycles prior to initial sterilisation. This leads to the formation of a passivated layer on the surface that protects the instrument against discolouring and corrosion.

New instruments should be stored in indoor air without protective packaging in a closed cabinet / drawer. Ensure that pertinent hygienic regulations are adhered to in each case.

In the case of new instruments which are to be stored for a longer period of time, we recommend that they be removed from the sealed plastic bag and treated with a medical oil approved for sterilisation (e.g. paraffin conforming to Ph. Eur.).

General instructions for reconditioning:

- Responsibility for professional treatment and preparation lies with the operator of the respective central sterile supply department and his or her employees.
- The treatment and preparation of medical products which are to be used in a low-bacteria or sterile condition should be realised employing suitably validated procedures and taking manufacturer specifications into consideration in a manner that guarantees the verifiable success of the procedure and ensures that the safety and health of patients, users or third parties are not endangered. Evidence of compliance should be compiled of treatment and preparation.
- Manufacturer specifications regarding the concentration, temperature, exposure, etc. of respective cleaning and disinfecting agents should be adhered to during treatment and

preparation.
- Excessive concentrations of chemicals can lead to damage on instruments and contribute to rendering the laser or electrolytic labelling illegible**.**

Process for treatment and preparation of surgical instruments:

Recommendation:
Frequent reconditioning has a minor impact on surgical instruments. Product service life is normally determined by wear and damage caused by use.

Instruments exhibiting visible damage should be returned to the manufacturer for professional repair.

⚠ *In all cases, we recommend machine cleaning and thermal disinfection of surgical instruments prior to sterilisation with damp heat.*

Preparation at location of use:

Directly after use, coarse dirt should be removed from instruments by immersion in cold tap water (<40°C). Do not use any fixing detergents or hot water (>40°C), as this will lead to fixation of residue which may negatively influence the success of cleaning. Moreover, blocking of the cannula should be prevented through rinsing of the cavities with a syringe.

Transportation:

Instruments should be kept in a closed and adequately dimensioned container for safe transportation. This should prevent any damage to the instruments.

A. Preliminary cleaning:

- The instruments are disassembled in as far as possible and the components immersed in cold tap water for 10 minutes, ensuring that any lumens and cavities are filled with water.
- Using a soft brush, thoroughly clean all component parts of the instruments individually under flowing cold tap water until all visible impurities are removed.
- Subsequent to this, thoroughly rinse all positions difficult to access such as hinges, contact surfaces, internal lumens, cavities, bored holes and threads with the water pistol (water jet pistol with a static water pressure of >2 bar) for a minimum of 20 seconds.
- Repeat this process until all visible impurities have been removed.

In the case of severe dirt or caking, preliminary cleaning is recommended in a US bath with the following parameters:

- Place the instruments in the metal sieve so that they do not touch each other.
- Immerse completely in a 0.8% Cidezyme solution.
- All cavities should be filled with the solution (fill lumens with a syringe if necessary).
- Clean at room temperature and 35 KHz. for >10 min.
- Following preliminary ultrasound cleaning, the instruments are removed and cavities, bored holes and threads rinsed with cold tap water from a water pistol for a minimum of 20 seconds in pulse mode.

B. Manual cleaning:

⚠ *Manual cleaning can only be recommended if machine conditioning in a cleaning and disinfecting unit is impossible and/or instruments do not have joints, cavities, gaps and lumens that are difficult to access.*

- Place the instruments in the metal sieve so that they do not touch each other.
- Immerse completely in a 0.8% Cidezyme/Enzol or Mucadont Zymaktiv cleaning solution.
- All cavities should be filled with the solution (fill lumens with a syringe if necessary).
- Clean at 45°C and 35 KHz. for > 10 minutes.
- Following ultrasound cleaning, the instruments are removed and cavities, bored holes and threads rinsed with cold tap water from a water pistol for a minimum of 20 seconds in pulse mode.
- The instruments are finally rinsed with cold, demineralised water.

C. Manual disinfection:

⚠ *Manual disinfection can only be recommended if machine conditioning in a cleaning and disinfecting unit is impossible and/or instruments do not have joints, cavities, gaps and lumens that are difficult to access.*

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

After removal from the disinfection bath, lay the instruments in demineralised water and rinse thoroughly. Dry after rinsing and realise sterilisation with damp heat.

D. Machine cleaning, thermal disinfection and drying:

Machine processes were validated with a Miele cleaning and disinfecting unit, model 7836CD.

Place the instruments in a disassembled state into a mesh tray on the infeed carriage. Where possible, connect instruments with lumens directly to the rinsing nozzles of the cleaning and disinfecting unit using a tube. Start the cleaning process with the following minimum settings:

1. 2 min. preliminary cleaning with cold tap water (16 °C ±2 °C).
2. Drain
3. 5 min. cleaning at 55°C. Dispense 0.5% MediClean forte with tap water.
4. Drain
5. 3 min. neutralisation with cold demineralised water (20 °C ±2 °C).
6. Drain
7. 3 min. rinsing with cold demineralised water (20 °C ±2 °C).
8. Drain

Settings for thermal disinfection:

Realise machine thermal disinfection, taking national requirements regarding the A0 value into consideration (see ISO 15883).

9. 2 min. rinsing with warm demineralised water (>40°C)
10. Heat to disinfecting temperature >93°C*.
11. Holding time at >90°C* for ≥ 10 min.

*Disinfecting temperatures relate to the upper and lower switching points of the cleaning and disinfecting unit thermostat

Drying:

12. The cleaning and disinfecting unit program should assure a drying duration of at least 20 minutes at max. 93°C.
13. Following expiry of the drying duration, the instruments are immediately taken out of the cleaning and disinfecting unit.

Manual drying:
If necessary, additional manual drying can be accomplished with the aid of a lint-free cloth. Dry cavities if necessary with sterile compressed air.

E. Care, functional testing and packaging:

A careful visual inspection of the instruments for cleanliness is conducted following the cleaning and disinfecting process. If residual impurities are identifiable, the entire cleaning and disinfecting process should be repeated until residue-free cleaning can be confirmed.

⚠ *If cleaning is not possible, the instrument should be withdrawn and excluded from further use. The instrument should be disposed of in this case.*

The instruments and their component parts should then be inspected for possible damage such as cracks and concealed, loose or missing parts. Reassemble all component parts subsequent to this and check the function of the instrument.

Treat threads and hinges with an approved medical maintenance oil. The oil used (e.g. paraffin conforming to Ph. Eur.) should not affect subsequent sterilisation.

⚠ *Withdraw defective instruments, label them and exclude from any further use. Beware of risk of injury when handling sharp-edged or pointed instruments.*

Packaging:

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

The instruments should be packaged in a manner that excludes the possibility of damage to the sterile barrier.

⚠ *Instruments should not be conditioned in the protective and transportation packaging sent with the delivery.*

F. Sterilisation with damp heat:

Sterilisation of products is preferably realised using the fractionated pre-vacuum method (pursuant to ISO 13060 / ISO 17665 and EN ISO 285) while taking respective national requirements into consideration.

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

The above specifications are recommendations of RKI/KRINKO for sterilisation with damp heat. These specifications were validated for our manual surgical instruments with the SMP No.23616 study at reduced settings (132°C, 4 min. holding time.

⚠ *Other regional and national regulations and directives may apply.*

⚠ *With regard to the treatment and preparation of medical products, a separate conditioning process should be employed in the case of patients suffering or suspected of suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), or the instrument should be disposed of immediately after use.*

Storage:
The storage conditions of the packaging manufacturer for maintaining an effective sterile barrier apply when it comes to the storage of sterilised instruments. The instruments themselves do not require any special storage conditions.

Repairs:
Do not carry out unilateral repairs. Servicing and repairs should only be realised by suitably trained and qualified personnel. Please contact the manufacturer or your medical technology department should you have any questions in this respect.

⚠ *Defective products should undergo the entire reconditioning process prior to being returned for repair. Moreover, a Hygiene Clearance Certificate from Zepf Medical Instruments GmbH should be included in each return delivery.*

This can be found in the service section on our website (www.zepf-medical-instruments.de). Where incidents which must be reported are involved, these must be reported without delay at the link https://www.zepf-medical-instruments.de/German:Meldeformular.asp.

Disposal:
No special measures are necessary with regard to disposal. Observe respectively applicable national or international laws and regulations during disposal.

Treatment validation, studies, information:
The following materials and machinery were used to validate individual treatment steps. Information in this respect can be obtained from the manufacturer.

Manual cleaning:

Cleaning agent:	ASP: Cidezyme/Enzol Merz Hygiene GmbH: Mucadont Zymaktiv
Ultrasound 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)
Cleaning/ Disinfecting unit:	Miele 7836CD
Infeed carriage;	Miele E 327
MIC carriage	Miele E 429

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

⚠ *It is the responsibility of the user to validate its process appropriately if the previously described chemicals and machinery are not available.*

It is the obligation of the user to ensure that the reconditioning process and all necessary operating media, material and personnel are suitable for achieving the required results.

The technological state of the art and national laws demand that these processes and the operating media used are kept in a validated and maintained condition.

Explanation of symbols used:

LOT	Batch designation of the medical product
REF	Order/catalogue number of the medical product
⚠	Warning, safety instructions
📖	Observe user instructions
CE	CE marking for Risk Class I medical products
🏭	Manufacturer
②	Instruments for single use only

Disclaimer:

Zepf Medical Instruments GmbH only delivers tested and flawless products to its customers. All our products are designed and manufactured to meet the highest quality standards. Any liability for products which have been modified from the original, misused or incorrectly conditioned or employed is excluded.

ZEPF MEDICAL Instruments GmbH assumes no liability for direct or consequential damage caused by improper use, handling or incorrect conditioning, sterilisation and maintenance. Failure to heed instructions, incorrect handling or incorrect use of products supplied by ZEPF MEDICAL Instruments GmbH shall result in the exclusion of all warranty claims. ZEPF MEDICAL Instruments GmbH cannot be held responsible for damage resulting from the above.

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