HI-TORQUE Guide Wires (CRM)

CAUTION: Federal (USA) law restricts this device to sale distribution, and use by or on the order of a physician.

Only physicians trained in the placement of Guidant implantable coronary venous leads should use this device.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with 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. 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 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. This device is sterilized with ethylene oxide gas or electron beam radiation. Refer to the product label for the specific method of sterilization. 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.

INTENDED USE

The HI-TORQUE Guide Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

INDICATIONS

Refer to the Guide Wire label for any additional product specific indications that may apply.

CONTRAINDICATIONS

HI-TORQUE Guide Wires are not intended for use in the cerebral vasculature.

Refer to the Guide Wire label for any additional product specific contraindications that may apply.

WARNINGS

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

Monitor all guide wire movement in the vessels under fluoroscopy. 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 that meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed or used for positioning, do not allow the tip to remain in a prolapsed condition; otherwise, damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

Movement of the guide wire within the lead may be restricted when the lead is positioned in tortuous vein sections. Slightly reposition the lead to regain free movement of the guide wire.

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

Perform all guide wire exchanges slowly to prevent air entry and / or trauma.

When introducing the guide wire, confirm that the lead tip is free within the vessel lumen and not pointed against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the lead.

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 guide wire may result in vessel damage and / or inaccurate torque response.

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

Free movement of the guide wire within the lead 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.

HI-TORQUE Guide Wire 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 use of devices compatible with HI-TORQUE Guide Wires are described in the instructions supplied with the respective device.

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

1. Prepare the lead according to the manufacturer's instructions. Be sure to flush the guide wire dispenser before removing the guide wire from the dispenser.
2. To remove the guide wire from the dispenser, push the exposed section of the 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. To avoid damaging the fragile guide wire tip, **do not grasp the tip of the guide wire** when 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 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.

Note: Do not reinsert the guide wire into the dispenser once it has been removed.

3. 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 a lead.
4. After the guide wire is withdrawn from the body, it should be gently wiped clean with saline-soaked gauze and kept wet.

DIRECTIONS FOR USE

A. Preload Technique

1. Carefully insert the distal end of the guide wire (floppy tip) through the terminal pin of the lead.
2. Advance the guide wire until its tip is just proximal to the lead tip.
3. After placing the guiding catheter, insert the lead-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 lead. Ensure intentional guide wire movement is still permitted.
5. If desired, attach the torque device by inserting the proximal end of the guide wire into the funnel shaped hole of the torque device cap; slide to desired location and tighten to secure.
6. Under fluoroscopy, advance the tip of the guide wire out of the guiding catheter and use the torque device (if applicable) to steer the guide wire into the selected vessel.
7. Maintain guide wire tip position while advancing the lead over the guide wire to the desired position.

8. If a different tip configuration or guide wire is indicated, carefully remove the guide wire while observing guide wire movement under fluoroscopy. If desired, the lead may be left in position to facilitate the advancement of the subsequent guide wire(s) distally.
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.

B. Bare Wire Technique

1. After placing the guiding catheter, insert a guide wire introducer through the hemostatic valve that is 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. If desired, attach the torque device by inserting the proximal end of the guide wire into the funnel shaped hole of the torque device cap; slide to desired location and tighten to secure.
5. Under fluoroscopy, advance the tip of the guide wire out of the guiding catheter and use the torque device (if applicable) to steer the guide wire into the selected vessel.
6. Remove the torque device (if applicable) and insert the proximal end of the guide wire through the distal tip of the lead.
7. Maintain guide wire tip position while advancing the lead over the guide wire to the desired position.
8. If a different tip configuration or guide wire is indicated, carefully remove the guide wire while observing guide wire movement under fluoroscopy. If desired, the lead may be left in position to facilitate the advancement of the subsequent guide wire(s) distally.
9. Reshape the guide wire tip according to standard practice or prepare the next guide wire.
10. Reinsert the guide wire following steps 1 through 7 of this section.

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Graphical Symbols For Medical Device Labeling