IFU 2.2 – Suction instruments

1. General Information:

CE 0483 ⚠

These operating instructions are an essential part of the suction instrument purchased. Please read and follow these instructions carefully and keep them in a clearly visible and accessible place for later use.

The application and reprocessing (cleaning, disinfection and sterilization) may only be carried out by trained specialists.

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

⚠ **Please note that our instruments are supplied non-sterile and must be prepared (cleaned, disinfected and sterilized) before first use (see Chapter 8-11).**

2. Designs:

Suction tubes are available with various:
- Suction tube diameters
- working lengths
- overall lengths
- handle plate arrangements
- suction interrupters
- hose connections (4-10 mm cone)

For detailed information on the available sizes/ variants, please refer to our current product or price list.

Accessories: Individual suction instruments are available with stylet to prevent closure of the suction instruments after use. These are included in the standard scope of delivery.

3. Intended use / indication

The purpose of the suction instruments is to aspirate blood and other liquids, as well as small tissue fragments from the surgical area in the course of invasive and surgically invasive procedures. They are designed for connection to suction devices via a flexible hose connection, but are guided and operated manually.

⚠ *Suction instruments must not come into direct contact with the central nervous system!*

4. Contraindications & restrictions of use

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

⚠ *The selection of the appropriate suction instrument is the responsibility of the experienced user.*

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

There are no other known contraindications.

5. 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 **0483**	CE Marking Identification number of the notified body MDC from risk class IIa, compliant with RL93/42/EEC
REF	Order number
LOT	Batch number
	Non-sterile product

6. Application and safety instructions

Failure to observe these application and safety instructions may result in injuries, malfunctions or other unexpected incidents.

⚠ All reusable suction instruments must be completely reprocessed (cleaned, disinfected, and sterilized) before first use and before each subsequent use. The same applies when an instrument is returned to the manufacturer.

⚠ Before each use, the suction instrument must be inspected for visible damage and wear, e.g., cracks, breaks or loose attachments, corrosion spots. Ensure the patency of the suction instruments before each use.

⚠ The products must be removed from their original packaging and placed in containers suitable for reprocessing before the first reprocessing.

⚠ 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.

⚠ When connecting the suction instruments to the suction pump, ensure a secure and tight connection of the flexible connection hose at all times during use.

⚠ Select a vacuum power (negative pressure) at the suction pump that is appropriate for the surgical procedure and the amount of liquid to be aspirated. If the vacuum power is too high, sensitive tissue structures may be damaged, and if the suction power is too low, it may not be possible to efficiently remove the amount of liquid that has been created. Observe the operating instructions of the suction pump manufacturer.

7. Instructions for use / combination product

Suction instruments are used in combination with surgical suction pumps. To do this, connect the instrument to the suction pump and check for leaks by closing the suction openings. The maximum vacuum of the suction unit must be approximately reached:
- Attach suitable hose to the hose connection of the suction cannula.
- Connect the hose to a suitable suction unit.
- Avoid fixing leaks or loose hoses with adhesive tape.

Regulating the suction power during the procedure:
The surgeon can regulate the suction power using the breaker hole (if present) on the suction cannula, e.g., to prevent suction on sensitive structures. The power set on the suction pump determines the maximum vacuum applied to the suction cannula and thus the maximum suction power of the cannula.

- Suction: Cover the suction interrupter on the handle plate with your thumb.
- Do not aspirate: Remove your thumb from the suction interrupter on the handle plate.
- Regulating the suction power (for suction cannulas with drop-shaped suction interrupter
- Partially cover the suction interrupter on the handle plate depending on the desired suction power.

After use:

Rinse the suction instruments immediately after use and send them for reprocessing (see 8.1 and 8.2). If this is not ensured, the suction instruments must be placed in cleaning solution to prevent them from drying out and clogging the lumen. If necessary, use a suitable stylet to prevent clogging.

8. Preparing of the suction instruments

⚠ Risk of infection

- Reprocess the instrument before first use.
- Reprocess the instrument before each use.
- Prepare the instrument before returning it to the manufacturer.
- Observe the instructions for use for the cleaning agents and disinfectants used and for the cleaning and sterilization equipment used.
- Wear personal protective equipment during reprocessing.
- Dispose of disposable components after first use.
- If prions and Creutzfeld-Jakob disease are suspected, observe special reprocessing requirements. If necessary, dispose of suction instruments after use.

Advice:
Further information on reprocessing is provided by the Robert Koch Institute (RKI) and the Working Group for Instrument Reprocessing (AKI):
- RKI: Hygiene requirements for the reprocessing of medical devices (www.rki.de, latest version).
- AKI: Instrument reprocessing done right (www.a-k-i.org, latest version)

8.1 Preparing of decontamination

To prevent surgical residues from drying, the following steps must be performed immediately after the operation.

- Remove accessories such as adapters and connection tubes and prepare them separately.
- Rinse the suction instrument with cold water.
- Remove coarse dirt with cold water.
- Thoroughly rinse the cavities with cold water.
- Transport the instrument to the reprocessing site only in a closed container to avoid product damage and contamination of the environment.
- If rinsing with cold water is not possible, the instrument must be wrapped in a damp cloth to prevent the residues from drying.

8.2 Precleaning

Precleaning prevents surgical residues from drying. It must therefore be performed directly after the operation.
Pre-cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert as part of machine reprocessing:

Cleaning	Dosage	pH-value
Neodisher Mediclean forte	0,5 %	12-14 (alkaline)

⚠ **WARNING**

Risk of infection and pyrogenicity from residues due to the use of unsuitable cleaning agents.
- Do not use fixing agents.
- Do not rinse under hot water. City water with temperature < 40°C
- Rinse cavities, bores and threads (if present) with a syringe: Approx. 3 x 20 ml, blow out with compressed air, approx. 3.5 bar.
- Pre-clean suction instruments in an ultrasonic bath with 0.5 % cleaning agent at the following settings:

Temperature	Frequenz	Duration
approx 50 °C	35-45 kHz	> 5 min.

- Turn and move the components several times during cleaning in the ultrasonic bath.
- After US treatment, remove from the bath and feed to machine cleaning and thermal disinfection in the WD.

CAUTION: Avoid damaging the product.
- Do not use scratching brushes or sponges.
- Use only cleaning agents listed in this chapter.
- Use disinfectants with corrosion protection.

8.3 Cleaning and disinfecting

⚠ **WARNING**

Risk of infection due to inadequate reprocessing. The suction instruments are reprocessed in disassembled condition without connected accessories.

Classification of the suction instruments according to RKI guideline:

1. critical, group B, when used sterilely. Reprocessing only possible by machine according to validated procedures and appropriately trained personnel.

2. semi-critical, group B, only possible for non-sterile use in natural orifices, e.g., in dental and ENT practices (mouth, nose, throat).

If prions and Creutzfeld-Jakob disease are suspected, special reprocessing requirements must be followed. These procedures have not been described within the scope of these reprocessing instructions. Please refer to Annex 7 of the recommendation "Hygiene requirements for the reprocessing of medical devices" by RKI and BfArM.

8.3.1 Mechanical cleaning (alkaline) and thermal disinfection (validated cleaning procedure)

Mechanical cleaning was validated with the Miele RDG PG 8535 cleaning device.
Alkaline machine cleaning was validated with the Neodisher Mediclean Forte cleaning agent from Dr. Weigert:

Cleaning	Dosage	Ph-value
Alkaline	0,5 %	12-14 (alkaline)

Preparation
- Place instruments in the washer-disinfector after pre-cleaning (see 8.2).
- Place suction instruments in a strainer tray on the MIS insertion carriage of the cleaning device in such a way that the cleaning agent has access to all internal and external surfaces.
- If available, connect irrigation cannulas to MIC insertion carriage.

The correct cleaning program is decisive for adequate cleaning success. Compare the following cleaning program with that of your cleaning machine and save it if necessary:

Start cleaning program:
1. pre-rinse with cold water: > 1 min., temp. < 40°C.
2. drain
3. repeated pre-rinse with cold water: 3 min. (temp. < 40°C)
4. emptying
5. cleaning with 0.5% alkaline detergent: >5 min. at 55°C, e.g. Neodisher Mediclean Forte 0.5%
6. drain
7. neutralize with warm water: approx. 40 °C, 3 min., neutralizing agent e.g. Neodisher Z 0.1%)
8. draining
9. rinsing with deionized water: 3 min. temp. approx. 40 °C
10. emptying
11. thermal disinfection > 90° C for 5 min.
12. drying with 15-25 min. at 90-110 °C. The program of the WD must include an appropriate drying phase.
13. open the machine and allow any remaining water vapor to escape.

Remove the product from the WD after the end of the program and cooling to room temperature.
If necessary, blow out the product additionally with medical compressed air until it is completely dry.

9. Testing and Maintaining

Proper care of the instruments prolongs their service life and must therefore be performed after each cleaning.

Visually check for cleanliness using an illuminated magnifying glass (20x magnification). If residual soiling can be detected, the complete cleaning cycle must be repeated until the product is visibly clean.

Carefully visually inspect the clean instruments using a lighted magnifier (20x magnification) for surface changes, such as traces of corrosion, cracks and all forms of mechanical defects and loose parts. Check for sharp edges and burrs.

- Do not use or repair damaged instruments, but immediately exclude them from further use (mark as defective and discard).
- Replace brittle and cracked seals (if present).
- Maintain moving parts (e.g., joints, rotating stopcocks) with medical oil.
- Remove excess oil.

⚠ WARNING
Risk of injury due to defective or damaged components.

10. Packaging

The suction 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 the standards ISO 11607 and EN 868.

11. Sterilisation

⚠ WARNING
Risk of infection due to inadequate reprocessing.
If prions and Creutzfeld-Jakob disease are suspected, special reprocessing requirements must be observed. Please refer to Annex 7 of the recommendation "Hygiene requirements for the reprocessing of medical devices" by the RKI and BfArM.

ATTENTION!
Avoid product damage. Observe the maximum load of the device. See the manufacturer's instructions for use.

Sterilization was performed by the manufacturer using the ZentraCert sterilization unit from F.&M. Lautenschläger under worst-case conditions. The validated worst-case parameters were: Half-cycle procedure at 132°C and 2 min holding time.

With this worst-case selection, the common autoclaving temperatures and holding times in Europe are adequately considered. We recommend the implementation of the respective current RKI guidelines.

For the following countries, there are deviating specifications that must be adhered to:

Country	Sterilization time
Germany	> 4 - 30 min.
France	≥ 18 - 30 min.
Switzerland	≥ 18 - 30 min.

Note: Holding times of >4-30 min. has no negative effect on the suction instruments.

Place instruments in the sterilization unit so that no components are in contact and the steam can circulate freely.
Set sterilization parameters (4-fold fractionated pre-vacuum), drying time 20 min.

Temperature	Pressure	Duration
134 °C	3 bar 44 psi	*/ See information in this chapter.*

Start sterilization process.

12. Storage of sterile 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.

13. 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.

14. Disposal

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.

15. Information on devices and agents used

The specifications for pre-cleaning, mechanical reprocessing and sterilization in the autoclave were validated under worst-case conditions and summarized in the following reports..

- Berger TUT Saugkanüle Final Report Aufbereitungsvalidierung maschinell 2020-04-28 11759
- Berger TUT Saugkanüle Final Report Sterilisationsvalidierung 2020-04-30 11760

The following materials and machines were used for validation:

Detergent:
- Neodisher Mediclean Forte 0.5% (alkaline cleaner).

Washer-disinfectors (RDG):
- Miele RDG PG 8535

Ultrasonic bath:
- Neodic Mediclean Forte 0.5% (alkaline cleaner)

Sterilization equipment:
- Lautenschläger ZentraCert

Sterilizing agent: moist heat, 132°C, 2 min. (worst case)

For the validation, the lower limits for the respective reprocessing steps were selected to ensure that the information provided in these reprocessing instructions leads to safer reprocessing results.

16. Limited useful life

The service life of surgical instruments is only insignificantly 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, the instruments must be marked and excluded from further use and replaced by functional instruments (see also chap. 9. Inspection and care).

17. 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 take place 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.

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