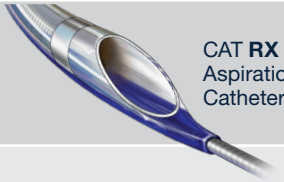
CHEETAH STUDY[1]

A Prospective, Multicenter Study to Evaluate the Safety and Performance of the CAT™ **RX** Aspiration Catheter in Patients with a High Thrombus Burden Acute Coronary Vessel Occlusion Prior to PCI

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**.



CAT **RX** Aspiration Catheter

Penumbra ENGINE®

400 Patients

25 Sites

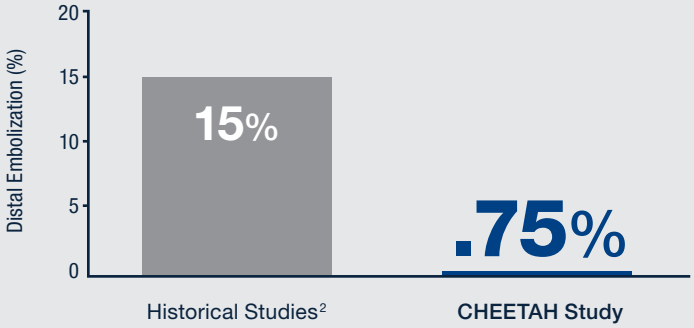
Primary Composite Endpoint Met
Safe in High-Risk Patient Population

96.5%	0
Freedom from MACE at 30 days[a]	Device related SAEs (including stroke[b])

Successful Thrombus Removal
High Rates of Flow Achieved

85%	97.5%
TIMI 2–3 flow post CAT **RX**	TIMI 3 flow at final angiography

Low Distal Embolization Rate



Improved Myocardial Perfusion

Achieving high myocardial blush grade (MBG 3) during PCI has been associated with improved outcomes in acute MI[3]

99.8% of patients with MBG 3 at final angiography

Sustained power aspiration with CAT RX is safe for removal of high thrombus burden with low rates of distal embolization and improved myocardial perfusion

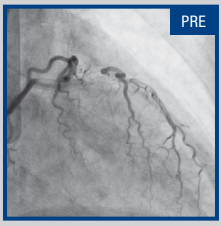
a. Composite of 30 day cardiovascular death, recurrent myocardial infarction, cardiogenic shock, or new or worsening New York Heart Association Class IV heart failure.
b. There were 3 (.75%) incidence of non-device related strokes as adjudicated by Independent Medical Reviewer.

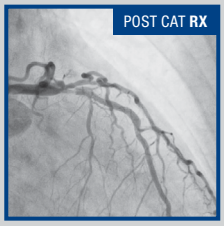
1. As presented at TCT 2021 by Dr. Jay Mathews, Manatee Memorial Hospital, FL.
2. Henriques JPS, Zijlstra F, Ottervanger JP, et al. Incidence and clinical significance of distal embolization during primary angioplasty for acute myocardial infarction. *Eur Heart J.* 2002 Jul;23(14):1112–1117. doi: 10.1053/euhj.2001.3035.
3. Rehman A, Malik J, Javed N, Iftikhar I, Sharif H. Myocardial blush grade: a determinant of left ventricular ejection fraction and adverse outcomes in STEMI. *Scott Med J.* 2021 Feb;66(1):34–39. doi: 10.1177/0036933020941260.

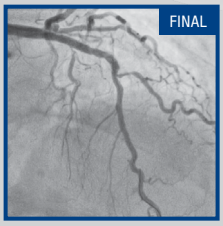
The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors. Penumbra ENGINE and Penumbra Pump MAX® were both used during CHEETAH study.

Get the Clot Out with CAT **RX**

Removal of Thrombus from **LAD**

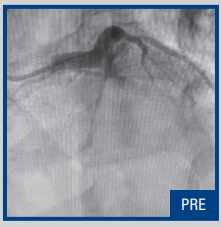


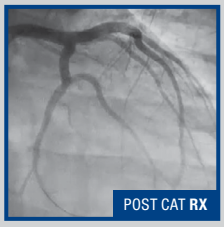


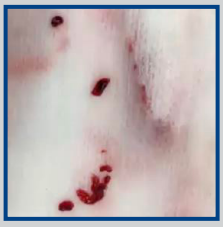


Dr. Jay Mathews,
Manatee Memorial Hospital, FL

Removal of Thrombus from **LCx**







Dr. Jon George,
University of Pennsylvania Health System, PA

Indigo Catheter Kit

Catalog Number	Description	Proximal OD	Distal OD	Compatibility	Working Length (cm)	Wire Platform (in.)	Compatible Penumbra Devices
CATRXKIT	Indigo CAT **RX** + Large Lumen Aspiration Tubing	–	5.3 F	6 F Sheath or Guide	140	.014	Separator™ **4**

Indigo Separator

Catalog Number	Description	Distal OD (in.)	Total Length (cm)	Compatible Penumbra Devices
SEPC4	Separator **4**	.035	200	CAT **RX**

Accessories

Catalog Number	Description	Compatible Penumbra Devices
PMXENGN	Penumbra ENGINE	Penumbra ENGINE Canister
IAPS3	Penumbra ENGINE Canister	Penumbra ENGINE

INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4 – Indication for Use
INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4: 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:** 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:** 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 Pump MAX® – Indication for Use
The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no contraindications. **Warnings/Precautions** • The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate. • Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow. • To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. • Do not position the pump so that it is difficult to operate the power cord disconnection device. • Remove and service the pump if liquids or solids have been drawn into the vacuum pump. • Do not use in the presence of a flammable anaesthetic mixture with air or nitrous oxide. • Do not use in oxygen rich environment. • To prevent fire or shock hazard, use replacement fuses of equal size and rating. • 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 patient. • Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the pump. Use only water-base solvents for cleaning. • Federal (USA) law restricts this device to sale by or on the order of a physician. • No modification of this equipment is allowed.

The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Images used with permission. Consents on file at Penumbra, Inc. Individual results may vary depending on patient-specific attributes and other factors. Case images and physicians may not be associated with CHEETAH Study. Penumbra ENGINE and Penumbra Pump MAX were both used during CHEETAH study. Photograph taken by and on file at Penumbra, Inc.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

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