AVALIGN
German Specialty Instruments Division

Indications for Use

AVALIGN Vessel Dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

Caution: **Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.**

Caution: **Surgical instruments should not be used by individuals who are not fully trained in proper cardiovascular surgical techniques. Consult relevant medical literature for the appropriate indications, techniques, and risks applicable to the corresponding cardiovascular procedure.**

Read the instructions for Use prior to using this 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!**

Instructions for Use

Warning:
Remove all protective caps and sheaths carefully. Prior to surgical use, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention:
Risk of damage - The instrument is a precision device. Careful handling is important for 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 confirm prior to use.

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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 use, the entire device, including its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

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 270°F 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 280°F.

Make certain that the instrument container is sealed in appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

AVALIGN instruments are reusable and meet AAMI 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 should be repaired by AVALIGN or by an authorized service agency only.

Warranty: All AVALIGN 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 original design.

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NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY TO 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.