Aufbereitungsanweisung / user manual

für wiederverwendbare chirurgische Instrumente / *for reusable surgical instruments*

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1. Manufacturer

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2. Field of application: ASANUS reusable surgical instruments, class I

This processing instruction also applies to product variants which are
- provided with a finishing layer,
- tagged with a RFID-Chip.

Excluded are products that
- are connected to active devices,
- are operated with energy by themselves,
- consist entirely of non-metallic material.

3. Basics

These instruction guide can't replace the training, carefulness and the user's knowledge of technology. We therefore assume that the respective legal rules, standards and recommendations (e.g. those of the RKI or also of the AKI) are known (see 25. Norm references).

Read this instruction very carefully before you prepare and employ the product for the first time! Keep this manual for further information.

4. Intended use and indication

Instruments may only be used, processed and disposed by adequately qualified medical staff.

Surgical instruments serve as standard instruments for surgical interventions in general surgery. The instruments may only be used by adequately qualified medical staff for the intended use in the medical specialties.
The attending doctor or rather the user is responsible for the selection of instruments for certain utilization and accordingly to the surgical use, the adequate training and information and the sufficient experience for the handling with the instruments.
Duration of treatment: temporary (< 60 min. under normal conditions) according to Medical Device Directive 93/42/EEC.

5. Contraindications

- CJD - Creutzfeldt-Jakob-Disease
- BSE - bovine spongiform encephalopathy
- TSE - transmissible spongiform encephalopathy

The instruments have not been validated for appropriate procedures for the destruction of prions.

After the instrument's utilization on patients with Creutzfeldt-Jacob disease (CJD) or its variations we refuse all responsibility for reutilization! We recommend destroying the instruments. A reprocessing and reuse also according to the RKI guideline takes place completely on own responsibility!

The application is contraindicated for purposes other than those specified.
Risks:
- Injuries of nerves, vessels, tissue
- Bleedings
- Infections
- Thrombosis
- Pulmonary embolism

Generally, complications occur rarely. The frequency and severity of complications depend on the type of examination.

6. Restrictions

Frequent reprocessing has little impacts on the lifetime, which is determined by insufficient cleaning, abrasion, damage and misuse.

7. Warning notices

After receipt of the products, please check the identity, completeness, intactness and functioning before preparing them for processing.

It's necessary to inspect the instruments for breakage, cracks, deformation, damage, noncorrupted surface and functioning before every application. Thereby you particularly have to check parts such as cutting edges, tips, points, ratchets, snaps, locking devices as well as all movable parts. . In case of a detachable instrument, check the screw or button which secures the instrument to prevent loss of parts during use.

Instruments that are fully worn, corroded, deformed, porous or otherwise destroyed have to be rejected. Use of these instruments is not permitted.

The instruments are generally delivered non-sterile! Before initial use and before all further use, the instruments must be prepared according to our care and cleaning instruction!

For all instruments, in particular for scissors, punches, retractors and fixation clamps, a mechanical and optical inspection must always be carried out. Prior to each use, inspect the medical device for damages, loose, bent, broken, cracked, worn or fractioned components. Do not leverage or twist the instruments during use. Instruments with a cutting width <3mm may only be used for cutting soft tissue or small bone structures. Do not cut bony cortex with these filigree instruments!

Particularly at handling, sterilizing, maintenance and packaging of fine surgical instruments (micro instruments), it has to be payed attention to a carefully and gentle handling. It persists a danger of linking of the hooks' ends into the netting of the wire baskets, as well as deforming and breaking of the tips ends. It's necessary to inspect the instruments for breakage, cracks, deformation, and damage before every application. Sort out damaged or defect instruments.

Dried or adherent biological material complicates the cleaning success and leads to corrosions if not removed completely. At temperatures above 45 ° C and when treated with aldehyde- or alcohol-based cleaners, biological material coagulates. Excessive use of neutral or basic cleaners can lead to unwanted chemical reactions with damage to the laser marking.

Deposits of chlorine and choride from drugs, saline solutions or wash water from cleaning processes can lead to corrosions such as pitting or stress corrosion and lead to the damage of ceramic coatings that make the instruments unusable. To avoid these risks, rinse instruments thoroughly with demineralised water and dry completely.

For safe use and processing, all points listed in this manual must be observed. Non-observance may result in injury and/or malfunction.

8. Combination with other products

If instruments are put together again after their disassembling, the separate parts must not be replaced by parts of other manufacturers, even if a part is exchangeable because of the product's specific function (e.g. different work iserts)! We recommend ordering miscellaneous accessories, e.g. instrument oil as well at ASANUS Medizintechnik GmbH.

9. Materials

Only steel according to DIN EN ISO 7153-1 for medical instruments is used.

10. Material durability

Cleaning and disinfecting agents must not contain the following components:
- organic, mineral, and oxidising acids
- powerful leaches (> pH 12,5)
- halogenated hydrocarbons, chlorine, iodine
- organic solvents like alcohol, acetone etc.
- ammoniac

11. Disposal and return consignments

Before being sent to ASANUS Medizintechnik GmbH for repair or return shipment, the instruments must be prepared and cleaned according to this user manual and safely packed. The acceptance of repairs and returned shipments can only be performed with the proper forms for returning. After a successful disinfection, defect or out-of-date instruments must be disposed professionally or returned to a recycling system.
To avoid damages, which may occur during transportation, please take care that the instruments are sent back in their original or in a comparable packaging with sufficient air bubble plastic. In case of damage, which occurred due to inappropriate packaging we have to transfer the costs to you.

12. Warranty

The responsibility for the instruments appropriate cleaning, disinfection and sterilization lies with the user.

National regulations, including restrictions, must be observed.

ASANUS Medizintechnik GmbH excludes any warranty claims and assumes no liability for direct or consequential damages which result from use for purposes other than intended, inappropriate use, employment, or handling, inappropriate treatment and sterilization, inappropriate maintenance and repairs and disregard of this instruction sheet. Repairs may only be made by companies or persons who are authorized by ASANUS Medizintechnik GmbH. In case of disregard any warranty will be excluded.

13. General basics for hygiene and processing

This manual describes a manual and an automatic cleaning method (with a cleaning and disinfecting machine). Where possible, the automated cleaning process is preferable because it provides more reproducible and reliable results. In addition, the extent of contact between the staff and contaminated products and cleaning agents can so be clearly limited. Brand-new instruments and instruments of repair returns have to be processed before their first utilisation just as used instruments. The transport protective package, protection caps, etc. are inapplicable for sterilization. Only approved agents (RKI, DGHM/VHA, FDA, etc.) may be used.

The personnel responsible for processing must be familiar with the requirements referenced under point 25. Whichever cleaning method is used, staff should use suitable protective clothing and equipment at all time.

Attention! Don't use alkaline cleaners >pH 7 for aluminium containing products.

Ceramic coated instruments must not be treated with oxidative cleaning processes such as Miele Orthovario and Oxivario processes or H_2O_2.
- Water quality according to DIN EN 285 annex B
- Sterilizers according to DIN EN 285 or DIN EN 13060
- Cleaning and disinfection machines according to DIN EN ISO 15883 part 1 & 2
- Only processes which are sufficiently device- and product specifically validated may be used for cleaning/disinfection/ sterilization.
- Observe your country's effective legal and hygienic rules, in particular for the different specifications concerning an effective inactivation of prions.

14. Transport

Storing and transport to the place of treatment have to take place in a closed container in order to avoid instrument damage and environmental contamination. Different kinds of steel should be separated to avoid galvanic reactions.

15. Preparation and pre-cleaning at the place of use

Residues caused by the usage have to be removed immediately!
- Brush, operate moving parts.
- Don't use metal brushes or steel wool!
- Soak instruments completely in cleaning solution.
- DO NOT put the instruments into common saline solution!
- Disassemble instruments as much as possible for cleaning.
- Ensure that the cleaning solution reaches all parts of cannulations etc., using a syringe.
- Machine cleaning and disinfection is only suitable for instruments with long or thin cannulations if the hot disinfection solution can actually flow through them and the entire length of the cannulation is cleaned at least three times with a bottle brush.
- Pay attention to proper handling and storage!
- Pre-cleaning in an ultrasonic bath is recommended.

16. Manual cleaning and disinfection

Only permitted in case of non-availability of a machine procedure and in exceptional cases. However, additional product and process-specific validation is then required under the responsibility of the user.
- Do not use metal brushes or steel wool!
- Narrow-lumened instruments and parts especially carefully clean!
- Use syringes to ensure that all parts of the cannulation are reached by the cleaning agent. Rinse all cannula with a bottle brush at least 3 x through to the entire length.
- Move instruments with joints and moving parts back and forth.
- The exposure times specified by the detergent manufacturer must be observed!
- Clean bone cutting instruments with a hard brush.
- Rinse instruments for at least 1 minute under running water until all traces of cleaning solution and other residues are removed.
- Pay attention to proper handling and storage!

Disinfection:
- For the disinfection, a sufficiently large bath is required the instrument can be completely immersed into.
- Prepare a bath of disinfectant according to the temperature and concentration data of the cleaning agent manufacturer and completely immerse the instrument for the specified period of use.
- Recommended exposure time at least 10 minutes
- Rinse the cannula at least 3 x with a syringe
- Rinse with clear running water for at least 1 minute. Demineralized water is recommended in the last rinse cycle.
- Dry the instruments either with medical compressed air, with clean lint-free cloths approved for single use, or in an oven below 110 °C.
- Check the instruments visually and, if necessary, repeat the cleaning process.

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17. Manual ultrasonic cleaning

Please pay attention to the instructions of the manufacturer of the cleaning and disinfection agents!

The used cleaning and disinfection agents must be suitable for the cleaning of steel-, titanium- and aluminium products.

- Maximum temperature: 50 °C / 122 °F
- Frequency: 35 - 45 kHz
- Time of cleaning: 4 - 5 minutes
- Put in instruments with opened joint
- Arrange instruments with lumen filled free of air bubbles and according to the sound!
- Instruments must be covered completely with the cleaning solution.
- After the ultrasonic cleaning, the instruments have to be flushed for at least 20 sec. with clear running water. Demineralized water is recommended in the last rinse cycle. Afterwards the instruments have to be dried.

18. Mechanical cleaning - thermal disinfection

After carrying out the pre-cleaning options described under 15. and 17., it is preferable to use mechanical cleaning / thermal disinfection in a washer/disinfector!

- Hinged and box-lock instruments must be loaded and cleaned in open position.
- Disinfecting requirement for semi critical medical devices/instruments: A_0=3000
- Disinfecting requirements for uncritical medical devices: A_0=600
- Place cannulas and suction tubes on suitable suction connections of the washer/disinfector for flushing in order to achieve perfect cleaning and disinfection.
- Put the MIC instruments disassembled on the MIC-trolley's inserts. Instruments that can't be inserted put openly into a tray on the MIC-trolley's.
- Start cleaning process
- Pre-rinse with cold water!

Description of validated cleaning process Vario TD:

- 1 min. pre-cleaning with cold water / emptying
- 3 min. pre-cleaning with cold water / emptying
- 5 min. cleaning with 0,5% alkaline/enzymatic cleaner at 55 °C / 131°F emptying
- 3 min. neutralize with warm water > 40° C/ 104 °F / emptying
- 2 min. intermediate rinse with warm water > 40 °C / 104 °F / emptying

Cleaning of stainless steel instruments and instruments with a high-tec surface:

- Alkaline up to pH 12,5 - cleaning time 10 minutes at 55 °C/ 131°F

Cleaning of titanium and endoscopic instruments:

- Mild alkaline/enzymatical cleaning up to pH 10,5 – cleaning time 10 minutes at 55 °C / 131 °F

Cleaning of instruments with RFID-Chip-System:

- Alkaline up to pH 12,5 - cleaning time 10 minutes at 55 °C /131 °F
  e.g. Neodisher MediClean Forte and Neodisher MediKlar.

Thermo-disinfection:

Thermo-disinfection is effected at temperatures of 80-95 °C (176-203 °F) and corresponding exposure time following the A_0-concept and EN ISO 15883.

Please also pay attention to the cleaning instructions according to the specifications of your cleaning agents manufacturer.

19. Control and maintenance

- Instruments have to be cooled down on room temperature!
- Inspect the instruments under a lighted magnifying glass.
- Joints, springs, bores and lumens must be inspected with special care.
- In case of residual contamination, the cleaning process must be repeated.
- Instruments must be reassembled prior to functional testing and sterilization.
- Maintain joints, threads and sliding surfaces with oil spray after cleaning and disinfection but before the function tests and sterilization.
- Use other care products (paraffin/white oil basic and free of silicone) only if they're approved for/to steam pressure sterilization and biocompatible.
- Locks must be checked.
- Cutting edges must not have any nicks. Surfaces must be smooth and level.
- Cutting and moving parts must be considered separately.
- Opposing cutting edges must close perfectly over their total length and width.
- Damaged instruments which do not fulfill these requirements must be sorted out for repairing or replacing, please see also point 11.

20. Packaging

Packages according to DIN EN 868 can be used. Chose the package so that the instruments fit in well. Use a sterilization indicator for the package and note the dates of sterilization and expiry.

21. Sterilization

Before sterilization, carry out manual pre-cleaning, machine cleaning, drying, inspection and maintenance and packaging!
To avoid the formation of stains and corrosion, the steam must be clean and must not contain any ingredients.

- Steam-sterilizer corresponding to DIN EN 13060 or DIN EN 285
- Steam sterilization with fractionated pre-vacuum according to DIN EN ISO 17665-1
- Other sterilization methods and the flash sterilization method are not permitted.

Validated procedure under worst-case parameters:
Pre-vacuum-phases: 3
Sterilization temperature: 132 °C / 270°F
Holding time: 3 minutes
Drying time: 1 minute

22. Storing

Dry, dustproof, without action of force from outside, without major temperature variation and not in close proximity to aggressive media, expedient in trays, containers, cupboards.

23. Confirmation – notices

The user is responsible that the realised processing with used equipment, materials and personnel in the treatment institute achieves the desired results.
In case of deviations from the stated, validated process parameters or if the said devices or cleaning agents are not available, it is the duty of the user to validate his reprocessing process himself.
This reprocessing instruction does not release the user from regularly validating his reprocessing process in accordance with national regulations, to ensure that the process is valid.

If the delivered instruments are split, there always has to be an instruction at every area of use/department.

This processing instruction can also be downloaded on **www.asanus.de**.

24. References for instruments with RFID-Chip

When the ARIS RFID system is tagged to external instruments, the manufacturer 's instructions for use remain unaffected and have to be considered.

The durability of the adhesive bond is critically dependent on the cleaning agents used and the machines.
Therefore, ASANUS Medizintechnik GmbH recommends a local validation of the processing with tagged sample instruments. Due to this a guarantee regarding the durability can't be given.
ASANUS Medizintechnik GmbH recommends inspecting the adhesive bond for cracks and crevices under a magnifying glass after each reprocessing process. Instruments that show cracks or crevices may be susceptible to inadequate cleaning. These instruments are new to be tagged. Furthermore, after each use, make sure that the chip is still properly attached to the instrument.

25. Norm references

- AKI-guide "Instrument Reprocessing" (Red Brochure)
- RKI-recommendation "hygiene requirements at the reprocessing of medical devices"
- DIN EN 285 large steam sterilizer
- DIN EN 868 packaging materials
  DIN EN ISO 11607 Packaging for terminally sterilized medical devices
- DIN EN 13060 small steam sterilizer
- DIN EN ISO 15883-1-3 Washer-disinfectors
- DIN EN ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer
- DIN EN ISO 17665-1 sterilization of health care products – moist heat - part 1
  DIN EN ISO 58953 ff. Sterilization – sterile supply

26. Information about used equipment and cleaning agents

The validation was carried out with the following equipment, cleaning agents and packaging materials:

Worst-case parameters:

Disinfection agents:
4% Mucocit-T, Merz Hygiene GmbH or
2% Bomix plus, Bode Chemie

Cleaning agents for manual cleaning process:
Enzymatic detergent: 0,8% Cidezyme/Enzol, ASP
0,8% Mucadont Zymaktiv, Merz

Cleaning agents for automatic cleaning process:
Enzymatic detergent: 0.5% Endozime, Ruhof, USA
Alkaline detergent: 0.5% Neodisher FA,
Fa. Dr. Weigert, Germany

Equipment:
Disinfector: G 7735 CD Miele: Disinfection program Vario TD
Autoclave: Selectomat HP666-1HR (MMM), loading capacity: 4 StU
Ultrasonic: Bandelin Sonorex RK 1028H, GR37

Sealing device: Hawo

Sterilization pouches: double, sterilization pouches Steriking flat rolls Type R43 und R44, Wipak

27. Labeling

REF	item number
LOT	batch number
	manufacturer
	manufacturing date
	refer to instruction for use
	Attention!
	non-sterile product
	latex-free
CE	European CE
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician