

Alviguide

Guiding Catheter

Definition

Alviguide guiding catheter has a large non-tapered lumen that allows contrast medium injections and pressure monitoring and facilitates the intravascular passage of interventional devices. Sterilized with ethylene oxide gas. Non-pyrogenic. For single use only. Do not resterilize.

Specifications

Specifications are found on the individual catheter pouch label.

Indications

The guiding catheter is intended to use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Contraindications

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

Warnings /Precautions

- Discard the guiding catheter after one procedure.
- Store in a cool, dark, dry place.
- Do not use open or damaged packages. Use prior to the "Use By" date as printed on the pouch label.
- Do not resterilize.
- Guiding Catheters are invasive devices that pose potential risk of injury or death.
- They are designed for use by physicians engaged in a specialized area of medicine. Accordingly, use of Guiding Catheters should be undertaken only by trained, experienced physicians who are aware of the potential complications and risks associated with intravascular catheter.
- Structural Integrity and/or function may be compromised through reuse or cleaning. In addition, catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused.
- Due to the size and relative stiffness of guiding catheters, extreme care must be used to avoid damage to the vessel walls through which this catheter passes. Inspect the guiding catheter before use to verify that its size, shape and condition are suitable for the specific procedure.
- This catheter may occlude smaller vessels. Care must be taken not to completely block blood flow.
- Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which incorporates the components of these agents.
- Do not expose to organic solvents.

- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance can not be determined, withdraw the catheter.
- Torquing the guiding catheter excessively while kinked may cause damage which could result in possible separation along the catheter shaft. Should the guiding catheter shaft become severely kinked, withdraw the entire system (guiding catheter, guide wire and catheter sheath introducer).
- Advancement, manipulation and withdrawal of the guiding catheter should always be performed under fluoroscopic guidance.
- Large internal lumen guiding catheters require less force on the syringe during injection. The maximum recommended injection pressure is 500 psi.
- Hand inject slowly.
- Employ aseptic techniques during removal from the package and during use.
- As with any surgical procedure, the application of "Universal Precautions" is recommended.
- To avoid damage to catheter or tip, grasp the luer and slowly withdraw the catheter from the package.

Adverse Effects/Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during or after the procedure. The following adverse reactions have been reported to be associated with the use of any intravascular catheters: Thrombus formation/emboli, arterial wall damage/dissection, plaque dislodgement, myocardial infarction, cardiac arrhythmia, infection, hematoma at the puncture site, stroke and death.

Possible complications include, but are not limited to the following:

- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation of the heart or vessel wall.

Instructions for use

- Remove the guiding catheter from its packaging.
- Inspect the guiding catheter upon removal from packaging to verify that it is undamaged. Warning: do not use a guiding catheter that has been damaged in any way. If damage is detected, replace with an undamaged guiding catheter.
- Prior to use, flush the guiding catheter lumen with a heparinized saline solution.
- Introduce the guiding catheter into the vasculature through the catheter sheath introducer, and/or over an indwelling guide wire using a percutaneous entry technique of choice.
- Administer local anesthesia prior to introduction. Advance the catheter and guide wire together to the selected vascular site.
- Set up a continuous heparinized saline flush attached to the guiding catheter hub. It is recommended that a continuous heparinized saline flush be maintained between the guiding catheter and any intraluminal device passed through it.

- Once in place, remove the guide wire.
- Under fluoroscopic guidance, advance the guiding catheter over the guide wire or introducer until desired position is attained.
- Remove the guide wire or introducer prior to the introduction of other intravascular devices or infusion of contrast agents.
- On completion of the procedure, it is recommended that the catheter be aspirated during withdrawal

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.