medical bees GmbH

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Products

These instructions are valid for the following listed product groups:

REF MB1-17-XXX-XX
MB1-20-331-XX

Important note

Before using the product, carefully read this User Manual, while keeping it easily available for the Operator or for appropriate service personnel.

Carefully read all the symbol-marked caution and warning texts. Incorrect use of the products may lead to serious injury to the patient, the user or other persons.

1 Application

The instruments shall be exclusively applied for the purpose for which they have been intended in the medical fields and used by educated and qualified personnel. The attending physician or user shall be responsible for the selection of instruments for specific applications or for surgical procedures, proper training and information, as well as for having the adequate experience in handling of the instruments.

1.1 Intended use and indications

The skull clamping system is used for self-holding fixation of the head, the neck and the vertebral column during surgical procedures.

1.2 Indication

For rigid fastening of the head during surgical operations on the head, the neck or the vertebral column.

1.3 Contraindications

No contraindications could be identified.

1.4 Complications

- Epicranium tear
- Skull fracture
- Epidural haematoma
- Dural tear
- Air embolism
- Leak of cerebro-spinal fluid
- Infection of puncture site
- Breaking of the clamp
- Traumatic arterio-venous fistula
- Traumatic aneurism of the superficial temporal artery
- Sinus fracture

1.5 Adverse effects

- Haemodynamic reaction

2 Precautionary measures and warnings

⚠ Handling of brand new instruments

Before initial use, brand-new tools and accessories shall undergo the entire reprocessing process once.

⚠ Functional impairment

Surgical instruments may corrode, and their functionality may be affected after contact with aggressive substances. For this reason, it is imperative to follow the Preparation Instruction and the Sterilisation Instruction.

⚠ Operating conditions

In order to ensure the safe operation of the above-mentioned products, their proper maintenance and care shall be indispensable. In addition, a functional and visual inspection should be carried out before every use of any instrument. Therefore, we would like to refer to the appropriate sections in these Instructions.

⚠ Reprocessing

Regarding the reprocessing of medical devices that have been used in patients, who are either suffering from or are suspected to be suffering from Creutzfeldt-Jakob disease (CJD) or from any of its variants (vCJD), it shall be necessary to observe the requirements contained in the appropriate enclosure of the directive concerning hospital hygiene and infection prevention, as specified in the publications of the Federal Health Bulletin. The medical devices that were used in the above-mentioned patient group, shall be safely be removed by incineration (European Waste Catalogue 180103) (Cat. IB). Dry heat, ethanol, formaldehyde and glutaraldehyde exert fixing, however, have no inactivating effect on TSE agents. Out of the available sterilisation processes, only steam sterilisation (in particular at 134°C for 18 minutes) indicated some limited effect.

⚠ Storage

There are no specific requirements for storage of the products before sterilisation. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

⚠ Preparation of surgical intervention

Antibacterial ointment shall be applied on the pins.

⚠ Application in children

In children, pins for children shall be used.

⚠ Positioning of the pins

When positioning the skull clamp, the thickness of the cranial bone shall be considered if possible. The pins shall not be placed near the big vessel of the epicranium, an earlier wound or before a sinus.

⚠ Removal of the pins

The pins shall not be removed as long as the patient is in the sitting position.

3 Liability and warranty

The guarantee for devices and accessories shall be cancelled in case of their unintended use and/or inappropriate operation, storage or transport. The Manufacturer shall assume no responsibility for damage that arises from repairs or maintenance provided by unauthorised service stations.

4 Sterility

NON STERILE As-delivered condition

The medical devices are delivered as non-sterile and shall be processed and sterilised by the user before the first and any further use, according to the following instructions.

5 Limitation of processing and waste disposal

Frequent reprocessing has little effect on the instruments. The life period of the device is normally determined by wear and damage during use. After the service life of the instrument is over, it should be submitted for professional disposal or recycling. It shall also be necessary to observe national regulations and disposal guidelines.

6 Processing

⚠ Warning tips

- The applied tap water shall meet drinking quality.
- Products shall be dismantled before cleaning.
- The dismantled products shall be assembled again before sterilisation.
- No cleaning agents containing chloride can be used in order not to affect the passive coating.

⚠ Place of use

Coarse impurities, residues, e.g. agents, used for haemostasis, skin disinfection and lubrication, as well as corrosive medicinal products, shall, where possible, be removed before the devices are placed aside.
Wherever possible, dry disposal shall be preferred (a humidified closed system)
Drying of residues on device surfaces shall be avoided!
Long delays before reprocessing, e.g. overnight or weekend must be avoided in both methods of disposal (<6 hours).

⚠ Transport

The products shall be immediately disposed of in dry condition after use. It means that the devices shall be handled wet in a closed container from the place of use to the place of reprocessing to avoid drying out.

Preparation for decontamination

The devices shall, where possible, be dismantled before subsequent processing stages or be submitted to reprocessing in an opened condition. No areas shall be left unwashed. The devices shall be reprocessed in suitable baskets or drainage bowls (tailored to the size of the products). The devices shall be fixed in a cleaning basket with a minimum distance from one another. Overlapping of devices on one another shall be avoided in order to exclude any damage during the cleaning process. The quantity and arrangement of the load on instrument trays shall be such as to exclude any negative impact of the cleaning process. The devices shall be arranged in such a way that water can freely flow out from cannulae, blind holes (blind bores) and hollow bodies.

Pre-cleaning process

Flush the devices under cold tap water of drinking quality (<40°C) as necessary to remove any visible soiling. Adhering dirt shall be removed with a soft brush. Movable parts on a device should be moved. Cavities, lumens, gaps and slots shall be intensively rinsed with a spray gun (or a similar device) (>60 s), using cold tap water of drinking quality (<40°C). Place the devices in an ultrasound bath (<40°C) with an alkaline cleaning agent (0.5% neodisher® MediClean forte), carry out acoustic irradiation for 5 minutes with a frequency of approx. 35 kHz. In doing so, follow the instructions of the cleaning agent manufacturer. Devices shall be placed in such a way as to cover all their surfaces, cavities, lumens and openings. Afterwards, the devices shall briefly (<15 s) be flushed with cold water. Movable parts should be moved. Cavities, lumens, gaps and slots shall be intensively rinsed again with a spray gun (or a similar device) (>30 s), using cold tap water of drinking quality (<40°C).

Cleaning / disinfection

A) Manual cleaning process

1. Place the devices in an ultrasound bath (<40°C) with an alkaline cleaning agent (0.5% neodisher® MediClean forte), carry out acoustic irradiation for 10 minutes with a frequency of approx. 35 kHz. In doing so, follow the instructions of the cleaning agent manufacturer.
2. Then clean the devices completely with a soft brush. Cavities and lumens, if present, shall be intensively flushed with a spray gun (or a similar device) (>30 seconds).
3. Rinse the devices under running tap water of drinking quality to remove the cleaning agent (>15 seconds).

Manual disinfection

1. Immerse the devices in an RKI- and VAH-listed disinfectant. In doing so, follow the instructions of the disinfectant manufacturer. It shall be guaranteed that the disinfectant reaches all the areas of the disinfected device (move parts in the disinfection bath and rinse any covered surfaces with a syringe - without a cannula - with the disinfecting agent).
2. The process is validated with the following disinfecting agent: 3% Korsolex Plus, 15 minutes.
3. Rinse of the devices (complete rinsing of inside and outside surfaces and cavities) in demineralised water >15 seconds.

Manual drying

Manual drying with a disposable lint-free cloth. In order to avoid as much water residues in cavities as possible, we recommend blowing them with sterile, oil-free compressed air.

The devices must not be heated above 140°C.

B) Automatic cleaning / disinfection process

(*Washing machine, a washer-disinfector acc. to EN ISO 15883*):

- Pre-clean for 1 minute in cold tap water of drinking quality <40°C
- Water draining
- Pre-clean for 3 minutes in cold tap water of drinking quality <40°C
- Water draining
- Clean for 5 minutes in a 0.5% alkaline cleaning agent (*0.5% MediClean*) with a temperature of 55°C±5°C
- Water draining
- Neutralisation for 3 minutes (0.1% *Neodisher® Z*) in cold tap water of drinking quality <40°C
- Water draining
- Rinse for 2 minutes in demineralised water <40°C

The special instruction manuals of automatic washer/disinfector manufacturers shall be followed.

Automatic disinfection

Automatic thermal disinfection in a washer/disinfector, with consideration of national requirements regarding A_0-value;

e.g. A_0- value 3000:

>5 minutes at 92°C±2°C

with demineralised water.

Automatic drying

Automatic drying acc. to the drying process of the washer/disinfector, for at least 30 minutes (at 60°C±5°C in the spray cabinet). Otherwise, perform manual drying with a lint-free cloth, blowing holes (lumens) with sterile, oil-free compressed air.

Inspections

After every cleaning, the devices shall prove to be macroscopically clean, i.e. free from any visual contaminations.

- Stained devices shall immediately be sorted out and submitted to a special processing.
- All movable parts shall be inspected with particular care.
- In cases where any defects or damage are identified, such devices shall immediately be sorted out.

Maintenance and care of instruments

Allow the devices to cool down to room temperature. “Maintenance” means the application of oil or instrument milk (emulsion of white oil in water). Devices with articulated joints or locks (forceps, clamps, etc.) or with metal sliding surfaces (punches, etc.) shall be treated with maintenance paraffin oil-based agents. The applied paraffin oil shall always conform with a valid pharmacopoeia and be physiologically safe, acc. to the “German Pharmacopoeia, 10th Edition (DAB 10)” or “The European Pharmacopoeia (Ph. Eur.)” or the “American Pharmacopoeia”, “United States Pharmacopeia (USP)”. The care agents reduce metal-on-metal friction and keep the devices functioning smoothly. After treatment with phosphoric acid and basic cleaners, laser printed devices may grow pale. Thereby, the coded signs and symbols may become impaired or simply disappear. In general, the devices have to be subject to continuous maintenance before functional tests. The care agents must ensure that in case of their constant application, “sticking” of joints, resulting from any additional effect, is also excluded.

Packaging

The devices are single-packed in a packaging, tailored to each device and standard-conformable, provided to sterilisation, acc. to DIN EN ISO 11607 or DIN EN 868 standards and sealed.

Sterilisation

Sterilisation of the devices is carried out, using a fractionated pre-vacuum procedure (acc. to DIN EN ISO 17665-1 standard), taking into account valid national requirements. Sterilisation shall be performed with the devices inside their sterilisation appropriate packaging.

The sterilisation process shall be carried out, using a fractionated pre-vacuum procedure with the following parameters:

134°C / 273.2°F,

duration of ≥5 minutes

3 pre-vacuum cycles

Drying in a vacuum for at least 20 minutes

The instruction manual of the autoclave manufacturer shall be followed, and the recommended guidelines shall be taken into account, regarding the max load of devices for autoclave sterilisation. The autoclave shall be correctly installed, maintained, validated and calibrated.

⚠ **Supplementary information**

The Reprocessor has the responsibility to guarantee that the reprocessing conducted with the equipment used, materials and personnel in the reprocessing facility achieves the required results. Therefore, in general, validation and routine monitoring of the applied procedures and of the used equipment shall be required.

7 Service, repairs and return shipment

⚠ **Service and Repairs**

The user shall not be allowed to carry out any repairs or implement changes in any device. The authorised personnel of the manufacturer shall be exclusively responsible and intended to provide services. Please, contact us, should you have any objections, complaints or comments, regarding our products.

⚠ **Return shipment**

Defective or non-conforming products shall be submitted to the entire reprocessing procedure prior to their return shipment for repair/service. In addition, the products shall be appropriately marked as "*hygienically safe*" or "*not decontaminated*".

8 Storage

- Protect the devices against mechanical damage.
- The devices shall be stored and transported in safe containers / packaging units.
- Handle with great care, protecting from dropping or falling.

For sterilisation as well as for the transport and storage of devices after sterilisation appropriate and recommended sterilisation containers shall be used (e.g. those acc. to DIN EN 868, ISO 11607 standard).

9 Test instruction

Prior to every use, the retractors shall be checked for fractures, cracks, deformations, damage and for proper functionality. It is especially essential to check areas, such as locks and snaps, as well as movable parts. Worn, corroded, deformed, porous or otherwise damaged retractors shall be sorted out. The stainless steels (non-corroding), used for production, create - based on their alloy technology - specific passive layers as protective layers. These steels only resist the effects of chloride ions and aggressive media and fluids conditionally! In addition to the efforts that have been undertaken by the manufacturer through the selection of proper materials and careful processing, the user of the retractors shall carry out professional and continuous maintenance and proper reprocessing.

9.1 Inspections

- Visual inspection for dirt or surface changes
- Visual inspection for fracture sites
- Inspect the working tips for integrity

10 Description of used symbols

⚠	Attention!
	Observe the User's Manual
REF	Article number
LOT	Batch designation
CE	CE symbol
NON STERILE	Information for not sterile device
	Name and address of the manufacturer