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. It is intended to facilitate the placement of catheters under fluoroscopy, ensuring that the tip is moving freely when torque is applied. It may be used in interventional and diagnostic intravascular procedures, including procedures in the coronary arteries. The True Form™ Reshapable Guide wire is intended to provide a smooth, low-friction pathway for catheter insertion. The high flexibility of the guide wire allows for easy manipulation in tortuous anatomy.

PREPARATION FOR USE
1. Open the pouch and remove the hoop from the hoop carrier. Gently wipe the hoop with heparinized saline prior to guide wire removal. If necessary, gently shape the hoop according to standard practices.
2. Flush the hoop with heparinized saline prior to guide wire removal.
3. Utilizing sterile technique, carefully open the pouch and remove the hoop from the hoop carrier hoop. Inspect the wire prior to use to ensure it is unfurled and straight.

INSTRUCTIONS FOR USE
1. For each procedure, use a new, flexible end first, into the prepared catheter lumen using a torque device. If the guide wire is to remain unused at any time during the procedure, be sure to rehydrate with heparinized saline prior to reinsertion.
2. Exercise caution to make sure the tip of the guide wire is not damaged. Extreme care should be taken when shaping the guide wire distal tip. Over-manipulation of this guide wire in the distal tip may cause damage. Graspable guide wires should not be used without a hoop to maintain straightness. Do not withdraw through a metal entry needle, metal sheath, or any catheter with a metal sheath that contains metal parts such as atherectomy catheters or laser catheters. Use of alcohol, antiseptic solutions, or other solvents must be avoided. Contact the closest authorized representative to provide or reduce clotting.
3. Do not attempt to move the guide wire without observing the guide wire tip. Always have a physician trained and/or experienced in the use of this device. If an obstruction is felt during insertion, stop advancement, rehydrate with heparinized saline and reinsertion.
4. If using a Y-connector on the catheter, do not manipulate the guide wire through the Y-connector as the guide wire may be damaged. Exercise caution to make sure the tip of the guide wire is not damaged. If the guide wire is to remain unused at any time during the procedure, be sure to rehydrate with heparinized saline prior to reinsertion.
5. Once the catheter is in position, gently reinsert the guide wire prior to any other procedures.
6. Gently remove the guide wire from the surface of the product when removing the guide wire from the patient using gentile with heparinized saline.

ADVERSE REACTIONS
Possible complications may include, but are not limited to the following:
- Vascular Dissection
- Myocardial Infarction
- Pulmonary Embolism
- Thrombosis
- Tissue Necrosis
- Vascular Perforation

Use of alcohol, antiseptic solutions, or other solvents must be avoided. Consider the use of systemic anticoagulation to prevent or reduce clotting. Extreme care should be taken when shaping the guide wire distal tip. Over-manipulation of this guide wire in the distal tip may cause damage. Graspable guide wires should not be used without a hoop to maintain straightness. Do not withdraw through a metal entry needle, metal sheath, or any catheter with a metal sheath that contains metal parts such as atherectomy catheters or laser catheters.

PRECAUTIONS
- Do not resterilize
- Do not attempt to move the guide wire without observing the guide wire tip. Always have a physician trained and/or experienced in the use of this device. If an obstruction is felt during insertion, stop advancement, rehydrate with heparinized saline and reinsertion.
- This device should be used only by physicians thoroughly trained in percutaneous intravascular techniques and procedures in relevant areas of the anatomy. The use of this device is intended for single use. An attempt to use the device as a resterilizable device may result in separation of the catheter or guide wire tip, damage to the catheter, or vessel perforation.

STORAGE
Store in a dry environment at room temperature. Avoid hot or humid temperatures, direct sunlight, UV rays or anywhere where the product could become wet when storing.

In clinical practice, the equipment may be contaminated and sterilized using ethylene oxide.

Non-pyrogenic
Sterilized using ethylene oxide
Do not use if package is damaged

Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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. 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 Guide wire
   - 1 Insertion tool/guide wire shaper
   - Flex straightener

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

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