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www.kapp-germany.de

Instructions for use

ORTHOMEDICAL GmbH · IMPLANTS CE 0483

Permanent and temporary YASARGIL Aneurysm and Vessel Clips

NON STERILE

1. Intended purpose

The permanent YASARGIL aneurysm and vessel clips serve for permanent clamping of cerebral aneurysms. The temporary YASARGIL aneurysm and vessel clips are supplied for temporary use for blood vessels and cerebral aneurysms.

Contraindications

The permanent aneurysm clips may only be used for permanent clamping of cerebral aneurysms and are contraindicated for any other application.

The temporary aneurysm clips are contraindicated for all other applications, except for temporary clamping of blood vessels and cerebral aneurysms. Temporary aneurysm clips may not be used for permanent clamping or implantation.

Application

Both the permanent and temporary YASARGIL aneurysm and vessel clips may only be used by suitably trained surgeons who are familiar with the necessary surgical techniques and use of these medical products.

MINI or STANDARD clips may only be used with the applicator instruments marked with MINI and STANDARD. Titanium clips and applicator instruments can also be recognised by their colours MINI = RED & STANDARD = BLUE. Phynox aneurysm clips must be used with the respective Phynox applicators. Titanium aneurysm clips must be used with the respective titanium applicators.

Warning!

Application of the aneurysm clips with applicators supplied by other manufacturers is not permissible. If the clips are not used with the correct applicators (Mini & Standard), failure or overstretching of the aneurysm clips can result!

Supply

The permanent and temporary aneurysm and vessel clips are not sterile when supplied and must be processed before use (refer to the Section "Processing aneurysm clips"). Each pack contains one aneurysm clip with a product description that states the closing force of the aneurysm clip, the article number (REF) and the serial number (SN).

The article number and serial number of the aneurysm clip is given on the enclosed label and must be attached to the surgical report of the patient.

Processing (cleaning, disinfection and sterilisation) of aneurysm clips

General information

The YASARGIL aneurysm clips are non-sterile when supplied and must be cleaned, disinfected and sterilised before use (cleaning and disinfection after removal of the transport packaging and sterilisation after packaging). Effective cleaning and disinfection is an essential requirement for effective sterilisation. Aneurysm clips that have already been in contact with a patient or are soiled should never be reused under any circumstances.

Within the scope of your responsibility for sterility of the aneurysm clips when they are used, please note that

- only adequate and validated methods that are suitable for the respective equipment and products may be employed for cleaning/disinfection/sterilisation
- the employed equipment (disinfector, steriliser) is regularly serviced and checked and
- the validated parameters are complied with during each cycle.

Please also comply with the legal regulations valid in your country as well as the hygiene regulations of the surgery or hospital. This applies in particular to the different specifications with regard to effective prion activation.

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Aneurysm clips that have already been in contact with a patient or are contaminated should never be processed and must be disposed of! Processing of contaminated products is the responsibility of the user.

Cleaning and disinfection

Basic principles

Machines should be used for cleaning and disinfection if possible (disinfector). Manual methods – also including use of an ultrasound bath – are only permitted if no machines are available due to their considerably lower efficiency and reproducibility and only without the use of the trays; these must also be confirmed by validation that is suitable for the product, process and equipment and on the sole responsibility of the user.

Pre-treatment

Pre-treatment is not necessary, as aneurysm clips that have already been in contact with a patient or are soiled should never be reused under any circumstances.

Machine cleaning/disinfection (disinfector/washer and disinfector)

When selecting the disinfector, always ensure that

- the disinfector efficiency is certified (e.g. DGHM or FDA approval or CE mark in compliance with DIN EN ISO 15883),
- a certified programme for thermal disinfection (A_0 value > 3000 or – on older devices – at least five minutes at 90 °C) is used (during chemical disinfection there is the risk of disinfectant residues on the aneurysm clips),
- the selected programme is suitable for the aneurysm clips and features sufficient rinsing cycles,
- only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- the air used for drying is filtered and
- the disinfector is regularly services and checked.

When selecting the cleaning agent system, always ensure that

- this is suitable for cleaning aneurysm clips made of metal and plastics,
- if no thermal disinfection is used, an additional suitable disinfectant with certified efficiency (e.g. VAH/DGHM or FDA approval or CE mark) is employed and that this is compatible with the cleaning agent and
- the employed chemicals are compatible with the employed aneurysm clips (refer to the section "Material resistance").

The concentrations specified by the cleaning agent and disinfectant manufacturer must always be complied with.

Procedure:

1. Place the aneurysm clips in the tray of the disinfector. Ensure that the aneurysm clips do not make contact with one another.
2. Start the programme.
3. Remove the aneurysm clips from the disinfector when the programme has been completed.
4. Check and pack the aneurysm clips in the tray as soon as possible after removal (refer to the sections "Inspection" and "Packaging", after subsequent drying if necessary at a clean location).

Evidence of the basic suitability of the implants for effective machine cleaning and disinfection was provided by an independent, accredited 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 applied.

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Inspection

After cleaning or cleaning and disinfection, check all aneurysm clips for corrosion, damaged surfaces, chips and contamination and remove damaged aneurysm clips (for quantitative restrictions on reusability refer to the section "Reusability"). Aneurysm clips that are still soiled must be cleaned and disinfected once more.

Packaging

Please pack the trays in single-use sterilisation packs (single or double pack) and/or sterilisation containers that meet the following requirements:

DIN EN ISO/ANSI AAMI ISO 11607

- suitable for steam sterilisation (minimum temperature resistance of up to 141 °C (286 °F), sufficient steam permeability)
- sufficient protection of the aneurysm clips or sterilisation packs against physical damage
- regular servicing in accordance with the manufacturer's specifications (sterilisation container)

Sterilisation

Only the following sterilisation methods may be used; other sterilisation methods are not permitted.

Steam sterilisation

- Fractionated vacuum method[1] (with sufficient product drying)
- Steam steriliser validated in compliance with DIN EN 13060 and DIN EN 285
- in compliance with DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Maximum sterilisation temperature 138 °C (280 °F; plus tolerance in compliance with DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisation time (exposure time at the sterilisation temperature) at least 20 minutes at 121 °C (250 °F) or at least 5 minutes at 132 °C (270 °F)/134 °C (273 °F)

[1] Use of the less effective gravity method is only permitted if the fractionated vacuum method is not available, can require considerably longer exposure times and specific product, method and device validation must be confirmed on the sole responsibility of the user.

Evidence of the basic suitability of the implants for effective steam sterilisation was provided by an independent test laboratory, using the steam steriliser Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum method. Typical conditions in clinics and surgeries as well as the procedure described in above were taken into consideration.

The flash sterilisation method is not permissible.

Do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation methods.

Storage

After sterilisation the aneurysm clips must be stored in a dry and dust-free place in the sterilisation pack.

Material resistance

When selecting the cleaning and disinfection agents, please ensure that the following substances are not contained:

- Organic, mineral and oxidising 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, ethers, ketones, benzines)
- Oxidising agents (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromide)
- Aromatic/halogenated hydrocarbons

Never clean the aneurysm clips and trays with metal brushes or steel wool.

All aneurysm clips and trays may only be exposed to temperatures of 141 °C (286 °F) or below!

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1. Reusability

The aneurysm clips may only be brought into contact once with one patient and only *cleaned, disinfected and* sterilised up to 40 times. The use of damaged or soiled aneurysm clips is the sole responsibility of the user.

Note:
Applicable national regulations must be complied with during processing if the patient has Creutzfeld-Jakob's disease (CJK), suspected CJK or possible variants.

No liability is accepted in the event of non-compliance.

1. Storage

We recommend storing the high-precision instruments and sensitive aneurysm clips in a suitable container supplied by Ortho Medical GmbH

WARNING: Only store the clip applicators in an open position, as otherwise the spring force of the applicator is lowered and this can cause irritation. Damage to the locking mechanism can also cause irritation and even loss of function during the clipping operation. If there is any suggestion of damage to the instrument, it must be checked and repaired.

1. CT & MR safety

Non-clinical trials have shown that all Yasargil aneurysm clips are MRT safe. A patient with a Yasargil aneurysm clip can be safely scanned immediately after fitting the aneurysm clip if the following conditions are satisfied:

Static magnetic field

- - Static magnetic field of 3 tesla or less
- - Maximum spatial gradient of the magnetic field of 720 Gauss/cm or less

MRT-related heating

In non-clinical trials, slight increases in temperature occurred with these aneurysm clips during a 15 minute MRT (i.e. per pulse sequence) with the 3 tesla MR system(3 tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, USA).
The experiments revealed that the maximum MRT-related warming of these aneurysm clips with a 3-Tesla send/receive RF-Body-Coil MRT scanner with an average full-body SAR of 2.9 W/kg (i.e. with a calorimetrically measured full-body average value of 2.7 W/kg) was +1.8 °C or less under these specific conditions.

Artefact information

The quality of the MRT images can be impaired if the examined area is exactly at the position or near the aneurysm clip shown below. For this reason it may be necessary to optimise the MRT parameters for each aneurysm clip.

MR = MR CONDITIONAL

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1. Visual features

PERMANENT aneurysm clips made of TITANIUM can be easily recognised by their spectral colours (red or blue), TEMPORARY aneurysms clips made of TITANIUM can be recognised by their gold colour.

PERMANENT aneurysm clips made of COBALT have a natural colour. TEMPORARY aneurysm clips made of COBALT can be recognised by the gold colour of the spring and the contact tongue.

The exact material designation of the aneurysm clip is stated on the label of the packaging.

2. Handling

Familiarise yourself with the use of the instruments and if necessary have use of the clips demonstrated by your sales partner.

Select the correct size of the aneurysm clip and bring it to the sterile environment in compliance with aseptic conditions. Inspect each aneurysm clip closely; any damaged or incorrectly aligned aneurysm clip must be discarded. Before implantation check the free movement of the aneurysm clip when the applicator jaws are open. If this is impeded, the system may not be used and must be checked.

To prevent damage, always handle the aneurysm clips with suitable care. Never open the aneurysm clip with your fingers and/or avoid mechanical manipulation of the aneurysm clip.

Ensure that the clip is correctly inserted into the orientation grooves of the jaws of the applicator (**see Fig.1**). Never use any applicators supplied by other manufacturers.
Release the handles to open the jaws of the applicator completely. If the applicator has a locking feature, this should not be engaged. Ensure that the aneurysm clip sits perfectly in the orientation grooves. Only actuate applicators with a locking feature (jaws close) until the lock engages. To spread the aneurysm clip completely, actuate the applicator handles as far as possible or press them together. The locking mechanism, if featured, is triggered automatically. When the aneurysm clip is closed, the applicator can be pulled back from the positioned aneurysm clip (in the direction of the orientation groove).

If the aneurysm clip is not correctly fitted into the applicator, or is not correctly positioned in the gripping jaws of the applicator (see Fig. 2 and 3), it can slip or become damaged when the gripping jaws of the applicator close around it. The closing force stated on the label can be lowered. An incorrectly fitted aneurysm clip can jump out of the applicator and constitute an operation risk.

It is particularly important to position the aneurysm clips correctly in the target tissue. This must be checked both while and immediately after it is fitted.

The "REF number" printed on the aneurysm clip and the serial number must be entered on the surgical and hospital records of the patient.

Caution: The closing force of the YASARGIL aneurysm clips stated on the packaging label can be lowered if the clips are repeatedly opened and closed.

Ortho Medical GMBH does not accept any liability for YASARGIL aneurysm clips that are not handled in compliance with the procedures recommended in these instructions.

Possible risks

The following serious side effects have been reported in connection with the use of the aneurysm clips:
Slipping of the clip, ejection of the clip from the applicator, breakage of the clip, tearing of the aneurysm, injury to brain vessels, haemorrhages and sudden death. Other side effects are wound infection and general operation-related complications.

Each patient must be informed of the possible risks involved with use of the YASARGIL aneurysm clips supplied by Ortho Medical GmbH.

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Figures and declarations

Fig.1
O
correct

Fig.2
X
wrong

Fig.3
X
wrong

	Manufacturer complies with the 93/42/EEC directive
	Always comply with instructions for use
	Not for reuse
REF	Order no./article no.
LOT	Lot no. / batch no.
NON STERILE	Non-sterile product
MR	MR conditional