

Alvision

Angiographic Catheter

Description

Alvision angiographic catheters incorporate an atraumatic tip. The catheters are available in various sizes and configurations. Sterilized with ethylene oxide gas. Non-pyrogenic. Single use only. Do not resterilize.

Specifications

Specifications are found on the individual catheter pouch label.

Indications

Alvision angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system.

Contraindications

The passage of catheters through synthetic vascular grafts should be avoided.

Warnings/ Precautions

- Angiographic catheters are invasive devices that pose potential risk of injury or death. Accordingly, use of angiographic catheters should be undertaken only by trained, experienced angiographers who are aware of the potential complications and risks of angiography.
- Extreme care must be taken to avoid damage to the vessel walls through which the catheter passes.
- This catheter may occlude smaller vessels.
- Care must be taken not to completely block blood flow.
- Do not reuse or reshape the catheter.
- The maximum diameter of the guide wire to be used is specified on individual pouch. Guide wire use has been associated with thrombus formation.
- Alvision angiographic catheters are designed for single use only and should be discarded after single use.
- Do not let catheters come into contact with organic solvents.
- Do not pressurize catheters to more than the rated maximum pressure as pointed on the pouch label.
- Careful inspection should be done to verify the size, shape and condition of the catheter as suitable for the specific procedure.
- Angiography should be undertaken only by an experienced angiographer. Catheters are supplied sterile and non-pyrogenic.
- Do not use if the package is open or damaged.
- The application of 'Universal Precautions' is recommended as with any surgical procedure.

- Avoid damaging the tip of the catheter during removal from the package.
- Rapid removal may result in damage to the catheter tip.
- Care should be taken to prevent or reduce clotting when any catheter is used.
- While in the vascular system, the catheter should always be filled with either flushing solution or contrast medium.
- Use of systemic heparinization should be considered.
- These catheters are designed for the injection of the contrast media and for physiologic measurement in conjunction with routine diagnostic procedures.
- Do not use if the date is after the use by date as printed on the label.
- Do not expose catheters to strong solvents or ionizing radiation.
- Do not store in excessive heat.
- Avoid prolonged exposure to UV light.

Adverse Reactions / Complications

The following adverse reactions have been reported to be associated with the use of angiographic catheters; Thrombus formation/emboli, arterial wall damage, plaque dislodgement, myocardial infarction, cardiac arrhythmia, stroke and death

The physician should be familiar with the current literature concerning the complications of angiography. The catheter may not function as designed or withstand the stresses of cleaning or reuse. Improper cleaning of catheter components exposed to biological materials may cause adverse reactions in the patient if used.

Some complications that may be observed are;

- Air embolism
- Hematoma
- Infection
- Perforation of the heart or vessel wall

Instructions for use

- Gently remove catheter hub first from the pouch to prevent damaging to the tip.
- The catheter should be introduced into the blood vessel with the physician's choice of vascular entry techniques.
- A guide wire should be used to straighten the catheters and prevent kinking during introduction.
- Thin wall catheters should be handled with extreme care to prevent kinking.

Terms of Warranty

Alvimedica guarantees that each and every component of this product has been manufactured, packed, tested and sterilized without any defect regarding workmanship or material. Each product has been tested prior to packaging. Alvimedica shall exchange any product with defect(s) from manufacturing or packaging with a new one. Alvimedica is not directly or indirectly responsible for

any injury or damage to or loss of the product resulting from the use of the product, nor is Alvimedica responsible for any injury, damage or loss that may result from re-use or re-sterilization.