Indications for Use

INSTRUMED Vascular Clamps are devices intended for temporary occlusion of blood vessels during open vascular or minimally invasive coronary surgical procedures.

Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician. Reusable non-sterile device.

WARNING

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!

Cleaning preparation before use

Warning:
Remove all protecting caps and sheats carefully. Before beginning to use the instrument, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected before use in surgery.

Attention:
Risk of damage - The vascular clamp is a precision device. Careful handling is important for the accurate functioning of the product. Improper external handling (e.g. bending, banging, dropping, etc.) can cause product malfunction.

Control function before use:
Before using, the general functioning and preparation of the instrument and accessories must be controlled. Please check before start-up.

Operation:
Cardiovascular procedures should be performed only by persons having adequate training and familiarity with cardiovascular techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performance of any cardiovascular procedure. Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully.
The sterile instrument is inserted into the body. The instrument must be operated only by trained personnel. Please observe general operating room technique.

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Decontamination / Cleaning / Sterilization

Decontamination:
Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories following the instructions in the IFUs.

Warning - Risk of infection!:
Before the initial use and before every further usage, the entire device, including its accessories must be decontaminated following. An inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or the user.

Cleaning
Clean the instrument externally with a soft sponge and a soft brush.

Sterilization:
Autoclave sterilization:
Use steam autoclave sterilization only. Standard autoclave cycle. Steam sterilize at 270ºF for fifteen (15) minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.) Caution: Autoclave temperatures should not exceed 280ºF.

Make certain that the instrument container is sealed in an appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.
INSTRUMED instruments are reusable and meet MAMI standards for sterilization. We guarantee our products to withstand a minimum of twenty (20) sterilization cycles when sterilized according to the criteria listed.

Maintenance:
Attention:
Apply lubricant only on the connecting elements (locking mechanism) and moving parts.
Repair:
To ensure that all repairs are completed according to the manufacturer's specifications, the precision device is repaired by INSTRUMED or by an authorized service agency only.
Warranty:
All INSTRUMED products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their originals.

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NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS LIKEWISE ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.