INSTRUCTIONS FOR USE:

AQUAREACH

Hydrophilic Guide Wire

DESCRIPTION :
Hydrophilic guide wires are constructed from a high quality, steerable, metallic core wire with a polymer coating. The metallic core wire is utilized throughout the entire length of the wire body. The polymer coating (jacket)extends across the entire length of the guide wire surface. A hydrophilic coating is applied over the radiopaque polymer jacket. The hydrophilic coating extends across the entire length of the guide wire surface. The hydrophilic coating, when activated, provides lubricity across the entire polymer surface allowing the guidewire to navigate through the vasculature. Guide wires are supplied sterile and non pyrogenic

CONTENTS:
None.

INTENDED PURPOSE-
The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

INDICATIONS :
The Hydrophilic Guide Wire is designed to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional Procedures.

INTENDED USER:
Qualified healthcare professionals (Cardiologists, Surgeon, or doctors who specialize in the heart, especially for vasculatory system).

PATIENT TARGET POPULATION:
The Hydrophilic 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 Hydrophilic Guidewire navigates the anatomy and facilitates placement of the associated device.

CONTRAINDICATIONS :
No-contraindications are known when using Hydrophilic guide wire in vascular procedures. Carefully used the list of contraindications in the instruction for use accompanying the other interventional device to be used with the guide wire.

LIMITATION OF DEVICE:
Use of Hydrophilic guide wires limited to diagnostic or interventional Procedure only.

USE ENVIRONMENT:
Hospital/Cath. Laboratory

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

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

WARNINGS:
- Failure to abide by the following warnings might result in damage to the vessel, shearing of the guide wire and release of plastic fragments from the Guide wire. Such pieces or fragments from the wire may have to remove from the vessel.
- Do not manipulate or withdraw the guide wire through a metal entry needle of a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in destructions and/or separation of the outer polyurethane coating requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement.
- Do not use the guide wire with devices which contain metal parts such as atherectomy catheter, laser catheter, or metal introduction device as they may cause the guide wire plastic coating to shear and/or sever the wire.
- Do not reshape guidewire by any means. Attempting to reshape wire may cause damage, resulting in the release or wire fragments into the vessel.
- When exchanging or withdrawing a catheter over the guide wire, secure and maintain the guidewire in place under fluoroscopy to avoid unexpected guidewire advancement otherwise, damaged to the vessel wall by the wire tip may occur.
- A retrieving device, such as gripper or basket forceps, can only be used after the guide wire has been removed from the patient's vessel. Using a retrieving device while the guidewire is in the vessel may cause the guide wire to break.
- Manipulate the guide wire slowly and carefully in the vessel while confirming of the behavior and location of guide wire tip under fluoroscopy. Improper manipulation of the guide wire without fluoroscopic confirmation may result in vessel preformation.
- Do not apply repetitive bending force to one specific point the device as this may cause damage to the guide wire .
- If any resistance is felt or if the tip's behavior and/or location seems improper, stop manipulating the guide wire and/or catheter and determine the cause by fluoroscopy. Continuing to manipulate or rotate the guide wire or failure to exercise proper caution may result in bending, kinking, and separation of the guide wire tip, and damage to the catheter, damage to the vessel.
- Do not attempt to use the guide wire if it has been bent, kinked or damaged. Use of damaged wire may result in damage to the vessel or the release of wire fragments into the vessel.
- Consider the use of systematic heparinization to prevent to reduce the possibility of thrombus formation on the surface of the Hydrophilic guide wire.

PRECAUTIONS:
- The Hydrophilic guide wire should be used by physician, who is well trained in manipulation and observation of guidewire under fluoroscopy.
- Sterile in unopened and undamaged unite package. Do not use if unit package or guide wire is broken or soiled. The Hydrophilic guide wire should be used immediately after opening the package and be disposed of safely andproperly after use, following local regulations for medical waste management.
- When using drug or a device concurrently with the guidewire m, the operator should have full damaged the guidewire m. For example when using guidewire m with any device that emits energy (laser, pressure, ultrasound, etc.) Confirm that the Hydrophilic guide wire is retracted into the positions where it will not be impacted by the energy.
- Consider the use of systematic heparinization.
- The surface of Hydrophilic guide wire is not lubricious unless it is wet. Before talking it out of its holder and inserting it through a catheter, fill the holder and the catheter with heparinization physiological saline solution.
- When reinserting the guide wire back into the holder, take care not to damage the wire hydrophilic polymer coating with the edge of the holder.
- Do not use a metal torque device with the guide wire .Use of a metal torque device may result in damage to the guide wire.
- Do not slip a tightened up torque device or Y-connector over the wire, as this may result in damage to the wire.
- Due to the slippery nature of the hydrophilic coating on the wire. TORQUE DEVICE, sold separately, is recommended for easier handling/manipulation of the wire.
- Due to variations of certain catheter tip diameter, abrasion of hydrophilic coating may occur during manipulation. If any resistance is felt during introduction of the catheter, it is advisable to stop using such catheters.
- Do not manipulate the guidewire m through a tightened up rotating hemostasis valve, as this may result in damage to the wire.
- After removal from the patient's vessel and prior to reinserting it into the same patient during the same catheterization, the Hydrophilic guide wire should be rinsed in a bowl full of heparinized physiological saline solution. Any blood residues still adhering to the wire can be removed by wiping once with a gauge moistened with heparinized physiological saline solution.
- Use of alcohol, antiseptic solution or other solvent must be avoided, because they may adversely affect the surface of

the guide wire.

•The Hydrophilic guide wire contain a metallic core, do not use with any inappropriate equipment (MRI).

•The entire operating should be carried out aseptically.

•This product has been sterilized by ethylene oxide gas.

ADVERSE EVENTS :

Adverse events that may be related to the use of Guide wire can include but may not be limited to following:

• Tissue trauma
• Infection
• Vessel perforation
• Hematoma
• Embolism
• Allergic reaction
• Thrombus formation
• Hemorrhage

Carefully read the list of complication in the instruction for use accompanying, The other interventional device to be used with the Guide wire.

DIRECTION FOR USE :

• Remove the Hydrophilic guide wire and the holder together from the package.
• Fill the holder with heparinized physiological saline solution through the hub of the holder using a syringe.
• Remove the Hydrophilic guide wire from the holder and inspect the guide wire prior to use, to verify that it is lubricated. If the guide wire cannot be easily removed from the holder, inject more heparinized physiological saline solution into the holder and try again.
• Prior to use, prime the catheter with heparinized physiological saline solution to ensure smooth movement of the guide wire within it.
• The Hydrophilic guide wire may slide entirely into the catheter or slip out of the catheter because of its low sliding friction.
• Keep at least 5cm.of wire extended out of the hub of the catheter during introduction.

PREPARATION FOR USE :

1. The surface of the hydrophilic guide wire is not lubricious unless it is wet. Before attempting to remove the guide wire from its dispenser, inject sterileheparinized saline solution into the luer lock hub end of the dispenser to fill the dispenser coil. This will completely cover the guide wire surface, activate the hydrophilic coating, and make the guide wire very lubricious.

WARNINGS:

1. Failure to hydrate the dispenser hoop prior to guide wire removal may result in guide wire damage and or difficult removal from the dispenser.
2. After hydrating the guide wire, gently grasp the J-straightener device and pull from the dispenser, once the straightener is separated from the dispenser, continue to remove the wire from the hoop.
3. If Hydrophilic guide wire is not properly hydrated, it will be difficult to remove from the dispenser. Inject additional heparinized saline solution into dispenser and repeat step # 2

PRECAUTION STATEMENT :

1. For single patient use only.
2. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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.
3. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection,including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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

POLY MEDICURE LTD.
Plot No. 33-34, Sector 68, IMT, Faridabad, Haryana-121004, India,
Web : www.polymedicure.com, Contact customer care executive:
+91-129-4287053, Email:customercare@polymedicure.com,
Address: Same as above

Rev. 02-25/11