MAXXWIRE® GUIDE WIRES

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

- The Merit Medical Endotek® MAXXWIRE® Guide Wire is composed of a stainless-steel core wire with a PTFE coated stainless-steel coil in lengths of 180cm and 260cm. The guide wire is welded at the distal and proximal tips and has a polished weld finish. The stainless steel construction provides increased stiffness for added strength, stability, and radiopacity.

Specifications include:

- Outer diameter range: 0.035"
- Length range: 180cm / 260cm
- Distal markers 1cm long and 1cm apart
- Tip shape: straight
- Wire stiffness profiles: Super Stiff body shaft with a flexible atraumatic tip

HOW SUPPLIED

The Merit Medical Endotek MAXXWIRE 180cm and 260cm guide wires are packaged sterile, non-pyrogenic in a plastic hoop. The wires are intended for single patient use only. Packaged individually 2 units per box. Refer to catalog for ordering information.

SPECIAL STORAGE AND/OR HANDLING

The Merit Medical Endotek MAXXWIRE guide wires should be kept dry.

INTENDED USE

The Merit Medical Endotek MAXXWIRE guide wire is used to facilitate the placement of devices during gastrointestinal and tracheobronchial procedures.

INDICATIONS FOR USE

The Merit Medical Endotek MAXXWIRE guide wire is indicated for use positioning catheters and other interventional devices within the gastrointestinal tract and tracheobronchial tree.

CONTRAINDICATIONS

The Merit Medical Endotek MAXXWIRE guide wires are contraindicated for use in the peripheral vasculature and central circulatory system.

PATIENT POPULATION

The Merit Medical Endotek MAXXWIRE guide wires are designed for use during adult gastrointestinal, and tracheobronchial 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 facilitates placement of associated non-vascular device(s).

INTENDED USER(S)

General Surgeons, Thoracic Surgeons, Otorhinolaryngologists (ENT), Gastroenterologists, Interventional Pulmonologists.

CLINICAL BENEFITS

The Merit Medical Endotek MAXXWIRE guide wires are part of a minimally invasive system used to assist in the delivery of compatible diagnostic or therapeutic medical devices into the gastrointestinal or pulmonary anatomy. Once delivery of the device is achieved, the associated device can be utilized to aid in diagnosis and treatment planning.

PERFORMANCE CHARACTERISTICS

- The Merit Medical Endotek MAXXWIRE guide wires are designed with performance characteristics for use in a patient's gastrointestinal or pulmonary anatomy.
- Atraumatic distal flexible tips to help facilitate introduction of the guide wire.
- Surface coating to assist in the smooth passage of the guide wire.
- Guide wire body stiffness that helps support successful delivery of associated devices.
- These performance characteristics aid in a safe and effective completion of the procedure.

POTENTIAL COMPLICATIONS

Potential complications which may result from the use of the device include but are not limited to: Soft Tissue injury, Infection, Inflammatory Reaction, Guide Wire Entrapment/Entanglement, Hemorrhage, and Foreign Body/Wire Fracture. Stated potential adverse events may require additional surgical intervention.

PRECAUTIONS

- This device is sterile if package is unopened or undamaged.
- Physicians should be trained with the use of diagnostic and interventional products and be familiar with the use of non-vascular devices and the literature concerning the complications of non-vascular procedures.
- Confirm compatibility of guide wire outer diameter with associated device inner diameter by testing the systems together prior to actual use.
- Confirm and maintain ability for free wire movement within the device.
- A guide wire is a delicate instrument. Any time that a guide wire is used it could result in adverse procedural complications and /or adverse patient outcomes.

WARNINGS

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.

WARNING: Do not use if the package is damaged or opened.

WARNING: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING: Avoid manipulating the guide wire through a metal needle or cannula, this could result in shearing of the guide wire leading to tissue damage, as well as potential release of wire fragments into the gastrointestinal or pulmonary anatomy.

WARNING: If resistance is noted either tactilely or visually under fluoroscopy (buckling), determine cause, and take appropriate steps to relieve the resistance. Manipulate the guide wire slowly and carefully to avoid damage to gastrointestinal or pulmonary anatomy.

WARNING: Hold guide wire in position while manipulating the catheter or device over the guide wire to prevent unintended distal wire tip movement.

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

INSTRUCTIONS FOR USE

Prior to use, carefully read all warnings and precautions noted in these instructions. Failure to do so may result in complications. Product is sterile if package is not opened or damaged.

Carefully examine all guide wires to verify that the product has not been damaged in shipment.

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the device. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient.

1. Employ an aseptic technique during removal from the package and use.
2. Inspect and prepare device(s) according to the manufacturer's instructions.
3. Insert the guide wire introducer into the guide wire port of the intended catheter or device.
4. Carefully advance the distal guide wire tip through the introducer and into the device lumen.
5. Remove the introducer by withdrawing it over the guide wire.
6. Under fluoroscopy or direct visualization and while maintaining position of the device, advance the guide wire to the targeted site.
7. Confirm wire position under fluoroscopy or direct visualization.
8. With the wire guide secured in place, advance the associated device to the target site.
9. Hold the guide wire in position while manipulating the catheter over the guide wire to prevent unintended movement of the distal wire tip.
10. Once device is secured in place, remove guide wire, following routine procedure protocols.
11. Inspect guide wire between utilizations to ensure no damage has occurred.
12. After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

WARNING: Extreme care should be taken when manipulating a catheter and wire combination within the non-vascular anatomy to avoid tissue damage. If resistance is felt during advancement, manipulation, or removal from the catheter, stop immediately and confirm the guide wire and catheter tip position under fluoroscopy. The guide wire and catheter should be removed as a unit when possible.

WARNING: When reintroducing a guide wire into a catheter or device, confirm that the catheter tip has free movement within the gastrointestinal or pulmonary anatomy.

WARNING: Always advance or withdraw a wire slowly. Free movement of the guidewire within a catheter provides valuable tactile information. Never push, auger, or withdraw a guidewire which meets resistance as this could potentially affect other indwelling devices. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. Test all systems for resistance prior to use.

SYMBOL	DESIGNATION
	Caution
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
MD	Medical Device
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Use by date: YYYY-MM-DD
REF	Catalog number
LOT	Lot number
	Manufacturer
	Date of Manufacture: YYYY-MM-DD
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Non-pyrogenic
	Single use
	Do not resterilize
	Keep Dry
	Single sterile barrier system
STERILE EO	Sterilized Using Ethylene Oxide
	2D Barcode

www.merit.com

Manufacturer:
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1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

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