TOTAL LENGTH of piece is 37 15/16

5 1/2 | 5 7/16 | 5 3/8 | 5 7/16 | 5 7/16 | 5 3/8 | 5 3/8

English

HI-TORQUE Guide Wires for PTCA, PTA, and Stents

CAUTION

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

This device should be used only by physicians trained in angiography and Percutaneous Transluminal Coronary Angioplasty (PTCA), and / or Percutaneous Transluminal Angioplasty (PTA).

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 Guide Wire for their intended uses, contraindications, and potential complications.

DESCRIPTION

The HI-TORQUE Guide Wire is a steerable guide wire available in several lengths and diameters. The distal tip is shapeable or, as an option, a preshaped "J" tip is available. Refer to the product label for product specifications (e g, wire length, diameter, and length of tip radiopacity).

HI-TORQUE Extendable Guide Wires: Some HI-TORQUE Guide Wires have a modified proximal end that permits the attachment of the DOC® Guide Wire Extension. Refer to the product label for Guide Wire Extension system compatibility. Joining the Guide Wire Extension to the guide wire facilitates the exchange of one interventional device for another, while maintaining guide wire position in the anatomy. After the interventional device exchange has been completed, the extension can be detached and the guide wire can be used in its original capacity.

.014 HI-TORQUE Guide Wires with Proximal Markers: Brachial and femoral markers located on the proximal segment of the 0.014" (0.36 mm) guide wire aid in gauging guide wire position relative to the guiding catheter tip when using bare wire technique. They are compatible with guiding catheters that are at least 90 cm (brachial) or 100 cm (femoral) long.

HI-TORQUE Guide Wires with Distal Radiopaque Markers: Some HI-TORQUE Guide Wires have distal radiopaque markers. Refer to the product drawing on the label to determine the presence and location of the markers. Markers are represented by the following designation: ■. A series of spaced markers are provided proximal to the coil as references in determining lesion length.

HI-TORQUE Guide Wires with Hydrophilic Coating: Refer to the product label for presence of a hydrophilic coating. When wet, a hydrophilic coating increases the lubricity of the guide wire surface.

HOW SUPPLIED

Sterile. Sterilized with ethylene oxide gas or electron-beam radiation. Refer to the product label for the sterile method. Non-pyrogenic. Do not use if the package is open or damaged.

Contents. One (1) guide wire.

Storage. Store in a dry, dark, cool place.

INDICATIONS FOR USE

This HI-TORQUE Guide Wire is intended to facilitate the placement of balloon dilatation catheters during Percutaneous Transluminal Coronary Angioplasty (PTCA) and Percutaneous Transluminal Angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

CONTRAINDICATIONS

Not intended for use in the cerebral vasculature or with atherectomy devices.

WARNINGS

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

Carefully observe the instructions under "Do Not" and "Do" below. Failure to do so may result in vessel trauma, guide wire damage, guide wire tip separation, or stent damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed.

Do Not:

- Push, auger, withdraw, or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.

Do:

- Advance or withdraw the guide wire slowly.
- Use the radiopaque marker of the interventional device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire.
- Observe the guide wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform exchanges slowly to prevent air entry and / or trauma.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel with the vessel wall.
- Use extreme caution when moving a guide wire through a non-endothelialized stent, or through stent struts into a bifurcated vessel. Use of this technique carries additional patient risks, including the risk that the wire may become caught on the stent strut.
- Consider that if a secondary wire is placed in a bifurcation branch, this wire may need to be retracted prior to stent deployment because there is additional risk that the secondary wire may become entrapped between the vessel wall and the stent.

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 guide wires. Using a damaged guide 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.

Never attach the torque device to the modified portion of the proximal end of the extendable guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC Guide Wire Extension.

HI-TORQUE Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire in a metal cannula or sharp-edged object.

PREPARATION FOR USE

Contraindications, warnings, and intended uses of interventional devices compatible with HI-TORQUE Guide Wires are described in the instructions supplied with the respective devices.

Prior to the interventional procedure, examine carefully all equipment to be used, including the interventional device, 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. Remove the guide wire from the dispenser by pushing the exposed section of the guide wire into the dispenser until the guide wire tip and a portion of the core exit the end of the hoop. Then grasp the core of the wire to remove it totally from the dispenser. Avoid damaging the fragile guide wire tip. Do not grasp the tip of the wire while removing it from the dispenser.
3. If indicated, the guide wire tip may be carefully shaped using standard tip-shaping practices. Do not use a shaping instrument with a sharp edge.

HI-TORQUE Guide Wires with Hydrophilic Coating

1. Before removing the guide wire from the wire dispenser, inject normal saline into the hub end of the dispenser to thoroughly wet the complete surface of the guide wire.
2. Carefully remove the guide wire from the dispenser, as suggested above in Preparation For Use, Step 2. If the guide wire cannot be removed easily from the dispenser, inject more normal saline and attempt to remove the guide wire again.
3. Do not reinsert the guide wire into the dispenser once it has been removed.
4. If the surface of the hydrophilic-coated wire becomes dry, wetting the surface with normal saline will renew the hydrophilic effect. Be sure to thoroughly rewet the guide wire before reintroduction into an interventional device.
5. After the guide wire is withdrawn from the body, it should be wiped clean with saline-soaked gauze and kept wet.

DIRECTIONS FOR USE

Over-The-Wire Type Systems (Preload Technique)

1. Carefully insert the guide wire through the guide wire lumen hub of the interventional device.
2. Advance the guide wire until its tip is just proximal to the interventional device tip.
3. If using a guiding catheter, engage the guiding catheter and insert the interventional device / guide wire assembly through the hemostatic valve. Advance the system through the guiding catheter until it is just proximal to the tip of the guiding catheter.
4. Tighten the hemostatic valve to create a seal around the interventional device. Ensure intentional guide wire movement is still permitted.
5. Attach the torque device to the guide wire, if desired.
6. Under fluoroscopy, advance the guide wire out of the interventional device while securing the interventional device in place. Use the torque device to steer the guide wire across the lesion.
7. Secure the guide wire in place while tracking the interventional device over it and into the lesion.
8. If a different tip configuration or guide wire is indicated, carefully remove the guide wire while observing guide wire movement under fluoroscopy.
9. Reshape the guide wire tip according to standard practice or prepare the next guide wire to be used.
10. Reinsert the guide wire following steps 1 through 7 of this section.

Rail Type Systems (Bare Wire Technique)

1. Engage the guiding catheter and then insert a guide wire introducer through the hemostatic valve attached to the guiding catheter.
2. Carefully insert the distal tip of the guide wire through the introducer and into the guiding catheter.
3. HI-TORQUE Guide Wires with Hydrophilic Coating: If a metal guide wire introducer was used, be sure to remove it before withdrawing or further manipulating the wire.
4. .014 HI-TORQUE Guide Wires with Proximal Markers: Advance the guide wire to the appropriate proximal marker. When the proximal marker is aligned with the knurled knob of the hemostatic valve, the guide wire tip is just proximal to the guiding catheter tip.
   Note: Use the most distal marker as a distance gauge when using a 90 cm brachial guiding catheter, and the most proximal marker as the distance gauge when using a 100 cm femoral guiding catheter.
5. Attach the torque device.
6. Under fluoroscopy, advance the guide wire out of the guiding catheter and into the selected vessel. Use the torque device to steer the guide wire across the lesion.
7. If a different tip configuration or guide wire is indicated, the guide wire may be removed as follows:
   a. Open the hemostatic valve and the flush line on the coronary manifold. Slowly withdraw the guide wire while observing guide wire movement under fluoroscopy.
   b. Close the hemostatic valve and coronary manifold flush line.
8. Reshape the guide wire tip according to standard practice or prepare the next guide wire.
9. Reinsert the guide wire following steps 2 through 6 of this section.
10. Remove the torque device and the guide wire introducer from the guide wire.
11. Secure the guide wire while tracking the interventional device over it and into the lesion.

INSTRUCTIONS FOR INTERVENTIONAL DEVICE EXCHANGE PROCEDURE

Over-The-Wire Type Systems (Preload Technique)

1. If using a HI-TORQUE Exchange Guide Wire, proceed to step 3.
2. If using a HI-TORQUE Extendable Guide Wire, extend the guide wire using the DOC Guide Wire Extension. Refer to the instructions included with the extension for specific information on the use of the HI-TORQUE Guide Wire as an exchange-length guide wire.
3. Maintain guide wire position while withdrawing the interventional device over the exchange-length guide wire.
4. Prepare the other interventional device per manufacturer's instructions.
5. Load the device onto the guide wire and advance it over the HI-TORQUE Exchange Guide Wire and across the lesion.
6. Proceed according to standard medical practices.

Rail Type Systems (Bare Wire Technique)

1. Maintain guide wire position while withdrawing the device over the guide wire.
2. Prepare the next interventional device per manufacturer's instructions.
3. Load the device onto the guide wire and advance it over the HI-TORQUE Guide Wire and across the lesion.
4. Proceed according to standard medical practices.

PATENTS

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

HI-TORQUE is a trademark of the Abbott Group of Companies registered in the United States.

Deutsch / German

HI-TORQUE-Führungsdraht für PTCA, PTA und Stents

Français / French

Guides HI-TORQUE pour ACTP, ATP et endoprothèses

FRONT SIDE OF PIECE

PPL2062278 (1/23/08)

CE 0086

HI-TORQUE Guide Wires for PTCA, PTA, and Stents

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Español / Spanish

Guías HI-TORQUE para ACTP, ATP y stents

Italiano / Italian

Fili guida HI-TORQUE per PTCA, PTA e stent

Português / Portuguese

Fios-Guia HI-TORQUE para ACTP, ATP e Stents

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Fold template along this center line to view the piece backed-up.

Svenska / Swedish

HI-TORQUE-ledare för PTCA, PTA och stentar

Nederlands / Dutch

HI-TORQUE voerdraden voor PTCA, PTA en stents

Dansk / Danish

HI-TORQUE guidewirer til PTCA, PTA og stents

Ελληνικά / Greek

Συρμάτινοι οδηγοί HI-TORQUE για PTCA, PTA, και Στεντ

Polski / Polish

Prowadniki HI-TORQUE do zabiegów PTCA, PTA i stentów

INSIDE OF PIECE

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6 5/8 | 6 13/16 | 6 13/16 | 6 5/8

TOTAL HEIGHT of piece is 13 7/16