English

Operating instructions

CE NON STERILE Rx only MD

medicon®
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

Rev.: 12-05-2021

Invasive and non-invasive medical devices

Carefully read the operating instructions and processing instructions prior to clinical application and keep them safe and at hand.

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1 General instructions for safe handling

– The medical devices are reusable, are supplied non-sterile and, for this reason, must be cleaned, disinfected and sterilised according to the instructions in section 'Processing' prior to their first use.

– The reusable medical devices are made of stainless materials approved for medical technology. The materials are corrosion-resistant and have excellent properties in a biological environment.

– Only allow the product and accessories to be operated and used by persons who have the necessary training, knowledge or experience with regard to application, function check and cleaning/sterilisation.
– The user as well as the relevant qualified personnel undertake to familiarise themselves with the products before their use.
– Read and observe the operating instructions.
– Only use the product as intended (see "Intended purpose").
– Clean brand-new product after removing the transport packaging and before the first sterilisation.
– Store brand-new or unused product in a dry, clean and protected location.
– Before each use, qualified personnel must:
  o visually check the product for loose, loose, bent, broken, cracked, worn and broken off parts.
  o check the product for proper function.
– Do not use a damaged or defective product. Immediately sort out damaged products or send them to the service centre specified in these operating instructions.
– Replace damaged parts immediately with original spare parts.
– All medical devices that can be disassembled must be disassembled for processing and sterilisation.
– In patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants, the relevant national provisions regarding processing must be followed and complied with.
– All serious incidents related to the device shall be reported to the manufacturer and to the competent authority of the Member State where the user and/or the patient is based.

2 Possible complications

The medical devices must not be used contrary to their intended purpose and scope.
Complications can be caused by non-functional or incorrectly processed medical devices.

3 MRI advice

Use of the medical devices in the proximity of MRI systems is dangerous. The individual medical devices must not be in the vicinity of the devices while MRI procedures are being carried out.

4 Application and handling

The surgeon is responsible for selecting the correct medical devices to be used.
Even when used normally, the reusable medical devices are subject to wear and mechanical stresses, but even more so if used too forcefully.
In order to avoid risks in connection with the compatibility of the products, use only accessories and instruments specifically approved by MEDICON eG.

5 Processing (cleaning, disinfection and sterilisation) of the products

For accessories used in combination with surgically invasive products, please observe the instructions on processing of surgically invasive products.
For a detailed overview of the processing (cleaning, disinfection and sterilisation) of products, please contact us by telephone or e-mail and we will send you a print version.

5.1 Machine cleaning/disinfection [washer-disinfector (WD)]

Thermal disinfection (in case of chemical disinfection, risk of disinfectant residues on the products).

Recommendation: A0 value >3,000	Older devices: at least 5 min. at 90°C/194°F
Sufficient number of rinsing cycles: at least three rinsing steps after cleaning (or neutralisation, if used).	
Use only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water for the final rinse. As an alternative, conductivity value control is recommended.	
The air used for drying must be filtered (oil-free, low in germs and particles), The WD must be regularly maintained, checked and calibrated.	

Cleaning agent
Must be generally suitable for cleaning medical devices.
Compliance with the concentrations, temperatures and application times as well as the manufacturer's specifications for the final rinse.
Process:
1. disassemble (if possible)
2. Ensure that the products do not touch during cleaning. If available: active flushing by establishing a connection to the flushing connection of the WD
3. Start the programme.
4. Disconnect the WD and remove the products at the end of the programme.
5. Check and pack the products.

5.2 Inspection

Inspect the products after cleaning or after cleaning/disinfection for corrosion, damaged surfaces, flaking, soiling and discolouration and separate any damaged products (for the restriction on the number of reprocessing cycles, see 'Reusability' chapter) Products that are still soiled must be cleaned and disinfected again.

5.3 Maintenance

Reassemble the disassembled products (see specific disassembly/assembly instructions). Instrument oils or grease must not be used.
In the case of lubricating joints, care should be taken to use only instrument oils (white oil, without further additives) which - taking into account the maximum sterilisation temperature applied - are approved for steam sterilisation and have a proven biocompatibility, and to apply only a small amount to the joints.

5.4 Sterilization

Country	Fractional vacuum process
Germany	at least 5 min. at 134 °C (273 °F)
USA at least	4 min. at 132 °C (270 °F), drying time at least 20 min.
France	at least 5 min. at 134 °C (273 °F)
Other countries	at least 5 min. at 132 °C (270 °F) / 134 °C (273 °F)

6 Limitation of reusability

The service life of reusable medical devices normally comes to an end as a result of wear and damage from use and processing.
Even when used normally, the reusable medical devices are subject to wear and mechanical stresses, but even more so if used too forcefully. Careful inspection and functional check of the medical device before use is the best way to determine the end of service life of the medical device. In order to prevent failure or mechanical damage to the medical devices during surgery, they must be checked before each use by qualified personnel to ensure that they are mechanically intact, that there are no deformations, and that the parts are fully functioning.
Evidence of damage and wear to a reusable medical device may include, but is not limited to, corrosion (i.e. rust, pitting), discolouration, excessive scratching, chipping, wear and cracking. Medical devices that are not functioning properly, medical devices with markings that are not readable by humans or machines, missing or removed (worn) part numbers, damaged and excessively worn parts must not be used and must be replaced, repaired or disposed of.

7 Service

For service and repair, please contact your national MEDICON eG representative.

8 Liability

CAUTION: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription.
In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version shall be authoritative. Only the latest revision of the operating instructions applies. Due to constant
technical development, the content of these MEDICON eG operating instructions is updated regularly. Please ensure
that you are using the current version. The version date and the revision number of the respective edition of the operating instructions is included in the printout. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions.
MEDICON eG will accept liability neither for changes or repairs made to the product without the prior written authorisation of MEDICON eG, nor for repairs that were not carried out by workshops authorised by MEDICON eG or the MEDICON Repair Service (MRS).

9 Removal

To avoid a risk of infection to third parties, the medical devices must be cleaned and sterilised before disposal. In addition, the medical devices must be disposed of in specific and appropriately labelled containers, in order to protect third parties from cutting injury.
Observe the applicable national laws when disposing of reusable medical devices!

10 Scope / Intended purpose / Indication / Contra-indications

GA	GATDN001	GATDN002	GATDN004	GATDN005	GATDN006
Scope	All reusable, non-invasive medical devices (sculpture knives/blades, plaster knives/saws, cartilage knives, autopsy knives, wire cut scissors, plate scissors, bandage scissors, plaster scissors, universal scissors, plaster spreaders, plaster casts) of Medicon eG which are assigned to risk class I according to Regulation (EU) 2017/745 (MDR), Annex VIII, Rule 1 and Rule 13.	All reusable, non-invasive medical devices (towel clamps, tubing clamps, meatus clamps, removing forceps, suture clip forceps) of Medicon eG that are not used in combination with an active medical device and are assigned to risk class I in accordance with Regulation (EU) 2017/745 (MDR), Annex VIII, Rule 1.	All reusable invasive medical devices not used in combination with an active medical device (gags, retractors, spatulas, pushers, holders, specula, probes, applicators, bougies, dilators, obstetric forceps, nasal dress forceps, tongue forceps, catheter forceps, grasp forceps, sut carriers, ear loops, ligators/accessories, magnetic eye probes) of Medicon eG, which are assigned to risk class I in accordance with Regulation (EU) 2017/745 (MDR), Annex VIII, Rule 5, 10.	All reusable, non-invasive medical devices (bowls, dishes, cups, jars, vessels, dispensers) and accessories or assistive devices (hammers, screwdrivers, insertion instruments) of Medicon eG that are not used in combination with an active medical device and are assigned to risk class I in accordance with Regulation (EU) 2017/745 (MDR), Annex VIII, Rule 1, 2.	All reusable, non-invasive medical devices (percussion hammers, tuning forks, stethoscopes, marking instruments) of Medicon eG that are not used in combination with an active medical device and are assigned to risk class I in accordance with Regulation (EU) 2017/745 (MDR), Annex VIII, Rule 1.
Intended purpose / indication	A reusable, non-invasive medical device whose temporary use is the cutting of medical devices or modelling of tissue.	A reusable, non-invasive medical device not used in combination with an active medical device, whose temporary use is to hold and/or grasp medical devices, such as cloths and tubes, or to hold intact skin.	A reusable invasive medical device not used in combination with an active medical device, whose temporary use is to spread, press, hold away, grasp, extract, dilate tissue or medical devices and for diagnostic purposes.	A reusable, non-invasive medical device not used in combination with an active medical device, that is used for the storage, deposition and/or presentation of tissue, fluids, other medical devices or medical supplies under proper hospital conditions, or used as an accessory or for assistance (hammers, screwdrivers, insertion instruments) with one or more specific medical devices.	A reusable, non-invasive medical device not used in combination with an active medical device, whose temporary use is for diagnostic and marking purposes.
Contra-indications	Invasive or surgically invasive use of the medical devices		Surgically invasive use of the medical devices	Invasive or surgically invasive use of the medical devices	

11 Description of symbols and icons

Symbol	Meaning
	Manufacturer
	Date of manufacture
LOT	Production lot number, batch
REF	Item number
NON STERILE	Non-sterile
	Caution
	Observe the operating instructions
MR	MRT unsafe
CE	CE marking
MD	Medical device
Rx only	Prescription only