Zoom Wire™ 14 Guidewire

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

Device Description
The Scientia Vascular Zoom Wire™ 14 Guidewire is a 0.014" steerable guidewire with a shapeable tip to aid in accessing vasculature. The guidewire is provided in different stiffness profiles. The guidewire has a hydrophilic polymer coating on the distal portion and a polytetrafluoroethylene (PTFE) coating on the proximal portion to reduce friction during manipulation in vessels. The distal portion of the guidewire tip is radiopaque to facilitate fluoroscopic visualization. The guidewire has an accessory kit consisting of a plastic introducer, (to aid with the insertion of the guidewire into a catheter hub and/or a hemostasis valve), a metal shaping mandrel (to aid in shaping of the distal tip) and a torque device (to attach to the proximal portion allowing the user to steer the guidewire during use). The Zoom Wire 14 Guidewire is not made with natural rubber latex.

This device is coated with a hydrophilic coating at the distal end of the device for a length of 46 cm. Please refer below for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Contents: One Zoom Wire 14 Guidewire, one plastic introducer, one metal shaping mandrel, and one torque device.

Indications for Use
The Zoom Wire 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

Contraindications
None known.

Potential Complications
Potential complications include, but are not limited to: aneurysm perforation / rupture, death, embolus, infarct, hemorrhage, infection, ischemia, neurological / intracranial sequelae, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel trauma / occlusion / perforation / dissection, tissue necrosis, other procedural complications including, but not limited to, anesthetic and contrast media risks, hemodynamic compromise, renal insufficiency, sterile inflammation or granulomas at access site and access site complications.

This device requires the use with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

Warnings and Precautions
- This guidewire should be used only by physicians trained in percutaneous interventional techniques and procedures.
- Inspect the guidewire prior to use for any damage such as kinks or bends. Do not use a damaged guidewire. Any guidewire damage may decrease performance resulting in patient injury or death.
- Zoom Wire 14 Guidewires are not safe for use in or near Magnetic Resonance Imaging (MRI) equipment.
- The Zoom Wire 14 Guidewire is supplied STERILE for single use only. Do not use if sterile barrier is damaged or package is opened.
- This device is intended for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or resterilizing may compromise device integrity and/or performance and may lead to device failure resulting in patient injury, illness, or death. Reuse, reprocessing or resterilizing also increases the risk of contamination and / or patient infection or cross-infection including, but not limited to, transmission of infectious disease(s) resulting in patient injury, illness, or death.
- The plastic introducer, the metal shaping mandrel and the torque device are included to aid the use of the guidewire and are not intended to enter the patient's body.
- Use the guidewire prior to the "Use By" date specified on the package.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the hydrated coated device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- The Zoom Wire 14 Guidewire should be manipulated under fluoroscopy. Do not attempt to move the guidewire without observing the resulting tip response. Advance and withdraw the guidewire slowly and carefully. Never advance or withdraw the guidewire against resistance that is felt or observed under fluoroscopy until the cause of the resistance is determined. Movement of the guidewire against resistance may result in damage to the guidewire or injury to the patient.
- Confirm the compatibility of the guidewire and other devices being used in the procedure.
- Securely fasten the torque device onto the guidewire during use to prevent the torque device from slipping and damaging the guidewire and/or its coating.
- Maintain a constant saline flush between the catheter and the guidewire during a procedure.

- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.
- Use caution when manipulating, advancing and/or withdrawing these devices through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage.

Guidewire Compatibility Information

Minimum Microcatheter ID: 0.0165" (0.42mm)
Confirm the compatibility of the guidewire with the microcatheter and any other interventional devices that will be used before actual use.

NOTE – Prior to using an interventional device with the Zoom Wire 14 Guidewire, review the device's labeling for the intended use, contraindications, potential complications, warnings, and precautions of the device.

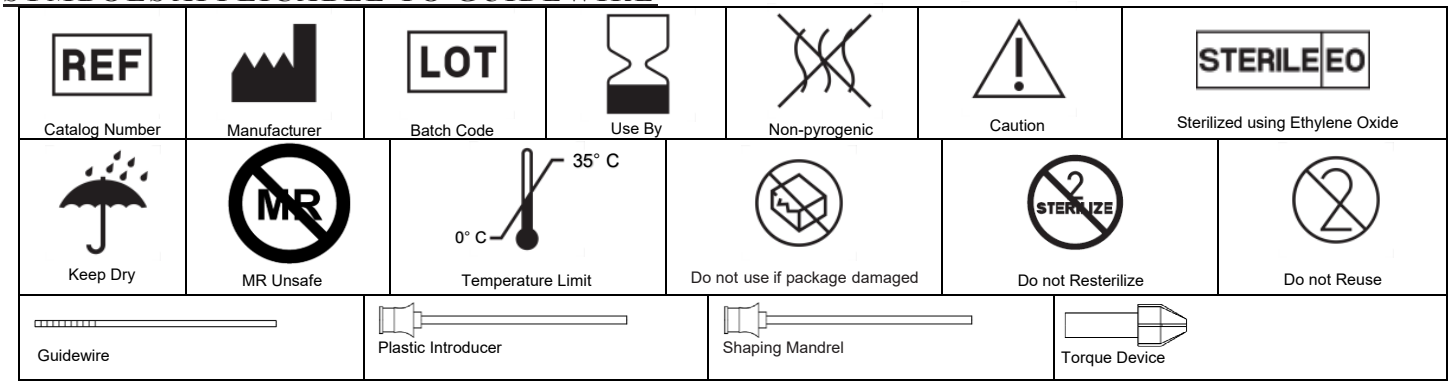
Instructions for Use

1. Before removing the guidewire from the packaging hoop, flush the hoop with a heparinized saline solution through the luer fitting connected to the end of the packaging hoop to hydrate the hydrophilic polymer coating. Do not allow the hydrated coating to dry.
2. Flush the lumen of the catheter with a heparinized saline solution before inserting the guidewire in the catheter.
3. Gently remove the guidewire from packaging hoop and inspect to verify that it is undamaged.
4. Carefully shape the guidewire tip per the following:
   - Place the guidewire tip across the supplied metal shaping mandrel.
   - Pinch the guidewire tip against the metal shaping mandrel.
   - CAREFULLY wrap the shapable distal tip of the guidewire around the metal shaping mandrel and GENTLY roll the distal tip of the guidewire. Repeat until desired shape is obtained. Do not pull on the guidewire tip as this could impact the device performance.
   - Carefully inspect the guidewire prior to use to verify the shaping did not damage the tip. If any damage is identified, do not use the guidewire.

   WARNING – Attempting to alter the shape of devices by bending, twisting, or similar methods beyond instructed methods may compromise the coating integrity and that damage to the coating may not always be noticeable to the naked eye.
5. Place an appropriate catheter using standard technique. Attach rotating hemostasis valve to the catheter luer connection and maintain a continuous flush.
6. Using the supplied plastic introducer as required, carefully insert the guidewire through the rotating hemostasis valve and into the hub of the catheter.
7. Tighten the valve around the guidewire to prevent backflow, but not to inhibit guidewire advancement.
8. Place the torque device on the proximal portion of the guidewire as needed. Loosen and tighten the torque device by rotating the white cap on the torque device.
9. Carefully advance the guidewire under fluoroscopy to the selected target site.

   WARNING – Use fluoroscopy to monitor guidewire movement. Be sure to observe distal tip movement whenever the proximal portion is moved or rotated. Always advance, retract, or rotate the guidewire slowly and carefully.
10. Hold the guidewire in place while tracking the catheter to the selected target site.
11. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

SYMBOLS APPLICABLE TO GUIDEWIRE



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