Boston Scientific

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ChoICE™
ChoICE™ PT
Luge™
Mailman™
PT Graphix™

Guidewires with ICE™ Hydrophilic Coating

℞ ONLY

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

REUSE WARNING

For single 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.

DEVICE DESCRIPTION

Boston Scientific ChoICE PT, PT Graphix, ChoICE, Luge, and Mailman Guidewires with ICE Hydrophilic Coating are steerable guidewires available with a nominal diameter of 0.014 in (0.37 mm) and in nominal lengths of 182 cm or 300 cm. All models are available with a shapeable Straight Tip or a preformed "J" Tip.

- **ChoICE PT** Guidewires with ICE Hydrophilic Coating feature a 35 cm radiopaque polymer sleeve, coated with ICE Hydrophilic Coating to provide lubricity, jacketing the distal core wire. The distal 2 cm is shapeable. The proximal section of the ChoICE PT Guidewire with ICE Hydrophilic Coating is coated with a fluorinated polymer (PTFE). Available tip flexibility/rail support profiles:

  Floppy - intermediate tip with floppy support;

  Extra Support - intermediate tip with extra support.
- **PT Graphix** Guidewires with ICE Hydrophilic Coating feature a 10 cm or 38 cm polymer sleeve, coated with ICE Hydrophilic Coating to provide lubricity, jacketing the distal tapered core wire. The distal most 2 cm is radiopaque and shapeable. The proximal section of the PT Graphix Guidewire with ICE Hydrophilic Coating is coated with a fluorinated polymer. Available tip flexibility/rail support profiles:

  Intermediate - intermediate tip with moderate support;

  Standard - standard tip with moderate support;

  Super Support - intermediate tip with super support.
- **ChoICE** Guidewires with ICE Hydrophilic Coating feature a 3 cm radiopaque spring coil at the distal end of the core wire that is shapeable. A polymer sleeve, coated with ICE Hydrophilic Coating to provide lubricity, jackets the tapered core wire between the spring coil and the proximal fluorinated polymer coating. Available tip flexibility/rail support profiles:

  Floppy - floppy tip with light support;

  Extra Support - floppy tip with extra support;

  Intermediate - intermediate tip with light support;

  Standard - standard tip with light support.
- **Luge and Mailman** Guidewires with ICE Hydrophilic Coating feature the same construction as the ChoICE Guidewires with ICE Hydrophilic Coating. Available tip flexibility/rail support profiles:

  Luge Moderate Support - floppy tip with moderate support;

  Mailman Super Support - floppy tip with super support.

Please see the product label for the specific overall length, tip configuration, and radiopaque tip length of the guidewire you are using.

Figure 1.

The 182 cm guidewires have a modified proximal end that permits the attachment of the AddWire Extension Wire. Joining the Extension Wire to the guidewire facilitates the exchange of interventional therapeutic devices while maintaining the guidewire position in the intravascular anatomy. After the device exchange has been completed, the extension can be detached, and the guidewire can be used in its original capacity. **CAREFULLY READ INSTRUCTIONS PACKAGED WITH THE EXTENSION WIRE PRIOR TO USE.**

Contents

ChoICE, ChoICE PT, Luge, Mailman, and PT Graphix Guidewires with ICE Hydrophilic Coating (check the label for product's characteristics prior to use).

Operating Principle

The guidewires are placed through a guide catheter that is inserted through an insertion sheath that is placed through a puncture site, typically at the groin or wrist, and guided through the patient's artery to the site of intervention. The guidewires are used to facilitate the positioning of catheters or other devices during diagnostic or interventional procedures. The guidewires establish a supportive pathway through the vascular system from the puncture site to and across the target vascular segment by guiding the catheters to follow for easier delivery to the treatment site. The distal radiopaque at the tip of the guidewires allow the radiographic visualization of the guidewire during interventional procedures.

Materials

- **ChoICE PT and PT Graphix** Guidewires with ICE Hydrophilic Coating are made of a stainless-steel core wire with a distal radiopaque polymer sleeve, coated with ICE Hydrophilic Coating. The proximal section of the guidewires is coated with a PTFE coating.
- **ChoICE, Luge, and Mailman** Guidewires with ICE Hydrophilic Coating are made of a stainless-steel core wire with a platinum spring coil at the distal end. The proximal end is coated with a PTFE coating. The tapered core wire is covered with a polymer sleeve and ICE Hydrophilic Coating.

For guidewires with the AddWire exchange system, the proximal section presents a stainless-steel thread coil.

Contains cobalt: CAS No. 7440-48-4; EC No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight.

Note: Core wire and thread coil in these devices are made with stainless steel which contains cobalt. Current scientific evidence supports that stainless steel containing cobalt used in these medical devices do not cause an increased risk of cancer or adverse reproductive effects.

Non-Pyrogenic

These devices meet pyrogen limit specification.

User Information

These devices should be used only by physicians and other health care professionals experienced in intravascular interventional techniques and procedures.

Patient Population

Patients undergoing interventional intravascular procedures.

INTENDED USE/INDICATIONS FOR USE

Boston Scientific ChoICE PT, PT Graphix, ChoICE, Luge, and Mailman Guidewires with ICE Hydrophilic Coating are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices.

These devices are indicated for use in conditions requiring the placement of device(s) during PTCA or other intravascular interventional procedures. They are not indicated for use in the cerebral vasculature.

Clinical Benefit Statement

The clinical benefit of the ChoICE PT, PT Graphix, ChoICE, Luge, and Mailman Guidewires with ICE Hydrophilic Coating is to facilitate percutaneous interventions, thereby improving blood flow to the treated anatomy.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (Eudamed) website: (https://ec.europa.eu/tools/eudamed).

CONTRAINDICATIONS

None known.

WARNINGS

- Carefully read all instructions prior to use of these products. Observe all warnings and precautions, failure to do so may result in complications.
- Guidewires should be used only by physicians and other health care professionals thoroughly experienced in their intended use.
- Prior to the procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity. Surface irregularities, bends or kinks may decrease performance characteristics.
- Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.
- Use extreme caution in patients who have had an allergic reaction to contrast agents and who cannot be adequately premedicated.
- The hydrophilic coating of these guidewires increases the possibility of vessel trauma compared to non-hydrophilic coatings. Maintain diligent control of the distal tip at all times during an intervention to avoid vessel trauma.
- Exercise care in handling the guidewire during a procedure to reduce the possibility of accidental breakage, bending, kinking, or separation. Resulting guidewire fractures might require additional percutaneous intervention or surgery.
- When advancing or removing the guidewire, always use fluoroscopic guidance with radiographic equipment that provides high-resolution images.
- Inspect the device prior to use for any surface irregularities and bends or kinks. Do not use if the device is damaged, irregular or any component detachment is detected before or during the procedure; breaks or deformations may result in vessel trauma, embolism or need for additional intervention or surgery.
- Never position or move the guidewire without observing the resultant tip response, as this may result in misplacement, vessel trauma, or other patient injuries.
- Never advance, withdraw and/or rotate the guidewire against resistance without first determining the reason for resistance under fluoroscopy. Do not rotate the guidewire if significant resistance is felt. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter, vessel trauma, or other patient injuries.
- Care should be taken when advancing a guidewire after stent deployment. A guidewire may exit between stent struts when recrossing a stent that is not fully apposed to the vessel wall. Subsequent advancement of any device over the guidewire could cause entanglement between the guidewire and the stent.

PRECAUTIONS

- Use the device prior to the "Use By" date noted on the package.
- Carefully remove the guidewire from the carrier tube to reduce the possibility of damage to the distal tip. Refer to PREPARATION section.
- Carefully check and match therapeutic device compatibility to the guidewire prior to use. Refer to Additional Items For Safe Use section.
- Boston Scientific guidewires are designed to be compatible exclusively with the AddWire Extension Wire for interventional device exchange. Do not use another extension or exchange system. Carefully check and match the compatibility of the guidewire diameter with the interventional device prior to use.
- These guidewires should only be used in devices having an inner lumen diameter greater than 0.015 in (0.39 mm).
- Sharp insertion tools may compromise the integrity of the polymer sleeve and/or coating. To avoid guidewire damage and possible shearing of polymer sleeve and/or coating, do not advance, withdraw, or manipulate the guidewire through a metal needle cannula.
- Excessive tightening of a torque device onto the guidewire may result in abrasion of the coating on the guidewire.
- Do not use a guidewire that has been damaged.
- Do not attempt to straighten a guidewire that has been kinked or bent. Do not advance a kinked guidewire into a balloon catheter or guide catheter as this may increase the potential of guidewire breakage or entrapment.
- Abrasion of the hydrophilic coating may be caused if increased frictional forces are encountered during the introduction of the guidewire into the catheter. The use of incompatible devices may result in damage to the guidewire or hydrophilic coating. If the coating is damaged or any resistance is felt during the introduction of the catheter, exchange the guidewire and the catheter.
- Do not wipe guidewire with dry gauze.

ADVERSE EVENTS

- Arrhythmia, including ventricular fibrillation or heart block
- Bleeding, hemorrhage or hematoma
- Cardiac arrest/cardiogenic shock
- Cardiac tamponade/Pericardial effusion
- Cerebrovascular accident (stroke or transient ischemic attack)
- Death
- Drug reactions including allergy
- Embolism (air, tissue, device fragments, plaque)
- Hemodynamic compromise including vasovagal reaction
- Infection
- Myocardial ischemia or infarction
- Organ insufficiency/failure (heart, lung, kidney)
- Pain (angina)
- Prolonged procedure time including additional intervention or surgery
- Radiation injury
- Thrombosis
- Vessel injury (spasm, dissection, perforation, rupture, arteriovenous fistula, pseudoaneurysm)

HOW SUPPLIED

Device Details

- These devices are available as single-packs or multi-packs. One guidewire is loaded into a carrier tube that consists of a distal straw and a hoop. This is loaded into a pouch and then packed into a carton. For multi-pack configurations, multiple pouches are included in one carton.
- These devices are sterilized using Ethylene Oxide (EO).
- Do not use if package is damaged or unintentionally opened before use. If damage is found, call your Boston Scientific representative.
- Do not use if labeling is incomplete or illegible.

Handling and Storage

These products have no special handling or storage requirements.

INSTRUCTIONS FOR USE

Additional Items for Safe Use

The following supplies are not provided and should be available prior to using the ChoICE, ChoICE PT, Luge, Mailman, or PT Graphix Guidewires with ICE Hydrophilic Coating:

- Appropriate introducer/guide sheath or guide catheter
- Contrast medium
- Hemostatic valve
- Heparinized saline or other appropriate flush solution
- Appropriate interventional/therapeutic devices compatible with the guidewire
- Torquing device
- Guidewire introducer
- Guidewire extension/exchange devices

Preparation

1. Prepare the interventional device according to the manufacturer's instructions. Be sure to flush the interventional device lumen with heparinized saline before introducing the guidewire.

   Note: Distal hydrophilic segment of the guidewire is located within the yellow portion of the dispenser tube with a distal tip nearest to the hub end [**A**].

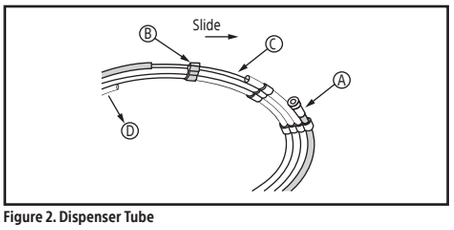

Figure 2. Dispenser Tube

2. Flush the dispenser tube with saline by injecting it into the hub end [**A**] of the dispenser. This hydrates the hydrophilic segment of the guidewire before removing the guidewire from the dispenser tube.
3. Remove wire retention clip [**B**].

   Note: Retention clip may be in a different location on dispenser tube than depicted.

4. Gently grasp guidewire [**C**] and slide into dispenser tube in the direction indicated in Figure 2. Repeat injection of saline into the dispenser tube if the guidewire cannot be easily moved.
5. Carefully remove the proximal end of the guidewire from the dispenser [**D**]. Repeat the injection of saline into the dispenser if the guidewire cannot be removed easily and attempt to remove the guidewire again. Do not reinsert the guidewire into the dispenser tube once it has been removed.

   Note: Do not pull the distal tip to remove the guidewire from the dispenser tube, as removal in such a manner may damage the guidewire tip.

6. Inspect the guidewire prior to use to verify that it is undamaged.
7. If desired, the guidewire tip may be carefully shaped according to standard tip shaping practices. Do not use a shaping instrument with a sharp edge.

   Note: If the surface of the hydrophilic-coated wire becomes dry, wetting the surface with saline will restore the lubricity. Be sure to thoroughly hydrate the guidewire before introduction into an interventional device.

Procedure

Over-the-Wire-Systems

1. Prior to inserting the guidewire into an interventional device, flush the device with heparinized saline. This will activate the lubricious coating of the device and also provide smooth movement of the guidewire within the device.

BSC (MB IFU Template 8.2677 x 11.6929 A4, 923100600), IFU, MB, CV Guidewires, en, 51473288-01A

2. Insert a guidewire insertion tool through the lumen hub of the interventional device.
3. Carefully insert the distal tip of the guidewire through the insertion tool into the interventional device and advance the guidewire until the wire tip is just proximal to the device tip.
4. Remove the insertion tool by withdrawing it over the proximal end of the guidewire.
5. The interventional device/guidewire system may now be inserted through the hemostatic valve and into the guide catheter.
6. Advance the system through the guide catheter until it is just proximal to the distal tip of the guide catheter.
7. Create a seal around the interventional device by tightening the hemostatic valve. Ensure that intentional guidewire movement is still possible.
8. If desired, attach a torque device to the guidewire.
9. Advance the guidewire out of the interventional device and into the vasculature beyond the lesion to be treated using accepted techniques while securing the interventional device in place. Do not move the guidewire without observing the response under fluoroscopy.
10. Secure the guidewire in place while tracking the interventional device over the guidewire and across the lesion.
11. If a different guidewire is required, carefully withdraw and remove the guidewire while observing guidewire movement under fluoroscopy.
12. Reshape the guidewire tip according to accepted techniques or prepare the next guidewire to be used and insert the guidewire according to Over-the-Wire Systems, Steps 1 through 10, above.

Single Operator Exchange System or "Bare Wire" Technique

1. Open the hemostatic valve and the flush line of the coronary manifold. Insert a guidewire insertion tool through the valve and into the guide catheter.
2. Carefully insert the distal tip of the guidewire through the insertion tool and into the guide catheter.
3. Remove the insertion tool and continue to advance the guidewire.
4. Tighten the hemostatic valve knurled knob so that the valve seals around the guidewire, but does not inhibit intentional guidewire movement.
5. Create a seal around the guidewire by tightening the hemostatic valve. Ensure that intentional guidewire movement is still possible.
6. Close the flush line on the manifold.

Note: If using a Boston Scientific guidewire with proximal markers, advance the guidewire to the appropriate proximal marker. Use the most distal marker as a distance approximation when using a 90 cm radial guide catheter and the most proximal marker as the distance approximation when using a 100 cm femoral guide catheter. When the appropriate proximal marker is aligned with the knob of the hemostatic valve, the guidewire tip is just proximal to the guide catheter distal tip.

7. If desired, attach a torque device to the guidewire.
8. Advance the guidewire out of the guide catheter and into the vasculature beyond the lesion to be treated using accepted techniques. Do not move the guidewire without observing the response under fluoroscopy.
9. If a different guidewire is required, carefully withdraw, and remove the guidewire according to accepted techniques while observing guidewire movement under fluoroscopy.
10. Reshape the guidewire tip according to accepted techniques or prepare the next guidewire to be used and insert the guidewire according to Single Operator Exchange System or "Bare Wire Technique," Steps 2 through 9, above.
11. Remove the torque device and secure the guidewire while loading and tracking the interventional devices over the guidewire and into the lesion.

Interventional Device Exchange Over-the-Wire Systems

1. Follow the instructions regarding the preparation and use provided above.

Note: If using a Boston Scientific extendable guidewire, extend the guidewire using the AddWire Extension Wire according to the instructions packaged with the Extension Wire.

2. To perform an exchange, maintain the position of the guidewire and carefully withdraw the interventional device over the guidewire.
3. Prepare the second interventional device as described by the manufacturer's instructions and load it onto the guidewire.
4. Advance the interventional device over the guidewire and across the lesion.

Interventional Device Exchange Single Operator Exchange System or "Bare Wire Technique"

1. To perform an exchange, maintain the position of the guidewire and carefully withdraw the interventional device over the guidewire.
2. Prepare the second interventional device as described by the manufacturer's instructions and load it onto the guidewire.
3. Advance the interventional device over the guidewire and across the lesion.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, the device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of following any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with a biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Assess the patient for hematoma and/or other signs of bleeding at the puncture site.

Any serious incident that occurs concerning this device should be reported to the manufacturer and relevant local regulatory authorities.

INFORMATION TO BRIEF THE PATIENT

The physician should consider discussing with the patient the intended use of the guidewires associated with the interventional procedure. In addition, the following points should also be discussed:

- The risks and benefits, including the review of potential adverse events listed in this document, both for the guidewire and for other interventional treatments likely to be employed.
- Patient allergies in particular the risk of allergies to contrast media.
- Post procedure instructions, including any follow up requirements, lifestyle changes, medications, and home care or rehabilitation guidelines.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

EU Importer: Boston Scientific International B.V., Vestastraat 6, 6468 EX Kerkrade, The Netherlands

The following are trademarks of Boston Scientific Corporation or its affiliates: ChoICE, Luge, Mailman, PT Graphix, ICE, and AddWire.

All other trademarks are the property of their respective owners.

SYMBOLS DEFINITION

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.
Additional symbols are defined at the end of this document.

Table 1. Symbol Definitions

	Contents		Open Here

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

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CE 2797

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