English

True Form®
RESHAPABLE GUIDE WIRE™

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION
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 guidewires are manufactured with a stainless-steel core wire, flattened at the distal end, with a 5cm Gold Plated Tungsten coil attached to the distal tip and is fully jacketed with a radiopaque filled polymer jacket. The guidewire is fully coated with a hydrophilic coating. The tip of the wire is shapeable and comes in both Straight and Angled configurations.

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

USER(S)
For use by healthcare professionals who are trained physicians.

PATIENT POPULATION
The True Form Reshapable Guide Wires are designed for use on adult patients during diagnostic and interventional procedures by trained physicians. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire to support the associated devices to be used during the procedure. The guide wire navigates the anatomy and facilitates placement of the associated devices.

How Supplied
Merit Medical guide wires are packaged in a plastic hoop, which is fitted with a flush port. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire be flushed with saline or heparinized saline prior to use (See directions for use - Note). Individually packaged one (1) per Carton, refer to catalog for ordering information.

INDICATIONS FOR USE
The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral vasculature for various diagnostic and interventional procedures. The True Form Reshapable Guide Wire is indicated for use in patients with peripheral vascular disease who require diagnostic or interventional procedures.

CONTRAINDICATIONS
The True Form Reshapable Guide Wire should not be used in the coronary or neurovasculature.

CLINICAL BENEFITS
True Form Reshapable Guide Wires are used to gain vascular access and for the delivery of medical devices. As part of a minimally invasive system, the guide wires help deliver devices that aid in diagnosis and treatment planning.

PERFORMANCE CHARACTERISTICS
True Form Reshapable Guide Wires are designed with performance characteristics for use in a patient's vasculature system. See individual labels for Diameter, Length, and Reshapable tip length.

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.
- 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 damage.
- 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, a metal dilator, or use this wire with devices that contain metal parts such as atherectomy 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
- Vascular Dissection
- Death
- Foreign Body Reaction
- Embolism
- Pulmonary Embolism
- Thrombosis
- Cerebral Infarction
- Chemical Toxic Effects
- Myocardial Infarction

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.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

WARNING: Anticoagulation therapy, per facility protocol, should be considered to reduce potential for thrombus formation on the device

WARNING
In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device.

WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

WARNING: There is insufficient safety and performance data to support use of the device in pediatric populations.

This device includes stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-4) defined as CMR 1B in a concentration above 0.1% weight by weight.

REUSE PRECAUTION STATEMENT: 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.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI- DI. https://ec.europa.eu/tools/ eudamed.

Basic UDI-DI: 088445048821DV

SYMBOL	DESIGNATION
	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service.
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep away from sunlight
	Keep dry
	Non-pyrogenic
	Contains Cobalt

CE 2797

MERIT MEDICAL®

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