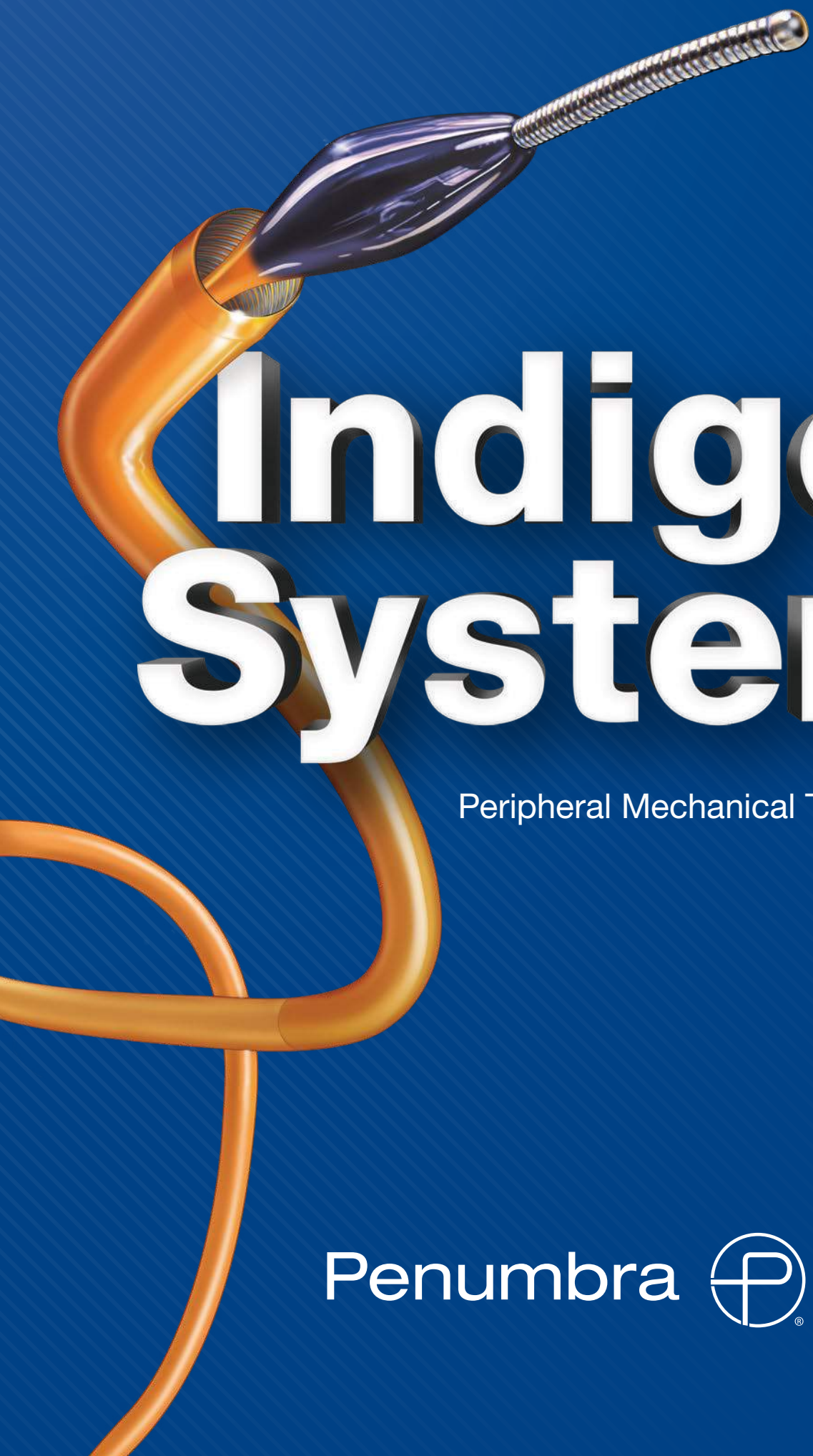


Indigo® System

Peripheral Mechanical Thrombectomy

Penumbra

Indigo® System Catheters

CAT 6

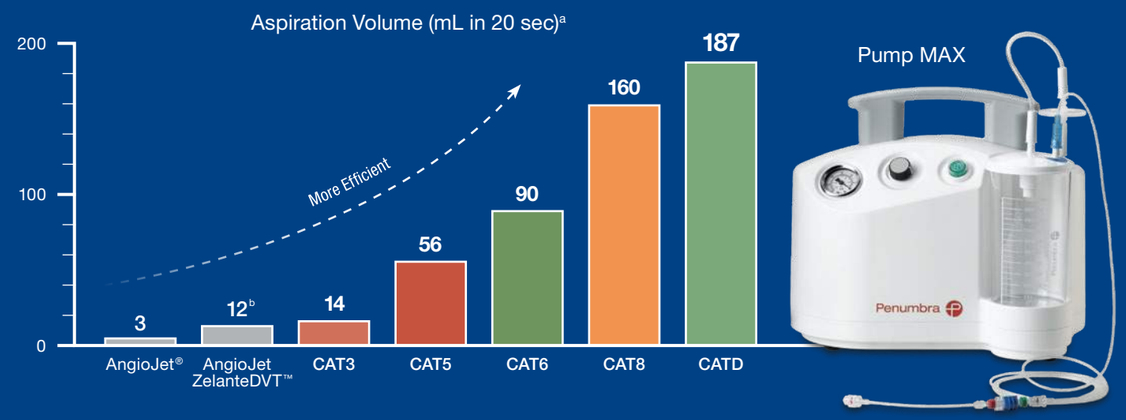
Arterial clot in larger arteries including SFA, popliteal, and viscerals

CAT 8

Arterial and venous clot in larger vessels where circumferential aspiration is desired

Aspirate, Don't Macerate

Power Aspiration with Pump MAX™



a, b. Tests performed and data on file at Penumbra, Inc. Bench tests may not be indicative of clinical performance.

Benefits of Power Aspiration[c]

- Atraumatic tracking
- No reported bradycardia or hypotension
- No reported hemolysis or renal failure
- No reported risk of hypotube overtorquing
- Can retrieve distal emboli

c. Based on clinical data and complaint information. Data on file at Penumbra, Inc.

Indigo® System Catheters

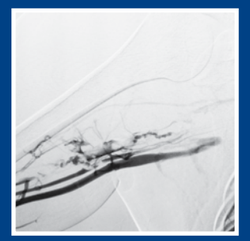
CAT D

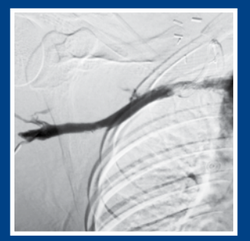
50 cm length for upper and lower arm AV fistula/graft thrombus aspiration

CAT 5&3

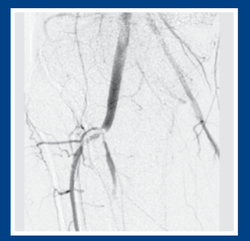
Smaller, distal reach for upper and lower arterial extremities

Get the Clot Out with **Indigo System**

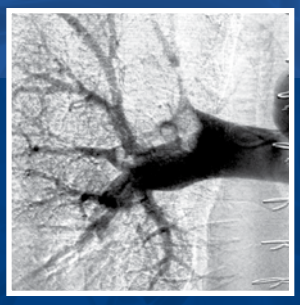




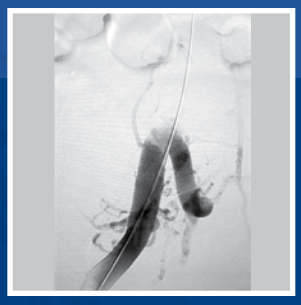
Aspiration of Thrombus from Subclavian Artery
Dr. Frank Arko, Sanger Heart and Vascular Institute, NC



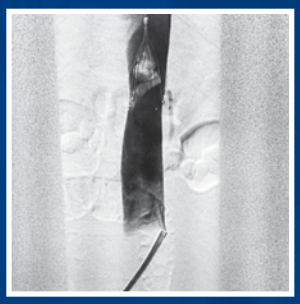
Aspiration of Thrombus from Tibioperoneal
Dr. James Benenati, Miami Cardiac and Vascular Institute, FL



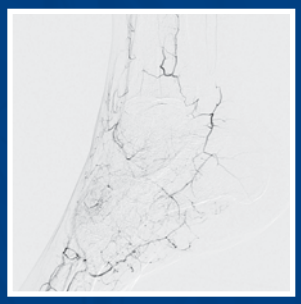
Aspiration of Thrombus from Pulmonary Artery
Dr. Paul Perkowski, Baton Rouge General, LA



Aspiration of Thrombus from IVC & Iliac Vein
Dr. Lawrence Whitney, Lakeland Regional Medical Center, FL



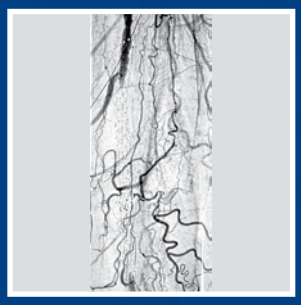
Aspiration of Thrombus from Occluded IVC Filter
Dr. Arashk Motiei, Mayo Clinic, MN



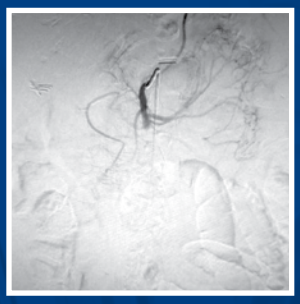
Aspiration of Thrombus from Anterior Tibial
Dr. Maria Antonella Ruffino, Città della Salute e della Scienza di Torino, Italy

Up to **8F Arterial** and **Venous** Indication

Aspiration of Thrombus from Iliofemoral Vein
Dr. Corey Teigen, Sanford Health, ND



Aspiration of Thrombus from Occluded SFA Stent
Dr. George Adams, REX/UNC Healthcare, NC

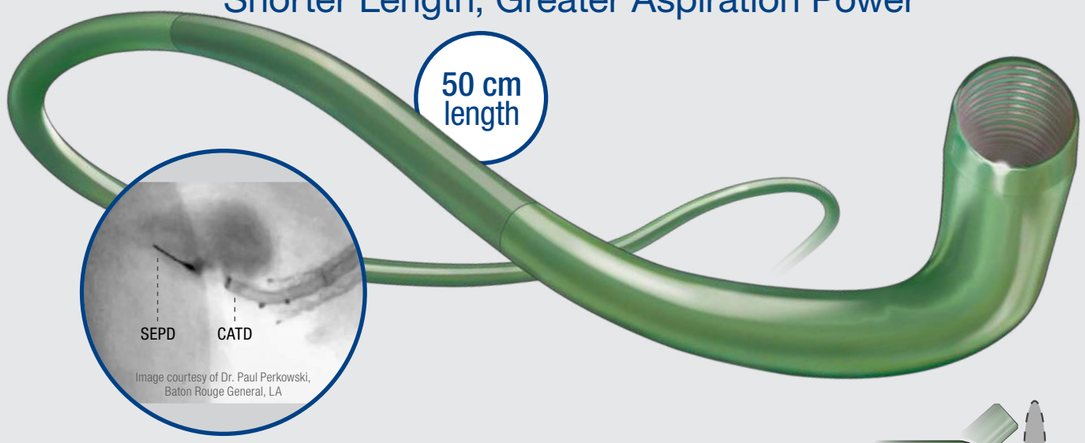


Aspiration of Thrombus from SMA
Drs. Rahul Patel & Robert Lookstein, Mount Sinai Hospital, NY

Aspiration of Thrombus from Pulmonary Artery
Dr. James Benenati, Miami Cardiac and Vascular Institute, FL

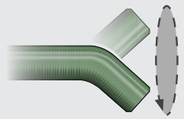
CATD | Latest Indigo® Technology

Shorter Length, Greater Aspiration Power [a,b]



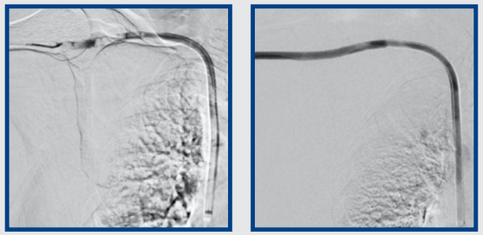
CATD aspirating occluded AV Fistula
with available **Separator™ D**

Tip Directionality for
Circumferential Aspiration

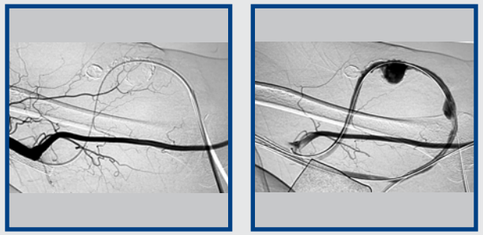


d. Data on file at Penumbra, Inc.

CATD for Fistula/Graft Thrombus Aspiration

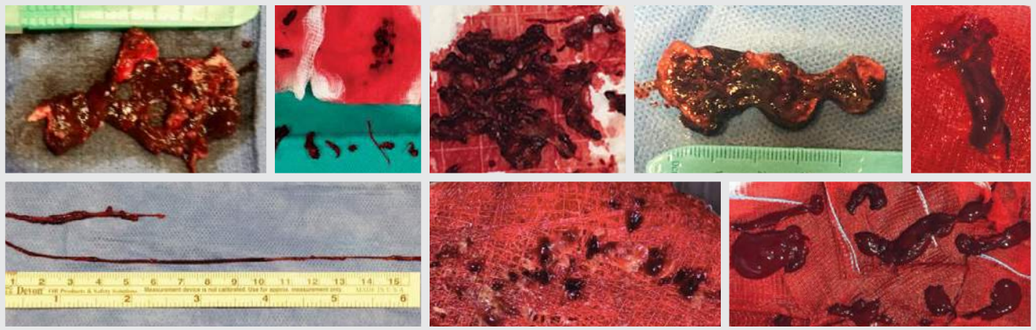


CATD in HeRO® Graft
Dr. Osman Ahmed, Rush University Medical Center, IL



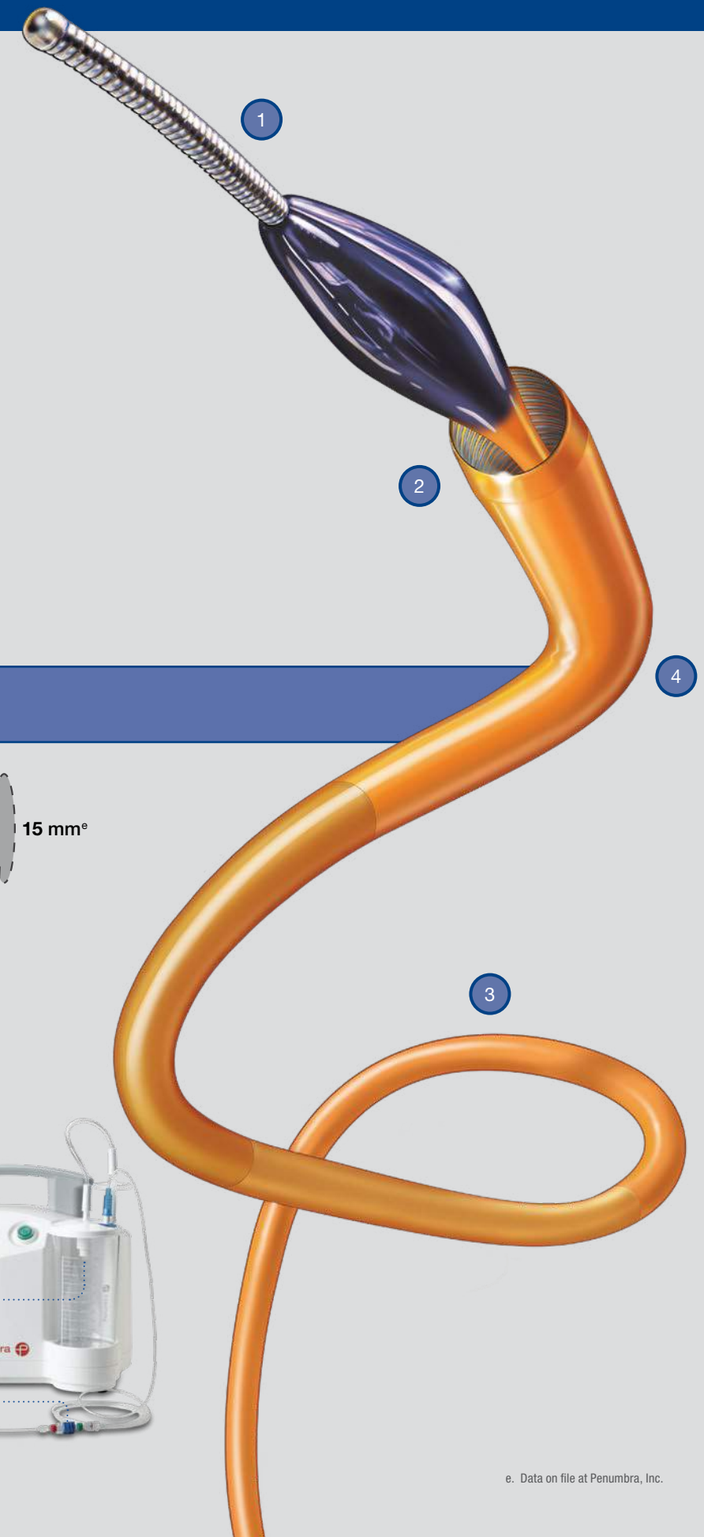
Aspiration of Thrombus from AV Fistula
Dr. Venkatpavel Tummala, Lakeland Regional Medical Center, FL

Thrombus Aspirated with **Indigo System**

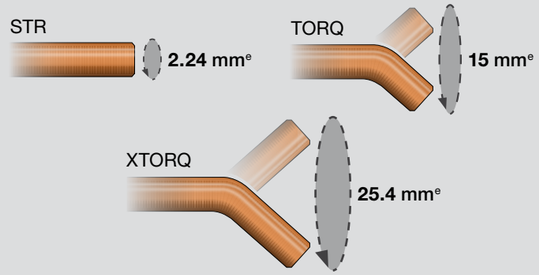


Indigo® System Features

1. **Mechanical Clot Engagement**
   Proprietary Separator™ Technology
2. **Maximized Aspiration Power**
   Large Lumen Aspiration
3. **Advanced Tracking Technology**
   Multiple Material Transitions
4. Tip Directionality for
   Circumferential Aspiration



CAT8 Tip Shapes



5. **Continuous Power Aspiration**
   with Penumbra Pump MAX™

e. Data on file at Penumbra, Inc.

PRISM Trial Results[f]

79 Patients

5 Centers

Corey Teigen, MD, Department of Interventional Radiology, Sanford Health, Fargo, ND
James F. Benenati, MD, FSIR, Miami Cardiac & Vascular Institute, Miami, FL
Richard R. Saxon, MD, San Diego Cardiac & Vascular Institute, San Diego, CA
George L. Adams, MD, North Carolina Heart & Vascular Research, Raleigh, NC
Luke Sewall, MD, Adventist Health Partners, Downers Grove, IL

Above Knee/Popliteal

77.3%

Below Knee

22.8%

Successful Revascularization
XTRACT with **Indigo**

87.2%

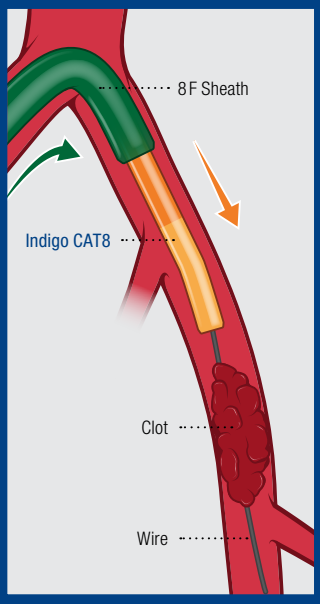
Successful Revascularization
Post All Interventions

96.2%

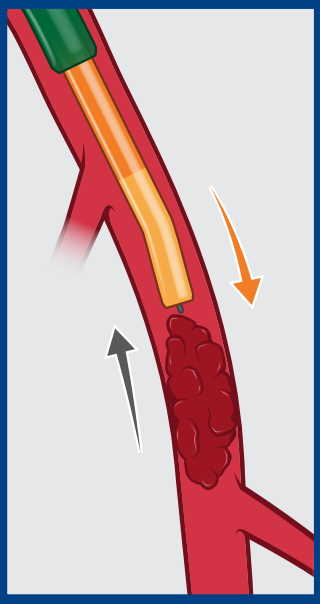
Successful Revascularization was defined as **TIMI 2–3 flow**

Conclusion: XTRACT Technique with Indigo System is Safe and Effective

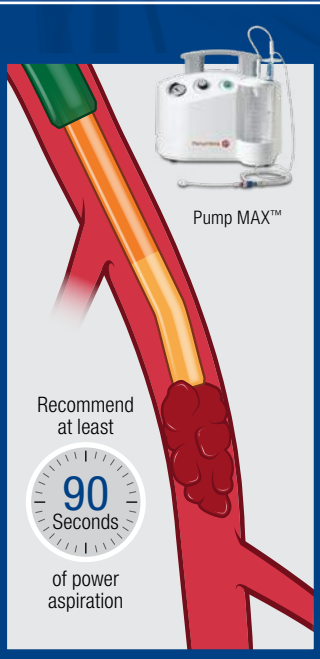
XTRACT Technique Used in PRISM Trial for Arterial Occlusions



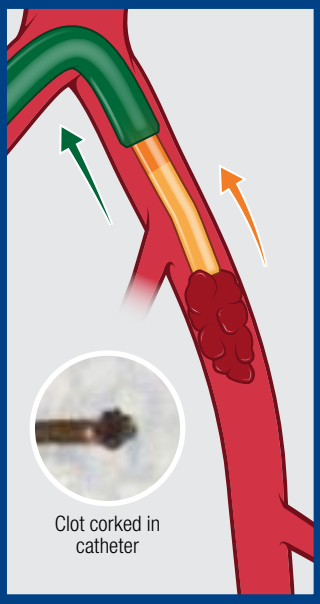
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo **CAT8** is advanced through sheath over a wire.



The Indigo **CAT8** is placed just proximal to the face of the clot and wire is retracted.



Aspiration is applied to Indigo **CAT8** via **Pump MAX** until **CAT8** becomes occluded *(recommend waiting at least 90 seconds).*



The Indigo **CAT8** is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes.

f. Saxon RR, Benenati JF, Teigen C, Adams GL, Sewall LE; PRISM Trialists. Utility of a Power Aspiration-Based Extraction Technique as an Initial and Secondary Approach in the Treatment of Peripheral Arterial Thromboembolism: Results of the Multicenter PRISM Trial. *J Vasc Interv Radio.* 2018 Jan;29(1):92-100. doi: 10.1016/j.jvir.2017.08.019.

Indigo® System

Ordering Information

Catalog Number	Description	Proximal OD	Distal OD	Length	Compatible Penumbra Devices
Indigo Kits				Working	
CATD	Indigo D + Large Lumen Aspiration Tubing	8.0 F	8.0 F	50 cm	Separator™ D
Indigo Catheters				Working	
CAT8XTORQ115	Indigo 8 XTorq Tip	8.0 F	8.0 F	115 cm	Separator 8
CAT8TORQ85	Indigo 8 Torq Tip	8.0 F	8.0 F	85 cm	Separator 8
CAT8STR85	Indigo 8 Straight Tip	8.0 F	8.0 F	85 cm	Separator 8
CAT6	Indigo 6	6.0 F	6.0 F	135 cm	Separator 6
CAT5	Indigo 5	6.0 F	5.0 F	132 cm	Separator 5
CAT3	Indigo 3	4.1 F	3.4 F	150 cm	Separator 3
Indigo Separators				Total	
SEPD	Separator D	n/a	.072"	90 cm	CATD
SEP8	Separator 8	n/a	.072"	150 cm	CAT8
SEP6	Separator 6	n/a	.055"	175 cm	CAT6
SEP5	Separator 5	n/a	.045"	175 cm	CAT5
SEP3	Separator 3	n/a	.028"	190 cm	CAT3
Accessories					
PMX110	Pump MAX™				MAX Canister
IAPS2	MAX Canister				Pump MAX
IST3	Large Lumen Aspiration Tubing				All Indigo Catheters

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.

Penumbra Pump MAX – Indication For Use
The Penumbra Pump MAX is indicated as a vacuum source for the 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 the 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.

Penumbra

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order.anz@penumbrainc.com

Product availability varies by country. 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 Indigo Aspiration System and Penumbra Pump MAX for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Images used with permission. Consents on file at Penumbra, Inc. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Please contact your local Penumbra representative for more information.

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