

Urological Guidewires

Prescriptive Information

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

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 labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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.

Intended Use/Indications for Use

Urological Guidewires are intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures. These guidewires are not intended for coronary artery, vascular or neurological use.

Contraindications

None known.

Warnings

- 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 tissue, 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 guidewire, damage to or breakage/separation of the guidewire, that may necessitate intervention.
- Use caution if using with a metal needle or cannula. If the guidewire is being used with a metal cannula or needle and the guidewire needs to be withdrawn, remove the guidewire and metal cannula/needle as a unit, to reduce potential damage to the wire. If a needle is used for initial placement, a plastic entry needle is recommended when using the 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 guidewire. Direct contact may cause damage to the wire and/or sever the wire.
- Do not reshape the 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 guidewire, secure and maintain the guidewire in place under fluoroscopy to avoid unexpected guidewire advancement. Otherwise damage to the urinary channel by the wire's tip may occur.

- Manipulate the 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 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 seems improper, **STOP** manipulating the guidewire and/or the catheter and determine the cause by fluoroscopy. Failure to exercise proper caution may result in bending, kinking, separation of the guidewire's tip, damage to the catheter, or damage to the urinary system. If necessary, remove the guidewire and ancillary device or scope as a complete unit to avoid complications.
- Do not attempt to use the 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 only be used after the guidewire has been removed from the patient's channel or duct. Using a retrieving device while the guidewire is in place may cause the guidewire to break.

Precautions

- Do not use this product without reading and understanding the complete instructions enclosed herein.
- 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 guidewire is broken, damaged or soiled. Return any defective product to Boston Scientific. All guidewires 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 a wire, the operator should have a full understanding of the properties/ characteristics of the drug or device so as to avoid damage to the wire.
- For hydrophilic wires only, the surface of the 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 physiological saline solution.
- The 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 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 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 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, hydrophilic guidewires should be rinsed in a bowl full of physiological saline solution. Use of alcohol, antiseptic solutions or other solvents must be avoided because they may adversely affect the surface of the guidewire.

Adverse Events

Complications which can result from the use of guidewires in urological applications include:

- Perforation of the urinary tract
- Acute Bleeding
- Hemorrhage
- Tissue Trauma
- Edema
- Foreign Object in Body
- Infection
- Hemoglobinuria
- Peritonitis

- Ureter Avulsion

Warning: Do not withdraw the guidewire through a metal cannula or needle. If the guidewire needs to be withdrawn, remove the guidewire and metal cannula or needle as a unit. Failure to do so 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 guidewire. Extreme caution should be observed when used with a one-wall puncture style needle.