ZIPwire™ Hydrophilic Guidewire
Prescriptive Information

Indications for Use
The ZIPwire Hydrophilic Guidewire is intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures. The ZIPwire Hydrophilic Guidewire is not intended for coronary artery, vascular or neurological use.

Warning
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- A thorough understanding of the technical principles, clinical applications, and risks associated with the use of guidewires is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in urologic endoscopic procedures. Care should be exercised to prevent perforation or trauma of the linings and associated tissues, channels or ducts.
- Failure to abide by the following warnings might result in damage to the channel or duct, abrasion of the hydrophilic coating, release of plastic fragments from the ZIPwire™ Hydrophilic Guidewire, damage to or breakage/separation of the ZIPwire Hydrophilic Guidewire, that may necessitate intervention.
- Do not manipulate, advance and/or withdraw the ZIPwire Hydrophilic Guidewire through a metal cannula or needle. Manipulation, advancement and/or withdrawal through a metal device may result in destruction and/or separation of the outer polymer jacket requiring retrieval. If a needle is used for initial placement, a plastic entry needle is recommended when using the ZIPwire Hydrophilic Guidewire. Extreme caution should be observed when used with a one-wall puncture style needle.
- Use extreme caution when using a laser, making sure to avoid contact with the ZIPwire Hydrophilic Guidewire. Direct contact may cause damage to the wire and/or sever the wire.
- Do not reshape the ZIPwire Hydrophilic Guidewire by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments to the urinary system.
- When exchanging or withdrawing a catheter over the ZIPwire Hydrophilic Guidewire, secure and maintain the wire in place under fluoroscopy to avoid unexpected wire advancement. Otherwise damage to the urinary channel by the wire's tip may occur.
- Manipulate the ZIPwire Hydrophilic Guidewire slowly and carefully in the urinary system while confirming the behavior and location of the wire's tip under fluoroscopy. Excessive manipulation of the ZIPwire Hydrophilic Guidewire without fluoroscopic confirmation may result in perforation or trauma of the linings or associated tissues, channels, or ducts. If any resistance is felt or if the tip's behavior and/or location seem improper, STOP manipulating the wire and/or catheter and determine the cause by fluoroscopy. Failure to exercise proper caution may result in bending, kinking, separation of the ZIPwire Hydrophilic Guidewire's tip, damage to the catheter, or damage to the urinary system. If necessary, remove the ZIPwire Hydrophilic Guidewire and ancillary device or scope as a complete unit to avoid complications.

- Do not attempt to use the ZIPwire Hydrophilic Guidewire if it has been bent, kinked, or damaged. Use of a damaged wire may result in damage to the linings and associated tissue, channels, or ducts or release of wire fragments into the urinary system.
- A retrieving device, such as a gripper or basket forceps, should not be used to grasp or encapsulate the ZIPwire Hydrophilic Guidewire. Doing so may cause damage to the wire or release of wire fragments into the urinary system.

Contraindications
None known.

PRECAUTIONS
- Do not use this product without reading and understanding the complete instructions enclosed herein.
- The ZIPwire Hydrophilic Guidewire has been sterilized by ethylene oxide gas. For single use only. Do not resterilize or reuse.
- The entire operation should be carried out in a sterile field.
- Product is sterile in an unopened and undamaged unit package. Do not use if the unit package or the ZIPwire Hydrophilic Guidewire is broken, damaged or soiled. Return any defective product to Boston Scientific. The ZIPwire Hydrophilic Guidewire should be disposed of safely and properly after use, following local regulations for medical waste management.
- When using a drug or a device concurrently with the ZIPwire Hydrophilic Guidewire, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the wire.
- The surface of the ZIPwire Hydrophilic Guidewire is not lubricious unless it is wet. Before taking it out of its holder and inserting it through a catheter, fill the holder and the catheter with sterile physiological saline solution.
- The ZIPwire Hydrophilic Guidewire should be advanced through the scope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device or patient.
- When reinserting the ZIPwire Hydrophilic Guidewire back into the holder, take care not to damage the wire's coating with the edge of the holder.
- Do not use a metal torque device with the ZIPwire Hydrophilic Guidewire. Use of a metal torque device may result in damage to the wire. Also do not slip a tightened up torque device over the wire, as this may result in damage to the wire.
- Due to the slippery nature of the hydrophilic coating on the ZIPwire Hydrophilic Guidewire, the operator may encounter some difficulties in handling the wire. A Boston Scientific Torque Device, sold separately, is recommended for easier handling/manipulation of the wire.
- Due to variations of certain catheter tip inner diameters, abrasion of the hydrophilic coating may occur during manipulation. If any resistance is felt during introduction of the catheter, it is advisable to stop using such catheters.
- After removal from the patient's urinary system, and prior to reinserting it into the same patient during the same catheterization, the ZIPwire™ Hydrophilic Guidewire should be rinsed in a bowl full of sterile physiological saline solution. Use of alcohol, antiseptic solutions, or other solvents must be avoided because they may adversely affect the surface of the wire.

Potential Complications
Complications which can result from the use of guidewires in urological applications include:
- Hemorrhage
- Tissue Trauma
- Perforation
- Inability to access target site
- False passage
- Infection
- Pain
- Dislodged catheter or stent

- Hematuria
- Vesicoureteral Reflux
- Iatrogenic lesions
- Urine leakage
- Urine retention
- Stricture
- Hematoma
- Death
- Additional Surgical Intervention

Manufactured by Lake Region Medical. Distributed by Boston Scientific.

Rx Only.
CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings,and instructions for use can be found in the product labeling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France**.**