GO2WIRE™

Guide Wire Extension

INSTRUCTIONS FOR USE

DESCRIPTION:

The GO2WIRE™ Guide Wire Extension Device is a PTFE* coated stainless steel guide wire attachment that is 0.035" (0.089 cm) in diameter and 155 cm length. The Extension Device has a 152.5 cm long coating of white PTFE* shrink tube. The non- coated stainless-steel attachment section is 2. 5 cm in length. It is compatible with the shorter length (145cm & 175cm) GO2WIRE™ Guide Wires that have been modified for attachment to the Extension Device. The Extension Device is supplied sterile, non-pyrogenic, and is intended for single patient use only

* Polytetrafluoroethylene (PTFE), a synthetic polymer which has lubricious properties.

USER(S)

For use by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

PATIENT POPULATION

The GO2WIRE™ Guide Wire Extension Device is designed for use in conjunction with GO2WIRE™ Guide Wire. The GO2WIRE™ Guide Wire is used during diagnostic and interventional procedures by trained physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire to support the associated device(s) to be used during the procedure. The guide wire navigates the anatomy and facilitates placement of the associated device(s).

HOW SUPPLIED

The GO2WIRE™ Guide Wire Extension Device is packaged in a plastic hoop, fitted with a J Introducer retention which is placed into a pouch. Each carton contains three (3) guide wires extensions, refer to catalog for ordering information.

INTENDED USE

The GO2WIRE™ Guide Wire Extension Device is intended, when attached to the Merit GO2WIRE™ Guide Wire, to facilitate the exchange of devices during diagnostic and interventional procedures.

INDICATIONS

The GO2WIRE™ Guide Wire Extension Device, when attached to the Merit GO2WIRE™ Guide Wire is indicated for use in patients with disease and/or lesions of the peripheral vasculature or central circulatory system, excluding coronary arteries and cerebral vasculature.

CONTRAINDICATIONS

The GO2WIRE™ Guide Wire Extension Device, when attached to the Merit GO2WIRE™ Guide Wire is contraindicated for use in the coronary arteries and cerebral vasculature.

CLINICAL BENEFITS

The GO2WIRE™ Guide Wire Extension Device, when attached to the Merit GO2WIRE™ Guide Wire has indirect clinical benefits for the patient since it assists other medical devices in achieving their intended purpose, without having a direct therapeutic or diagnostic function itself. It is used to facilitate the exchange of devices during diagnostic and interventional procedures that may have a direct therapeutic or diagnostic function.

PERFORMANCE CHARACTERISTICS

The Merit GO2WIRE™ Guide Wire Extension Device is designed with performance characteristics to easily extend the length of the guide wire for the purpose of associated device exchanges when required.

• Atraumatic proximal tip edge to facilitate introduction of an associated device

• Surface coating to allow smooth passage of associated devices over the length of the Extension Device

• Extension Device shaft stiffness that supports successful delivery of associated devices

• Precision threaded connection coupler for secure attachment and easy detachment to the proximal threaded portion of the guide wire

These performance characteristics aid in the safe and effective completion of device exchanges during the procedure.

POTENTIAL COMPLICATIONS:

Potential complications which may result from the use of the device include but are not limited to:

1. Refer to original GO2Wire™ Guide Wire instructions for use for potential complications of guide wire usage.

2. Separation of the Extension Device from the guide wire body

3. Potential loss of wire tip position in the vasculature

4. Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.

INSPECTION PRIOR TO USE:

Product is sterile if package is unopened and undamaged. Prior to use, carefully examine all devices to verify that the sterile package or product has not been damaged in shipment. Prior to and during use, inspect the Extension Device carefully. Do not use a damaged device.

PRECAUTIONS:

PRIOR TO USE:

1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications.

2. Confirm the compatibility of the extension wire with other interventional devices being used by testing the systems for any resistance prior to actual use. Free movement of the extension wire within the interventional device must be confirmed and maintained.

3. The extension wire should be completely hydrated with saline or heparinized saline prior to removal from the flush dispenser hoop

NOTE: Distal tip of extension wire may be positioned inside the dispenser hoop to protect the extension wire sleeve.

WARNING: The safety and effectiveness of the GO2WIRE™ Guide Wires has not been established in the coronary arteries or in the cerebral vasculature.

WARNING: Preclinical testing with this device showed the potential for clot formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be considered to reduce the potential for thrombus formation on the device.

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.

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.

GUIDE WIRE Extension Device PREPRATION:

1. Employ aseptic technique during removal from the package and use.

2. Remove and dispose the extension wire J Introducer retention from the dispenser hoop to expose the extension wire sleeve.

3. Attach flush solution filled syringe to dispenser flush port.

4. Inject saline until dripping out opposite end to completely fill the dispenser hoop.

5. Detach syringe from dispenser flush port.

6. Inspect, prepare, and flush associated device(s) to be used according to the manufacturer's instructions (If applicable).

NOTE: To reduce the potential of clot formation, it is recommended that the guide wire Extension Device be flushed with saline or heparinized saline prior to use.

DIRECTIONS FOR USE:

1. Gently position the proximal end of the guide wire into the threaded extension wire sleeve.

2. Rotate the extension wire sleeve clockwise approximately 3 to 5 rotations until the Extension Device feels secure to the wire.

NOTE: Extension Device is fully threaded when the extension portion contacts the white guide wire jacket.

3. Test connection security by grasping the wire and the Extension Device on each side of the joint and gently pulling to confirm secure connection.

4. Prepare the exchange catheter as directed in the device instructions for use. Withdraw the previously inserted catheter over the extended guide wire.

5. Examine connections to confirm integrity of the joint connection and confirm wire tip position in the vasculature under fluoroscopy before advancing another catheter.

6. Load and advance the catheter onto the proximal end of the guide wire Extension Device maintaining position of the guide wire tip and catheter under fluoroscopy.

7. When exchange is completed, remove the Extension Device. Gently grasp the extension wire sleeve and turn counter- clockwise 3 to 5 rotations.

8. Maintaining position of the guide wire in the vasculature, gently pull the extension portion away from the wire body to separate the Extension Device from the wire.

Caution: Do not torque or manipulate the guide wire Extension Device, the Extension Device does not contain torquing abilities like the guide wires. Attempted torquing only results in limited maneuverability of the attached guide wire. The Extension Device is used for catheter exchanges only. Torquing and other manipulations may be resumed after removal of the Extension Device from the guide wire.

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

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

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: 0884450BUDI318PR

SYMBOL	DESIGNATION
	Single Use
	Do Not Re-sterilize
	Caution
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged or Opened and Consult Instruction for Use
	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
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Non-Pyrogenic
MD	Medical Device
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog Number
	Date of Manufacture
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date
UDI	Unique Device Identifier
	Keep Dry
	Keep away from Sunlight
	Contains Cobalt

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CE 2797

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