English

NON STERILE

℞ only

CE 0123

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# OPERATING INSTRUCTIONS

Carefully read the operating instructions and processing instructionsmprior to clinical application and keep them safe and at hand.
The instructions and notes contained therein must be followed.

**TABLE OF CONTENTS**



## 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.
– 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:
  • visually check the product for loose, loose, bent, broken, cracked, worn and broken off parts.
  • 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.
– 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 INTENDED PURPOSE

The MAPN Trocar sleeves are used to maintain surgical access in thoracolumbar surgery. The MAPN Trocar sleeves are for miniaturised subperiosteal paravertebral access techniques, as well as for transmuscular ones.

## 3 INDICATIONS

– Micro-discectomy
– Laminectomy
– Foraminotomy
– Spinal canal stenosis
– Lumbar fusion
– Posterior lumbar intervertebral fusion (PLIF)
– Transforaminal lumbar interbody fusion (TLIF)

## 4 CONTRAINDICATIONS

Applications contrary to the intended use of the product. Patients who are at general risk from surgery.

## 5 POSSIBLE COMPLICATIONS

With excessive loads due to pulling and pushing forces during maintanance of the surgical access, irritation, local circulatory disorders in the skin and damage to the soft tissue and muscles may occur.
This may cause tissue necrosis, impaired wound healing and infections. Furthermore, an overloading of the MAPN Trocar sleeves may lead to breakage of the instrument. So that there is no overloading of the MAPN Trocar sleeves or tensions being applied to soft tissues, it is the responsibility of the surgeon to extend the surgical wound if necessary, in order to bring about a corresponding degree of relief. The medical devices must only be used for the intended use and purpose.
Complications can be caused by non-functional or incorrectly processed medical devices.

## 6 MRI ADVICE

MR
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.

## 7 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.

## 8 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.

## 9 SERVICE

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

## 10 PROCESSING (CLEANING, DISINFECTION AND STERILISATION) OF MEDICAL DEVICES

For the detailed and product-specific processing (cleaning, disinfection and sterilisation) of products, please note the valid MPK:
Here you will find one of the following processing instructions, please observe the specific processing instructions for your product:
MPK12-1

Geometric features:
Products with longer/narrower single lumen Luer/LuerLock

Flushing volume
50 ml (disposable syringe) / flushing gun

Brush:
Standard brushes, long brush (length >510 mm: diameter approx. 4 mm)

| Special/additional procedure for | | |
|---|---|---|
| Disassembled,flush five times on the inside, brush on the outside and inside | Disassembled, flush five times on the inside, brush on the outside and inside | Disassembled, attach outer tube to flushing mandrel,place small parts in small parts basket, standard basket for other parts |
| Disassemble, flush five times on the inside, brush on the inside and outside | Disassembled, flush five times on the inside, brush on the outside | Disassembled, standard basket, sleeve of coupling in small parts basket |

Packaging:
Reassemble, if possible

Sterilisation:
Standard

Permitted maximum number of cycles:
As long as the functional check has been carried out by the user without problems and the legibility of the labelling including the coding is ensured, the medical device can be processed in accordance with these validated processing instructions. A limitation of the number of processing cycles is not necessary due to the investigations carried out by us and their results.

Classification recommendation according to KRINKO/RKI/ BfArM recommendation (only Germany, if used as intended):
Critical B

### 10.1 General principles

All products must be cleaned, disinfected and sterilised before every use; this applies in particular to the first use after delivery because all products are supplied non-sterile (cleaning and disinfection after removing the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation. As part of your responsibility for the sterility of the products, please ensure during use:
– that as a matter of principle only validated methods that are sufficiently specific for equipment and product are used for cleaning / disinfection and sterilisation, that the devices used (washerdisinfector (WD), steriliser, etc.) are regularly maintained, checked and calibrated, and that the validated parameters are adhered to for each cycle.

Please also ensure during use that you collect soiled medical devices separately and do not place them back in the sterilisation tray to prevent heavier contamination of the loaded sterilisation tray.
Clean/disinfect the soiled medical devices, sort them onto the sterilisation tray and then sterilise the fully loaded sterilisation tray.
Please also follow the legal provisions that apply in your country as well as the hygiene regulations that apply in the medical practice or hospital.
Note:
The products are to be used by trained personnel only.
Processing may be carried out only by trained personnel in the central sterile supply department (CSSD) / processing unit for medical devices of the clinic or in the processing room of the medical practice. The clinic or medical practice is also responsible for the selection and use of the necessary protective equipment and hygiene measures. Consider deviating and/or additional specifications for some products in the table 'Special instructions'.

### 10.2 Cleaning and disinfection

Principles
For the cleaning and disinfection, an automated process [washer-disinfector (WD)] should be used where possible. A manual process, including one in which an ultrasonic bath is used (frequency range 35 kHz), should be used only if an automated process is not available or according to countryspecific requirements (e.g. in Germany an automated process is mandatory for critical B products) due to the considerably lower effectiveness and reproducibility. Pre-treatment must be carried out in both cases. The concentrations, temperatures and application times specified by the manufacturer of the cleaning agent or detergent and disinfectant as well as the instructions for final rinsing must be strictly observed. Only use freshly prepared solutions, only use sterile or low-germ (maximum 10 germs/ml) and low-endotoxin (maximum 0.25 endotoxin units/ml) water (e.g. purified water / highly purified water) and only use a soft, clean and lint-free cloth (caution: care should be taken with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can get stuck!)
and/or filtered air.
Pre-treatment
Immediately after use (within 2 h at most) coarse contamination must be removed from the products. If, due to the duration of the application or as a result of organisational aspects, this time cannot be observed, the user must determine and validate measures on their own responsibility in order to prevent the soiling from complete drying:
Process:
1. Disassemble the products as much as possible (see specific disassembly/assembly instructions).
2. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Move movable parts back and forth at least three times during pre-rinsing. If applicable (see table 'Special instructions'): Rinse all lumens of the products at least three times (tools and minimum volume depend on the cavity to be rinsed).
3. Place the disassembled products in a sufficiently large pre-cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified application time so that the products are completely covered. Ensure that the products do not touch during cleaning. Support the pre-cleaning by completely brushing all inner and outer surfaces (at the beginning of the application time, for tools see table 'Special instructions'). The brushes for the channels must be slightly larger than the inner diameter of the respective channel; the shaft length of the brush must be at least as long as the channel. Move all movable parts back and forth at least three times during the pre-cleaning. If applicable (see table 'Special instructions'): Rinse all lumens of the products at least three times at the end of the application time (tools and minimum volume depend on the cavity to be rinsed).
4. Activate the ultrasonic device for another minimum application time (but not less than 5 min).
5. Then remove the products from the pre-cleaning bath and rinse them thoroughly with water at least three times (at least 1 min). Move movable parts back and forth at least three times during the final rinse.
If applicable (see table 'Special instructions'):
Rinse all lumens of the products at least three times (tools and minimum volume depend on the cavity to be rinsed).
When selecting the cleaning agent to be used,1 observe that
– it is generally suitable for cleaning invasive medical devices made of metals and plastics,
– the cleaning agent is suitable for ultrasonic cleaning (no foam formation),
– the cleaning agent is compatible with the products (see table "Material compatibility").

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

– When selecting the WD, ensure
– that the washer-disinfector has as a matter of principle proven effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
– that where possible, a tested programme for thermal disinfection (A0 value > 3,000 or, for older devices, at least 5 min. at 90 °C/194 °F) is used (in the case of chemical disinfection, there is a risk of disinfectant residues on the products),
– that the programme used is suitable for the products and includes a sufficient number of rinsing cycles (at least three depleting steps after cleaning (or neutralisation, if used) or conductivity value control is recommended to effectively prevent detergent residues),
– that for the final rinse only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used,
– that the air used for drying is filtered (oil-free, low in germs and particles) and that the washerdisinfector is regularly maintained, checked and calibrated.
– When selecting the cleaning agent system, ensure that
– if thermal disinfection is not used, a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that
– this is compatible with the cleaning agent used, and
– the chemicals used are compatible with the products (see section 'Material compatibility').

The concentrations, temperatures and application times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant as well as the instructions for final rinsing must be strictly observed.
Process:
1. Disassemble the products as much as possible (see specific disassembly/assembly instructions).
2. Place the disassembled products in the washer-disinfector. Ensure that the products do not touch. If applicable (see table 'Special instructions'): Enable active flushing by establishing a connection to the flushing connection of the WD.
3. Start the program.

| Step | Description | Medium | Temperature [°C] | Duration [min.] |
|---|---|---|---|---|
| 1 | Pre-rinse | Water | < 30 | 1 |
| 2 | Emptying | - | - | - |
| 3 | Cleaning | Alkaline cleaning agent: Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg) Concentration: 0.2 to 1% (according to detergent manufacturer's specifications) | 55 | 10 |
| 4 | Emptying | - | - | - |
| 5 | Rinsing | Deionised water | < 30 | 1 |
| 6 | Emptying | - | - | - |
| 7 | Disinfection (thermal) | - | 95 | 5 |
| 8 | Drying | Hot air | 100 | 25 |

4. Disconnect the WD and remove the products at the end of the programme.
5. Check and pack the products as soon as possible after removal (see 'Inspection', 'Maintenance' and 'Packaging'); where applicable, after additional drying in a clean location. Proof of general suitability of the products for effective automated cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using a G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie GmbH & Co., Gütersloh) and the Neodisher MediClean forte pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account for this.

### 10.4 Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant, ensure that
– that these are generally suitable for cleaning or disinfecting medical devices made of metals and plastics,
– that the cleaning agent is suitable for ultrasonic cleaning (no foam formation),
– that a disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA/EPA

– approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, and
– that the chemicals used are compatible with the products (see section 'Material compatibility').

During manual cleaning, disinfection with a possible risk of injury and infection, further occupational health and safety measures (e.g. protective clothing, goggles, gloves; room air filtration) must be observed according to national regulations (e.g. TRBA 250 in Germany).

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The concentrations, temperatures and application times specified by the manufacturer of the cleaning agent and disinfectant as well as the instructions for final rinsing must be strictly observed. Only use freshly prepared solutions, only use sterile or low-germ (maximum 10 germs/ml) and lowendotoxin (maximum 0.25 endotoxin units/ml) water (e.g. purified water / highly purified water) and only use a soft, clean and lint-free cloth (caution: care should be taken with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can get stuck!) and/or filtered air.

Process: Cleaning

1. Disassemble the products as much as possible (see specific disassembly/assembly instructions).
2. Place the disassembled products in a sufficiently large cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified application time so that the products are completely covered. Ensure that the products do not touch during cleaning. Support cleaning by completely brushing all inner and outer surfaces with a soft brush. The brushes for the channels must be slightly larger than the inner diameter of the respective channel; the shaft length of the brush must be at least as long as the channel. Move all movable parts back and forth several times during cleaning. If
applicable (see table 'Special instructions'): Rinse all lumens of the products at least five times at the beginning and end of the application time (tools and minimum volume depend on the cavity to be rinsed).
3. Activate the ultrasonic device for another minimum application time (but not less than 5 min).
4. Then remove the products from the cleaning bath and rinse them thoroughly with water at least three times (at least 1 min). Move movable parts back and forth several times during the final rinse. If applicable (see table 'Special instructions'): Rinse all lumens of the products at least five times (tools and minimum volume depend on the cavity to be rinsed).
5. Check the products (see 'Inspection' and 'Maintenance' chapters).

Disinfection

6. Place the disassembled, cleaned and inspected products in the disinfection bath for the specified application time so that the products are fully covered. Ensure that the products do not touch during cleaning. Move all movable parts back and forth several times during disinfection. If applicable (see table 'Special instructions'): Rinse all lumens of the products at least five times at the beginning and end of the application time (tools and minimum volume depend on the cavity to be
rinsed).
7. Then remove the products from the disinfection bath and rinse them thoroughly with water at least five times (at least 1 min). Move movable parts back and forth several times during the final rinse. If applicable (see chapter 'Special instructions'): Rinse all lumens of the products at least five times (tools and minimum volume depend on the cavity to be rinsed).
8. Blow the products dry using filtered compressed air.
9. Pack the products as soon as possible after removal (see 'Packaging' chapter); where applicable, after additional drying in a clean location.

Proof of general suitability of the products for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using Cidezyme/Enzol pre-cleaning and cleaning agent and Cidex OPA disinfectant (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account for this.

**10.5 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.

**10.6 Maintenance**

Reassemble the disassembled products (see specific disassembly/assembly instructions). Instrument oils or grease must not be used. Exception (only for special medical devices, see table 'Special instructions', not for implants):
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.

**10.7 Packaging**

Sort the cleaned and disinfected products into the corresponding sterilisation tray. Please pack the products or the sterilisation trays in sterilisation containers or very large products in single-use sterilisation packs (single or double packaging) that meet the following requirements (material/process):
– DIN EN ISO / ANSI AAMI ISO 11607 (for the USA: FDA clearance)
– Suitable for steam sterilisation (temperature resistance of at least 138 °C (280 °F) and adequate steam permeability)
– Sufficiently protect the products or sterilisation packages against mechanical damage
– Regular maintenance in accordance with the manufacturer's specifications (sterilisation container)
– A maximum weight of 10 kg per package/content of the sterilisation container must not be exceeded.

**10.8 Sterilization**

For the sterilisation, only the sterilisation methods listed below may be used; other sterilisation methods are not permitted.
Steam sterilisation
– Fractionated vacuum method (with adequate product drying)5 Steam steriliser according to DIN EN 13060 / DIN EN 285 or ANSI AAMI ST79 (for the USA: FDA clearance)
– Validated in accordance with DIN EN ISO 17665 (current IQ/OQ (commissioning) and productspecific performance qualification (PQ))
– Maximum sterilisation temperature 134 °C (273 °F plus tolerance according to DIN EN ISO 17665)
– Sterilisation time (exposure time at the sterilisation temperature):

| Country | Fractional vacuum process | Gravitation process |
|---|---|---|
| Germany | at least 5 min.at 134 °C (273 °F) | not permitted[4] |
| USA at least | 4 min. at 132 °C (270 °F), drying time at least 20 min. | not recommended[4] |
| France | at least 5 min.at 134 °C (273 °F) | not permitted[4] |
| Other countries | at least 5 min. at 132 °C (270 °F) / 134 °C (273°F) | not permitted[4] |

Proof of general suitability of the products for effective steam sterilisation was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum process as well as the LAWTON MEDOIL. Typical conditions in hospitals and medical practices as well as the method described above were taken into account for this.
The flash sterilisation method is not permitted as a matter of principle. Also do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation.

**10.9 Storage**

After sterilisation the products must be stored in the sterilisation packaging in a dry and dust-free environment.

**10.10 Material compatibility**

When selecting cleaning agents and disinfectants, ensure that these do not contain any of the following ingredients:
– organic, mineral or oxidising acids (minimum permissible pH value 5.5)
– alkaline solutions / strong alkaline solutions (neutral/enzymatic (max. permissible pH 8.5, mandatory for products made of aluminium or other alkali-sensitive materials, see table 'Special instructions') or alkaline cleaning agent (max. permissible pH value 11) recommended.
– organic solvents (e.g. alcohols, ethers, ketones, benzines)
– oxidising agents (e.g. hydrogen peroxide)
– halogens (chlorine, iodine, bromine)
– aromatic/halogenated hydrocarbons

Never clean any products, sterilisation trays and sterilisation containers with metal brushes or steel wool. The products, sterilisation trays and sterilisation containers must not be exposed to temperatures above 138 °C (280 °F).

**10.11 Reusability**

The products can be reused with due care and provided they are not damaged or soiled; any further use or use of damaged and/or soiled products is the responsibility of the user. In case of nonobservance, any liability is excluded.

**10.12 Safety information and warnings**

– Ensure that all equipment involved in the processing procedure is qualified and maintained according to the manufacturer's specifications.
– Risk of injury and infection during transport packaging for the processing of sharp-edged or pointed medical devices, as well as in case of carelessness of the personnel during manual cleaning or disassembly processes, when loading or unloading the loading trolleys of a washerdisinfector.
– Repair work may be carried out only by the manufacturer. (Caution: Otherwise, the person who carries out the repair automatically becomes the responsible manufacturer!)
– If unsuitable process parameters or media are used or if washer-disinfectors (including ultrasonic devices) are loaded inappropriately, residues from the processing procedures may remain on the medical device.
– When cleaning in the ultrasonic bath, the basic rules applicable for this purpose (no excessive loading, degassing, etc.) must be observed.
– The media used in the functional test must not cause any re-contamination or crosscontamination. Testing facilities are to be included in regular hygiene measures.
– Instrument surfaces optimised for ultrasound imaging (e.g. sound-reflecting surfaces on biopsy cannulas) may have their reflectance reduced by deposits, surface roughening or deformation and contrast less well in the ultrasound image.
– Electrical radiation: Systems compatible with magnetic resonance can produce artefacts in magnetic resonance imaging by changing their properties in the form of magnetisation or changes in internal resistances, or can damage tissue by inducing eddy currents.
– Suitable, hygienically specified and regularly tested media must be used for drying.

Legend

1. If you use a cleaning and disinfecting agent for this purpose (e.g. for reasons of occupational safety), please take into account that it should be aldehyde-free (otherwise blood contamination would be fixed), have a proven effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of the products and be compatible with the products (see 'Material compatibility' chapter).
Please note that the disinfectant used during the pre-treatment serves only to protect personnel and cannot replace the later disinfection step that must be carried out after cleaning is completed.
2. If you consider a lower water quality to be sufficient on the basis of national recommendations (e.g. KRINKO/RKI/BfArM recommendation on processing in Germany), this is your sole responsibility.
3. At least three vacuum steps
4. The use of the gravitational method is not permitted in the European Union. The use of the less effective gravitational method outside the European Union is only permitted if the fractionated vacuum method is not available. It requires significantly longer sterilisation times and must be validated by the user specifically for the product, device, process and parameters.
5. The actual drying time required depends directly on parameters that are the sole responsibility of the user (load configuration and density, steriliser condition, ...) and must therefore be determined by the user. Nevertheless, the drying time should not fall below 20 minutes.

**11 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 operating instructions is updated regularly. Please ensure that you are using the current version. The version date 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).

**12 DISPOSAL**

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!

**13 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 0123 | CE marking |
| ℞ only | Prescription only |