Indigo® System | Mechanical Thrombectomy

CAT RX

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.

Data presented at ACC 2019:

"Initial Experience with a Mechanical Aspiration Catheter for Thrombus Removal During Percutaneous Intervention: A Multicenter Retrospective Case Series"*

KEY RESULTS

TIMI 3

93.2%

Post-CAT RX TIMI 3 flow

CAT RX TIME

35 sec

Median aspiration time with CAT RX

STROKE

0%

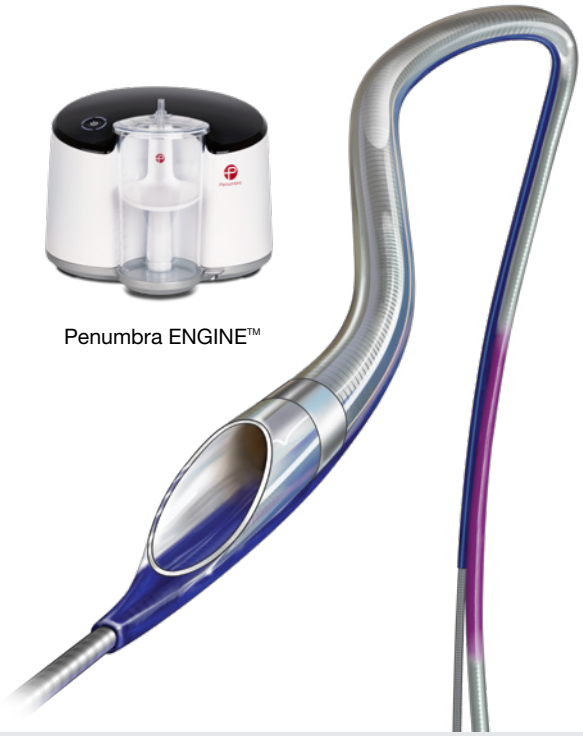
Incidence of stroke

59 patients

With fresh, soft thrombi in the RCA, LAD, or Circumflex

76.3%

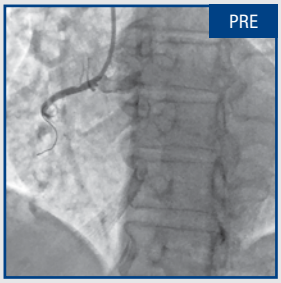
Of patients with an occlusion of TIMI 0 flow pre-procedure

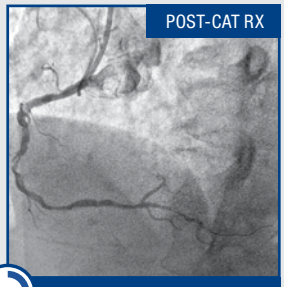


Penumbra ENGINE™

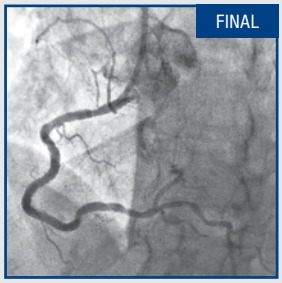
Aspiration of Thrombus from RCA

Dr. Suhail Dohad,
Cedars-Sinai Medical Center, CA



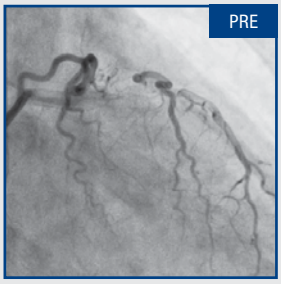


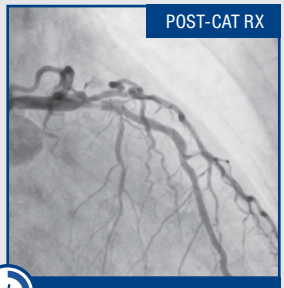
Duration of Angiogram: **15 sec**



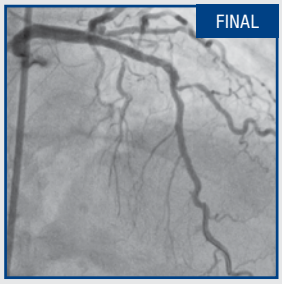
Aspiration of Thrombus from LAD

Dr. Jay Mathews,
Manatee Memorial Hospital, FL





Duration of Angiogram: **32 sec**



* Mathews SJ, Brown C, Kolski B, et al. Initial experience with a mechanical aspiration catheter for thrombus removal during percutaneous intervention: a multicenter retrospective case series.
Poster presented at: American College of Cardiology's 68th Annual Scientific Session; March 16-18, 2019; New Orleans, LA
Images used with permission. Consent on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes. Duration of angiogram provided by consenting physician.

Ordering Information

Indigo® Catheter Kits

Catalog Number	Description	Proximal OD (F)	Distal OD (F)	Compatibility (Sheath or Guide)	Working Length (cm)	Wire Platform (in)	Compatible Penumbra Devices
CATRXKIT	**Indigo CAT RX** + Large Lumen Aspiration Tubing	–	5.3	6.0 F Sheath or Guide	140	.014	Separator™ **4**
CAT8XTORQ115KIT	**Indigo 8 XTORQ Tip** + Dynamic Aspiration Tubing	8.0	8.0	8.0 F Sheath	115	.014–.038	Separator **8**
CAT8TORQ85KIT	**Indigo 8 TORQ Tip** + Dynamic Aspiration Tubing	8.0	8.0	8.0 F Sheath	85	.014–.038	Separator **8**
CAT8STR85KIT	**Indigo 8 Straight Tip** + Dynamic Aspiration Tubing	8.0	8.0	8.0 F Sheath	85	.014–.038	Separator **8**
CAT6KIT	**Indigo 6** + Dynamic Aspiration Tubing	6.0	6.0	6.0 F Sheath	135	.014–.038	Separator **6**
CAT5KIT	**Indigo 5** + Dynamic Aspiration Tubing	6.0	5.0	6.0 F Sheath	132	.014–.038	Separator **5**
CAT3KIT	**Indigo 3** + Dynamic Aspiration Tubing	4.1	3.4	5.0 F Sheath	150	.014–.025	Separator **3**
CATD	**Indigo D** + Large Lumen Aspiration Tubing	8.0	8.0	8.0 F Sheath	50	.014–.038	Separator **D**

Indigo Separators

Catalog Number	Description	Distal OD (in)	Total Length (cm)	Compatible Penumbra Devices
SEP8	Separator 8	.072	150	CAT8
SEP6	Separator 6	.055	175	CAT6
SEP5	Separator 5	.045	175	CAT5
SEPC4	Separator 4	.035	200	CAT **RX**
SEP3	Separator 3	.028	190	CAT3
SEPD	Separator D	.072	90	CATD

Accessories

Catalog Number	Description	Compatible Penumbra Devices
PMXENGN – ***Now!***	Penumbra **ENGINE**™	**ENGINE** Canister
IAPS3 – ***Now!***	**ENGINE** Canister	Penumbra **ENGINE**

Indigo Aspiration Catheters and Separators – Indication For Use
As part of the Indigo Aspiration System, the Indigo Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

Indigo Aspiration Tubing – Indication For Use
As part of the Indigo Aspiration System, the Indigo Sterile Aspiration Tubing is indicated to connect the Indigo Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump – Indication For Use
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

Contraindications
Not for use in the coronaries or the neurovasculature.

Warnings
- The Indigo Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not advance, retract or use any component of the Indigo System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or separator against resistance may result in damage to the device or vessel.
- Do not use the Indigo Aspiration System with a pump other than the Penumbra Aspiration Pump.

Precautions
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use the Indigo Aspiration System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Indigo Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Indigo Aspiration Tubing valve when aspiration is complete is not recommended.
- The Indigo Separator is not intended for use as a guidewire. If repositioning of the Indigo Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard microcatheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Indigo Aspiration Catheter because it may damage the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; intimal disruption; myocardial infarction; emergent surgery; fibrillation; hypotension; respiratory failure; peripheral thromboembolic events.

Indigo CAT RX Aspiration Catheters and Indigo Separator 4 – Indication For Use
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 Sterile Aspiration Tubing is indicated to connect the Indigo CAT RX Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump – Indication For Use
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

Contraindications
The Indigo Aspiration System is contraindicated in:
- The removal of fibrous, adherent or calcified material (e.g. chronic clot, atherosclerotic plaque)
- The cerebral vasculature

Warnings
- The Indigo Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not advance, retract, or use any component of the Indigo Aspiration System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or separator against resistance may result in damage to the device or vessel.
- Do not use the Indigo Aspiration System with a pump other than the Penumbra Aspiration Pump.

Precautions
- **The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) has not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.**
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use the Indigo Aspiration System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Indigo Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Indigo Aspiration Tubing valve when aspiration is complete is not recommended.
- The Indigo Separator 4 is not intended for use as a guidewire. If repositioning of the Indigo CAT RX Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard guidewire techniques.
- Do not use Indigo Separator 4 to macerate or retrieve thrombus distal to the catheter tip. Indigo Separator 4 is intended to be used with Indigo CAT RX Aspiration Catheter to clear the distal end of the catheter lumen should it be blocked with thrombus.
- Do not use automated high-pressure contrast injection equipment with the Indigo CAT RX Aspiration Catheter because it may damage the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; intimal disruption; myocardial infarction; emergent surgery; fibrillation; hypotension; respiratory failure; peripheral thromboembolic events.

Penumbra ENGINE – Indication For Use
The Penumbra ENGINE is indicated as a vacuum source for Penumbra Aspiration Systems.

Contraindications
There are no contraindications.

Warnings/Precautions
- The canister is intended for single use only. Do not reuse. Reuse may result in canister cracking or vacuum filter blockages, which may result in the inability to aspirate.
- Do not block bottom air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the Penumbra ENGINE so that it is difficult to remove the power cord. The means of mains disconnect is to remove the power cord.
- Only use replacement fuse with correct rating (see Table 1 for fuse rating).
- Remove and service the Penumbra ENGINE if liquids or solids have been drawn into the Penumbra ENGINE.
- Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- Do not use in an oxygen rich environment.
- To prevent fire or shock hazard, use a replacement power cord of equal rating.
- Do not re-infuse blood or fluid from the canister back into the patient.
- Do not use petroleum based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the Penumbra ENGINE. Use only water-based solvents for cleaning.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the Penumbra ENGINE. Otherwise, this could result in degradation of the performance of this equipment.
- Common emitters (such as RFID emitters, security systems, diathermy equipment, and portable transmitters) should not be used in close proximity to the Penumbra ENGINE as they can interfere with and result in degradation of the performance of the equipment.
- Equipment is not safe for MR use.
- No modification of this equipment is allowed.

Penumbra

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