Raptor Aspiration Catheter Safety & Warnings

Contraindications

There are no known contraindications

Potential Complications

Potential adverse events include, but are not limited to, the following:

- Acute occlusion
- Allergic reaction and anaphylaxis from contrast media
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Kidney damage from contrast media
- Air embolism
- Device malfunction
- Distal embolization, including to a previously uninvolved territory
- Emboli/embolic stroke
- False aneurysm formation
- Fever
- Pseudo aneurysm
- Seizure
- Access site complications (hematoma or hemorrhage, sterile inflammation, granulomas)
- Additional surgical intervention
- Arteriovenous fistula
- Hypotension/hypertension
- Infection, sepsis
- Acute myocardial infarction
- Infarction/necrosis
- Inflammatory responses
- Intracerebral/intracranial hemorrhage
- Cerebral infarct
- Ischemia
- Neurological deficits including stroke
- Vessel spasm, thrombosis, dissection, or perforation
- Thrombus formation

- Inability to completely remove thrombus
- Tissue necrosis, transient or long-lasting
- Drug reactions (e.g., coagulopathy, renal insufficiency/failure, allergic reaction)
- Death

Potential Risks Associated with X-ray Exposure: This device requires fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and the number of procedures increase. 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

- The Raptor Aspiration Catheter should only be used by physicians who have received appropriate training in interventional techniques and treatment of acute ischemic stroke.
- The Raptor Aspiration Catheter has been verified for use with the Balt Aspiration Tubing Set and a compatible aspiration pump. The pump must be capable of delivering vacuum pressures between -20 inHg and -25.6 inHg during use.
- The device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use if the pouch is open or damaged. Product will remain sterile for the labeled shelf life if stored under the recommended conditions and if the packaging is not compromised or damaged.
- Do not use automated high-pressure contrast injection equipment with the Raptor Aspiration Catheter as it may damage the device.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the Raptor Aspiration Catheter or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per steps 2 and 5 in the Preparation and Use section of this IFU with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Inspect the Raptor Aspiration Catheter prior to use. Do not use the device if any damage or irregularities are observed.
- Do not use the Raptor Aspiration Catheter System with Ethiodol or Lipiodol based contrast media as this may cause damage to the device.
- Do not use organic solvents as this may cause damage to the device.
- The Introducer Sheath is not intended for use inside the patient’s body. Ensure that the Introducer Sheath is

removed from the Raptor Aspiration Catheter once the distal shaft of the Raptor Aspiration Catheter is placed inside the patient's body.

- Do not perform more than 3 clot retrieval attempts with the Raptor Aspiration Catheter.
- Confirm vessel diameter. Do not use the Raptor Aspiration Catheter in arteries with diameters smaller or equal to the distal outer diameter of the Raptor Aspiration Catheter.
- Excessive aspiration with the distal tip of the Raptor Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.
- If flow from the lumen becomes stagnant during aspiration do not attempt to clear the inner lumen of the Raptor Aspiration Catheter by infusion. Remove the Raptor Aspiration Catheter from the patient's body before attempting to clear the lumen.
- Use caution when manipulating, advancing, or withdrawing the Raptor Aspiration Catheter through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, or withdrawal past sharp or beveled edges may result in destruction or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage.
- The Raptor Aspiration Catheter has been evaluated for compatibility with a stent-retriever device and may be used in combination with these devices. Refer to the stent-retriever device Instructions for Use for recommended clot retrieval steps.
- The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.
- Do not use the device if any damage or irregularities are observed.
- The introducer sheath is not intended for use inside the patient's body. Ensure that the introducer sheath is removed from the Raptor Aspiration Catheter once the distal shaft of the Raptor Aspiration Catheter is placed inside the patient's body.
- Do not exceed a maximum of 3 total passes of a maximum aspiration time of 60 seconds per pass.
- Excessive aspiration with the distal tip of the Raptor Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate the location of the catheter distal tip under fluoroscopy prior to aspiration.
- Do not attempt to clear the inner lumen of the Raptor Aspiration Catheter by infusion while keeping the device in the patient's body.

Precautions for Use

- Use prior to the "Use By" date specified on the product package.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Raptor Aspiration Catheter in conjunction with fluoroscopic visualization. Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible, to limit patient and physician exposure to X-ray radiation doses.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- Inspect the catheter system before use to verify that its size and condition are suitable for the specific

procedure.

• Manually flush heparinized saline through the catheter lumen prior to insertion.

• Maintain a constant infusion of appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.

• If flow through the catheter becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

• 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 device safety and performance.

• Ensure that the device is hydrated as stated in the Preparation and Use section to avoid any potential impact to the coating performance. Once the 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. Soaking time should not exceed one (1) hour.

• Hydrophilic coating may swell when exposed to excessive aqueous media resulting in a tight fit of introduced devices.

• The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.

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