Brief Summary Document

Overview

Product
Sensor™ Nitinol Wire with Hydrophilic Tip– IFU 51291502

Rx Statement
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a skilled and licensed practitioner.

Urologists trained in endoscopic procedures or personnel supervised by urologists trained in endoscopic procedures. Other users who come into contact with the device clinically are nurses and technicians.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/INDICATIONS FOR USE
The Sensor Urological Guidewire is 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
There are no known contraindications associated with the use of this product.

WARNINGS
• 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 If the guidewire is being used with a metal cannula or needle and the guidewire needs to be withdrawn, remove the guidewire and metal cannula/needle as a unit, to reduce potential damage to the wire.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.

• A retrieval device, such as a grasper or basket forceps, should only be used after the guidewire has been removed from the patient's channel or duct. Using a retrieval device while the guidewire is in place may cause the guidewire to break.

PRECAUTIONS

• 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.

• The surface of the guidewire hydrophilic tip 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.

• After removal from the patient's urinary system, and prior to reinserting it into the same patient during the same catheterization, the Sensor Urological Guidewire 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.

POTENTIAL ADVERSE EVENTS

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

- Perforation of the urinary tract
- Hematuria
- Tissue Damage
- Infection
- Pain
- Obstruction
- Hemorrhage
- Hematoma
- Edema
- Inflammation
- Unretrieved Device Fragments
- Ureter Avulsion