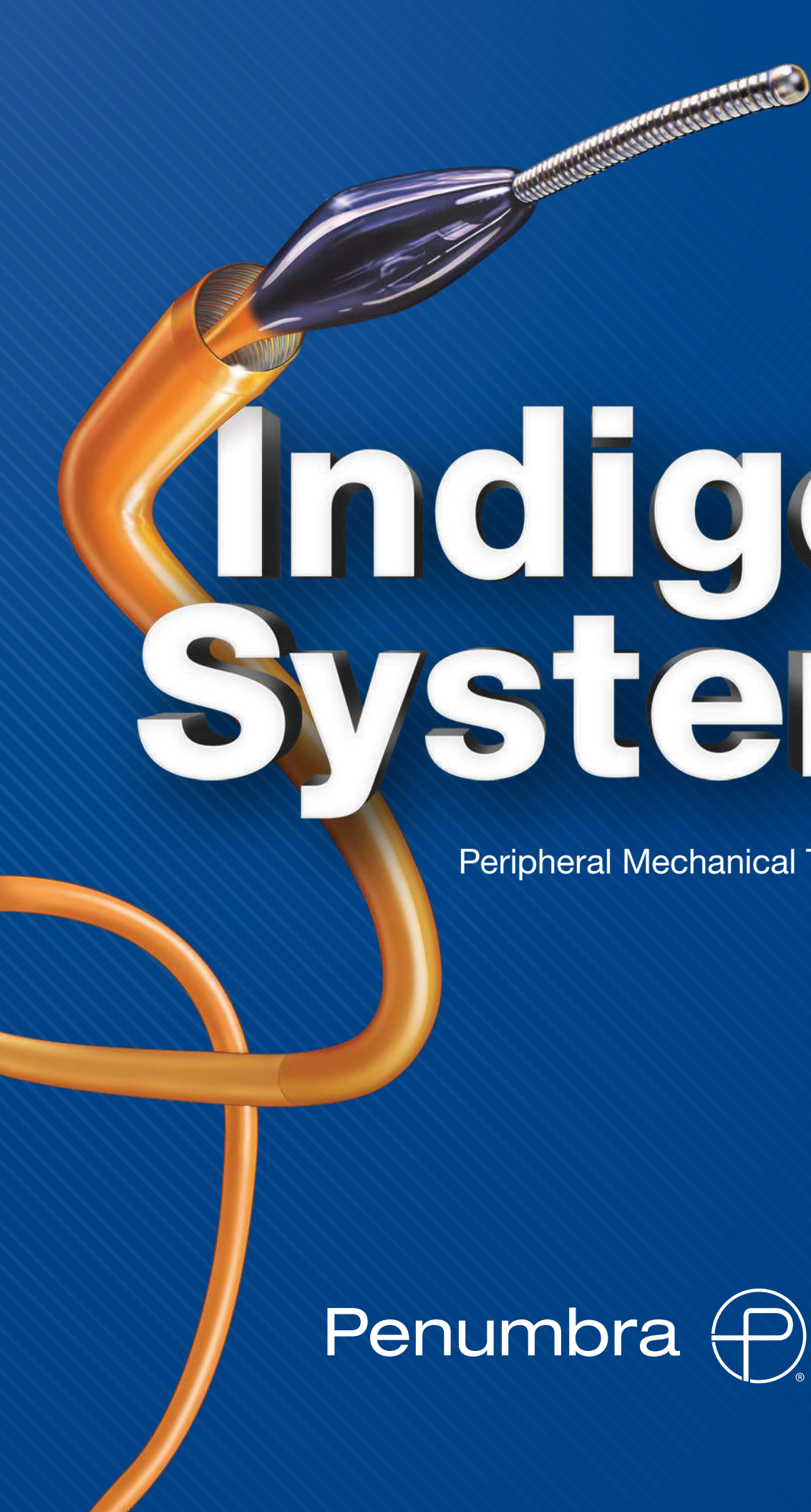


A detailed illustration of the Indigo System catheter. It features a long, flexible orange catheter tube that curves across the frame. At the distal end, there is a dark purple, bulbous dilation catheter with a braided metal wire extending from its tip. The background is a solid blue with a subtle diagonal line pattern.

# Indigo<sup>®</sup> 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



CAT  
D

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

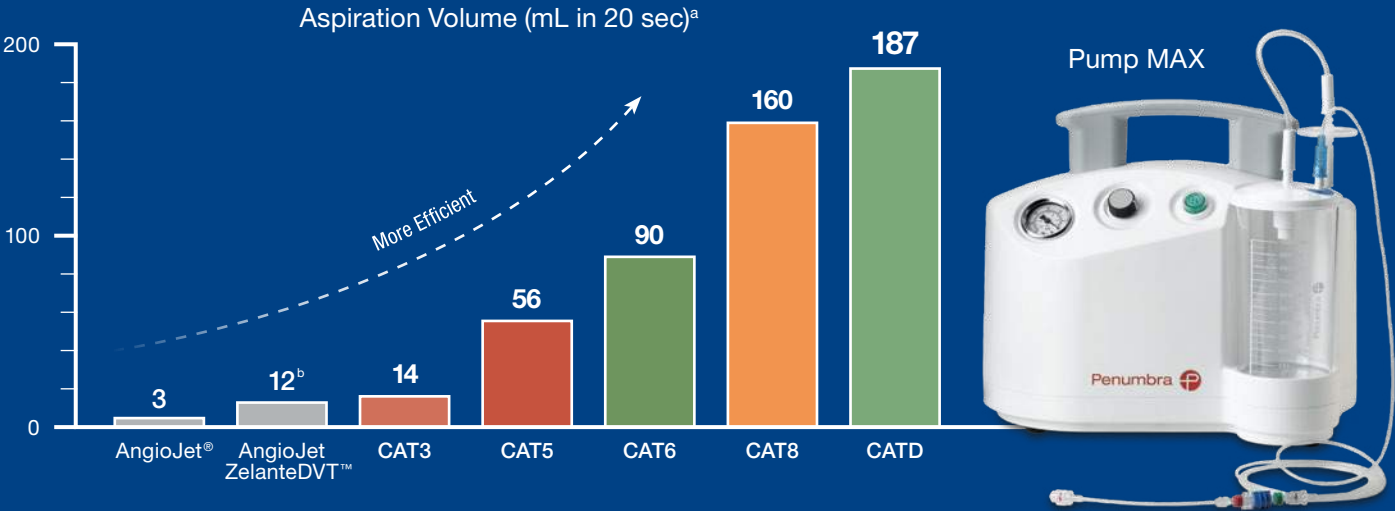


CAT  
5 & 3

Smaller, distal reach for upper and lower arterial extremities

## 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.

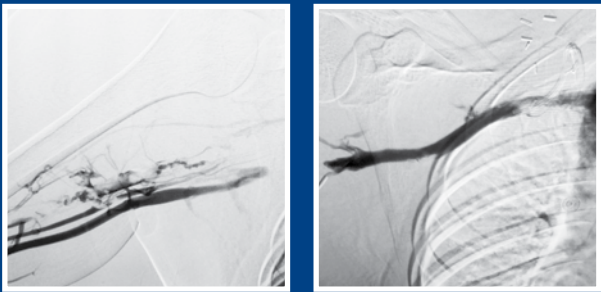
### Benefits of Power Aspiration<sup>c</sup>

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

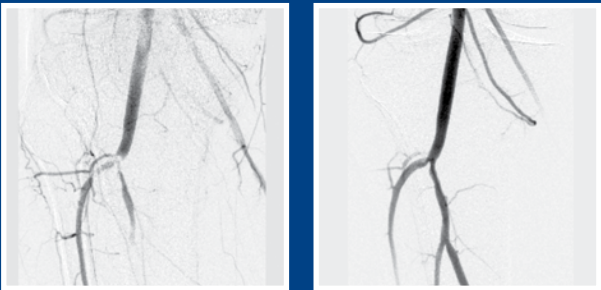
c. Based on clinical data and complaint information. Data on file at Penumbra, Inc.

# Indigo® System Catheters

## Get the Clot Out with Indigo System



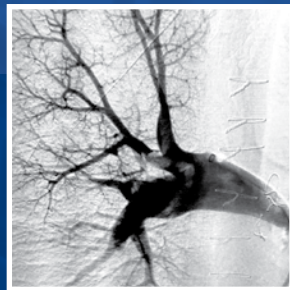
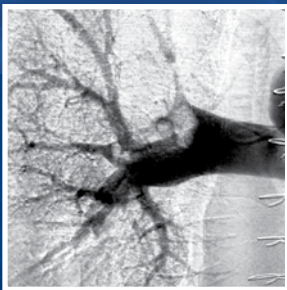
Aspiration of Thrombus from Subclavian Artery  
Dr. Frank Arko, Sanger Heart and Vascular Institute, NC



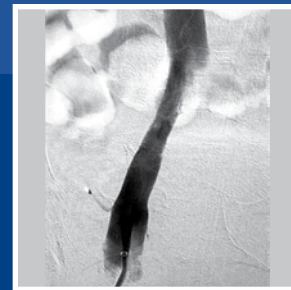
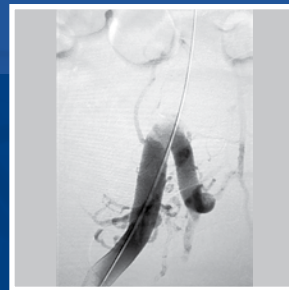
Aspiration of Thrombus from Tibioperoneal  
Dr. James Benenati, Miami Cardiac and Vascular Institute, FL



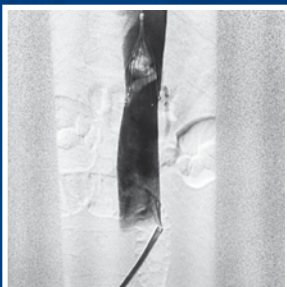




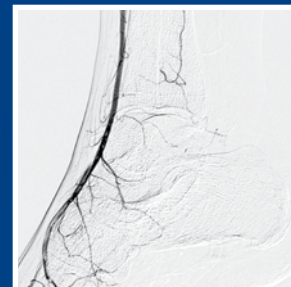
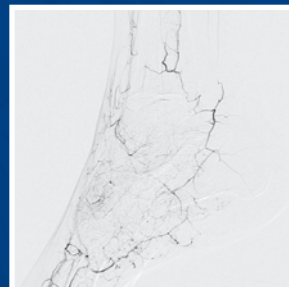
**Aspiration of Thrombus from Pulmonary Artery**  
Dr. Paul Perkowski, Baton Rouge General, LA



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

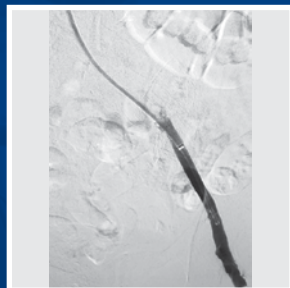


**Aspiration of Thrombus from Occluded IVC Filter**  
Dr. Arashk Motiei, Mayo Clinic, MN

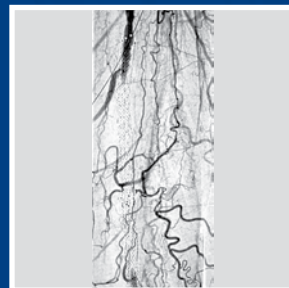


**Aspiration of Thrombus from Anterior Tibial**  
Dr. Maria Antonella Ruffino, Città della Salute e della Scienza di Torino, Italy

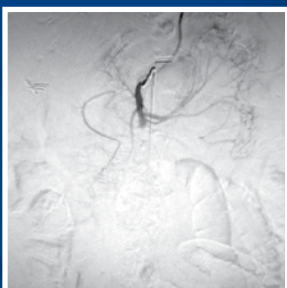
## Up to 8F Arterial and Venous Indication



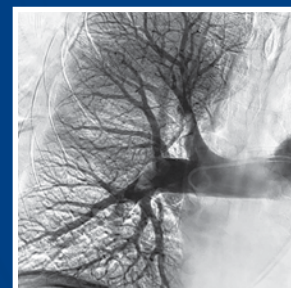
**Aspiration of Thrombus from Iliofemoral Vein**  
Dr. Corey Teigen, Sanford Health, ND



**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

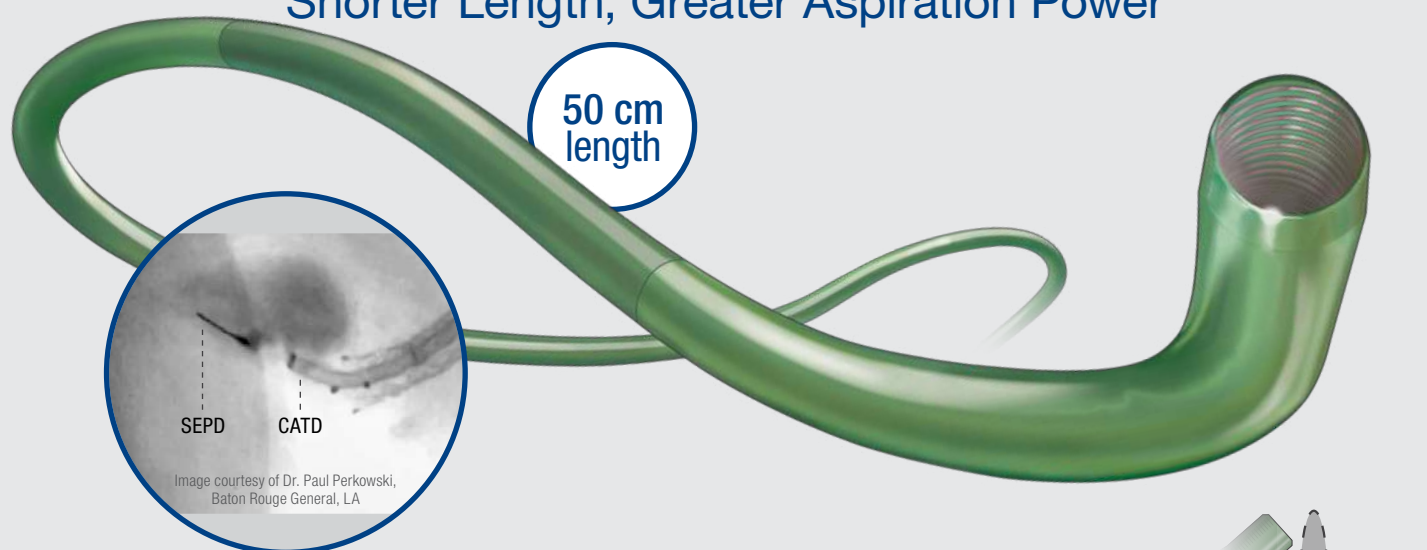


**Aspiration of Thrombus from Pulmonary Artery**  
Dr. James Benenati, Miami Cardiac and Vascular Institute, FL



Shorter Length, Greater Aspiration Power<sup>a,b</sup>

50 cm length



SEPD CATD

Image courtesy of Dr. Paul Perkowski, Baton Rouge General, LA

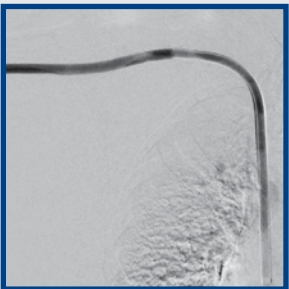
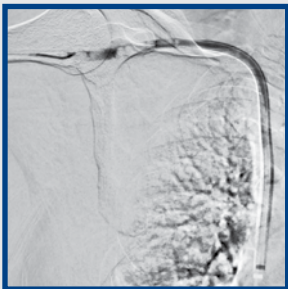
CATD aspirating occluded AV Fistula with available Separator™ D

Tip Directionality for Circumferential Aspiration

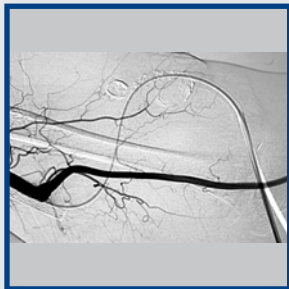
16 mm<sup>d</sup>

d. Data on file at Penumbra, Inc.

CATD for Fistula/Graft Thrombus Aspiration

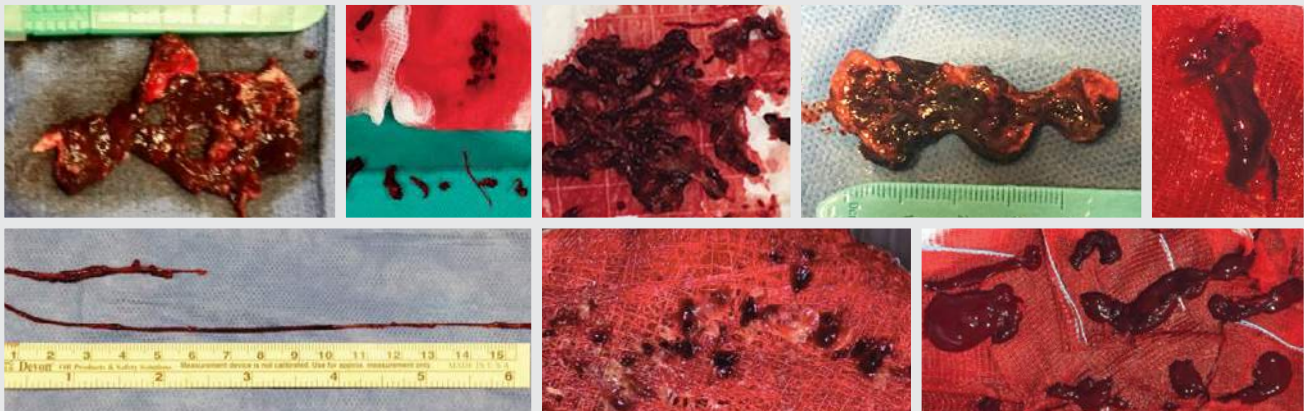


CATD in HeRO® Graft  
Dr. Osman Ahmed, Rush University Medical Center, IL



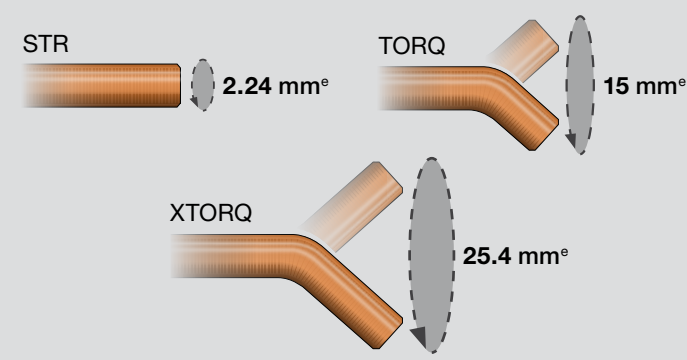
Aspiration of Thrombus from AV Fistula  
Dr. Venkatpavel Tummala, Lakeland Regional Medical Center, FL

Thrombus Aspirated with Indigo System



- 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

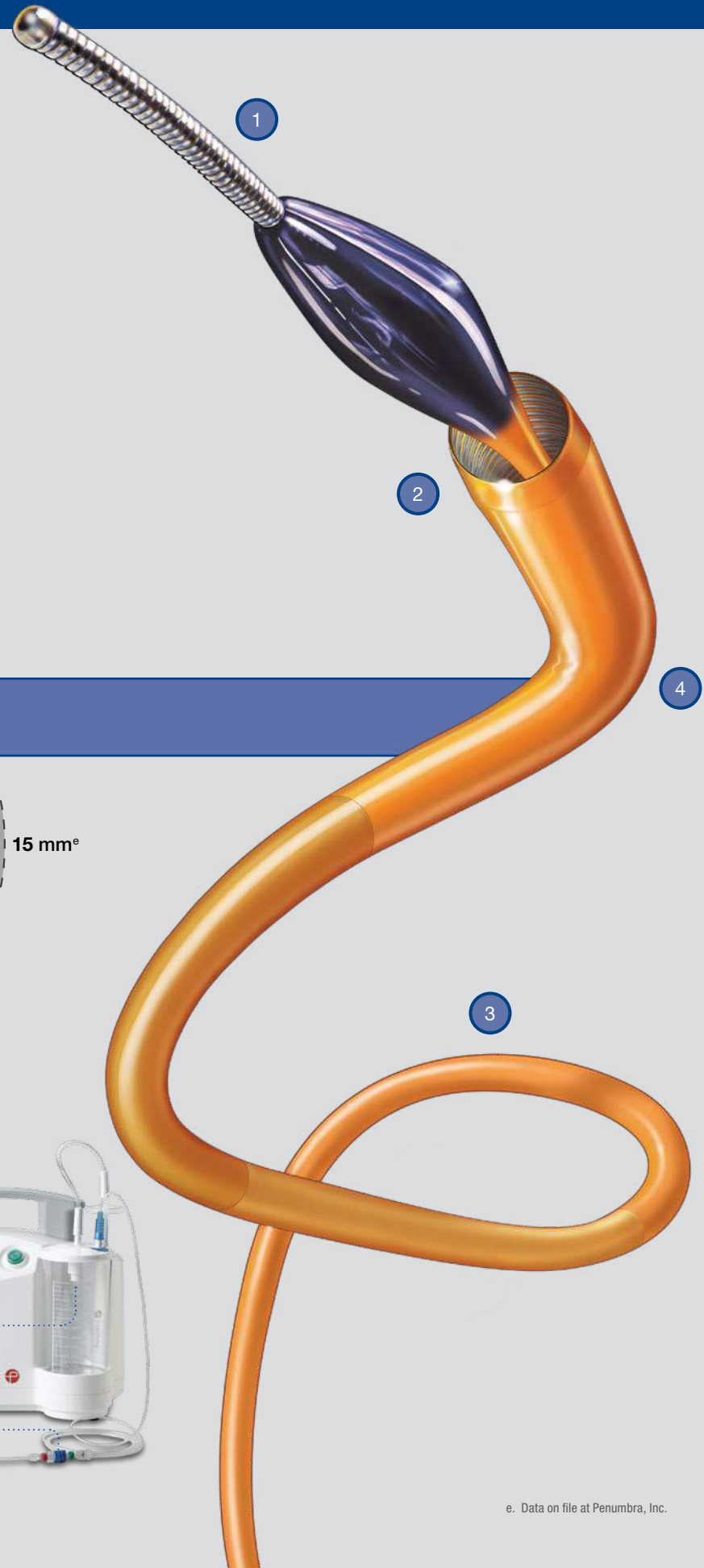


- 5 Continuous Power Aspiration  
with Penumbra Pump MAX™

Maximized power

Continuous suction

Hands-free aspiration



e. Data on file at Penumbra, Inc.

# PRISM Trial Results<sup>f</sup>

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%

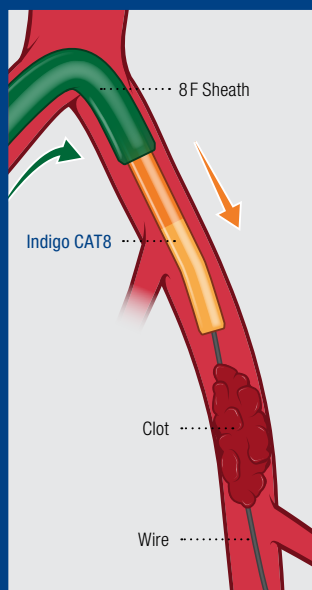
Successful Revascularization  
**Post All Interventions**

96.2%

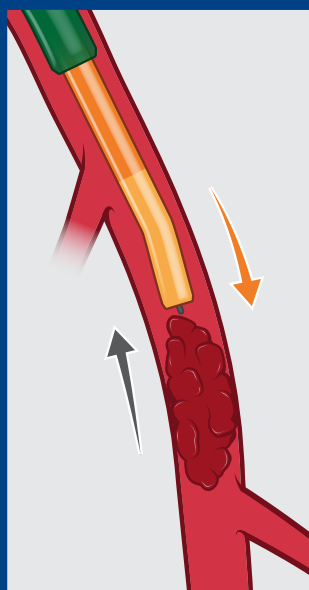
Successful Revascularization was defined as TIMI 2–3 flow

**Conclusion:** XTRACT Technique with Indigo System is Safe and Effective

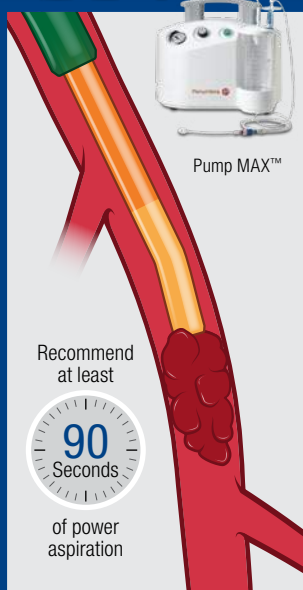
## XTRACT Technique Used in PRISM Trial for Arterial Occlusions



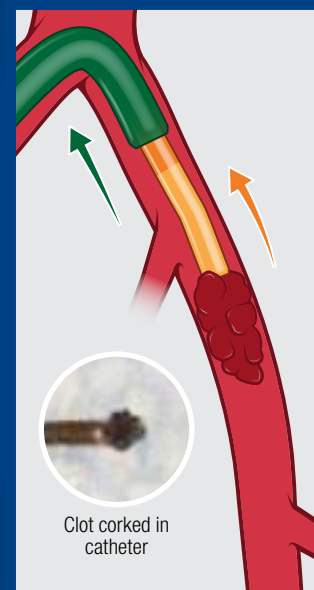
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.



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 Radiol*. 2018 Jan;29(1):92-100. doi: 10.1016/j.jvir.2017.08.019.



## Ordering Information

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



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F +61-1300 817 026  
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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