Zebra™ Guidewires

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

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

- For single use only. Do not reuse, reprocess or resterilize.
- Use of this device should be restricted to use by or under the supervision of physicians trained in urologic endoscopic procedures.
- 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.
- 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 retrieval device while the guidewire is in place may cause the guidewire to break.
- Warnings can be found in the product labeling supplied with each device.

Potential 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

Precautions
• When using a drug or a device concurrently with a polymer-coated 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.
• Precautions can be found in the product labeling supplied with each device.
• Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.