1. General Information:

CE 0483 ⚠

These instructions for use and reprocessing are an essential part of the self-locking retractors and rib spreaders purchased.

Please read and follow these instructions carefully and keep them in a clearly visible and accessible place for later use.

The application as well as the reprocessing (cleaning, disinfection and sterilization) may only be performed by trained specialists according to validated procedures. See chapter 9, Preparation of instruments.

The manufacturer accepts no liability for consequences resulting from improper handling, preparation and care as well as storage of the products.

⚠ **Please note that our instruments are supplied non-sterile and must be reprocessed (cleaned, disinfected and sterilized) before first use. See 9. preparation of the instruments.**

2. Handling

The selection, handling and use of the instruments described here are carried out exclusively by the professionally qualified surgeon and appropriately trained and instructed surgical staff.

3. General Purpose

Self-retaining retractors and spreaders represent reusable instruments that provide and maintain open access to the surgical site during surgical procedures. Surrounding tissue, cartilage and bone, is mechanically pushed aside to ensure visualization of the surgical site for the surgeon and to provide access for the instruments required to perform the procedure.

4. Typical indications and areas of application

The instruments may only be used in accordance with their general purpose. The use of self-locking retractors and spreaders takes place primarily during open surgical procedures, in cases where stable access to the surgical site is required during prolonged procedures.

For Example in the

- Abdominal surgery
- Spinal surgery (Laminectomy)
- Cardiothoracic surgery
- Ear, nose and throat surgery
- General Surgery

5. Contraindications & restrictions of use

Patients in whom there is a general surgical risk. The instruments are used exclusively by medical personnel specially trained in surgical techniques.

⚠ **The selection of the appropriate retractor self-locking/spreader is the responsibility of the experienced user.**

- The instruments are not specifically intended for monitoring, diagnosing, controlling or correction of a defect in the heart or central circulatory system in direct contact with these parts of the body.
- The instruments are not intended to be used in direct contact with the central nervous system.
- The instruments are not intended to deliver energy in the form of ionizing radiation..
- The instruments are not intended to exert a biological effect or to be fully or significantly absorbed
- The instruments are not intended for the administration of drugs..

There are no other known contraindications.

6. Typical Designs

The design of the retractors is adapted to the anatomical conditions and the type of surgical procedure. (For retractor models and order numbers, see the current Berger Surgical catalog) The range covers all surgical disciplines where surgical access is required, whereby access can be via a surgical opening, an injury or a natural body orifice. The products are intended for short-term use.

Self-retaining retractors:

They are predominantly used in the superficial area, whereby the access is prepared sharply or bluntly. After opening the wound, the two blades are inserted and the instrument is fixed in place by a locking mechanism (rack, ratchet) integrated in the handle. The retractors are available straight or bent in the handle and, if necessary, with a branch joint so that variable bending upwards or downwards is possible and the handle of the retractor does not obstruct the surgeon. Typical applications are in ENT or vertebral column surgery.

Abdominal Retractor

Various self-retaining systems are available for abdominal surgery, in which different sized sheets (valves) can be inserted or hooked into either a free ring or frame. The sheets are typically used to temporarily hold back the edges of an abdominal incision, or to temporarily hold off an organ or tissue during a surgical procedure. The user has flexibility in selecting the appropriate sheets and their number

Spreader, rib

They are also referred to as thoracic locks. Two blunt and wide metal hooks (valves or blades) are slidably attached to each other on a serrated rail. After transection of the intercostal space (intercostal space) and opening of the pleura parietalis, the hooks are inserted into the wound along each of the upper and lower ribs and spread by a crank device.

This provides rigid, wide-open access to the thorax and its organs, as well as to the intercostal space (mediastinum), through which most lung and thoracic surgical procedures (pneumonectomy, pleurectomy, lobectomy, creation of the upper anastomosis in mediastinally extended gastrectomy, etc.) can be performed.

For operations on the heart, sternotomy is the more common approach; in this case, too, the rib spreader is placed between the severed halves of the sternum to keep the surgical field open.

7. Explanation of signs


Observe the instructions for use.


Manufacturer of the medical device


Attention! Check the instructions for use for important safety-related information, such as warnings and precautions..

CE
Marking

0483
Identification number of the notified body MDC from risk class IIa, compliant with RL93/42/EEC


Order number


Batch number


Non-sterile product

8. Application and safety instructions

Failure to follow these application and safety instructions may result in injury, malfunction or other unexpected occurrences.

⚠ All reusable medical devices must be completely reprocessed (cleaned, disinfected, and sterilized) before first use and before each subsequent use. The same also applies to the return of an instrument to the manufacturer. For this purpose, the instruments must be removed from their original packaging. Suitable containers or packaging must be used for reprocessing.

⚠ Risk of injury to patient and user: The products may have sharp edges or pointed ends. This must be taken into account during handling and use.

⚠ When using retractors, unintended damage to surrounding tissue structures may occur, such as soft tissue injury and tissue weakening and necrotization, and even fracture of bony structures.
Care must be taken
- that retractors are expanded only as far as necessary for safe surgical intervention.
- that the pressure of the retractor blades on the laterally compressed wound tissue does not lead to permanent tissue damage (e.g., necrotization). If necessary, moist abdominal drapes are placed underneath to protect the tissue or to relieve the tissue at certain intervals during longer procedures.
- that the retractor is used safely and stably.

⚠ Defective products must not be used as a matter of principle and must have undergone the entire reprocessing process before being returned

⚠ Do not overload the instruments. Overloading due to the application of excessive force can lead to fractures, bending and malfunctions of the medical device and to injuries to the patient or user. Do not bend bent instruments back to their original position, risk of breakage.

⚠ Do not use a damaged or defective product. Immediately sort out damaged or corroded products, label them and exclude further use.

⚠ Avoid improper throwing or dropping of instruments..

⚠ The safe combination of the products with each other or of the products with implants must be checked by the user before clinical use.

⚠ To avoid any contact corrosion, instruments with damaged surfaces must be discarded immediately!

⚠ In case of use of the products in patients with Creutzfeldt-Jakob disease or HIV infection, we decline any responsibility for reuse.

9. Preparation of the instruments

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This requires validation and routine monitoring of the process.

We would like to point out that it is essential to take into account the national regulations in connection with reprocessing.

We recommend the following validated procedure for reprocessing our reusable surgical instruments.

Preparation for disinfection and cleaning

Instruments should be disinfected and cleaned as soon as possible after use (within 2 hours). Instruments that can be disassembled must be disassembled for cleaning.

Contaminants should not dry on the objects in order not to make disinfection and cleaning even more difficult.

Cleaning: (recommendation mechanical cleaning)

Manual pre-cleaning:

Place the instruments immediately or at the latest 2 hours after use and remove visible contamination with a soft brush. Cavities must additionally be rinsed through 3 x 10 sec (rinsing gun, etc.) Use a suitable cold cleaning solution (< 40°C), Neodisher ® MediClean forte; 0.5% strength. Then briefly rinse instruments under clear water. Instruments with hard-to-reach surfaces are treated for 5 min in a US bath at 35 kHz. Temperature 50°C.

Machine cleaning:

Instruments with lumens must be rinsed through during machine cleaning.

Pre-rinse

Cold water without additive to remove coarse dirt and foam-forming substances.

Cleaning

Perform cleaning at 55°C ± 2°C for at least 5 minutes. For machine cleaning of thermostable and thermolabile instruments, we recommend the alkaline cleaner Neodisher ® MediClean forte; 0.5% in the machine.

If elevated chloride concentrations are present in the water, pitting corrosion and stress corrosion cracking may occur on the instruments. Such corrosion can be minimized by using alkaline cleaners or fully demineralized water.

Neutralization

The addition of an acid-based neutralizing agent facilitates the rinsing off of alkaline cleaning agent residues. Even when using neutral detergents, the use of a neutralizer is recommended if the water quality is unfavorable, e.g. if the salt content is high, in order to prevent the formation of deposits. It is recommended that neutralization be carried out with Neodisher® Z in warm water (approx. 40°C). 0.1% solution

Rinsing

Deionized water without additives; Thermal disinfection/final rinse

Perform thermal disinfection at 92°C ± 2°C for at least 5 min (A0 value of >3000).

Drying

Sufficient drying must be ensured by the washer-disinfector or by other suitable measures. Carry out drying at 55-60°C for approx. 30 min. If residual moisture is still present, subsequent drying can be carried out in the drying cabinet at 60°C. However, the drying time depends on the load and the wash ware.

Sterilization

STERILIZER: Steam autoclave with fractionated pre-vacuum: temperature: 134° Celsius, with a holding time of 5 to a maximum of 20 minutes and subsequent drying. At least three pre-vacuum cycles.

Instrument sterilization

Sterilization accessories, such as packaging/storage materials, must be adapted to both the instruments and the sterilization process used.

In order to avoid damage (joint tension cracks, loss of clamping force) to instruments with a grid lock due to tension occurring during heating and cooling during the sterilization process, these instruments may only be closed in the first detent.

CAUTION:

Surgical instruments that are chromium-plated, whose chromium protection is damaged, in these places corrosion emerges from the black dots. For this reason, such instruments should not be sterilized together with stainless instruments, as the flash rust will transfer to the stainless instruments. This is not visible on the chromium-plated instruments, because the rust cannot settle on chrome. However, the stainless instruments are not covered by this layer, so we do not recommend sterilizing surgical instruments that still have a chromium-plated surface with stainless ones in the same sterilizer.

Steam sterilization

When using steam sterilizers to sterilize surgical instruments, it must be ensured that sterilizing steam is used without contamination. Steam for sterilization purposes must comply with DIN 58946-Part 7 and DIN EN ISO 17665-1. If these requirements for steam quality are not met, impurities such as oil, chemicals, metal chips or rust can lead to contamination and/or consequential damage to instruments. Damage due to extraneous rust is primarily caused by steam supply systems that are not designed in chrome nickel steel. The manufacturer's operating instructions for steam sterilizers must be observed to avoid any disadvantages. To avoid possible disadvantages for the instruments, DIN 58946, part 6 "Operation of large sterilizers", paragraph 5, must be observed. Sterilization packaging must comply with DIN 58952 and DIN 58953.

Instruments must be stored dry after sterilization until use. The dryness of the instruments and the sterilization packaging must be achieved after cooling down to room temperature (23 + 2°C).

Excessive condensation during sterilization is avoided by observing the recommended maximum weight of loaded sterilization trays. Drying is facilitated by wrapping the trays in a cloth inside the containers or the outer paper packaging.

Preparation Validated according to Report No.
• Final Report Aufbereitungsvalidierung maschinell 2020-04-28 11759 u. 11756
• Final Report Sterilisationsvalidierung 2020-04-30 11760 u. 11757

Applicable standards and specifications:

For cleaning, disinfection and sterilization, the following sources must be particularly observed:

>> DIN EN ISO 17664 Information to be provided by the manufacturer for the reprocessing of resterilizable equipment.

>> EN 285 Sterilization - Steam sterilizers - Large sterilizers.

>> DIN EN ISO 17665 Sterilization of medical devices - Validation and routine control for moist heat sterilization.

>>DIN EN ISO 17665 Sterilization of medical devices - Requirements for medical devices to be sterilized in the final packaging and labeled as "sterile" - Part 1: Requirements for medical devices sterilized in the final packaging.

>> DIN 58946-7 Sterilization; Steam sterilization; Constructional requirements for large sterilizers, Instrument reprocessing done right.

>> AK Instrument Reprocessing: http://www.a-k-i.org

>> Recommendations for validation and routine monitoring of moist heat sterilization processes for medical products, DGKH recommendation. http://www.dgkh.de

>> Requirements for hygiene in the reprocessing of medical devices, Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on "Requirements for hygiene in the reprocessing of medical devices". http://www.rki.de

Limitation of reprocessing

Frequent reprocessing has little effect on reusable surgical instruments. The end of the product life is usually determined by wear and damage from use. At the end of the product life, direct the surgical instruments to a proper disposal or recycling system.

Care

Care" means the application of instrument oil (physiologically harmless kerosene oil according to DAB 8, Ph.Eur. or Usp) or instrument milk (emulsion of hydrocarbon, white oil, in water) to the surface (especially to the moving parts/joints) of the surgical instruments. As a matter of principle, surgical instruments must be subjected to adequate care, namely before functional testing. Care products must guarantee that the joints do not "stick together" due to their cumulative effect, even if they are used continuously.

10. Inspection and care

Proper care and maintenance of the instruments prolongs their service life and must therefore be performed after each cleaning.
Check the surface of the instruments intensively after cleaning using an illuminated magnifying glass (20x) according to the following criteria:
- Visual cleanliness without the slightest residual dirt, otherwise repeat the cleaning process completely.
- Superficial cracks, especially at weld seams, screw connections, and seals, replace instruments or components if necessary.
- Surface changes, such as roughness and signs of corrosion, replace instruments or components.

Perform a functional test with the assembled instrument and check the following criteria:
- Stability of all moving parts, replace loose or defective components.
- Safe functioning of the joints and locking mechanisms, without them having too much play or being too sluggish, if necessary, give instruments for repair.
- Shape of blades and valving, replace bent or damaged valving.

Maintenance and care activities are limited to lightly wetting the moving parts (joints, locking mechanisms, etc.) with a little medical oil and removing excess oil.

⚠ Do not use or repair damaged instruments, but discard them immediately, mark them and exclude them from further use. When handling during preparation and testing, be sure to consider any possible risk of injury from sharp edges and tips. Rib spreaders can have a considerable weight, this should be considered during handling.

11. Limited service life

The service life of surgical instruments is only marginally influenced by the number of reprocessing cycles performed, if they are carried out according to the validated procedures described here. Rather, it depends on the gentle and careful handling of the instruments in all phases of use, reprocessing, transport and storage.

The end of the service life is reached when the prescribed visual and functional inspection reveals signs of wear or defects that limit the functionality of the product. In this case, it is essential to mark the instruments and exclude them from further use and replace them with functional instruments.

Furthermore, the end of the usage cycle is reached when the clear identification of the instruments is no longer given due to the missing marking.

12. Packaging

The instrument must be packaged appropriately before sterilization so that the sterile barrier is maintained after removal from the sterilizer. Pack the instrument in accordance with ISO 11607 and EN 868 standards. If necessary, pack and store heavy rib spreaders separately from the rest of the instrument set.

13. Storage of sterilized products

To avoid shortening the shelf life and loss of germ-tightness, the following storage conditions must be observed:
- Store sterile product closed in a clean, dust-free and dry sterile container.
- Protect from direct light.
- Store sterile container in a clean and dry environment with controlled humidity at room temperature.
- Do not store sterile containers near aggressive substances (e.g., alcohols, acids, bases, solvents and disinfectants).

Note: Also observe your internal storage standards for sterilized products.

14. Reporting obligations

⚠ In order to comply with international regulatory requirements, we as a manufacturer are obliged to monitor our products even after delivery. This can only be done without any gaps if our customers and users commit themselves to comply with the following rules:

Product defects that have occurred during proper use of our products should be reported directly to the manufacturer or your supervising specialist dealer. Defects in which patients, users or third parties have been harmed by the products (so-called reportable incidents) must be reported immediately to the manufacturer and, if necessary, to your competent, responsible authority. This reporting of incidents must be done immediately after they occur so that important reporting deadlines can be met. The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your servicing dealer will be pleased to help you with this.

After receipt of your notification, we will inform you within a reasonable time frame about the further measures required.

15. Repair

⚠ **WARNING**

Risk of injury due to improper repair.
Repairs may only be carried out by the manufacturer or by persons authorized by the manufacturer.

⚠ **WARNING**

Risk of infection from unsterile instruments.
Reprocess the instrument before returning it to the manufacturer. Return the reprocessed instrument in its original packaging to the manufacturer.

/ See last page for manufacturer's address.

16. Dispose

Valuable raw materials can be recovered through environmentally compatible disposal. Dispose of the product in an environmentally friendly manner in accordance with the applicable hospital guidelines after prior reprocessing.

Berger Surgical
Medical Products GmbH

Take-off-Gewerbepark 4
D-78579 Neuhausen ob Eck

Phone: +49 (0) 7467 / 94977-0
Fax: +49 (0) 7467 / 94977-68
Web: www.berger-surgical.de
Mail: info@berger-surgical.de

Output status: 03/2021