Instructions for Use

/Vessel Clip System

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Instructions for Use
/Cleaning & Sterilization

For following product groups of Frimed GmbH:
- Vessel Clip Systems (applying forceps and vessel clips)

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 Frimed 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 instrument. 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.

Handling
Treat the 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!).

Preparation (cleaning, disinfection and sterilization)

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 instruments 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 instruments and be compatible with the instruments (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 instruments as far as possible and remove the jaw protection. Rinse all lumina of the instruments 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 disinfectant, it must be ensured
- that the disinfectant 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 instruments),
- that the used program is suited for microsurgical instruments 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 microsurgical instruments 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 instruments (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 instruments into the disinfecter. Please ensure that the instruments do not touch each other. Place the instruments in opened position (it may be required to unlatch the grip-spring for this). If applicable: Connect all lumina of the instruments to the rinsing connector of the disinfecter.
2. Start the program.
3. Take the instruments out of the disinfecter after the program is finished.
4. Check and package the instruments 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 instruments for effective cleaning and disinfection using a machine was confirmed by an independent certified test laboratory using the disinfecter G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher med (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.
Instruction for Use

Vessel Clip System

Procedure: Cleaning
1. Dismantle the microsurgical instruments as far possible.
2. Put the dismantled instruments into the cleaning bath for the specified contact time such that the instruments 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 microsurgical instruments 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 instruments 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 microsurgical instruments five times using a disposable syringe (minimum volume 10 mL).
4. Check all instruments (see section “Checking” and “Maintenance”).

Disinfection
5. Put the dismantled, cleaned and checked microsurgical instruments into the disinfection bath for the specified contact time such that the instruments are sufficiently covered. Please ensure that the instruments do not touch each other.
   If applicable: Rinse all lumina of the microsurgical instruments 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 instruments 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 instruments five times using a disposable syringe (minimum volume 10 mL).
7. Dry the instruments by blowing filtered compressed air.
8. Package the microsurgical instruments as quickly as possible after taking them out (see section “Packaging”, if required, after letting them dry in a clean place).

Maintenance
- Treat the joints of the Memory Instruments with instrument oils after every preparation. 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 instruments.
- Instruments which are sent in for repair works must be prepared completely for sanitary reasons.

Packaging
Sort the cleaned and disinfected instruments into the corresponding sterilization tray.

Please package the instruments 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 instruments / 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 procedure1 (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.

The general suitability of the instruments 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, radiosterilization, formaldehyde or ethylene oxide sterilization and plasma sterilization, either.

Storage
Do not store the instruments 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 lye (maximum permissible pH value 10.9, neutral/enzymatic or slightly alkaline cleaning agent recommended)
- organic solvents (e.g. alcohols, ether, ketones, benzine)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

Never clean any instruments and trays with metal brushes or steel wool.

All instruments and trays may only be exposed to temperatures NMT 141 °C (286 °F).

Reusability
The instruments can – if appropriate care is taken and they are undamaged and not contaminated – be reused up to 500 times; the user himself/herself shall be responsible if he/she uses the instruments more often or uses damaged or contaminated instruments.

Any liability shall be excluded in case of non-compliance.

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

Explanations of used symbols

Consult operating instructions

Catalogue number

Manufacturer

not Sterile

Lot Number

R, only U.S. federal law restricts this device to be sold by or on the order of a physician only.