True Form™

Reshapable Guide Wire

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT
The True Form™ Reshapable Guide wire is a hydrophilically coated and polymer jacketed stainless steel guide wire with a 2 cm shapeable distal tip. The True Form Reshapable Guide Wire may be packaged with the following components:

- 1 Torque device
- 1 Insertion tool/ guide wire shaper
- 1 Tip straightener

INDICATIONS FOR USE
The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral and coronary vasculature for various diagnostic and interventional procedures.
The True Form Reshapable Guide Wire should not be used in the neurovasculature.

CONTRAINDICATIONS
There are no known contraindications with the use of this product.

PRECAUTIONS

- ℞ Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.
- Do not use in case of any surface irregularities, bends, or kinks. Any damage of the guide wire may change its characteristics likely to affect its performance.
- Use the device prior to the "Use Before" date noted on the package.
- For single patient use only. 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. 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.
- This device should be used only by physicians thoroughly trained in percutaneous intravascular techniques and procedures in relevant areas of the anatomy.
- Do not attempt to move the guide wire without observing the guide wire tip. Always maintain visualization of the guide wire under appropriate imaging.
- Do not push, pull, or rotate the wire against resistance. If resistance is met, discontinue movement of the guide wire, determine the reason for resistance and take appropriate action before continuing. Movement of the catheter or guide wire against resistance may result in separation of the catheter or guide wire tip, damage to the catheter, or vessel perforation.
- The hydrophilic coating has a lubricious surface only when properly hydrated.
- Do not wipe the guide wire with dry gauze as it may damage the hydrophilic coating.
- Do not move the torque device on the guide wire when the torque device is tightened as it may damage the guide wire.
- If using a Y-connector on the catheter, do not manipulate the guide wire with the Y-connector in the locked position as the guide wire may be damaged.
- Do not expose guide wires to extreme temperatures.
- Extreme care should be taken when shaping the guide wire distal tip. Over-manipulation of the guide wire distal tip may cause damage. Damaged guide wires should not be used.
- Do not withdraw through a metal entry needle or metal dilator, or use this wire with devices that contain metal parts such as artherectomy catheters or laser catheters.
- Use of alcohol, antiseptic solutions, or other solvents must be avoided.
- Consider the use of systemic anticoagulation to prevent or reduce clotting.

STORAGE
Store the True Form Reshapable Guide wire in a cool, dark, dry area.
Avoid hot or humid temperatures, direct sunlight, UV rays or anywhere where the product could become wet when storing.

ADVERSE REACTIONS
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications listed below. Possible complications may include, but are not limited to the following:

- Hemorrhage
- Systemic or Disseminated Infection
- Ischemia
- Thrombus formation
- Vessel spasm
- Vessel damage
- Inflammatory reaction – Systemic
- Vasoconstriction
- Vascular Perforation
- Myocardial Infarction
- Vascular Dissection
- Death
- Foreign Body Reaction
- Embolism
- Pulmonary Embolism
- Thrombosis
- Cerebral Infarction
- Chemical Toxic Effects

PREPARATION FOR USE

1. Utilizing sterile technique, carefully open the pouch and remove the hoop from the pouch.
2. Flush the hoop with heparinized saline prior to guide wire removal.
3. Gently remove the guide wire from the carrier hoop and inspect the wire prior to use to verify that it is undamaged.
4. If desired, the distal tip of the guide wire can be carefully shaped to the desired tip shape according to standard practices. **Warning**: If the guide wire is to remain unused at any time during the procedure, be sure to rehydrate with heparinized saline prior to reinsertion.

INSTRUCTIONS FOR USE

1. Carefully insert the guide wire, flexible end first, into the prepared catheter lumen using a guide wire insertion tool. Test the guide wire for free movement within the catheter. Exercise caution to make sure the tip of the guide wire is not damaged. **Warning:** If resistance is felt during advancement, stop movement to assess and define cause of resistance. Remove wire and inspect tip for damage prior to proceeding.
2. To aid in steering the guide wire, secure the supplied torque device by slipping the torque device over the proximal end of the guide wire. When the torque device is in the desired location on the guide wire, secure the torque device in place.
3. Use accepted angiographic techniques to steer and position the guide wire in the intended location(s) as needed. **Warning:** Always maintain visualization of the guide wire under fluoroscopy, ensuring that the tip is moving freely when torque is applied.
4. When the desired guide wire position is achieved, secure the guide wire in place while gently advancing the catheter over the wire and into the treatment location.
5. Once the catheter is in position, gently remove the guide wire prior to any intervention.
6. Gently wipe away blood on the surface of the product when removing the guide wire from the patient using gauze wet with heparinized saline

℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	2	Single use
⚠	Caution: Consult accompanying documents. Read instructions prior to use.	2 STERILIZE	Do not resterilize
STERILE EO	Sterilized using ethylene oxide		Do not use if package is damaged
	Non-pyrogenic		

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