FEHLING Yasargil Clip Applying Forceps	**REF:** MKG-7, MKG-8, MKH-7, MKH-8, MLB-3, NHC-1, NHZ-8 ***Memory Clip Appliers:*** NIB-0, NIB-1, NIB-2, NIB-3, NIB-4, NIB-5, NIB-6, NIB-7, NIB-8, NIB-9, NIC-0, NIC-1

Warnings: Prior to processing, a risk assessment on the instrument must be performed.

FEHLING Yasargil clip applying forceps may only be used, processed and disposed of by competent medical personnel!

Intended use:

The Yasargil clip appliers are used to open and close the Yasargil aneurysm clips.

Using the applying forceps, the aneurysm clip is applied, repositioned in or removed from the target tissue. The clip applying forceps have no function of their own and may only be used in combination with the suited Yasargil Aneurysm Clips.

The Yasargil aneurysm clip applying forceps may only be used in combination with the corresponding Yasargil Aneurysm Clips and are contraindicated for all other applycations.

Using the clip applying forceps for other manufacturer's aneurysm clips is not permitted!

Before use:

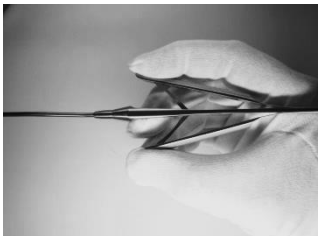
FEHLING Yasargil clip applying forceps are delivered in non-sterile condition and must be cleaned and sterilized before each use (see chapter "Reprocessing").

Perform a safety check before each use of the clip-applying forceps. Check for cracks, breaks or mechanical malfunctions (see "Maintenance, control and functional testing"). Pay attention to defaults on critical points such as tips, cuttings, lockings and on all movable parts.

During use:

⚠	Always handle the clip applying forceps with necessary care. Take measures for protection against damage during transport, cleaning, maintenance, sterilization and storage. Avoid impacts and selective loads!
⚠	Avoid contact of the instruments with abrasive substances (see „Resilience of the material"); this may result in corrosion and impairment of function up to complete uselessness. This applies particularly for the use of acids or abrasive cleaners (read and observe the directions of the respective cleaning agent as provided by the manufacturer!)
⚠	The clip applying forceps marked MINI or STANDARD must only be used with the respective MINI or STANDARD aneurysm clips. The Titanium clip applying forceps (only jaws) and titanium clips can also be identified by their different color coating: MINI = red, STANDARD = blue. **Applying a clip with the wrong clip applying forceps may lead to impairment of the clip's closing force!** **THIS WILL CAUSE OVEREXPANSION OR MALFUNCTION OF THE CLIP!**
	Note for Yasargil Memory Aneurysm Clip applying forceps: The special shape of the Yasargil Memory applying forceps offers the best possible overview of the surgery field. The memory shafts allows bending of the shaft and the jaws can be put in almost every position. After sterilization, the memory shaft returns to its original bayonet shape. The locking mechanism has been integrated in the handle of the clip applying forceps to protect it from external forces. Nevertheless, special attention must be paid to the fact that this clip applying forceps has to be cleaned and sterilized separately in appropriate containers in order to protect the function of this locking device.

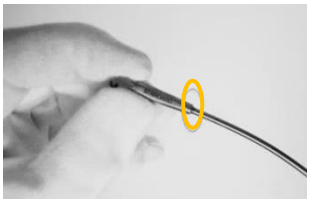
Locking mechanism:

Handle	Clip	Description
	 Jaws fully opened → no clip	The handles of the clip applying forceps are fully opened. The locking mechanism is not locked.
	 When the locking mechanism is engaged, the clip is fixed in the applying forceps and partially opened. (The opening angle of the clip in fixed position may vary for each applying forceps.)	Insert the clip into the guiding slots of the jaws of the applying forceps and press the handles of the applying forceps carefully, until the mechanism locks. **Please note:** The function of the locking mechanism must be controlled before the insertion of the clip!
	 Clip is opened / spreaded completely	Compress the handles of the applying forceps completely. The locking mechanism is unlocked automatically. **Please note:** Both handles have to be pressed completely to release the locking mechanism.

Memory shaft

The memory shaft has to be held with both hands in the area where the bending is required.

⚠ **Attention: Do not bend the memory shaft in the connection areas of the shaft: Increase risk of breakage!**



After sterilization, the memory shaft returns to its original bayonet shape.

Reprocessing:

Restriction for reprocessing:
Frequent reprocessing has only minor effects on these instruments.

Usually the end of the product service life is determined by wear and damage due to utilization (see also “Reusability”).

All clip applying forceps must be cleaned, disinfected and sterilized before each use.

This applies in particular for the first use, as all clip applying forceps are delivered in non-sterile condition. Clean and disinfect after removing the transport protection packing including jaw protection, and sterilize after packaging.

Effective cleaning and disinfection are essential requirements for effective sterilization!

Please note:

- Make sure that the procedures used for cleaning/disinfection and sterilization are validated and suitable for device and products used.
- Make sure that the devices (disinfector, sterilizer) used are maintained and checked on a regular basis.
- Make sure that the validated parameters are complied with in every cycle.

During use, make sure to collect contaminated instruments separately; do not put them back into the instruments tray, in order to avoid severe contamination of the instrument tray. Clean/disinfect the contaminated instruments, then sort them back into the instruments tray and sterilize the completely equipped instruments tray.

Do not place in NaCl solution (risk of hole or stress crack corrosion).

Please also comply with the legal regulations applicable in your country and the doctor's office's/hospital's sanitation regulations. This applies in particular to the different specifications regarding effective prion inactivation.

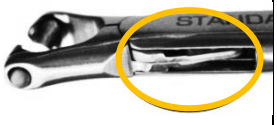
⚠ **The jaw protection serves only for protection during transport and sterilization; the clip applying forceps must not be cleaned/disinfected with the jaw protection attached!**

If possible, mechanical processing should be used for cleaning and disinfection. Due to the significantly lower effectiveness and reproducibility, a manual procedure – even when an ultrasonic bath is used – should only be used if mechanical processing is not available.

Pre-treatment must be performed in any case.

Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	Make sure that traces of blood, tissue and medication are removed from the clip applying forceps directly after termination of the surgery (within a maximum of 2 hours). Remove the jaw protection, unlatch the grip spring, if required, and bring the forceps into an opened position. Use running water or a disinfectant solution. The disinfectant should be aldehyde-free (otherwise, blood contamination would be fixed) and have a proven efficacy (e.g. VAH/DGHM or FDA authorization or CE labeling); it should be suited for the disinfection of the clip applying forceps and be compatible with the clip applying forceps (see "Resilience of the material"). Use only soft brushes or a clean soft cloth that you use only for this purpose. Never use metal brushes or steel wool to remove contaminations. If applicable: - Dismantle the forceps as far as possible and remove the jaw protection. - Rinse all lumina of the clip applying forceps five times using a disposible syringe (with a minimum volume of 10 ml). - Move the mobile parts back and forth several times during the pre-cleaning. Please note that the disinfectant used in the pre-treatment is only for personnel safety and cannot act as a substitute for the disinfection step performed later (after the cleaning). Avoid overfilling of instrument sets and washing trays – use appropriate instrument carriers only. Be particularly careful that the mouths/points do not get stuck in the mesh when placing and removing the instruments into/from the set baskets.
Cleaning/Disinfection acc. to DIN EN ISO 15883-1	When selecting the disinfector, it must be ensured that - the disinfector always has proven efficacy (e.g. DGHM or FDA authorization or CE labeling according to EN ISO 15883-1), - - if possible – a tested program for thermal disinfection (A_0-value > 3000 or – for older devices – at least 5 min at 90 °C) is used (if chemical disinfection is used, there is a risk of residues of the disinfectant on the clip applying forceps), - the used program is suited for applying forceps and contains sufficient rinsing cycles,

	- only sterile or low-germ (< 10 germs/ml) and low-endotoxin (< 0.25 endotoxin units/ ml) water is used (e.g. purified/highly purified water), - the air used for drying is filtered and - the disinfector is maintainted and checked on a regular basis. When selecting the cleaning agent system used, it must be ensured that - it is generally suited for cleaning clip applying forceps made of metals and plastics, - unless thermal disinfection is used, a suited disinfectant with proven efficacy (e.g. DGHM or FDA authorization or CE labeling) is used additionally and that it is compatible with the cleaning agent used and - the products used are compatible with the clip applying forceps (refer to “Resilience of the material”). The concentrations specified by the manufacturer of the cleaning agent / disinfectant must be complied with in any case.
Cleaning: mechanically acc. to DIN EN ISO 15883-1	**Procedure:** 1. Put the dismantled applying forceps into the disinfector. Ensure that the forceps do not touch each other. Place the forceps in opened position (it may be required to unlatch the grip-spring to do so). If applicable, connect all lumina of the applying forceps to the rinsing connector of the disinfector. 2. Start the program. 3. After the program is finished, take the applying forceps out of the disinfector. 4. Check and package the applying forceps as quickly as possible after taking them out (see sections “Checking” and “Packaging”); if appropriate, after additional drying in a clean place. The general suitability of the applying forceps for effective cleaning and disinfection using a machine was confirmed by an independent certified test laboratory using the disinfector G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher mediclean (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account.
Cleaning/Disinfection: Manually	When selecting the cleaning agent and disinfectant used, it must be ensured that - they are generally suited for cleaning/disinfecting instruments made of metals and plastics, - the cleaning agent – if applicable – is suited for ultrasonic cleaning (no formation of foam), - a disinfectant with proven efficacy (e.g. VAH/DGHM or FDA authorization or CE labeling) is used and that it is compatible with the cleaning agent used, and - the chemicals used are compatible with the instruments (refer to “Resilience of the material”). If possible, combined cleaning agents/disinfectants should not be used. Combined cleaning agents/disinfectants can only be used in cases of very slight contamination (no visible contaminations). The concentrations and exposure times specified by the manufacturer of the cleaning agent/disinfectant must be complied with in any case. Use only freshly-made solutions, only sterile or low-germ (< 10 germs/ml) and low-endotoxin (< 0.25 endotoxin units/ml) water (e.g. purified/highly purified water) and only filtered air for drying. **Procedure:** **Cleaning** 1. Dismantle the applying forceps as far as possible.

	2. Put the dismantled forceps into the cleaning bath for the specified exposure time such that the forceps are sufficiently covered (use ultrasonic support or a soft brush, if appropriate). Please ensure that the instruments do not touch each other. If applicable: Rinse all lumina of the clip applying forceps at least five times at the beginning and at the end of the exposure time using a disposable syringe (minimum volume 10 ml). Move all movable parts back and forth at least five times at the beginning and at the end of the exposure time. 3. Take the forceps out of the cleaning bath and subsequently rinse them under running water for at least 1 min. If applicable, rinse all lumina of the clip applying forceps five times using a disposable syringe (minimum volume 10 ml). 4. Check all applying forceps (refer to “Control” and “Maintenance”). **Disinfection** 5. Put the dismantled, cleaned and checked clip applying forceps into the disinfector bath for the specified exposure time such that theforceps are covered sufficiently. Ensure that the forceps do not touch each other. If applicable, rinse all lumina of the clip applying forceps at least five times at the beginning and at the end of the exposure time using a disposable syringe (minimum volume 10 ml). Move all movable parts back and forth at least five times at the beginning and at the end of the exposure time. 6. Take the forceps out of the disinfection bath and rinse them off thoroughly under running water for at least 1 min. If applicable, rinse all lumina of the clip applying forceps five times using a disposable syringe (minimum volume 10 ml). 7. Dry the clip applying forceps by blowing filtered compressed air. 8. Package the applying forceps as quickly as possible after taking them out (see section “Packaging”); if appropriate, after additional drying in a clean place. The general suitability of the applying forceps for effective manual cleaning and disinfection was confirmed by an independent certified test laboratory using the cleaning agent Cidezyme/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.
Control:	Check all applying forces after cleaning or cleaning/disinfection for corrosion, damaged surfaces, cracks and contaminations. Sort out damaged aneurysm clip applying forceps (see „Re-usability“ for re-use limitation in numbers). Applying forceps that are still contaminated must be cleaned and disinfected again.
Maintenance:	***Note for applying forceps with joints (especially Yasargil Memory applying forceps)*** After each preparation, apply a small amount of instrument oil unto the joints of the applying forceps. Ensure that only instrument oil (white oil) that – taking into account the maximum sterilization temperature used – is authorized for steam sterilization and has proven biocompatibility is used and that only the jaw and joint parts are treated with as little oil as possible. 
	Sort out worn, corroded, deformed, porous or otherwise damaged clip applying forceps. For reasons of hygiene, instruments must be reprocessed before sending them in to be repaired.
Packaging:	**Separately:** acc. to standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.

	Sets: Sort the cleaned and disinfected clip applying forceps into the corresponding sterilization tray. Package the applying forceps or trays in disposable sterilization packs (single or double pack) and/or sterilization containers that comply with the following requirements: - EN ISO/ANSI AAMI ISO 11607 - suited for steam sterilization (temperature resistance up to NLT 141 °C (286 °F), sufficient steam permeability) - sufficient protection of the clip applying forceps / sterilization packs against mechanical damage - regular maintenance in accordance with the manufacturer's specifications (sterilization container)
Sterilization: ⚠	**The following sterilization procedures shall be used for sterilization; other sterilization procedures are prohibited.** **Steam sterilization** - Fractionated vacuum procedure [1)] (with sufficient drying of the product) - steam sterilizer in compliance with EN 1360 / EN 285 - validated according to EN ISO 17665 (former EN 554 / ANSI AAMI ISO 11134) (valid IQ/OQ (consignment) and product-specific performance qualification) - maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665 (former EN 554 / ANSI AAMI ISO 11134) - sterilization time (exposure time at sterilization temperature) NLT 20 min at 121 °C (250 °F) or NLT 3 min [2)] at 132 °C (270 °F) / 134 °C (273 °F) [1)] The use of the less effective gravitation procedure is only permitted if the fractionated vacuum procedure is not available; it may require significantly longer exposure times and must be confirmed with a product-, procedure- and device-specific validation under the user's sole responsibility. [2)] or 18 min (prion inactivation) The general suitability of the applying forceps for effective steam sterilization was confirmed by an independent certified test laboratory using the steam sterilizer Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum procedure. Typical conditions in hospitals and doctor's offices and the procedure described above were taken into account. ⚠ **Flash sterilization must not be used. Do not use hot air sterilization, formaldehyde or ethylene oxyde sterilization or plasma sterilization, either.**
Storage: ⚠	Do not store the applying forceps in metal containers, except for stainless steel or aluminium containers. Avoid direct exposure to sunlight. After Sterilization, the instruments must be stored dry and free from dust in the sterilization pack.
Additional information: ⚠	**Resilience of the material** When selecting the cleaning agents and disinfectants, please ensure that they do not contain the following components: - organic, mineral or oxidizing acids (minimum permissible pH value 5.5) - strong alkaline solutions (maximum pH value 10.0, neutral/enzymatic or slightly alkaline agent recommended) - organic solvents (e.g. alcohols, ether, ketones, benzine) - oxidants (e.g. hydrogen peroxide) - halogens (chlorine, iodine, bromine) - aromatic/halogenated hydrocarbons Never use metal brushes or steel wool for cleaning. Don't expose clip applying forceps and trays to temperatures > 141 °C (286 °F)

Reusability: ⚠	If appropriate care is taken and the instruments are undamaged and not contaminated, the clip applying forceps can be reused up to 500 times; the user has the sole responsibility for using the applying forceps more often or using a damaged or contaminated forceps. All liability shall be excluded in case of non-compliance. **Caution: Federal law restricts this device to sale by or on order of a physician!**

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.

⚠	Any modification to the device or deviation from these instructions for use will result in exclusion of liability. Subject to change without notice.

Symbols

Manufacturer	Follow the instructions for use.	Article number	CE marking
Protect from excessive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Lot number	Warning

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