



When you purchase these instruments, you are acquiring high-quality products. This user manual describes how to handle and use them correctly.

Retention systems: clips, retractors

Basic UDI-DI 4046826;A002;03;P6

Manufacturer in accordance with EU MDR 2017/745



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1 General information

Surgical retractors are instruments used in medicine to hold tissue or body structures apart or to spread them. They are frequently used during surgical procedures to allow better access to specific areas of the body. Depending on their intended use and size, retractors/spreaders can have different shapes and designs. Retractors are used to assist the surgeon in performing precise and effective medical procedures by passively holding open the access route to the surgical site.



The instruments must therefore be cleaned, disinfected and sterilised before use. Please observe the following instructions. These ensure that the instruments function correctly and reliably.

2 Intended use

Self-retaining retractors are used to keep the surgical field open. This involves holding tissue, muscles, organs or bones apart during surgery.



The surgical instruments are not intended for use on the central nervous system (CNS) or the central circulatory system.

3 Indications

Use for holding the surgical field open during general surgical procedures.

4 Contraindications

The use of self-retaining retractors is generally contraindicated when the use of other surgical techniques is indicated.

Furthermore, contraindications apply

- in cases of general inoperability;
- if the patient is unwilling;
- if the technical requirements are not met.

The attending physician must decide, based on the patient's general condition, whether the intended procedure can be performed.

5 Possible side effects and complications



The surgical instruments must not be used contrary to their intended purpose and scope of application.

Complications may be caused by instruments that are not in working order or have been reprocessed incorrectly.

6 Warning / Safety precautions



- The surgical instruments are reusable, are supplied non-sterile and must therefore be cleaned, disinfected and sterilised prior to first use, in accordance with the instructions described in the user manual.
- The reusable surgical instruments are manufactured from stainless steel and materials approved for medical use. The materials are corrosion-resistant and exhibit excellent properties in a biological environment.
- The product and accessories must only be operated and used by persons who have the necessary training, knowledge or experience regarding their use, functional testing and cleaning/sterilisation.
- The user and the relevant specialist personnel undertake to familiarise themselves with the instruments before they are used.
- Read and follow the instructions for use.
- Use the product only for its intended purpose (see Intended Use).
- Clean the brand-new product after removing the transport packaging and before the first sterilisation.
- Store brand-new or unused products in a dry, clean and protected place.

- Before each use, the product must be:
 - Visually inspect for: loose, bent, broken, cracked, worn or chipped parts.
 - Checked for proper function.
- Do not use a damaged or defective product. Immediately discard damaged products or send them to the service centre specified in these instructions for use.
- Replace damaged parts immediately with original spare parts.
- All instruments that can be dismantled must, where applicable, be dismantled for reprocessing and sterilisation.
- All serious incidents occurring in connection with the product must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

7 MRI notes



The use of medical devices poses a risk in an MRI environment. Individual medical devices must not be in the immediate vicinity of the equipment whilst these procedures are being performed.

8 Use and handling



The surgeon is responsible for the correct selection of the medical devices to be used.

Reusable medical devices are subject to wear and mechanical stress even during normal use, but particularly so when excessive force is applied.

Use only the accessories and instruments specifically designed for this purpose by MEDICON eG to avoid risks associated with product compatibility.

9 Decontamination, cleaning and sterilisation

Note on transmissible spongiform encephalopathies (e.g. Creutzfeldt-Jakob disease, CJD/vCJD)

In patients with confirmed or probable CJD/vCJD, special requirements regarding the reprocessing of medical devices must be observed. Standardised cleaning, disinfection and sterilisation procedures may not be sufficient to reliably inactivate prions.

If the use of single-use devices is not possible, medical devices that may have been contaminated with prions or where such contamination cannot be ruled out must be handled in accordance with applicable national and international recommendations (e.g. RKI, WHO). Depending on the risk assessment, this may also include disposal as infectious waste.

In cases of suspicion, the relevant recommendations must be followed. Reuse is only permitted if contamination can be reliably ruled out.

Even in cases of undiagnosed CJD/vCJD, it must be borne in mind that certain tissues (e.g. CNS, eye, lymphatic tissue) may pose an increased risk of prion contamination. In such cases, additional or adapted reprocessing procedures may be required. The selection of suitable procedures is the responsibility of the operator, taking into account the applicable guidelines.

The reprocessing procedures described in these instructions for use have not been specifically validated for their efficacy against prions.



Cleaning solutions containing hydrogen peroxide and/or washing solutions with high alkalinity may cause discolouration. This may result in the loss of the coding function. Only cleaned and disinfected instruments may be sterilised.

9.1 Preparation for decontamination

Preparation serves to ensure effective cleaning and disinfection. It must be carried out prior to both machine and manual cleaning.

- Instruments must be removed from the instrument tray and placed on suitable instrument holders (e.g. wire mesh trays) in a manner suitable for rinsing.
- The arrangement must ensure that the subsequent cleaning is not impaired by rinsing shadows or concealed surfaces.
- Products with multiple components must be completely disassembled before cleaning.
- Movable parts must be opened.
- Coarse soiling must be removed immediately after use to prevent organic residues from drying on.

These include in particular:

- Removing coarse contamination by rinsing under cold water (< 35 °C)
- Operating moving parts to expose all relevant surfaces
- Ensuring the patency of lumina, channels and cavities (e.g. by flushing with suitable aids)

During transport and temporary storage, the instruments must be kept moist (e.g. using damp cloths or suitable pre-treatment solutions) to prevent drying out.



Damaged or non-functional products must not be reprocessed and must be discarded.

9.2 Machine cleaning and disinfection

Cleaning must be carried out mechanically in a washer-disinfector (RDG). The RDG must meet the requirements of DIN EN ISO 15883-1.

Cleaning process (example of a validated cycle):

Process step	Parameter
Pre-rinse	< 45 °C, ≥ 2 minutes
Cleaning	55 °C, 10 minutes, alkaline detergent (e.g. Neodisher MediClean forte 0.5%)
Intermediate rinse	< 30 °C, ≥ 1 minute, deionised water
Thermal disinfection	≥ 90 °C, ≥ 5 minutes (A0 ≥ 3000)
Drying	100 °C, 25 minutes

9.3 Manual cleaning



Note:

Manual cleaning has been tested as part of the manufacturer's validation. However, its effectiveness is only confirmed within the validated parameters described below. Deviations (e.g. different concentrations, chemicals, times or temperatures) must be validated by the operator in accordance with DIN EN ISO 17664-1.

1. Pre-cleaning

- Remove coarse dirt under cold running water.
- Operate all moving parts fully.
- Flush the lumen, threads and bores at least 5 times using a syringe or flushing lance.
- Keep instruments damp until cleaning to prevent organic dirt from drying on.

2. Enzymatic cleaning (soaking + brushing + ultrasonic cleaning)

- Prepare an enzymatic cleaner (e.g. Cidezyme®/Enzol® 0.8%).
- Soak the instruments for 1 minute **without** ultrasound.
- Brush all surfaces and lumens (for at least 1 minute).
- **Activate** the ultrasonic bath for 5 minutes, temperature 37–40 °C.

3. Rinsing

- Rinse thoroughly under running water.
- Rinse the lumens at least 5 times.
- Completely remove any cleaning agent residues from the instruments.

4. Manual disinfection

- Place the instruments in OPA solution (e.g. Cidex® OPA).
- Leave to soak for the time specified by the manufacturer.
- Fill the lumen with disinfectant.

5. Final rinsing

- Rinse the instruments at least 5 times with tap water.
- Finally, rinse with deionised or demineralised water to prevent residues.
- Rinse the lumen at least 3 times.

6. Drying

- Dry the instruments completely with compressed air.
- Blow through the lumen actively.
- If necessary, dry thoroughly with a lint-free cloth.

9.4 Inspection and testing

After cleaning, disinfection and drying, all products must be inspected visually and functionally. The inspection serves to ensure that the medical device has been thoroughly cleaned, is undamaged and is in working order.

The following criteria must be checked:

- Cleanliness: no visible dirt, no residues of cleaning agents or disinfectants, no moisture in lumens or joints
- Surfaces: no corrosion, no discolouration, no chipping, no excessive scratches
- Mechanics: free movement of all parts, full functionality, correct alignment
- Lumen: clear and unobstructed, with no residues or blockages
- Markings: item numbers, laser markings and codes must be fully legible

Action to be taken in the event of non-conformities:

- If visible residues are present: Clean and disinfect the product again
- In the event of functional defects or damage: Reject, repair or replace the product
- Products with illegible markings or lacking identifiability must not be reused



The inspection must be carried out by qualified personnel prior to each sterilisation and prior to each clinical use.

9.5 Maintenance and inspection

Following the inspection, products with moving parts must be maintained in accordance with the relevant functional requirements.

Lubrication:

- Joints and moving parts must only be lubricated if this is necessary for proper function.
- Only biocompatible instrument oils suitable for steam sterilisation may be used (e.g. white oils without further additives).
- Lubricants must be used sparingly and applied only to the designated functional points.
- Lubricants must not be introduced into lumens, threads or bores unless this is explicitly specified.

Maintenance:

- Damaged, worn or malfunctioning instruments must be removed from service and, if necessary, repaired.
- Products must only be sterilised when fully assembled and in working order.



The operator is responsible for regular functional checks, maintenance and documentation.

9.6 Packaging

Prior to sterilisation, the medical devices must be packaged in suitable sterile barrier systems that comply with the requirements of DIN EN ISO 11607-1/-2.

Packaging requirements:

- Use of a validated sterile barrier system (e.g. film/non-woven pouches, Tyvek pouches, container systems)
- Packaging material must be suitable for the planned sterilisation method (e.g. steam sterilisation)
- Packaging must be undamaged, clean and in good working order
- The packaging must allow for complete sterilisation and aseptic removal

Guidance on loading (operator responsibility):

- Instruments must be completely dry, clean and free of residues
- Instruments must be arranged in trays, containers or bags in accordance with the AEMP's validated loading instructions
- Instruments must not damage the packaging material
- Loading must ensure that the steam can reach all surfaces to be sterilised

Operator's responsibility:

- The operator is responsible for selecting the sterilisation barrier system and validating the packaging process
- The packaging must be checked for integrity before each sterilisation



Only fully dried and correctly packaged products may be sterilised.

9.7 Sterilisation

A validated steam sterilisation procedure must be used to sterilise the instruments.

Sterilisation procedure:

- Fractional vacuum process (at least three-stage fractional)
- Steam steriliser in accordance with DIN EN 13060 or DIN EN 285
- Validation in accordance with DIN EN ISO 17665

Sterilisation parameters:

- Temperature: 132 °C
- Holding time: at least 4 minutes

Additional requirements:

- Sufficient product drying must be ensured.
- The method used must be suitable for achieving a Sterility Assurance Level (SAL) of 10^{-6} .
- National requirements and guidelines must be taken into account.

9.8 Further information on reprocessing

A validated, machine-based cleaning and disinfection process is generally preferable to manual cleaning, as it ensures greater process reliability. Effective cleaning is a prerequisite for successful sterilisation.

The following points must be observed during mechanical reprocessing:

- Ensure that the sieve trays are loaded in a manner suitable for rinsing.
- Trays must not be overloaded.
- Avoid areas where water cannot reach due to large items.

The times and temperatures specified in these instructions for use represent minimum requirements and must not be undercut.

Deviations from the described procedures are only permitted if they have been validated by the operator.

9.9 Cleaning agents

Suitable detergents must be used for cleaning in accordance with the procedure applied.

Machine cleaning:

The validation of machine-based reprocessing was carried out using the following alkaline detergent as an example:

- neodisher® MediClean forte (Dr. Weigert GmbH & Co. KG)

The cleaning agent used must have comparable properties, in particular:

- alkaline pH range (approx. pH 10–11 in the working solution)
- Suitability for removing blood, protein and tissue residues
- Material compatibility with the materials used

Manual cleaning (enzymatic):

Enzymatic cleaning agents must be used for manual cleaning, e.g.:

- Cidezyme® / Enzol®

Recommended parameters:

- Dosage: 0.8%
- pH value (working solution): approx. 7.5 – 8.5

Here too, alternative cleaning agents must have comparable properties in terms of cleaning performance and material compatibility.



If different cleaning agents are used, it is the operator's responsibility to ensure the effectiveness of the process.

10 Limitations on reusability

The end of the service life of reusable medical devices is determined by wear, material fatigue and damage, which can result from both intended use and repeated reprocessing.

Even under normal handling, the products are subject to mechanical stress, particularly when significant force is applied.

Before each use, the medical device must be carefully inspected by qualified personnel for mechanical integrity, deformation and full functionality. A thorough visual and functional inspection is the best method for determining the end of the service life and preventing failure during the procedure.

Typical signs of damage or wear:

- Corrosion (e.g. rust, pitting)
- Discolouration or changes in material
- Excessive scratches, abrasions or spalling
- Cracks or breaks
- Bent or deformed instrument parts
- Restricted movement of joints or mechanisms
- Missing, damaged or illegible markings (e.g. item numbers, laser markings)

Rejection and replacement:

Medical devices exhibiting one or more of the above characteristics must not be used further. They must be replaced, repaired or disposed of properly.

No fixed maximum number of reprocessing cycles is specified, as the actual service life depends on usage, handling and reprocessing conditions.

11 Service

For service and repairs, please contact your local MEDICON eG representative.

12 Storage and disposal

12.1 Storage

Reusable instruments must be stored in such a way that their sterility is maintained until use. Storage must be in a dry place, protected from dust and mechanical damage. Significant temperature fluctuations, which may lead to the formation of condensation, must be avoided. The permissible storage period depends on the sterilisation barrier system used and the storage conditions, and must be determined by the operator.

12.2 Disposal

Before disposal, the products must be free of potentially contaminated material. To this end, the products must be reprocessed in accordance with these instructions for use, where applicable.

If there are any sharp edges or damage, the item must be disposed of in such a way as to prevent any risk to persons.

13 Liability

Note for the USA



Under US federal law, this product may only be purchased in the USA by a doctor or on a doctor's prescription.

Validity of the instructions for use

Always use the latest version of these instructions for use. Due to technical developments, the instructions for use are updated regularly. The version date and revision number are indicated on the document.














Disclaimer

MEDICON eG accepts no liability for damage resulting from:

- improper use
- use not in accordance with the intended purpose
- incorrect handling, care or maintenance
- failure to comply with these instructions for use
- modifications or repairs carried out without the consent of MEDICON eG
- Repairs carried out by unauthorised persons or organisations

In the event of modifications or unauthorised repairs, liability for defects shall also lapse.

14 Explanation of symbols and pictograms

	Manufacturer		Not MRI-safe
	Date of manufacture		Caution
	Production batch number, batch		CE marking
	Item number		Medical device
	Non-sterile		Prescription only
	Follow the instructions for use		Quantity
	LDPE (low-density polyethylene)		