



FEHLING Clamps for vessels, hollow organs and tissues



This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.

Clamps may only be used, reprocessed and disposed of by qualified medical personnel!

Clamps are intended for re-use.

1) Intended purpose

Clamps are used for the short-term occlusion of vessels and hollow organs as well as for clamping and retaining tissue.

Additional information regarding the intended purpose

Duration of application: clamps are only intended for short-term use.

Field of application: clamps are used in all patients where vessels and hollow organs need to be occluded briefly as well as where tissue needs to be grasped and held.

User profile: clamps may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: clamps are only to be used in controlled environments (e.g. OR).

2) Indications

Every surgical procedure in which vessels and hollow organs must be occluded briefly and in which tissue must be grasped and retained by clamping.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual clamp model are contraindicated. There are no generally applicable contraindications for the use of clamps. Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

In medical literature, the following adverse effects are described that can possibly occur during the intended use of clamps:

- Infections
- Lesions of surrounding structures (tissues, nerves, vessels)
- Risk of ischemia due to clamping structures for too long
- Necroses
- Injuries of the endothelium
- Perforation of tissues, vessels and cavities
- Detachment of plaques from the vascular intima/plaque rupture
- Post-bleeding
- Blood clots (thrombosis or embolism)



Before using the vascular clamps, the vessels to be clamped should be palpated to find a suitable site without calcifications. In most cases, this can minimize the risk of plaque rupture or vascular injury.



Medical devices may, for example, contain chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.



5) Prior to use

FEHLING clamps are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see 6) Reprocessing).



Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").



Clamps must be handled with care during storage, transportation and cleaning!
Avoid striking and applying pressure to clamps, so as not to cause any consequential damage! Do not overstrain functional parts!



Always keep clamps with a lock in a released state. This counteracts premature fatigue of the spring tension.



Use only sterilized products of sound quality!

6) Reprocessing



The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.



The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.



The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.



The instruments may only be used, reprocessed and disposed of by qualified medical personnel.



Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!



Do not clean titanium instruments with oxidative processes (processes using hydrogen peroxide H₂O₂, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments.



Always keep micro instruments separate from general instruments and, if possible, do not clean them together with other instruments in the WD.
To prevent deformation or breakage, protect micro instruments from spinning around in the instrument tray. Risk of injury!

Limitations on reprocessing

Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").



General information on reprocessing	<p>Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsorex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning.</p> <p>Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result.</p> <p>There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.</p>
Initial treatment at the place of use	<p>Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete.</p> <p>The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).</p>
Preparation prior to cleaning	<p>It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking).</p> <p>Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.</p>
Disassembly	See 10) Disassembly
Manual pre-cleaning	<p><u>Validated procedure:</u></p> <p>Equipment: Basin Soft brush Water spray gun (or similar)</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40°C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40°C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2% Neodisher® MediClean forte with water (potable water quality, <40°C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath.



	<ul style="list-style-type: none"> During the exposure time, use appropriate brush (not a wire brush) to remove coarse contamination. Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	<p>Avoid overfilling instrument trays and washing trays - use only suitable instrument holders.</p> <p>When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh.</p> <p><u>Validated procedure:</u></p> <p>Equipment: Washer-disinfector G 7835 CD (Miele) / PG 8535 (Miele)</p> <p>Cleaning program: Des-Var-TD (G 7835 CD)</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Preparation:</u></p> <ul style="list-style-type: none"> Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. If applicable, loosen springs Ensure that the inside of all cavities is also completely rinsed. Ensure that no areas are left unwashed. Connect the Luer connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> Pre-wash for 3 minutes with cold water (potable water quality, <40°C) Emptying Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® MediClean forte in water (potable water quality) at 55°C Emptying Rinse for 2 minutes with water (potable water quality, <40°C) Emptying Rinse for 1 minute with cold deionized water (<30°C) Emptying Thermodisinfection for 5 minutes with deionized water (>90°C) Dry for 30 minutes (90°C) <p>After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.</p>
Cleaning: Manually	<p><u>Validated procedure:</u></p> <p>Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p>



	<p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40°C) for 10 minutes. Move any movable parts, if present, back and forth over the entire range of movement. Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. Rinse the instruments for at least 20 seconds with a water spray gun (or similar). <p><u>Ultrasonic cleaning:</u></p> <ul style="list-style-type: none"> Clean for 10 minutes at <40°C with 0.5 - 2% cleaning solution at 35 kHz After ultrasonic cleaning, rinse the instruments with a water spray gun (or similar) for at least 20 seconds. Rinse the instruments for at least 10 seconds with water (potable water quality, <40°C). Deionized water (<40°C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.
Disinfection: Manually	<p>Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).</p> <p><u>Validated procedure:</u></p> <p>Equipment: Basin Bandelin Sonorex Digitec</p> <p>Disinfectant: Korsorex® med AF (Bode Chemie GmbH)</p> <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> After cleaning, place the products in an ultrasonic bath (35 kHz, <40°C) with a suitable disinfectant solution (e.g. 0.5% Korsorex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. After disinfection, rinse all products thoroughly with deionized water (<40°C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. Ensure that no residues remain on the products. Dry with sterile, oil-free compressed air.
Drying	<p>If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120°C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.</p>
Assembly	<p>See 9) Assembly</p>
Maintenance, checking and testing	<p>For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization.</p> <p>Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components.</p> <p>Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms.</p>



	<p>All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear.</p> <p>In particular, inspect the critical points on moving parts and in the working area.</p> <p>Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer.</p> <p>Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!</p>
Packaging	<p>Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.</p> <p>Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.</p>
Sterilization	<p>Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285.</p> <p><u>Validated procedure:</u></p> <p>Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert</p> <p><u>Procedure/Parameters:</u></p> <p>Cycle type: 3 pre-vacuum phases</p> <p>Sterilization temperature: 132 – 134°C</p> <p>Holding time: 4 – 5 minutes</p> <p>Drying time: 20 minutes</p> <p>When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).</p>
Storage	<p>In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.</p> <p>Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension.</p> <p>Instruments must be transported to their place of use in a closed, puncture-proof sterile container.</p>
Disposal	<p>These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.</p>



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



Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability!
Subject to change without notice.

7) Configuration and application

As a rule, clamps consist of two branches, which are connected by a closure. The clamping effect of the distal ends can be created in two ways:

- Two branches with proximal handles are pressed together via a hypomochlion, causing the jaws to move toward each other at the distal end. The clamp is secured by means of a lock.
- The clamp is consistently kept in a locked state by spring force (through crossed branches or a spiral compression spring). The distal ends are spread apart by squeezing the branches together.

Due to the variety of possible anatomical and physiological conditions, the clamps differ in their specific characteristics, such as, for example, the overall length, the length and shape of the branches and the length and design of the working ends and design of the handles, etc.



Bulldog clamps marked with a "V" are clamps for veins and can only withstand weak pressure. Bulldog clamps marked with an "A" are clamps for arteries and can withstand strong pressure.



Use only sterilized products of sound quality!



Prior to inserting the clamp, ensure that the surgical field has been prepared accordingly beforehand.



Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.



Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.



The choice of clamp depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the clamps used are of the correct size and have adequate stability.

During use



Incorrect application can lead to plastic deformation, such as bending of the branches or jaws, and even to breakage of these parts.



Risk of breakage due to overload is possible. Risk of injury!



Do not use clamps to grasp and/or hold objects which are too hard or too large.



Always store micro instruments separately from other instruments, including at the operating table!



8) Required accessories

No accessories are required for using the clamps.
Clamps are stand-alone instruments and therefore a combination with other products is not intended. However, there is an exception, bulldog clamps and vascular clips may also be placed on the respective tissue with the aid of application forceps.

9) Assembly

Assembly of the clamp is not necessary.

10) Disassembly










Disassembly of the clamp is not necessary.

11) Obligation to report serious incidents



The user is obliged to report serious incidents relating to the medical device to the manufacturer per e-mail to vigilance@fehling-instruments.de or via the report form at <https://www.fehling-instruments.de/en/complaint/> and the competent authority of the Member State where the user is registered.

Symbols

In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:

 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 CE marking	 CE marking	 Oil can for points to be lubricated

To contact the manufacturer:

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