As part of the Indigo Aspiration System, the Indigo CAT RX Aspiration Catheters and Indigo Separator™ 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.
INDIGO™ Aspiration Tubing – Indication for Use

As part of the INDIGO Aspiration System, the INDIGO™ Aspiration Catheters and Separator 4 are indicated for the removal of fresh, soft emboli and thrombi from the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

• The INDIGO Aspiration System should only be used for patients who are not receiving heparin through an arterial line or filter system.
  
• Do not use near a high-power source or electronic equipment.

Precaution

The INDIGO Aspiration System should only be used for patients who are not receiving heparin through an arterial line or filter system. Do not use near a high-power source or electronic equipment.

Lightning

Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation of the device. Placing guidewire too distal in the pulmonary vasculature or excessive manipulation of aspiration/withdrawal of thrombus distal to the catheter tip. INDIGO SEPARATOR 4 is intended to be used with INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4 – Indication for Use

Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; hematoma; leakage; thrombosis; or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR against resistance. Do not use automated high-pressure contrast injection equipment with the INDIGO Aspiration System.

Contraindications

There are no known contraindications.

Warnings/Precautions

• The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.

• The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. Contraindications: The INDIGO Aspiration System is contraindicated in: The presence of an active, perfused thrombolytic agent, such as tPA, urokinase, or streptokinase. The simultaneous use of heparin and aminocaproic acid, as well as the presence of a flammable anesthetic mixture with air or nitrous oxide. To avoid the risk of embolism, the equipment must not be connected to major vascular access sites with patent or recent history of embolism. To maintain a constant infusion of appropriate flush solution at the target vasculature location. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. To verify that they are operating normally. The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. Contraindications: The INDIGO Aspiration System is contraindicated in: The presence of an active, perfused thrombolytic agent, such as tPA, urokinase, or streptokinase. The simultaneous use of heparin and aminocaproic acid, as well as the presence of a flammable anesthetic mixture with air or nitrous oxide. To avoid the risk of embolism, the equipment must not be connected to major vascular access sites with patent or recent history of embolism. To maintain a constant infusion of appropriate flush solution at the target vasculature location. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. To verify that they are operating normally.