

INSTRUCTIONS FOR USE:

VASOGUIDE - Guiding Catheter :

DESCRIPTION:

Guiding Catheter are specialized diagnostic intravascular catheters used for the coronary diagnostic angiography performed as part of diagnostic cardiac catheterization. The basic design of Guiding catheter comprises of a catheter tube having a proximal end and a distal end. A Nylon lumen extends from the proximal end of the Guiding Catheter to the distal end of the catheter and is configured to serve as a conduit for contrast media delivery, catheter flushing and pressure measurement during cardiac catheterization procedure. The lumen of the catheter is also designed to house a guidewire. The Guiding Catheter are designed to allow access into the arterial vasculature from access sites such as femoral, radial, and brachial arteries. Guiding Catheter manufactured with different material (Polycarbonate, Pebax, Polyurethane, Polyamide, Stainless Steel, Nylon.

INTENDED USE:

Guiding Catheters are intended for use in general intravascular, coronary and peripheral applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced.

INDICATIONS:

Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.

INTENDED USER:

Cardiologists or doctors who qualified, specialized and trained in the cardiology/ or vascular medical procedure.

PATIENT TARGET POPULATION:

The Guiding catheter is designed for use during diagnostic and interventional procedures by trained cardiac physicians, using their education and experience. The physician determines based on the individual patient(s) medical Condition. The appropriate Guiding Catheter to support the associated device to be used during the procedure.

CONTRAINDICATIONS :

None specific to this device.

LIMITATION OF DEVICE:

Use of Guiding Catheter limited to cardiac and vascular procedure only.

USE ENVIRONMENT: Hospital/Cath. Laboratory

PERFORMANCE CHARACTERISTICS:

- Engages with simple clockwise & counter clockwise rotation
- High Flexibility
- Superior Surface Smoothness
- Excellent 1:1 Torque Control as designed double wire stainless steel braiding
- Large inner lumen for superior flow rates
- Atraumatic soft tip
- Max. Pressure: 1200 PSI / 84 bar
- Guidewire Compatibility : 0.038"/ 0.97mm

INFORMATION ON MEDICAL DEVICE INTENDED TO BE USED WITH OTHER DEVICES:

Guiding catheter are designed to be used with guidewire, pressure device and extension line.

EXPECTED CLINICAL BENEFITS:

The clinical benefits derived from Guiding catheter are achieved indirectly. The device itself helps in the establishment of cardiac access into artery for administration of radiopaque media, guidewires, and therapeutic agents to selected sites in the vascular system. The indirect clinical benefits are as follows:

- Angiography / Angioplasty may eliminate the need for surgery. If surgery remains necessary, it can be performed more accurately. Catheter guiding presents a very detailed, clear, and accurate picture of the blood vessels. This is especially helpful when a surgical procedure or some percutaneous intervention is being considered.
- By selecting the blood vessels through which the catheter passes, it is possible to assess vessels in several specific body sites. In fact, a smaller catheter may be passed through the larger one into a branch artery supplying a small area of tissue or a tumor; this is called super-selective angiography.
- Unlike computed tomography (CT) or magnetic resonance (MR) angiography, use of a catheter makes it possible to combine diagnosis and treatment in a single procedure. An example is finding an area of severe arterial narrowing, followed by angioplasty and placement of a stent.

RISKS ASSOCIATED WITH RE-USE:

Cross contamination/infection, device will not function as per intended use.

STORAGE AND HANDLING CONDITION:

Store in between 5°C to 35 °C and protect from excessive heat, direct sunlight, and moisture.

WARNINGS AND PRECAUTIONS:

- Do not use if package is opened or damaged or any other anomaly is observed.
- Use product immediately after opening the individual pack.
- Carefully read instructions for use before using the product.
- The product should be used only by qualified healthcare professionals.
- For single patient use only. Do not reuse, reprocess, or re-sterilize this product. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or create a new risk of contamination of the device, which could result in patient injury, illness, or death. Cleaning, disinfection, and re-sterilization may compromise the essential material and design characteristics of the device and lead to device failure.
- Do not use after the Use-by Date.
- Use aseptic technique during the entire procedure.
- Administer appropriate anti-coagulation therapy to reduce potential thrombosis. If the patient is not appropriately anti-coagulated, thrombus formation may occur. Testing without anti-coagulation shows variable amounts of thrombus formation on the device surface.
- After use, this product may be a biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Only physicians trained in intravascular angiographic procedures should use or supervise the use of the Guiding catheter.
- Carefully inspect the Guiding catheter before use to verify that the size, shape, and condition of the catheter are suitable for the intended procedures.
- Do not expose Guiding catheter to UV light.
- Do not use the catheter if the catheter package has been opened or damaged before use.
- Do not heat or bend the Guiding catheter.
- Select a Guiding catheter with optimal tip shape and optimal size, taking into account the access site, the target site, and the patient's anatomy.

CAUTIONS :

- When using a drug or device with the Guiding catheter, be aware of the properties and characteristics of the drug or device and exercise caution due to avoid damaging the Guiding catheter and user should follow the IFU of such drug / device to be used with the Guiding catheter.
- Avoid using alcohol, antiseptic solutions, and other solvents with the Guiding catheter.

ADVERSE EVENTS:

Adverse events that may occur or require intervention include, but are not limited to, the following:

- Thrombus formation
- Embolization
- Infection
- Arterial, venous, or heart wall damage or perforation

- Plaque dislodgement
- Hematoma at puncture site
- Cardiac arrhythmia
- Myocardial infarction
- Vascular occlusion
- Death
- Access site pain
- Allergic and neurological reactions
- Vasospasm
- Stroke and transient ischemic attack
- False aneurysm
- Arteriovenous fistula

2. INSERTION TECHNIQUE:

- The Guiding catheter may be introduced into the selected vessel by Cut down technique, Seldinger technique, or introducer methods. When using an introducer, ensure that it is a French size greater than or equal to the selected Guiding catheter.
- Introduce the Guiding catheter into the vascular system over a guidewire and carefully advance it under fluoroscopic control.
- To remove the Guiding catheter, reinsert the guidewire to straighten the tip of the Guiding catheter. Slowly withdraw the Guiding catheter and guidewire under fluoroscopic control

3. REMOVING THE CATHETER:

- At The Completion Of Angioplasty Procedure, Aspiration During Withdrawal of the Catheter is Recommended.

Safe disposal information of medical device:

After use, this product may be a biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

PRODUCT IDENTIFICATION AND MODEL:

See label for information on pattern of catheter tip and shape, effective length, catheter outer diameter, maximum guidewire diameter, maximum pressure & number of side hole.

REPORTING OF INCIDENT TO MANUFACTURER & COMPETENT AUTHORITY:

For providing feedback on this product write to : customercare@polymedicure.com

WARRANTY DISCLAIMER:

Although the Guiding catheter, hereafter referred to as "product "has been carefully designed, manufactured and tested prior to sale, the product may fail to perform its intended function satisfactory for a variety of reasons. The warnings contained in the product labeling provide more detailed information and are considered an integral part of disclaimer of warranty. Polymed therefore disclaims all warranties, both expressed and implied, with respect to the product. Polymed shall not be liable for any incidental or consequential damages caused by any use, defect, or failure of the product, whether the claims is based on warranty, contract, Tort, or otherwise.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law any part or term of this disclaimer of warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this disclaimer of warranty shall not be affected and all rights and obligations shall be construed and enforced as if this disclaimer of warranty did not contain the particular part or term held to be invalid.



Cautions



See Instructions for use



Product reference/Art. No.



For single use only



Do not Resterilize



Do not use if packaging or product has been damaged or contaminated



Batch Number



Date of Manufacturing



Use by / Expiry date



Sterilised by Ethylene Oxide



Single Sterile Barrier System



Manufactured by



Non Pyrogenic



Storage Condition



Keep Away from Sunlight



Keep Dry



Medical Devices



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