Carrier Safety & Warnings

Contraindications

There are no known contraindications.

Potential Complications

Possible complications include, but are not limited to, the following:

- Death
- Occlusion
- Vessel Injury
- Hemorrhage
- Nerve Damage
- Neurological Deficits
- Puncture Site Injury
- Vasospasm
- Infection
- Inflammatory Response
- Cardiac Arrythmia
- Thromboemboli and Ischemia

Precautions

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

- Inspect the Carrier Delivery Catheter prior to use. Verify size and condition are appropriate. Do not use the device if kinks, damage, or irregularities are observed.
- Do not use open or damaged packages.
- Do not resterilize or autoclave.
- Store in a dry place at room temperature and away from light.
- Do not use the product after the use-by date.
- The Carrier Delivery Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- Manually flush heparinized saline through the Carrier Delivery Catheter prior to insertion.
- Use the Carrier Delivery Catheter in conjunction with fluoroscopic visualization.

- Do not advance or withdraw the device when resistance is met without careful assessment of the cause using fluoroscopy. Moving or torquing the device against resistance may damage the Carrier Delivery Catheter or vessel. If the cause cannot be determined, withdraw the device.
- Torquing the Carrier Delivery Catheter excessively while kinked may damage the device, resulting in separation of the device. Withdraw all ancillary devices (guide catheter, the device, and guidewire) if the device is severely kinked.
- If flow through the Carrier Delivery Catheter becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Extreme care must be taken to avoid damage to the vasculature through which the Carrier Delivery Catheter passes.
- The Carrier Delivery Catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- The presence of calcification, irregularities, or other devices may damage the Carrier Delivery Catheter and/or 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 and potentially affect its insertion or removal.
- Avoid wiping the device with dry gauze, as this may damage the device coating.
- Avoid excessive wiping of the distal segment containing hydrophilic coating.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device, as this may cause unpredictable changes in the coating which could affect the safety and performance of the device.
- Ensure the device is hydrated as stated in the Preparation for Use section to avoid any potential impact to the coating performance. Once the Carrier Delivery Catheter is hydrated, do not allow it to dry.
- Avoid pre-soaking devices for extended durations when the device is not in use, as this may impact coating safety and performance.
- Hydrophilic coating may swell when exposed to aqueous media, resulting in a tight fit of introduced devices.
- Verify catheter compatibility when using other ancillary devices commonly used in intravascular procedures.
- Use of organic solvents may damage the Carrier Delivery Catheter and/or hydrophilic coating.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

Warnings

- Do not use if pouch is open or damaged. Product will remain sterile if the packaging is not compromised or damaged.
- The Carrier Delivery Catheter is intended for single use only. Do not reuse, resterilize, or reprocess. Discard the Carrier Delivery Catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused.

- This device is coated with a hydrophilic coating at the distal end. Please see table above for specific coating measurements. Refer to the Preparation for Use section for further information on how to prepare this device to ensure that it performs as intended. Failure to abide by the warnings in the Instructions for Use might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Inspect the Carrier Delivery Catheter prior to use. Do not use the device if any damage or irregularities are observed.
- Do not exceed pressures greater than 100 psi (690 kPa). Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip during infusion.
- Not intended for use with power injectors.
- The Introducer Tube is not intended for use inside the patient body. Ensure that it is removed from the Carrier Delivery Catheter once the distal shaft of the Carrier Delivery Catheter is placed inside the patient body.
- The Steam Shaping Mandrel is not intended for use inside the patient body. Ensure that it is removed from the Carrier Delivery Catheter prior to introduction into the Rotating Hemostatic Valve (RHV) or other accessories.
- Check the size of the vessel under fluoroscopy. Ensure that the Carrier Delivery Catheter is suitable for the vessel size.
- Do not use the Carrier Delivery Catheter with stents, flow diverters, retrievers, occlusion coils, glue, glue mixture or non-adhesive liquid embolic agents.
- Do not use the Carrier Delivery Catheter for delivery of liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).