

Ballast Safety & Warnings

Potential Complications

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

- acute vessel occlusion
- allergic reaction
- air embolism
- death
- device malfunction
- distal embolization
- emboli
- false aneurysm formation (i.e. dissection)
- hematoma or hemorrhage at puncture site
- infection
- inflammatory responses
- Sterile inflammation or granulomas at the access site and tissue necrosis
- Intracranial hemorrhage
- ischemia
- neurological deficits including stroke
- vessel spasm, thrombosis, dissection or perforation
- 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.

Precautions for Use

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

- Store in a cool, dry, dark place.
- Do not use kinked or damaged devices.
- Do not use opened or damaged packages.
- Use prior to the "Use by date."
- Do not autoclave, resterilize or reuse. This device is intended for single use.
- Use the Ballast 088 Long Sheath in conjunction with fluoroscopic visualization.
- Inspect the product before use to verify that its size and condition are suitable for the specific procedure.
- Manually flush and hydrate Sheath prior to insertion.
- Do not advance or withdraw the Ballast 088 Long Sheath against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device.
- Moving or torqueing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of appropriate flush solution.
- If flow through the Sheath 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 Sheath passes.
- The Sheath may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

- Torqueing the Sheath may cause damage which could result in kinking and possible separation along the sheath shaft. Should the system become severely kinked, withdraw the entire system.
- An appropriate anticoagulation therapy should be applied per institutional guidelines.
- 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 because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Ensure that the device is hydrated as stated in this instructions for use to avoid any potential impact to the coating performance.
- 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.
- Avoid pre-soaking devices for extended durations when the device is not in use, as this may impact coating safety and performance.
- Do not shape catheter tip.
- Hydrophilic coating may swell when exposed to aqueous media resulting in a tight fit of introduced devices.

Warnings

- The Ballast™ 088 Long Sheath should only be used by physicians who have received appropriate training in interventional techniques.
- Do not reuse. The device is intended for single use only. Discard the Sheath after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Sheaths 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. Please refer to the Instructions for Use section 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.