Brief Summary Document

Overview

Product

Zebra™ Straight Tip, Angle Tip, Guidewire IFU 51649601

Rx Statement

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

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 Zebra 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

None known

WARNINGS

- Failure to abide by the following warnings might result in damage to the channel or duct, abrasion of the PTFE 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 If the guidewire is being used with a metal cannula or needle and the guidewire needs to be withdrawn, remove the guidewire and metal cannula/needle as a unit, to reduce potential damage to the wire.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.
- 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 retrieving 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 retrieving device while the guidewire is in place may cause the guidewire to break.
- When using the Torque Vise, do not overtighten the collar as it can lead to guidewire damage by affecting the integrity of the wire or its coating.

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 guidewire should be advanced through the scope using short, deliberate 2 cm to 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.

POTENTIAL ADVERSE EVENTS

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

- Allergic Reaction
- Edema
- Hematuria
- Hematoma
- Hemorrhage
- Infection
- Inflammation
- Obstruction
- Pain and discomfort
- Perforation of the urinary tract
- Tissue Damage
- Unretrieved Device Fragments
- Ureteral Avulsion

Adverse events may require additional medical or surgical intervention