

RADIFOCUS® GLIDEWIRE®

ENGLISH

INSTRUCTIONS FOR USE

Read the following warnings, precautions and directions for use carefully.

INDICATIONS FOR USE

The Glidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.

WARNINGS

Failure to abide by the following warnings might result in damage to the vessel, shearing of the GLIDEWIRE, and release of plastic fragments from the GLIDEWIRE. Such pieces or fragments from the wire may have to be removed from the vessel.

- Do not manipulate or withdraw the GLIDEWIRE through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in destruction 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 GLIDEWIRE with devices which contain metal parts such as atherectomy catheters, laser catheter, or metal introduction devices as they may cause the GLIDEWIRE plastic coating to shear and/or sever the wire.
 - Do not reshape the GLIDEWIRE by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the vessel.
 - When exchanging or withdrawing a catheter over the GLIDEWIRE, secure and maintain the guide wire in place under fluoroscopy to avoid unexpected guide wire advancement; otherwise damage to the vessel wall by the wire's tip may occur.
 - A retrieving device, such as a gripper or basket forceps, can only be used after the GLIDEWIRE has been removed from the patient's vessel. Using a retrieving device while the GLIDEWIRE is in the vessel may cause the GLIDEWIRE to break.
 - Manipulate the GLIDEWIRE slowly and carefully in the vessel while confirming the behavior and location of the wire's tip under fluoroscopy.
- Excessive manipulation of the GLIDEWIRE without fluoroscopic confirmation may result in vessel perforation. If any resistance is felt or if the tip's behavior and/or location seems improper, stop manipulating the GLIDEWIRE and/or the catheter and determine the cause by fluoroscopy. Failure to exercise proper caution may result in bending, kinking, separation of the guide wire's tip, damage to the catheter, or damage to the vessel.
- Do not attempt to use the GLIDEWIRE if it has been bent, kinked or damaged. Use of a damaged wire may result in damage to the vessel or the release of wire fragments into the vessel.

PRECAUTIONS

- The GLIDEWIRE should be used by a physician, who is well trained in manipulation and observation of guide wires under fluoroscopy.
- The GLIDEWIRE has been sterilized by ethylene oxide gas. For single use only. Do not resterilize or reuse.
- The entire operation should be carried out aseptically.
- Sterile in an unopened and undamaged unit package. Do not use if the unit package or the guide wire is broken or soiled. The GLIDEWIRE should be used immediately after opening the package and be disposed of safely and properly after use, following local regulations for medical waste management.
- When using a drug or a device concurrently with the GLIDEWIRE, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the GLIDEWIRE.
- The surface of the GLIDEWIRE is not lubricious unless it is wet. Before taking it out of its holder and inserting it through a catheter, fill the holder and the catheter with heparinized physiological saline solution.
- When reinserting the GLIDEWIRE back into the holder, take care not to damage the wire's hydrophilic coating with the edge of the holder.
- Do not use a metal torque device with the GLIDEWIRE. Use of a metal torque device may result in damage to the wire. Also, do not slip a tightened up torque device over the wire, as this may result in damage to the wire.
- Due to the slippery nature of the hydrophilic coating on the GLIDEWIRE, the operator may encounter some difficulties in handling the wire. A RADIFOCUS TORQUE DEVICE, sold separately, is recommended for easier handling/manipulation of the wire.
- Due to variations of certain catheter tip inner diameters, abrasion of the 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 GLIDEWIRE 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 GLIDEWIRE 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 gauze moistened with heparinized physiological saline solution. Use of alcohol, antiseptic solutions or other solvents must be avoided, because they may adversely affect the surface of the GLIDEWIRE.
- Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature.
- Federal law (U.S.A) restricts this device to sale by or the order of a physician.

DIRECTIONS FOR USE

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

REF Code No.
Référence

LOT Lot No.
Numéro de lot

Expiry date
Utiliser avant

STERILE EO

Sterilized by ethylene oxide.
Stérilisé à l'oxyde d'éthylène.



Read the instructions for use.
Lire le mode d'emploi.



For single use only.
Strict usage unique.

Manufacturer
Fabricant

FRAGILE



FRAGILE

KEEP AWAY FROM RAIN



EVITER LA PLUIE

KEEP AWAY FROM SUNLIGHT



EVITER LES RAYONS DU SOLEIL

TERUMO

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MADE IN JAPAN

