ELCON MEDICAL INSTRUMENTS GMBH

INSTRUCTION MANUAL for surgical instruments

	**Please observe instruction manual**		

Field of application

Instruments for use in various surgical fields

Safe handling and preparation

- All instruments of *ELCON Medical Instruments GmbH* are delivered unsterile and have to be cleaned, disinfected and sterilized before application by the user. Exception: All instruments marked „sterile“.
- Instruments that are intended for single use may not be treated for reuse.
- The user shall make himself familiar with the instrument and its functions before use.
- Instruction manuals delivered by *ELCON Medical Instruments GmbH* must be read, adhered to and preserved.
- Instruments are always to be used according to their intended use.
- New or unused instruments have to be stored at a dry, clean and protected place.
- The instruments have to be checked before each use for their usability and functionality. Especially areas as well as functions concerning surface, measuring, compatibility, form, blades, tips, joints, locks, ratchets and moveable components should be checked carefully for malfunction.
- Do not use damaged instruments. Do not carry out repairs by yourself. Service and repair should only be carried out by accordingly qualified personnel.
- Do replace damaged parts only by original replacement parts.

Validated reconditioning

Note

- Applicable national legal regulations and norms of treatment have to be adhered to.
- In case of patients with Creutzfeldt-Jakob-disease (CJD), suspects of CJD disease or possible variants the respective valid national regulations concerning treatment of the products have to be adhered to.
- Pure manual cleaning – even if it includes the use of an ultra sonic bath – should only be made if no machine-based cleaning method is available, due to the significantly lower effectiveness and reproducibility.
- The successful reconditioning of this medical product can only be ensured after duly validating in the treatment process. This is under the responsibility of the user/treatment personnel. Due to process tolerances, the indications of the manufacturer are only to be seen as guidelines for the reconditioning processes actually available at the user.
- Further current information on treatment may also be found at www.a-k-i.org

Instrument treatment

General information

Dried or fixed operational residues may make cleaning difficult or ineffective and may lead to corrosion of the stainless steel. This is why not more than 6 hours should lie between the use of the instrument and its treatment. Furthermore it should not be exposed to temperatures of more than 45°C before cleaning, because this may fix residues, and no fixing disinfectants should be used (active agents: aldehyde, alcohol).
If neutralizers or basic cleaning agents are overdosed, the stainless steel may be chemically affected or markings fade.
Chlorine or chloride residues as e.g. contained in operational residues, tinctures, medicines, saline fluids, tap water for cleaning, cleaning/disinfectant agents, may lead to corrosion of the stainless steel (pitting and stress corrosion) and thus damage of the products. To remove these layers, the instruments have to be thoroughly rinsed with fully demineralized water and afterwards be dried.
Only process chemicals recommended by the manufacturer of the chemicals for their cleaning and disinfection effect as well as compatibility to the material may be used. Any application specifications as e.g. concerning temperatures, concentration, treatment times etc. are to be strictly adhered to. Otherwise this may lead to the following problems:

Visual material transformation as e.g. fading or changes in colour of titanium or aluminium. Aluminium surfaces may visibly change already at a pH value of >8 in the application-/user solution or material damage as e.g. corrosion, cracks, breaking, premature aging or swelling may occur. You may find further details for hygienically safe and material preserving/value preserving reconditioning at www.a-k-i.org - Red Brochure - „Proper maintenance of instruments“.

Preparation before cleaning

- Pre-clean instruments, if necessary.
- Recondition the instruments immediately after use.

- Use appropriate cleaning and disinfectant agents when using wet disposal. Rinse the product thoroughly with running water before machine-based cleaning and disinfection.
- Rinse instruments with lumen by means of a single use syringe (minimum volume 50ml) five times.
- If necessary, clean the product with ultrasound – see cleaning/disinfection.

Wet disposal
When using wet disposal, it is advisable to immerse the instruments in a combined detergent-disinfectant solution that has no protein-fixing effect. Disinfecting agents containing aldehyde should be avoided, because they have a fixing effect.

Dry disposal
In hospitals with central Sterile Supply Department (CSSD) closed systems are used to transport contaminated medical devices from the operating theatres and wards to the CSSD. Wherever possible, so-called "dry disposal" should be preferred.

Waiting times
With both modes of disposal long waiting times until treatment, e.g. overnight or a weekend, have to be avoided, due to danger of corrosion and for better cleanability. Experience shows that with dry disposal waiting times of up to 6 hours do not present any problem.

1. Cleaning/disinfection

Product may be damaged due to improper cleaning/disinfection agent and/or excessive temperatures!
Cleaning and disinfectant agents have to be authorized for surgical steel and be used according to the prescriptions of the manufacturer.
Observe indications concerning concentration, temperature and exposure.
Maximum admissible cleaning temperature of 55°C must not be exceeded.

Ultrasound cleaning

Perform ultrasound cleaning:
- as effective mechanical support (recommended frequency 35 kHz) to the manual cleaning/disinfection.
- for pre-cleaning of products with dried-on residue before machine-based cleaning/disinfection. With 0,5% Neodisher Mediclean Forte for 10min
- as integrated mechanical support of machine-based cleaning/disinfection.
- for post-cleaning of products when residues have not been removed during machine-based cleaning/disinfection.

If micro-surgical products can be fixed safely and adequate for cleaning in machines or storing supports, they should be cleaned and disinfected machine-based.

2. Manual cleaning/disinfection

Phase	Step	T [°C/°F]	T [min]	Conc. [%]	Water quality	Chemicals
I	Pre-cleaning	RT	10-30	5-20ml/l	VE-W	neodisher® LM 2
II	Disinfecting cleaning	RT (cold)	15[1]	3,0[1]	T-W (preferably VE-W)	neodisher® Septo MED [1]bactericidal/fungicidal [2]limited virucidal (incl. HIV, HBV, HCV)
			30[1]	2,0[1]		
			60[1]	1,0[1]		
			5[2]	0,75[2]		
III	Intermediate rinsing	RT	-	-	T-W	-
IV	Final rinsing	RT	-	-	VE-W	-
V	Drying	RT	-	-	-	-

T-W: potable water
VE-W: fully demineralized water
RT: room temperature

After manual cleaning/disinfection visible surfaces have to be checked for residues. If necessary, the cleaning process has to be repeated.

Phase I
- Pre-cleaning of the instruments approx. 10 - 30 min in immersing- or ultrasound basin with the adequate cleaning agent.

Phase II
- No metal brushes or other, surface damaging scouring agents may be used – danger of corrosion!
- Instruments have to be disassembled and opened as far as possible. All surfaces must be completely wetted with the disinfecting agent solution. Air bubbles should be removed.
- Instruments must be cleaned with an appropriate cleaning brush until no more residues are visible on the surface.

- Non-visible surfaces, as e.g. at instruments with covered gaps, lumen or complex geometries have to be brushed at least 5 minutes or until no more residues can be removed. Mobile components such as fixing screws, joints, etc. must be moved during cleaning.

Phase III

- After expiration of the exposure time the instruments have to be rinsed/flushed thoroughly and completely (all accessible surfaces) with potable water at least (preferably fully demineralized water).

Phase IV

- Instruments have to be completely rinsed/flushed with fully demineralized running water (any accessible surfaces).
- The remaining water must drip off sufficiently.

Phase V

- Instruments must be completely dried by means of compressed air.

3. Machine-based cleaning/disinfection with manual pre-cleaning

Phase	Step	T [°C/°F]	T [min]	Water quality	Chemicals
I	Pre-cleaning	cold	1	-	-
II	Cleaning	55°C ± 5°C	5	VE-W	neodisher® MediClean forte (0,5%)
(III)	(Neutralization may be omitted when using neodisher® MediClean forte)	-	-	-	neodisher® Z
IV	Intermediate rinsing	RT	1	VE-W	-
V	Thermal disinfection	> 90°C	5		
VI	Post-rinsing	90°	5	VE-W	-
VII	Drying	60°C ± 5°C	30	-	-

T-W: potable water
VE-W: fully demineralized water

- Instruments have to be deposited on cleaning-appropriate wire-mesh baskets (avoid spots difficult to reach by rinsing). Products with joints have to be deposited with open joints.
- The use of fully demineralized water for cleaning as well as in the final test is recommended. The neutralization, which is necessary with classical, alkaline detergents, may be left out here..
- The application solution mentioned above has to be rinsed off completely with water (preferably fully demineralized).
- Visible surfaces have to be checked for residues after the machine-based cleaning/disinfection.
- If necessary, the cleaning process must be repeated.

Control, care and testing

- Instruments must cool down to ambient temperature.
- Instruments have to be checked after every cleaning and disinfection for: cleanliness, function and damage, e.g. isolation or loose, bent, broken, split, worn-out and dismantled parts.
- Compatibility with the related instrument set has to be checked.
- Damaged instruments have to be immediately rejected.

Packing

- Instruments with fine working tips have to be adequately protected.
- Instruments have to be sorted in the related stock or deposited on appropriate wire-mesh baskets. It has to be ensured that – where applicable – blades are protected.
- Wire-mesh baskets must be packed appropriate to the sterilization method (Ensure that the packing prevents recontamination of the product between treatment and reuse).

4. Sterilization

- Norm-adhering packing of the instruments for sterilization in sterile bags according to ISO 11607-1. Any deviation from the recommended packing must be validated.
- Ensure that the sterilising agent can reach all outer and inner surfaces (e.g. by opening valves and taps).
- Validated sterilization method

- Steam sterilization by fractionated vacuum method (3 vacuum phases)
- Steam sterilizer according to EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST 46-1993 and validated according to EN 554/ISO 13683
- Sterilization by fractionated vacuum method at temperatures of 132°C to 137°C / Exposure time 5min / Drying time 10min
- On simultaneous sterilization of several products in a steam sterilizer: It has to be ensured, that the maximum admissible charge of the steam sterilizer, according to the indications of the manufacturer, is not exceeded.

5. Storage

- Reconditioned instruments must be stored in germ-proof packing and dust-protected in a dry, dark room with constant temperature.

6. Disposal

- Surgical instruments have to be disposed of professionally.

The treatment indications are NOT APPLICABLE to the following products:

Item-No.	Product
367-591 to 367-533T **367-7211 to 367-7291T** **367-8211 to 367-8291T**	Yasargil aneurysm applying forceps with tube shaft (not detachable, without irrigation port)
482-1100-28 to 482-3414-23 **443-000 to 444-9999** **432-800 to 432-949**	laryngeal forceps with tube shaft (not detachable, without irrigation port) endo-laryngeal micro-surgical instruments with tube shaft (not detachable, without irrigation port), bronchoscopy instruments with tube shaft (not detachable, without irrigation port), antrum punches with tube shaft (not detachable, without irrigation port), micro ear forceps with tube shaft (not detachable, without irrigation port), nasal forceps with tube shaft (not detachable, without irrigation port), nasal scissors with tube shaft (not detachable, without irrigation port)
	rectal biopsy forceps with tube shaft (not detachable, without irrigation port)
	bone implants
412-500 to 412-549	chucks (three-jaw-chuck)
550-000 to 555-006	oscillating electrical autopsy saws
400-450 to 400-453; **400-490 to 400-492**	oscillating electrical plaster saws
426-6000 bis 426-6084A	flexible medullary reamers, cannulated
412-300 bis 412-307-110	micro motor systems, micro pressure motor systems, accumulation and pressurized air motor systems
412-310 bis 412-395-64	chucks (three-jaw-chucks, rapid chucks, inserts)
230-01-000 bis 230-86-030	arthroscopes, otoscopes, sinuscopes, naso-pharyngo-laryngo-fiber optics, laryngoscopes, bronchoscopes, laparoscopes, cystoscopes, hysteroscopes (optics)
370-2100 bis 370-2983	arthroscopy punches with tube shaft mit Rohrschaft (not detachable, without irrigation port)

For these products the user has to perform his own validations concerning reconditioning.

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