

**GB / USA**

**Instructions for Use**

**Important instructions for use!**

Please read this information before using the instrument!

By purchasing this instrument you have decided for a German high quality product. To ensure the function and safety of the instrument at long sight please observe the following points:

**First use of new instruments**

All instruments of Ortho Medical GmbH are delivered in non-sterile condition and must be cleaned and sterilized before using. Therefore, please pay attention to the following instructions (see chapter "Preparation (cleaning, disinfection and sterilization)"). Exempted from that are all instruments marked with the comment "sterile".

**Safety control**

Before each use, it is important to inspect (optical control) the clip applying forceps. Make sure that there are no cracks, breakings or mechanical malfunctions. Pay attention to defaults on critical points such as tips, cuttings, lockings and on all movable parts.

**Usage/Application**

The YASARGIL aneurysm clip applying forceps serve for opening and closing the YASARGIL aneurysm clips. Using the forceps, the aneurysm clip is applied, repositioned or removed in 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.

**Contraindications**

The YASARGIL aneurysm clip applying forceps may only be used in combination with the corresponding YASARGIL aneurysm clips of Ortho Medical GmbH and are contraindicated for all other applications. Using the clip applying forceps for other manufacturers' aneurysm clips is not permitted.

**Handling**

Treat these surgical instruments always with the necessary care. Take measures for protection against damages in transporting, cleaning, maintenance, sterilization and storage.

Avoid the contact of the instruments with abrasive substances (see chapter "Resilience of the material"); this can result in corrosion and damage of function right up to complete uselessness. This particularly applies for the use of acids or abrasive cleaners (it is vital to read and observe the directions of the cleaning agent producer!).

Aneurysm clips made of steel (Phynox) should only be used with the appropriate steel (Phynox) forceps. Aneurysm clips made of titanium should only be used with the appropriate titanium forceps.

MINI or STANDARD YASARGIL aneurysm clips may only be operated with the respective applying- and removing forceps with marking STANDARD or MINI.

STANDARD titanium clip applying forceps as well as some models of MINI titanium clip applying forceps can also be identified by their different color coding (only jaws):  
STANDARD = blue and MINI = pink.

**By using the wrong clip applicator (MINI/STANDARD), the clip's closing force can be damaged. This might cause functional disturbance or an over bending of the clip.**

*Note for YASARGIL Memory applying forceps*

The special shape of YASARGIL Memory clip applying forceps offers to the user the best possible view over the surgery field. The memory shaft allows bending of the shaft and the jaws in almost every position. After sterilization the memory shaft turns back into original condition. The locking mechanism has been integrated in the handle of the clip applying forceps to protect it from external forces. 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**

Handles	Clip	Description
	  <i>Jaws fully opened -&gt; no clip</i>	<i>The handles of the clip applying forceps are fully straddled. The locking mechanism is not locked.</i>
	  <i>In the case of a snapped locking mechanism the clip is fixed in the applying forceps and partially opened. (The opening of the clip in fixed position can vary from one clip applying forceps to another).</i>	<i>Put the clip into the slots of the jaws and press the handles of the applying forceps carefully until the mechanism locks. <b>Please note:</b> The function of the locking mechanism should be controlled before the insertion of the clip!</i>
	  <i>Full spread / opening of the clip</i>	<i>Compress the handles of the applying forceps completely. The locking mechanism is untied automatically.</i>

**Important: Both handles have to be pressed through completely to untie the locking mechanism.**

#### Memory Shaft

The memory shaft should 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. Increased risk of breaking!



After sterilization the memory shaft turns back into original condition.

#### Preparation (cleaning, disinfection and sterilization) of YASARGIL aneurysm clip appliers

##### General basics

All instruments are delivered in non-sterile condition and must be cleaned, disinfected and sterilized before use (cleaning and disinfection after removing the transport protection packing (including jaw protection) and sterilization after packaging). Effective cleaning and disinfection is an essential requirement for effective sterilization.

As you are responsible for the sterility of the instruments during use, please see to it

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

Please ensure already during the use to collect contaminated instruments separately and do not put them back into the instruments tray in order to avoid stronger contamination of the equipped instruments tray. Clean/disinfect the contaminated instruments, subsequently sort them back into the instruments

tray and then sterilize the completely equipped instruments tray.

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; cleaning/disinfection with the jaw protection on is not permissible in any case.**

##### Cleaning and disinfection

##### Basics

If possible, a machine procedure (disinfector) should be used for cleaning and disinfection. Due to the significantly lower effectiveness and reproducibility, a manual procedure – even when an ultrasound bath is employed – may only be used if no machine procedure is available.

The pre-treatment must be performed in both cases.

##### Pre-treatment

Major contaminations must be removed from the clip applying forceps immediately after use (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 for that; the disinfectant should be aldehyde-free (otherwise, blood contaminations would be preserved) and have proven efficacy (e.g. VAH/DGHM or FDA authorization or CE labeling), be suited for the disinfection of the clip applying forceps and be compatible with the clip applying forceps (see section "Resilience of the material"). Only use a soft brush or a clean soft cloth that you use only for this purpose, never metal brushes or steel wool, for manually removing 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 disposable syringe (minimum volume 10 mL).

Move the mobile parts forth and back several times during the pre-cleaning.

Please bear in mind that the disinfectant used during the pre-treatment is only for protection of persons and cannot act as a substitute for the disinfection step performed later (after the cleaning).

##### Cleaning/disinfection using a device (disinfector / cleaning and disinfection device)

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 DIN EN ISO 15883),
- that – 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 the risk of residues of the disinfectant on the aneurysm clip applying forceps),

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	<p>Ortho Medical GmbH Hauptstraße 5 D-78589 Dürbheim / Germany Tel. 07424/9403-0 Fax. 07424/9403-43 <a href="http://www.orthomedical.de">www.orthomedical.de</a></p>	<p><b>Gebrauchsanweisung</b> <b>ORIHOMEDICAL</b> GmbH · IMPLANTS</p> <p>CE 0483</p> <p> </p> <p></p> <p><b>YASARGIL – Clip pliers for aneurysm clips</b></p>
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- that the used program is suited for applying forceps and contains sufficient rinsing cycles,
- that only sterile or low-germ (NMT 10 germs/mL) and low-endotoxin (NMT 0.25 endotoxin units/mL) water (e.g. purified water/highly purified water) is used,
- that the air used for drying is filtered and
- that the disinfectant is maintained and checked on a regular basis.

When selecting the cleaning agent system used, it must be ensured

- that it is generally suited for cleaning aneurysm clip applying forceps from metals and plastics,
- that – unless thermal disinfection is used – a suited disinfectant with proven efficacy (e.g. DGHM or FDA authorization or CE labeling) is additionally used and that it is compatible with the cleaning agent used and
- that the chemicals used are compatible with the applying forceps (see section “Resilience of the material”).

The concentrations specified by the manufacturer of the cleaning agent/disinfectant must in any case be complied with.

Procedure:

1. Put the dismantled applying forceps into the disinfectant. Please ensure that the forceps do not touch each other. Place the forceps in opened position (it may be required to unlatch the grip-spring for this). If applicable: Connect all lumina of the applying forceps to the rinsing connector of the disinfectant.
2. Start the program.
3. Take the applying forceps out of the disinfectant after the program is finished.
4. Check and package the applying forceps as quickly as possible after taking them out (see the sections “Checking” and “Packaging”), if appropriate after additionally drying at 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 disinfectant 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 in doing so.

#### Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant used, it must be ensured

- that they are generally suited for cleaning / disinfecting instruments from metals and plastics,
- that the cleaning agent – if applicable – is suited for ultrasound cleaning (no formation of foam),
- that 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
- that the chemicals used are compatible with the instruments (see section “Resilience of the material”).

Combined cleaning agents/disinfectants should not be used, if possible. Combined cleaning agents/disinfectants can only be used in cases of very slight contamination (no visible contaminations).

The concentrations and contact times specified by the manufacturer of the cleaning agent/disinfectant must in any case be complied with. Use only freshly-made solutions, only

sterile or low-germ (NMT 10 germs/mL) and low-endotoxin (NMT 0.25 endotoxin units/mL) water (e.g. purified water/highly purified water) and only filtered air for drying.

Procedure: Cleaning

1. Dismantle the applying forceps as far possible.
2. Put the dismantled forceps into the cleaning bath for the specified contact time such that the forceps are sufficiently covered (use ultrasound 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 the end of the contact time using a disposable syringe (minimum volume 10 mL). Move all movable parts at least five times at the beginning and the end of the contact time back and forth.
3. Take the forceps out of the cleaning bath then and thoroughly rinse them off for at least 1 min under running water.  
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 (see section “Checking” and “Maintenance”).

Disinfection

5. Put the dismantled, cleaned and checked clip applying forceps into the disinfection bath for the specified contact time such that the forceps are sufficiently covered. Please 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 the end of the contact time using a disposable syringe (minimum volume 10 mL).  
Move all movable parts at least five times at the beginning and the end of the contact time back and forth.
6. Take the forceps out of the disinfection bath and thoroughly rinse them off for at least 1 min under running water.  
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 clip applying forceps as quickly as possible after taking them out (see section “Packaging”, if required, after letting them dry 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 Cidezime/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

#### Control

Check all applying forceps after cleaning or cleaning/disinfection for corrosion, damaged surfaces, splitting and contaminations and scrap damaged aneurysm clip

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	<p>Ortho Medical GmbH Hauptstraße 5 D-78589 Dürbheim / Germany Tel. 07424/9403-0 Fax. 07424/9403-43 <a href="http://www.orthomedical.de">www.orthomedical.de</a></p>	<p><b>Gebrauchsanweisung</b> <b>ORIHOMEDICAL</b> GmbH · IMPLANTS  <b>0483</b></p> <p>   <b>YASARGIL – Clip pliers for aneurysm clips</b></p>
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applying forceps (please refer to the section “Re-usability” for re-use limitation in numbers). Applying forceps that are still contaminated must be cleaned and disinfected again.

#### Maintenance

Treat the joints of the Memory applying forceps with instrument oils after every preparation (in particular YASARGIL Memory applying forceps). It should be ensured that only instrument oils (white oil) that – taking into account the maximum sterilization temperature used – are authorized for vapor sterilization and have proven biocompatibility, are used and that the jaw and joint parts are only treated with as little oil as possible.



- Scrap outworn, corroded, deformed, porous or otherwise damaged clip applying forceps.
- Instruments which are sent in for repair works must be prepared completely for sanitary reasons.

#### Packaging

Sort the cleaned and disinfected clip applying forceps into the corresponding sterilization tray.

Please package the applying forceps or trays in disposable sterilization packs (single or double pack) and/or sterilization containers that comply with the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suited for vapor sterilization (temperature resistance up to NLT 141 °C (286 °F), sufficient vapor permeability)
- sufficient protection of the aneurysm clips / sterilization packs against mechanical damage
- regular maintenance in accordance with the manufacturer’s specifications (sterilization container)

#### Sterilization

Only the sterilization procedures listed in the following shall be used for sterilization; other sterilization procedures are impermissible.

#### Vapor sterilization

- fractionated vacuum procedure<sup>1</sup> (with sufficient drying of the product)
- Vapor sterilizer in compliance with DIN EN 13060 / DIN EN 285
- Validated according to DIN EN ISO 17665 (previously: DIN 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 DIN EN ISO 17665 (previously: DIN 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 at 132 °C (270 °F)/134 °C (273 °F)
- 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 or 18 min (prior inactivation)

The general suitability of the applying forceps for effective vapor sterilization was confirmed by an independent certified test laboratory using the vapor sterilizer Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum procedure. Typical conditions in hospitals and doctor’s offices as well as the procedure described above were taken into account in doing so.

#### Flash sterilization is never permissible.

Do not use hot air sterilization, radio sterilization, formaldehyde or ethylene oxide sterilization and plasma sterilization, either.

#### Storage

Do not store the applying forceps in metal containers, except for stainless steel or aluminum containers. Avoid direct exposure to sunlight.

After the sterilization, the instruments must be stored dry and free from dust in the sterilization pack.

#### Resilience of the material

When selecting the cleaning agents and disinfectants, please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- strong lyes (maximum permissible pH value 10.9, neutral/enzymatic or slightly alkaline cleaning agent recommended)
- organic solvents (e.g. alcohols, ether, ketones, benzene)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

#### Never clean any aneurysm clip applicators and trays with metal brushes or steel wool.

All aneurysm clips and trays may only be exposed to temperatures not more than 141 °C (286 °F)!

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**Reusability**

Based on the product design and the material used it is not possible to determine a precise limit with regard to the maximum possible number of reprocessing cycles. The serviceable life of the products is determined by their function as well as by a careful handling. The reprocessing procedures can have an impact on the visual features of YASARGIL clip applying forceps. If a clear identification (STANDARD/MINI) is no longer recognizable, the products have to be discarded or must be given for inspection/repair.

**Repairs / dispatch for reparation at Ortho Medical GmbH**

Never attempt to perform repairs by yourself. Service and repair work may only be performed by persons qualified and trained accordingly. For any question on these matters, please contact the manufacturer.

**Attention:** Before you send defective products back for repair, these products must have undergone the entire reprocessing process as described in the processing instructions. Please enclose a statement or evidence of cleaning, disinfection and sterilization with your return.

**Ortho Medical GmbH assumes no responsibility for the performance of YASARGIL aneurysm clip appliers that are handled or used in a manner contrary to the recommended procedures stated herein.**

**Caution:**

**Federal law restricts this device to sale by or on order of a physician!**

**Explanations of used symbols**

-  Consult operating instructions
-  Reference number
-  Manufacturer
-  Date of production
-  Delivered in non-sterile conditions
-  Lot number
-  CE sign
-  Not for reuse

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