INSTRUCTIONS FOR USE

Description:
Merit Medical hydrophilic guide wires are constructed from a high quality, steerable, metallic core wire with a polymer coating utilizing a sophisticated construction process. A hydrophilic coating is applied over the radiopaque polymer jacket. Guide wires are supplied sterile, non-pyrogenic and are intended for single use only.

Indications for use:
Guide wires are used to facilitate the subsequent introduction(s) of intravascular devices during diagnostic and interventional Cardiology and Radiology angiographic procedures. Hydrophilic guide wires may also be utilized in other diagnostic and therapeutic Radiology procedures.

Warnings/Adverse Reactions:
Care should be taken when manipulating a guide wire inside a vessel during device placement and removal. Guide wires should be manipulated only under fluoroscopy. If resistance occurs and the cause of resistance cannot be determined, remove the guide wire and device as a unit. Never advance the guide wire against resistance without first determining the reason for the resistance under fluoroscopy. Excessive force against resistance may result in damage to the wire and/or to the vessel.

Other potential adverse reactions which may result from the improper use of a guide wire include, but are not limited to:

- Thrombus
- Emboli
- Arterial or venous vessel wall damage
- Plaque dislodgment
- Hematoma at the puncture site
- Infection
- Vessel perforation
- Vessel spasm
- Hemorrhage
- Vascular thrombosis

The physician should be familiar with the literature concerning the complications of angiography.

Cautions:
AT LEAST 5 CM OF THE WIRE SHOULD PROTRUDE FROM THE DEVICE HUB AT ALL TIMES TO PREVENT THE WIRE FROM SLIDING ENTIRELY INTO THE DEVICE DUE TO THE LOW SLIDING FRICTION OF THIS WIRE.

AVOID MANIPULATING OR WITHDRAWING THE HYDROPHILIC GUIDE WIRE BACK THROUGH A METAL NEEDLE OR CANNULA. A SHARP EDGE MAY SCRAPE THE COATING OR SHEAR THE GUIDE WIRE. A CATHETER, INTRODUCTOR SHEATH OR VESSEL DILATOR SHOULD REPLACE THE NEEDLE AS SOON AS THE GUIDE WIRE HAS BEEN INSERTED INTO THE VESSEL.

For single use only do not reuse, reprocess or resterilize. Inspect wire for damage prior to use, do not use any unit if package is opened or damaged. This device is sterilized by ethylene oxide gas. It is recommended that a plastic torque device be used to handle the hydrophilic guide wire. Use of a metal torque device may damage the guide wire surface coating. Federal law (USA) restricts this device to the sale and use only by or on the order of a physician.

Preparation for use:
1. Before attempting to remove the guide wire from its' dispenser, inject sterile heparinized 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 will make the guide wire very lubricious.

WARNING: FAILURE TO HYDRATE DISPENSER HOOP PRIOR TO GUIDE WIRE REMOVAL MAY RESULT IN GUIDE WIRE DAMAGE AND OR DIFFICULT REMOVAL FROM THE DISPENSER.