

Hi-Torque Steerable Guide Wire

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

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This device should only be used by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

STERILE. Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if package is open or damaged.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the Hi-Torque Steerable Guide Wire for their intended uses, contraindications, and potential complications.

1.0 DESCRIPTION

The Hi-Torque Steerable Guide Wire has been designed to provide torsional control. The distal tip is shapeable and radiopaque. The Hi-Torque Steerable Guide Wire is available in several lengths and diameters. Refer to the product label for product specifications.

2.0 CONTENTS. One (1) Hi-Torque Steerable Guide Wire, one (1) Torque Device

3.0 STORAGE. Store in a dry, dark, cool place.

4.0 WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND / OR REUSE.

Observe all guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur.

Torquing a guide wire against resistance may cause guide wire damage and / or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw, or torque a guide wire which meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform all exchanges slowly to prevent air entry and / or trauma. Wipe the wire before all exchanges.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit from the device. Use the radiopaque marker of the interventional device to confirm position.

5.0 PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged wires. Using a damaged wire may result in vessel damage and / or inaccurate torque response.

Confirm the compatibility of the guide wire diameter with the interventional device before actual use.

Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

6.0 INDICATIONS

The Hi-Torque Steerable Guide Wire is intended for use in angiographic procedures to introduce and position diagnostic and interventional devices within the peripheral vasculature during percutaneous procedures. The wire can be torqued to facilitate navigation through tortuous vessels.

The Hi-Torque Steerable Guide Wire is not intended for use in the coronary or neurovasculature.

7.0 CONTRAINDICATIONS

The Hi-Torque Steerable Guide Wire is not intended for use in the coronary or neurovasculature.

8.0 PREPARATION FOR USE

Prior to the interventional procedure, all equipment to be used, including the interventional device, should be examined carefully for defects. Do not use any defective equipment.

1. Prepare the interventional device according to the manufacturer's instructions. Be sure to flush the guide wire lumen before introducing the guide wire.

2. To remove the guide wire from the dispenser, push the movable segment of the dispenser to expose the distal section of the wire. Then grasp the core of the wire to remove it totally from the dispenser. To avoid damaging the fragile guide wire tip, **do not grasp the tip** of the wire to remove it from the dispenser.
3. The guide wire tip may be carefully shaped using standard tip shaping practices. Do not use a shaping instrument with a sharp edge.

9.0 DIRECTIONS FOR USE

1. Insert a guide wire introducer into the hemostatic valve. Carefully advance the distal tip of the guide wire through the introducer into the sheath or device lumen. Remove the introducer by withdrawing it over the wire.
2. Attach a compatible torque device to the guide wire, if desired.
3. To facilitate vascular selection, the tip of the guide wire should be steered carefully.
4. Confirm guide wire placement in two projections to assure that the distal tip is intraluminal in the correct vessel and not within a side branch.
5. Hold the wire in place while tracking a catheter over it.

If a different tip configuration is desired, the distal tip of the guide wire can be reshaped according to standard practices.

Hi-Torque Steerable Guide Wire is threaded at the proximal end to allow use of the LOC® Guide Wire Extension. Attaching the LOC Guide Wire Extension to the Hi-Torque Steerable Guide Wire allows catheter exchange using the original wire, obviating the need to use an exchange length wire.

Details regarding the LOC Guide Wire Extension are described in the instructions for use supplied with the device.

10.0 PATENTS AND TRADEMARKS

This product and / or its use are covered by one or more of the following United States Patents: 5,007,434; 5,135,503; 5,341,818; 5,411,476; 5,637,089; 6,165,292; 6,379,369; 6,419,745; 6,461,453; 6,491,648; 6,592,570; 6,599,557; 6,602,228; 6,666,829; 6,673,025; 6,695,915; 6,733,819; RE 34,466. Other U.S. patents pending. Foreign patents issued and pending.

LOC is a registered trademark of the Abbott Group of Companies.

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Graphic Symbols for Medical Device Labeling

REF Catalogue number	 Sterilized using ethylene oxide
F French size	 Manufacturer
 Consult instructions for use	 Batch code
 Contents (Numeral represents quantity of units inside)	 Date of manufacture
 Do not reuse	 Use by

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