



Reusable Surgical Instruments



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IMPORTANT INFORMATION – PLEASE READ BEFORE USE

PRODUCT GROUPS:

Drills	Cannulae, catheters	Saws
Bougies, dilators	Chisels	Scissors
Dermatomes	Knives, scalpels	Snare instruments
Diagnostic instruments	Suture instruments	Specula
Plaster cast instruments	Tweezers	Punches
Hammers	Dissection instruments	Strippers
Manual instruments	Curettes	Tissue retractors, hand-held
Forceps	Clamps	Laryngoscopes

INTENDED USE:

Frimed Medizintechnik GmbH manufactures instruments as standard instruments for surgical use in general surgery. The treating doctor is, however, responsible for selecting the instruments for a specific application or for surgical use. The doctor is also responsible for ensuring that the surgical team are appropriately trained and receive sufficient information as well as having adequate experience in the use of the instruments.

The individual intended uses of the product groups and the associated article numbers are listed in the appendix.



WARNINGS:

- The surgical instruments are intended for uninterrupted use for up to 60 minutes.
- The surgical instruments are not intended for use in ophthalmology.
- All surgical instruments are sold nonsterile.
- All surgical instruments must be cleaned, disinfected and sterilized before and after use.
- Do not use strongly alkaline or acidic cleaning solutions.
- None of the surgical instruments may be used on either the central circulatory system or the central nervous system.

“Central circulatory system” refers to the following blood vessels: *pulmonary artery, ascending aorta, aortic arches, descending aorta to the aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachiocephalic trunk, cardiac veins, pulmonary veins, superior vena cava and inferior vena cava.*

“Central nervous system” refers to the brain, meninges and the spinal cord.

Limitations on reprocessing:

- Regular reprocessing (with ultrasound, manual cleaning, sterilization) has minimal effects on the instruments.
- Thoroughly inspect the products before every use to ensure that they are functioning correctly.
- The service life of the products is normally determined by wear and tear or damage during surgical use.
- Signs of damage and wear and tear to a product may include corrosion (rust, pitting), discolouration, deep scratches, flaking, wear and cracks. Products that do not function properly, products with illegible identification, missing or removed (worn) article numbers, and damaged and severely worn out products must not be used.
- Do not use damaged instruments. They must be disposed of in accordance with standard hospital procedures.

DIRECTIONS

Point of use:

- Remove any contamination with a single-use wipe/paper towel.
- All instruments should be rinsed with a high-pressure water jet.

Transport:

It is recommended that contaminated instruments are transported in a closed, clean container.
It is recommended that the product is processed 2 hours after use at the latest.

Preparing for decontamination:

Wear personal protective equipment (gloves, a water-repellent apron, face shield or safety glasses, and follow the instructions of the manufacturer of the detergent or disinfectant).

For cleaning/disinfection of the instruments, an automated process (washer-disinfector) should be used. According to the RKI guideline "Hygiene Requirements for the Reprocessing of Medical Devices", a manual process is not recommended due to the considerably lower effectiveness. The disadvantages of manual reprocessing lie primarily in the issues of reproducibility and standardisation along with protection of personnel.

Pre-cleaning:

Equipment: Personal protective equipment (as listed above), cold tap water ($20^{\circ}\text{C} \pm 2^{\circ}\text{C}$) of at least drinking quality (corresponding to the RKI guideline), high-pressure spray gun.

- 1) Rinse the products for at least 1 minute with a high-pressure spray gun, paying special attention to critical and difficult to access areas.

Cleaning: Manual

- Before manual cleaning and subsequent manual disinfection: Pre-clean the products (see section on "Pre-cleaning").
- **Equipment:** Cleaning solution: multi-step enzymatic cleaner (e.g. Neodisher Medizym), plastic brushes (e.g. Interlock #09095, #09084, #09050, #09068), container for cleaning solution, tap water ($20^{\circ}\text{C} \pm 2^{\circ}\text{C}$) of at least drinking quality (corresponding to the RKI guideline).
 - 1) The cleaning solution must be prepared according to the manufacturer's instructions (e.g. Neodisher Medizym 0.5% solution).
 - 2) Immerse the product in the cleaning solution.
 - 3) The soaking time must correspond to the manufacturer's instructions (at least 20 minutes for Neodisher Medizym 0.5% solution).
 - 4) During the soaking time, the product remains immersed in the solution; at the same time the outer surfaces and cavities are brushed with the cleaning brushes (e.g. #09084) to remove soiling from the surfaces.
 - 5) Clean the inner surfaces, the working parts and blind holes on surgical instruments with cleaning brushes (e.g. #09095, #09050, and #09068) at least 15 times to remove soiling from the surfaces.
 - 6) During the soaking time, the product remains immersed in the solution; at the same time, narrow cavities on the surgical instruments, like all other difficult to access areas inside the products, are cleaned at least 15 times with a soft brush to remove visible soiling.

Pay special attention to critical and difficult to access areas where the effectiveness of the cleaning cannot be visually checked.
 - 7) Remove the product from the cleaning solution.
 - 8) Rinse the product for 1 minute under running tap water, ensuring that all surfaces are rinsed for at least 10 seconds.
 - 9) Check the cleanliness; if there is visible residual contamination, the above steps must be repeated.

Disinfection: Manual

- **Equipment:** Use an aldehyde-free disinfectant such as Bomix Plus from Bode Chemie GmbH. When using a disinfectant for manual disinfection, the material compatibility must be checked beforehand. Containers for disinfectant solution, tap water ($20^{\circ}\text{C} \pm 2^{\circ}\text{C}$) of at least drinking quality (corresponding to the RKI guideline), ultrasonic bath (35 kHz), deionised water (free of facultative microorganisms in accordance with the KRINKO/BfArM recommendation), lint-free cloths or compressed air gun with medical-grade compressed air (corresponding to the European Pharmacopoeia), a 20 mL syringe (e.g. B. Braun # 4606205V)
 - 1) The disinfectant solution (e.g. Bomix Plus 1% solution) must be prepared according to the manufacturer's instructions in an ultrasonic bath.
 - 2) Immerse the product completely in the disinfectant solution.

- 3) The soaking time must correspond to the manufacturer's instructions.
- 4) Fill a 20 mL syringe with disinfectant (e.g. Bomix Plus 1% solution) and while the product is soaking flush narrow cavities and blind holes on the surgical instruments and all other difficult to access areas of the product at least 5 times.
- 5) **Pay special attention** to critical and difficult to access areas where the effectiveness of the cleaning cannot be checked with a visual inspection.
- 6) After the soaking time (e.g. 15 minutes for Bomix Plus 1% solution), start a 5 minute ultrasonic cleaning (35 kHz).
- 7) Switch the ultrasonic cleaning off.
- 8) Remove the product from the disinfectant solution.
- 9) Rinse the product for at least 1 minute under running tap water.
- 10) Repeat the rinsing step for at least 1 minute using deionised water.
- 11) Wipe the product with a lint-free single-use cloth or towel or dry it using compressed air.

Cleaning and disinfection: Automated

- If there is visible residual contamination in gaps, openings, joint surfaces, threads and other difficult to access areas: pre-clean the instruments (see section on "Pre-cleaning") and continue with manual cleaning.
- **Equipment:** System for thermal disinfection (washer-disinfector) as defined by DIN EN ISO 15883-1/-2 with a thermal program (temperature 90°C–93°C), mild alkaline detergent (e.g. Neodisher Mediclean Forte 0.5%), lint-free cloths or compressed air gun with medical-grade compressed air (corresponding to the European Pharmacopoeia).
 - 1) Place all parts of the product in a suitable cleaning tray/rack for thermal disinfection (washer-disinfector) or connect surgical instruments with lumens to irrigating ports on a suitable cleaning tray/rack.
 - 2) Close the washer-disinfector and start the thermal programme; the programme parameters are listed in the following table.
 - 3) Remove the product when the programme has finished.
 - 4) Check if the product is completely dry. Wipe the product if required with a lint-free single-use cloth or towel or dry it using compressed air.

Programme step	Water	Dosage	Time	Temperature
Pre-rinse	Municipal water		5 minutes	Cold
Dose detergent		Neodisher Mediclean Forte 0.5%		
Cleaning			10 minutes	55°C
Rinsing	Deionised water		2 minutes	Cold
Thermal disinfection			A ₀ value >3000 ¹ (e.g. 5 minutes, 90°C)	
Drying			15 minutes	Up to 120°C

¹ Under some circumstances, authorities require compliance with different methods (parameters for the disinfection) for their area of responsibility

Maintenance, inspection and checking:

Equipment: Silicone-free instrument oil for use on medical devices that is suitable for steam sterilisation (e.g. Sterilit® spray from B. BRAUN, Aesculap or other suppliers).

- Inspect all components of the product under good lighting for any residual contamination. For any components with visible residual contamination, repeat the manual cleaning (including pre-cleaning) and automated cleaning and disinfection or manual disinfection.
- Check the product for completeness, damage and functionality.
- Check long products for twisting.
- Do not use damaged instruments.
- Lubricate any moving parts of the instrument with silicone-free instrument oil that is suitable for steam sterilisation.

Wrapping:

Wrap in a sterile-barrier system as defined in DIN EN ISO 11607 or DIN 58953 (double-wrapped sterilisation paper was used for the validation).

Sterilisation (Germany, validated):

Equipment: Steriliser as defined by DIN EN 13060 and/or DIN EN 285

- Pre-vacuum, 134°C (273°F) and a sterilisation time of at least 5 minutes

- Sterilise the product disassembled, if possible.
 - 1) Place the wrapped product in the sterilisation chamber.
 - 2) Start the programme.
 - 3) Remove the product when the programme has finished and allow it to cool.
 - 4) Check if the wrapping is tightly sealed and dry.
- Drying time at least 20 minutes

Due to the parameters used during the validation of the sterilisation process, longer holding times and/or higher temperatures were covered.

Other possible sterilisation times and sterilisation temperatures:

USA: at least 4 minutes at 132°C (270°F), drying time at least 20 minutes

France: at least 5 minutes (for prion inactivation 18 minutes) at 134°C (273°F)

Other countries: at least 5 minutes at 132°C (270°F) / 134°C (273°F)

Service life:

The products are intended for repeated use. The end of the product service life is normally determined by wear and damage after use. All reusable surgical instruments are verifiably designed for at least 50 sterilisation cycles in the autoclave with moist heat at 134°C and a period of 3 minutes.

Additional sterilisation cycles beyond the service life defined here are possible but are the responsibility of the user and should be confirmed by additional testing.

The products have also reached the end of their service life if

- the products no longer function
- the products are worn
- the identification of the products is no longer legible

Storage:

Storage period and shelf life are defined by the user.

- The instruments must be stored in a dry, clean and moisture-free environment with no direct sunlight.
- Do not store in locations where chemicals release corrosive vapours or where fluctuating temperatures or humidity lead to the formation of condensation on the instruments.

Other information:

Only validated processes may be used for reprocessing medical devices.

Symbols used:



Manufacturer



Catalogue number



Batch code



Caution



Nonsterile



Consult instructions for use



Keep dry



Keep away from sunlight



Medical device



Date of manufacture



0483 CE mark with the Notified Body number



CE mark



Please note the precise product descriptions and special features of the reprocessing and sterilisation in the following sections.

Appendix with intended use / indication for the product groups listed above.

Products	Intended use	CE mark	
		CE 0483	CE
Drills (021... 024... 026... 032... 037... 046...)			
Drills	Drills are used to form holes in bone using hand-powered drives (hand crank, T-handle).	X	
Awls	Awls are used to form holes in tissue, mucous membranes and corneas or to perforate or dissect bone and cartilage	X	
Trephines	Trephines are surgical instruments with a cylindrical blade for removing bone fragments, cornea, e.g. in eye surgery, and tissue. Trephines are also used to take bone biopsies from bone marrow, e.g. for bone cancer or leukaemia.	X	
Bougies and dilators (025... 027... 030...)			
Bougie / dilator	These instruments are used to expand and dilate hollow organs and body cavities.		X
Dermatomes (010...)			
Dermatome	Special instrument/knife for producing thin layers of skin for grafting or for removing (excising) skin lesions	X	
Diagnostic instruments (018... 030... 032... 034... 037...)			
Dynamometer	Instrument/device for measuring the contraction force of a muscle group		X
Goniometer	Goniometers are instruments for determining joint angles, axis deviations of the spine and range of motion of extremities.		X
Mirror	Mirrors are auxiliary instruments for examination, e.g. of the larynx and the mouth/throat area.		X
Tuning fork	Instrument for examining hearing ability		X
Caliper	Instruments for measuring distances and sizes (pelvic measurement, ophthalmic caliper)		X
Ruler	Instrument for measuring lengths		X
Plaster cast instruments (020...)			
Plaster saw	Instrument for sawing plaster casts		X
Plaster cutter	Cutter for cutting or scraping off plaster casts		X
Plaster scissors	Scissors for cutting plaster casts		X
Plaster spreader	Instrument for spreading apart plaster casts after sawing or cutting		X
Hammers (018... 024...)			
Mallet for bone surgery	Mallets are used to bend bone plates, insert bone nails or, together with chisels / osteotomes, to collect bone fragments	X	
Percussion hammer with and without needle	Percussion hammers are used in diagnostics to check reflexes and mechanical vibrations		X
Manual instruments (016... 017... 019... 024... 025... 026... 027... 030... 032... 037...)			
Elevator	Elevators are levering instruments to lever out bone fragments	X	
Enucleator	Enucleators are used to scoop out or to dissect tissue	X	
Probes, bulbous probe, hollow probe	Probes are inserted into body cavities or tissues for examination of treatment.	X	
Spatulas	Spatulas are used to apply, extract, mix or remove substances, for holding or pressing back tissue or for diagnosis.	X	
Finger guard	Finger guards are used as protection against bite injuries during examinations and treatment in the dental sector.		X
Tendon passer	Surgical instrument for guiding tendons	X	
Hypophysectomy instruments	Instruments for manipulation and dissection in neurosurgery	X	

Cannulae (017... 034...), catheters (027... 035...)			
(Ear) cannulae	Cannulae are used to drain secretions and fluids as well as to insufflate powdered medications		X
Catheters	Catheters are used to drain fluids and secretions Hollow organs such as the bladder or the ears can be probed, drained, filled or flushed.		X
Ear syringe	Ear syringes are used to flush the auditory canal		X
Clamps (015...025...027...030...037...085...)			
Clamps	These instruments are intended to grip, join or clamp organs, vessels and tissues.	X	
Bulldog clamps	Bulldog clamps are used to clamp blood vessels and vessel stumps and to dissect or grip tissue in surgery.	X	
Laryngoscopes (018...)			
Laryngoscope	Laryngoscopes are instruments for examining the neck, pharynx and larynx and for use during intubation		X
Chisels (024... 035...)			
Chisels, osteotomes	To remove or separate bones in ENT, orthopaedic surgery and reconstructive surgery.	X	
Knives and scalpels (010... 024...)			
Knives/scalpels	Knives and scalpels are used to cut skin, tissue and vessels.	X	
Suture instruments (019... 034... 037...)			
Suture passer, hollow lumen passer	The instrument is used to guide and manipulate sutures during wound closure.	X	
Ligature needle	Ligature needles are used to place ligatures on blood and lymph vessels	X	
Redon needle	Redon needles are used to place a drainage tube	X	
Surgical needles	Surgical needles are used for suturing during wound closure	X	
Needle holder	Surgical instrument to hold needles during wound closure	X	
Tweezers (013... 025... 032... 035...)			
Tweezers	Tweezers are used to grip and dissect tissue and vessels. They are also used to hold sutures during wound closure.	X	
Dissection instruments, curettes (024... 027... 030...034...)			
Bone files	Files for smoothing bone fragments		
Curettes	Instrument for scraping out or shaving off tissue or bone	X	
Bone rasp	Bone rasps for processing and removing bone in bone surgery	X	
Sharp spoon	Sharp spoons are instruments for surgical removal of soft tissue on bone or periosteum.	X	
Saws (021... 024... 026... 035...)			
Wire saws	Saws for sectioning bones while protecting soft tissue		
Amputation saws	The amputation saw is used to separate body parts.	X	
Finger ring saws	Saw to cut through finger rings		X
Scissors (011... 012... 020... 046...)			
Scissors	Scissors are used to cut through tissue, bone, organs, clothing, dressing materials and other medical aids.	X	
Snare instruments (034... 035... 037...)			
Haemorrhoidal ligators	Haemorrhoidal ligators are intended for interrupting the flow of blood to haemorrhoidal tissue. This interruption is created by placing a rubber ring around the tissue.		X
Snare instrument, tonsil snare	Snare instruments are used to ligate vessels, polyps or to pinch off tonsils.	X	
Ear loops	Ear loops are used to gently clean the auditory canal		X
Tourniquet	Instrument to bind vessels	X	
Specula (027... 030... 034... 035...)			
Ear speculum	Ear specula are used for examinations and procedures in the external auditory canal and the eardrum		X
Nasal speculum	The nasal speculum is a spreading instrument for the ala of the nose and to hold back nasal hairs.		X

Rectal speculum	Rectal specula are used to open and dilate the anal cavity and the rectum		X
Anoscope	Anoscopes are used to examine the sphincter muscles or the anal cavity.		X
Vaginal speculum	Vaginal specula are used for gynaecological examinations (spreading) of the vagina.		X
Punches (026... 034... 035...)			
Bone punches	A bone punch is a robustly constructed instrument with a sharp working end that is used to remove bone and bone fragments.	X	
Punches	A punch is a robustly constructed instrument with a sharp working end that is used to remove tissue, cartilage and bone fragments.	X	
Sterilisation containers, containers (85... 091... 92... 093... 094... 095... 097... 98... 99...)			
Sterilisation containers	Sterilisation containers are used for sterilisation, storage and transport of medical instruments and accessories. Used medical instruments are placed in sterilisation containers for reprocessing and are cleaned, disinfected and sterilised ready for use with the next patient.		X
Containers	Containers are used for transport and clean storage of medical instruments.		X
Bowls	Medical bowls are used as an aid during surgery, for placing instruments, suture needles, etc. or for collecting human tissue and body fluids.		X
Vertical storage container	Vertical storage containers are used to store sterile clamps		X
Wire pusher	Wire pushers are used for easy removal of cerclage and guide wires during surgery		X
Strippers (017... 024...)			
Tendon stripper	Tendon strippers are surgical instruments that are used for removing tendons	X	
Vein stripper	Vein strippers are surgical instruments for surgical removal of varicose veins	X	
Tissue retractors, hand-held (016... 037...)			
Tissue retractors (hand-held)	Hand-held tissue retractors are used to keep delicate tissue and organs away from the surgical field. Sharp tissue retractors are used to hold back less delicate tissue.	X	
Forceps (013... 015... 018... 019... 021... 024...)			
Forceps	Forceps are used to grip tissue, bone, vessels and aids.	X	
Obstetric forceps	Forceps for obstetrics		X
Cotton swab forceps	Cotton swab forceps are used to hold medical aids and materials	X	
Wire cutters, wire nippers	Cutters for cutting and shortening wires in bone surgery	X	
Bone cutting forceps, rongeur forceps, laminectomy forceps	Forceps for cutting and preparing bone and bone fragments	X	
Clip applying forceps	Forceps for placing wound clips for wound closure	X	
Wire twisters, wire grasping pliers	Wire twisters for gripping and processing wires in bone surgery	X	
Kidney stone forceps	Forceps for grasping kidney stones	X	
Gall stone forceps	Forceps for grasping gall stones	X	
Sharp nasal forceps	Forceps for preparing cartilage and bone fragments in rhinology	X	
Steriliser forceps	Forceps for grasping sterilised instruments	X	

Special features of certain instruments for reprocessing and sterilisation:

INTERVERTEBRAL DISC PUNCHES

Intervertebral disc punches with article numbers 026-700-001 to 026-754-006 are dismantled for better reprocessing:

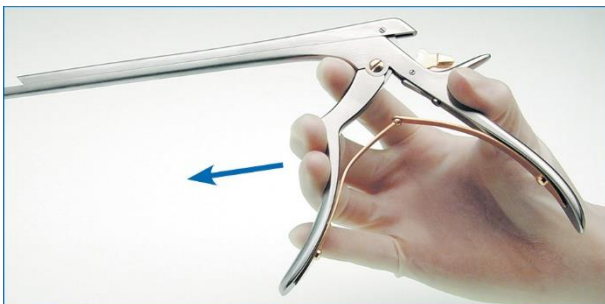
Instructions for dismantling intervertebral disc punches:



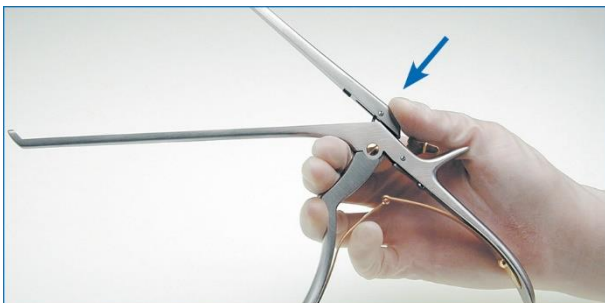
Close the handle...



press the lock downward...



open the handle again...



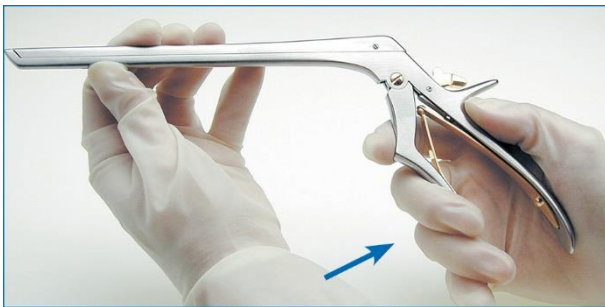
and press down on the base of the shaft...

The instrument can now be reprocessed.

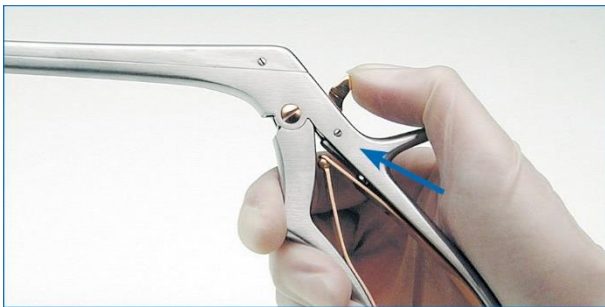
When the reprocessing is complete, the instrument is reassembled.



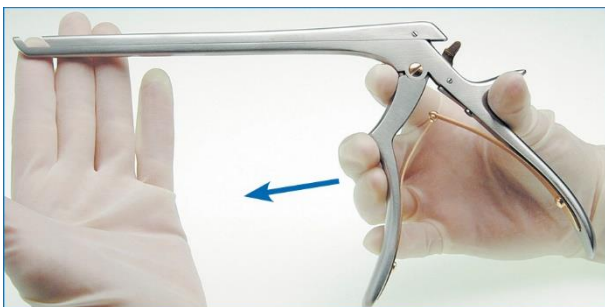
Place the parts of the shaft together...



close the handle...



press the lock upward...



and open the handle again...

The instrument can now be stored sterile until it is next used.

BONE HOLDING FORCEPS

Bone holding forceps with article numbers 024-790-230 to 024-799-190 are dismantled for better reprocessing:

Instructions for dismantling bone holding forceps:



The forceps are opened out...



until the notches align...



The legs now separate from each other.

The instrument can now be reprocessed.

When the reprocessing is complete, the instrument is reassembled.



Place the legs one over the other...



engage them together...



and close the forceps again.

The instrument can now be stored sterile until it is next used.

OBSTETRIC FORCEPS

Obstetric forceps with article numbers 030-911-280 to 030-927-440 are dismantled for better reprocessing:

Instructions for dismantling obstetric forceps:



The obstetric forceps are opened out...



the legs now separate from each other.



The instrument can now be reprocessed.

When the reprocessing is complete, the instrument is reassembled.



Place the legs one over the other...



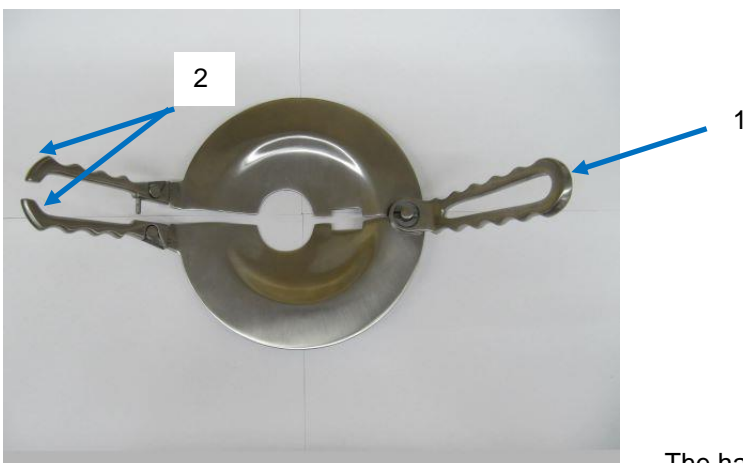
engage them and close the obstetric forceps again.

The instrument can now be stored sterile until it is next used.

AMPUTATION RETRACTORS

Amputation retractors with article numbers 021-060-000 to 021-062-000 are dismantled for better reprocessing:

Instructions for dismantling amputation retractors:



The handles can be separated...



by turning handle (1) to the inside



and turning handles (2) downward. They then separate.



The instrument can now be reprocessed.

When the reprocessing is complete, the instrument is reassembled.



Handles (2) are inserted and turned upward.



Handle (1) is placed on and turned outward.



The instrument can now be stored sterile until it is next used.

LARYNGOSCOPES

Reprocessing laryngoscopes:

Sterilisation with bulb

All spatulas can be sterilised in the autoclave at 134°C (at 3 bar positive pressure) with no concerns about contact damage. The bulbs and the removable lamp holders must be removed before sterilisation. It is recommended to carry out sterilisation with ethylene oxide or disinfection in a solution.

Sterilisation with cold light source

All cold-light spatulas can be sterilised in the autoclave at 134°C (at 3 bar positive pressure). However, to extend the service life of the glass fibres incorporated in these spatulas, sterilisation with ethylene oxide or disinfection in a solution is recommended. Cold-light spatulas must not be cleaned with ultrasound. Flash sterilisation and hot air sterilisation and the use of chemical agents are not permitted.

Sterilisation of handles

Battery handles can only be sterilised with ethylene oxide or disinfected in a solution. To do so, the batteries must first be removed. Sterilisation in an autoclave or using hot air sterilisation is not permitted.