INSTRUCTIONS FOR USE:

FILOFLEX
PTFE Guidewire

DESCRIPTION:
PTFE Guidewire for percutaneous entry and guidance of catheters, the Diagnostic Guidewire complements our diagnostic catheter and catheter sheath introducer lines. Performance, endurance, and safety are built into each Guidewire with solid tensile strength to minimize the likelihood of stretching or fracturing. PTFE Guidewire have a stainless-steel shaft. The shaft is either, PTFE and Heparin coated, or uncoated. Guide wire length, diameter, core configuration, flexibility type, tip configuration are all indicated on the product label.

CONTENT :
none.

INTENDED PURPOSE:
Guide Wire is used to facilitate the placement and exchange of devices during diagnostic and interventional procedures in the peripheral circulatory system and the central circulator y system excluding the coronar y arteries and the neurovasculature.

INDICATIONS:
Guidewires are intended for use in the percutaneous introduction of catheters.

INTENDED USER:
For use by physicians trained in diagnostics and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

PATIENT TARGET POPULATION:
The Guide wires are designed for use during diagnostic and interventional procedures by trained physicians. Using their education and experience, the physicians determines based on the individual patient, the appropriate Guide wire to support the associated device to be used during the procedure. The Guidewire navigates the anatomy and facilitates placement of the associated device.

CONTRAINDICATIONS:
None known.

LIMITATION OF DEVICE:
Use of PTFE guidewire in diagnostics and interventional radiology, cardiology, nephrology, and vascular surgery procedures only.

USE ENVIRONMENT:
Hospital/Cath. Laboratory.

INFORMATION ON MEDICAL DEVICE INTENDED TO BE USED WITH OTHER DEVICES:
PTFE Guidewire designed to be used with:
- PTCA Balloon Dilatation Catheter
- Pressure device
- Extension line
- Flushing Cannula
- Re-Collapse Device
- Re-use Clip
- Guiding catheter
- Y- connector, Guidewire,
- Torque device

EXPECTED CLINICAL BENEFITS:
The Guide wire has indirect clinical benefits for the patient since it assists other medical device in achieving there intended purpose, without having a direct therapeutic or diagnostic function itself. It is used to gain vascular system and placement of compatible diagnostic or therapeutic medical devices that have direct therapeutic or diagnostic function.

RISKS ASSOCIATED WITH RE-USE:
Cross contamination/infection, device will not function as per intended use.

STORAGE AND HANDLING CONDITION:
Store in between 15°C to 25 °C and protect from excessive heat, direct sunlight, and moisture.

REPORTING OF INCIDENT TO MANUFACTURER & REGULATORY AUTHORITY:
For providing feedback on this product write to: customercare@polymedicure.com

PERFORMANCE CHARACTERISTICS:
The Guide wire is designed with performance characteristics for use in patients' vasculature system.
- Atraumatic distal flexible tip to facilitate introduction into the vasculature.
- Surface coating to allow smooth passage of the guide wire through the vasculature.
- Guide wire body stiffness that supports successful delivery of associated devices.

INSPECTION PRIOR TO USE:
The product is sterile if the package is unopened and undamaged. Prior to use, carefully examine all guidewire to verify that the sterile package or product has not been damaged in shipment. Prior to and during use, inspect the guidewire carefully for coil separation, bends or kink which may have occurred. Do not use Guide wire.

PRECAUTIONS PRIOR TO USE:
1. The physicians should be trained in the use of angiography and angioplasty product and potential procedural complications.
2. Confirm the compatibility of the Guidewire with other interventional device being used by testing the systems for any resistance prior to actual use. Free movement of the guide wire within the interventional device must be confirmed maintained.
3. The Guide wire should be completely hydrated with saline or heparinized saline prior to removal from the dispenser hoop.
4. To Avoid Guide wire tip damaged during removal from the dispenser hoop, first remove the proximal guide wire body from the retention clip, then slide guidewire forward towards the flush hoop dispenser allowing the distal wire tip to exit.

NOTE:
Distal tip wire may be positioned inside the flush hoop to protect the fragile tip.

5. Gently grasp guide wire tip and J straightener together as a unit gently pull forward to withdraw the fragile distal wire tip from the dispenser.
6. The tip of guide wire may be shaped using standard tip shaping practices. Do not shape the wire surface against a sharp edges, this may result in damaged to the wire surface.

WARNINGS:
The safety and effectiveness of the Guide wire has not been established in the coronary arteries or in the neurovasculature.

ADVERSE EVENTS :
Adverse events which may result from the use of the device include but are not limited to:
- Air embolism/ thromboembolism
- Allergic reaction
- Arteriovenous (AV) fistula
- Cardiac arrhythmia
- Embolism
- Hematoma
- Hemorrhage
- Infection or sepsis/infection
- Myocardial ischemia and/or infraction
- Pseudo aneurysm
- Stroke (CVA)/Transient ischemic Attack (TAI)
- Thrombus
- Vessel osculation
- Vessel perforation• Vessel Dissection
- Vessel Trauma or Damage
- Vessel spasm
- Wire entrapment/Entanglement
- Foreign body/Wire Fracture

Some of the stated potential adverse events may require additional surgical intervention. Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.

DIRECTION FOR USE:

GUIDE WIRE PREPRATION:
1. Employ and aseptic technique during removal from the package and use.

2. Attach flush solution filled syringe to flush dispenser hoop.
3. Inject saline until dripping out opposite end to completely fill the dispenser hoop.
4. Detached syringe from flush dispenser hoop.
5. Inspect, prepare, and flush the associate device to be used according to the manufacturer's instructions.
6. Dispense guide wire into the luer port of the catheter.

NOTE:
To reduce potential of clot formation, it is recommended that the guide wire be flushed with saline or heparinized saline prior to subsequent uses.

INSTRUCTION FOR USE:
Use extreme caution withdrawing PTFE guide wire back through a metal needle, the sharp edge of the needle scrape the coating.
1. Attach a compatible hemostasis valve to the catheter luer, if desired.
2. Insert the guide wire J-straightener into the hub luer of the intended catheter of device.
3. Carefully advance the distal guide wire tip through the J -Straighter and device lumen. Remove the straightener by withdrawing it over the guide wire.
4. Attached a compatible torque device to the guide wire, if desired to provide directional control of the guide wire tip.
a. Loose the cap of the torque device.
b. Insert the proximal end of the guide wire into the proximal end of torque device cap
c. Once torque device is located to the desired location on the wire, tighten the cap to secure the torque device into the guide wire.
5. Always advance and manipulate the guide wire under fluoroscopic guidance to:
a. Prevent potential damaged to the vasculature
b. Confirm the guide wire placement and location
c. Assure the distal tip is intraluminal and in the intended vessel.
6. Hold the guide wire in position while manipulating the catheter over the guide to wire prevent unintended movement of the distal wire tip.

WARNING:
a. Wire advancement with excessive force may cause coil penetration and / or vessel damage. Never force a wire that meets resistance, immediately asses the tip under fluoroscopy to determine cause of resistance and/or the need for additional action to free the guide wire tip.
b. Manipulate a guide wire when resistance is felt may cause guide wire damage, tip separation, and / vascular injury.
c. Extreme care should be taken when manipulating a catheter and wire combination to prevent possible intravascular tissue damage. If resistance is felt during advancement. Manipulation, or removal stop immediately and confirm wire position under fluoroscopy.
d. The guidewire and catheter should be moved and removed as a unit when possible.
e. When reintroducing a guidewire into a catheter or device within a vessel, confirm the catheter tip is free within the lumen (not against the vessel wall).
f. Always advanced or withdraw wire slowly. free movement of the guidewire within a vessel or catheter provides valuable tactile information.
g. Test all systems for resistance prior to use.

REUSE PRECAUTION STATEMENT:
1. For single patient use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and /or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or restrilization may also create a risk of contamination of the device may lead to injury, illness or death of the patient.
2. Store in a cool, dark, dry place.
3. Do not use if package is open or damaged.
4. Use prior to "Use by" date.
5. Do not withdraw a PTFE guidewire through a metal-cannula needle. Withdrawal may damage the guide wire coating.

DISCLAIMER OF WARRANTY:

NOTE:
Although the catheter, thereafter refered to as "product", has been manufactured under carefully controlled conditions, polymed and its affiliates has no control over conditions under which this product is used. Polymed and its affiliates, therefore, disclaims all warranties, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchant/ability or fitness for a particular purpose. Polymed and its affiliates shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind polymed and its affiliated to any representation or warranty with respect to the product.


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

Sterilized by Ethylene Oxide


Single sterile barrier system with protective packaging inside


Manufactured by


Non Pyrogenic

Storage Condition


Keep Away from Sunlight


Keep Dry

Medical Device

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POLYMED

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