

Indigo System

A stylized pen nib, primarily orange with a purple section and a silver metal tip, is positioned diagonally across the text. The nib is integrated into the letter 'o' of 'Indigo' and loops around the 'm' of 'System'. The background is a dark blue with a subtle, repeating pattern of diagonal lines.

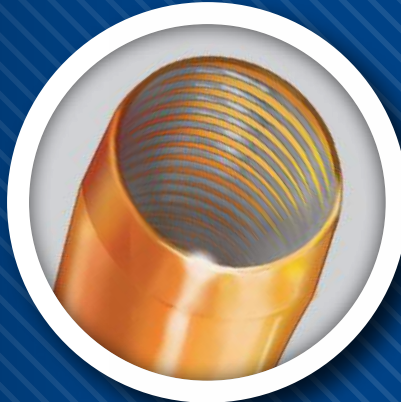
Penumbra 

**Mechanical
Clot Engagement**



Proprietary Separator™
Technology

**Maximized
Aspiration Power**



Large Lumen Aspiration

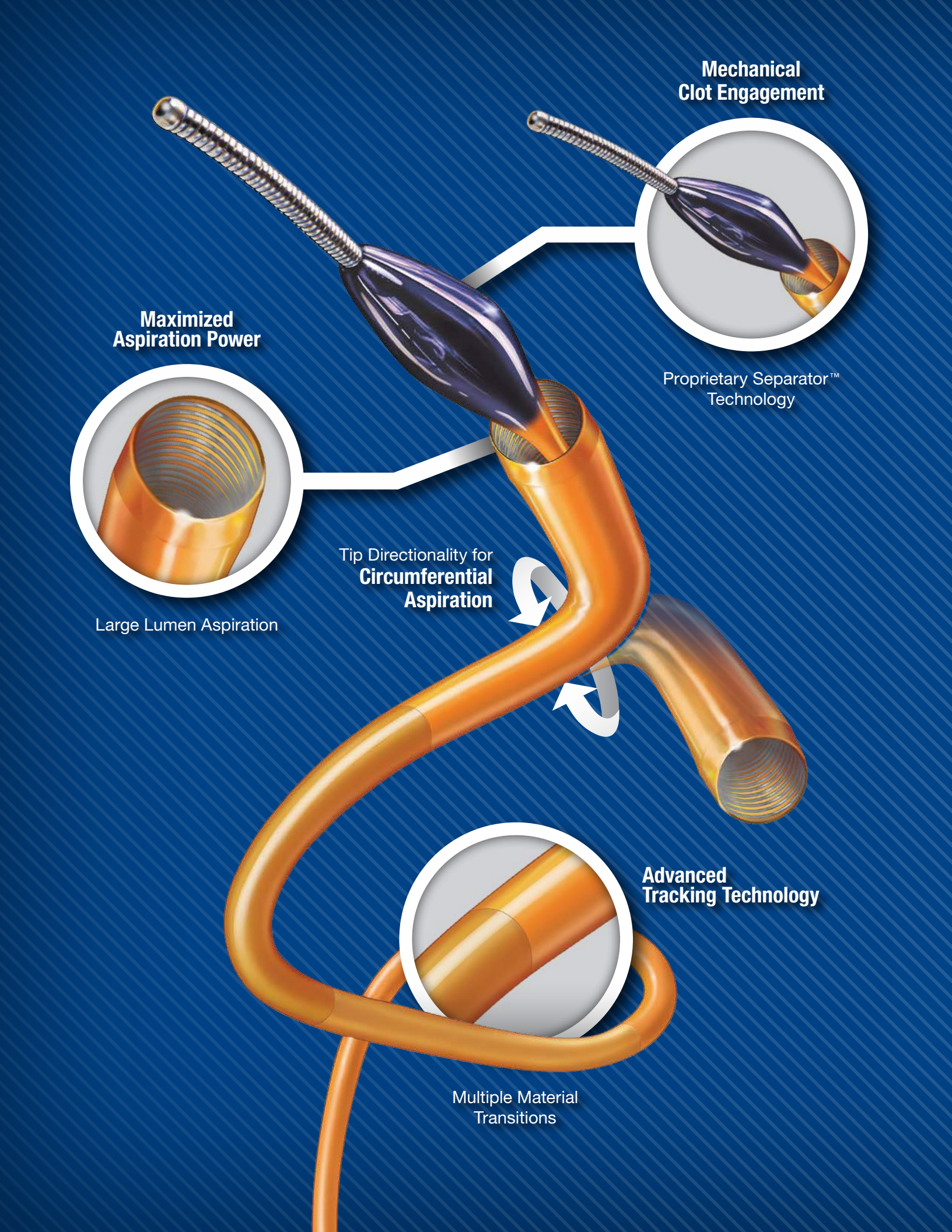
Tip Directionality for
**Circumferential
Aspiration**



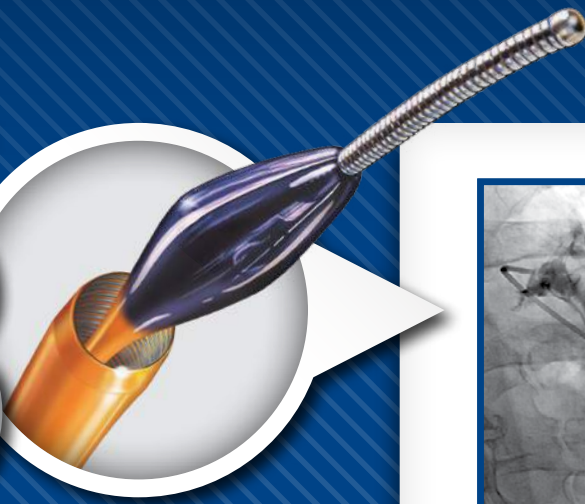
**Advanced
Tracking Technology**



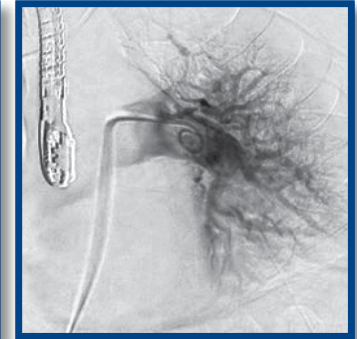
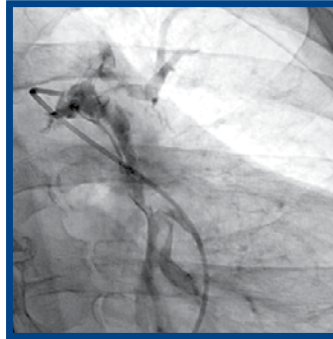
Multiple Material
Transitions



**CAT
8**



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



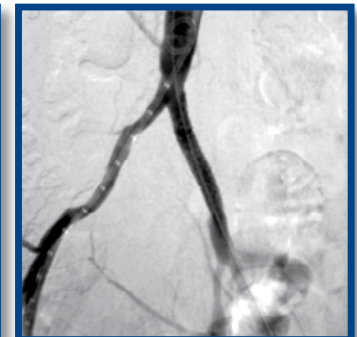
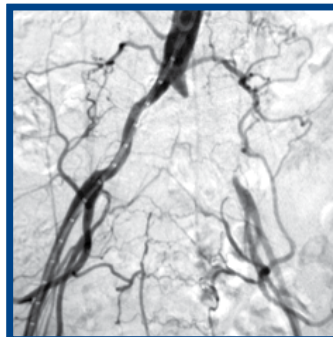
Extraction of Thrombus from Pulmonary Artery

Drs. Alex Powell & James Benenati, Miami Cardiac and Vascular Institute, FL

**CAT
6**



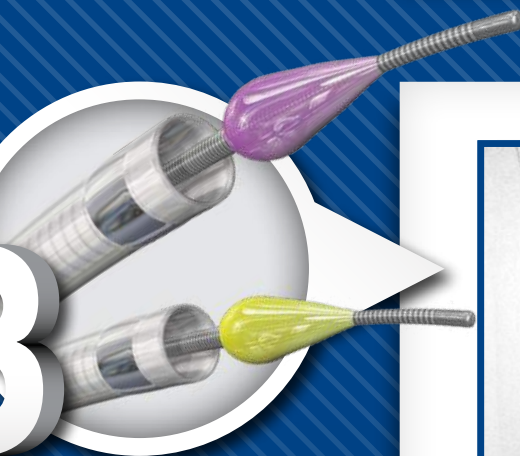
Arterial clot in larger arteries including SFA, popliteal and viscerals



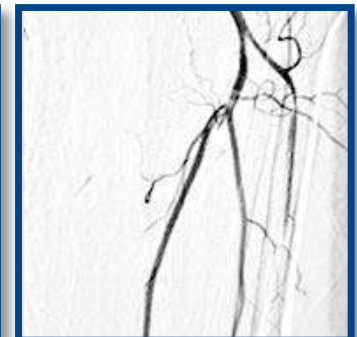
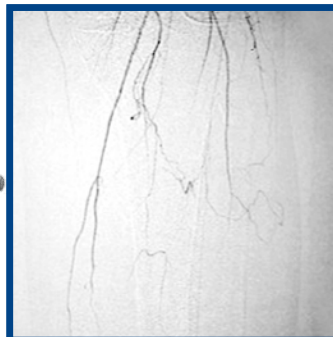
Extraction of Thrombus from Common Iliac Artery

Dr. Paul Perkowski, Baton Rouge General, LA

**CAT
5
&
3**

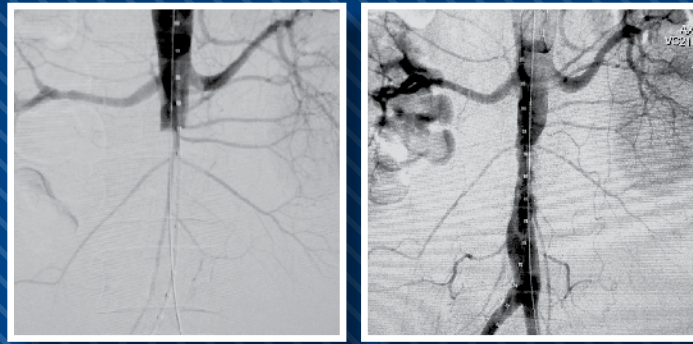


Smaller, distal reach for upper and lower arterial extremities cases



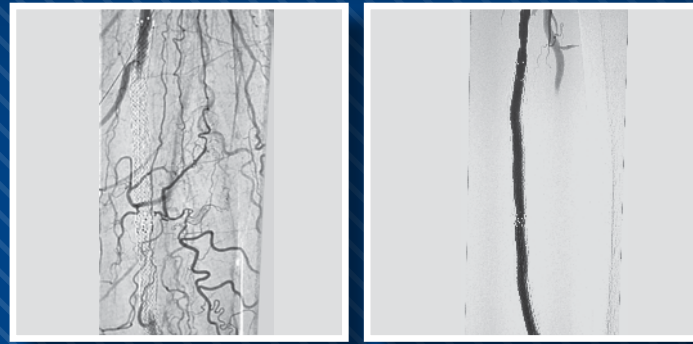
Recanalization of Trifurcation

Dr. Matthew Loe, St. Paul Radiology, MN



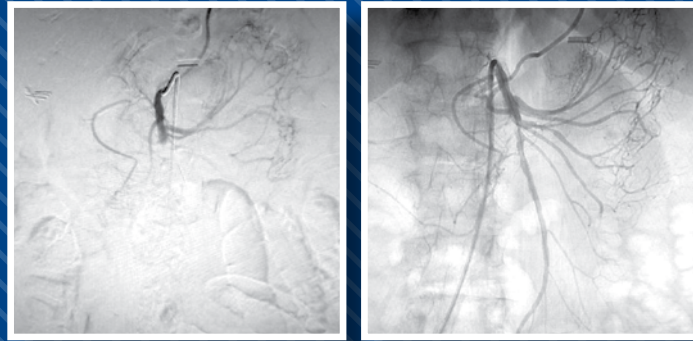
Recanalization of Occluded Aorta

Dr. Frank Arko, Sanger Heart and Vascular Institute, NC



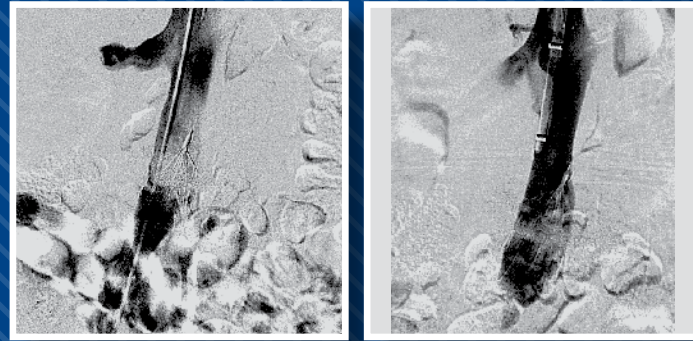
Recanalization of Thrombosed SFA Stent

Dr. George Adams, REX/UNC Healthcare, NC



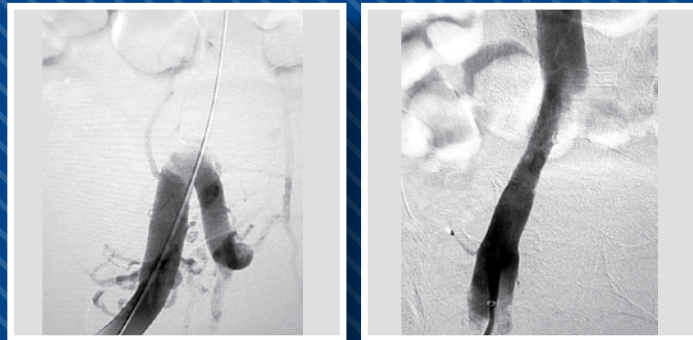
Removal of SMA Embolus

Drs. Rahul Patel & Robert Lookstein, Mount Sinai Hospital, NY



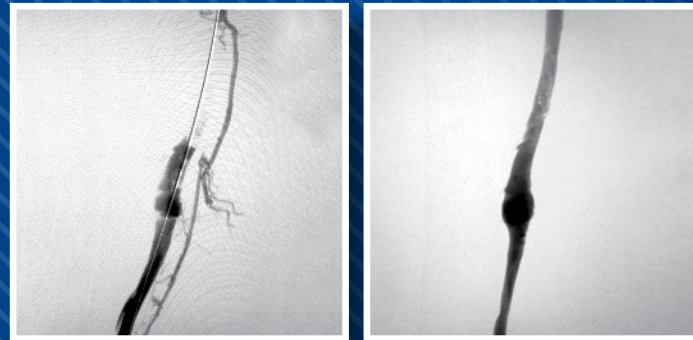
Extraction of Thrombus from IVC Filter

Dr. Jonathan Ha, Hunter Holmes McGuire Virginia Medical Center, VA



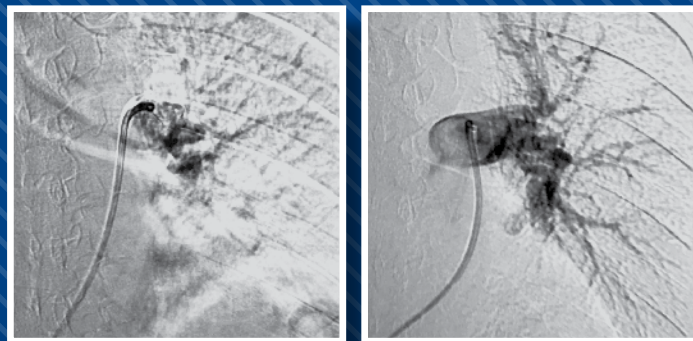
Extraction of Thrombus from Iliac Vein

Dr. Lawrence Whitney, Lakeland Regional Medical Center, FL



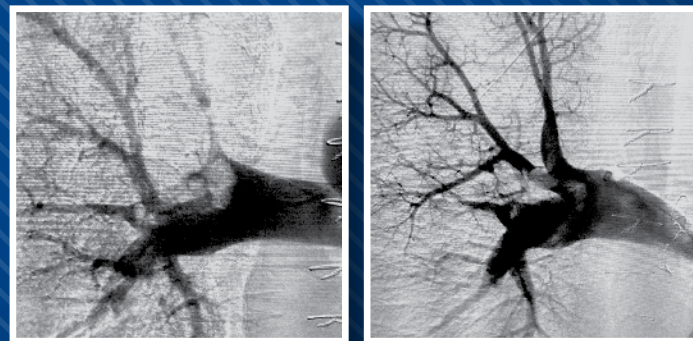
Extraction of Thrombus from Iliac Vein

Dr. Mahmood Razavi, St. Joseph Hospital, Orange, CA



Extraction of Thrombus from Pulmonary Artery

Dr. Ezell Askew, Jr., St. Joseph's Medical Center of Stockton, CA



Extraction of Thrombus from Pulmonary Artery

Dr. Paul Perkowski, Baton Rouge General, LA

Full Vacuum

Flow Rate
(cc/sec)

1.4^a

Manual
Aspiration
Catheters

2.0^b

Wall
Suction

3.25^b

Indigo[®]
System

Up to 90%
more suction
with Indigo

Continuous suction

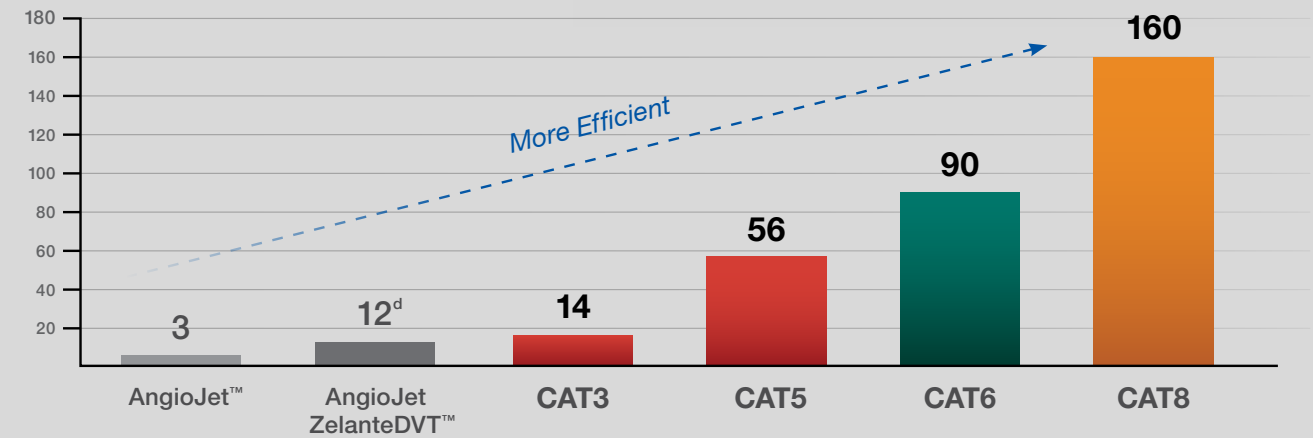
Simple setup with
hands-free aspiration

Maximized power

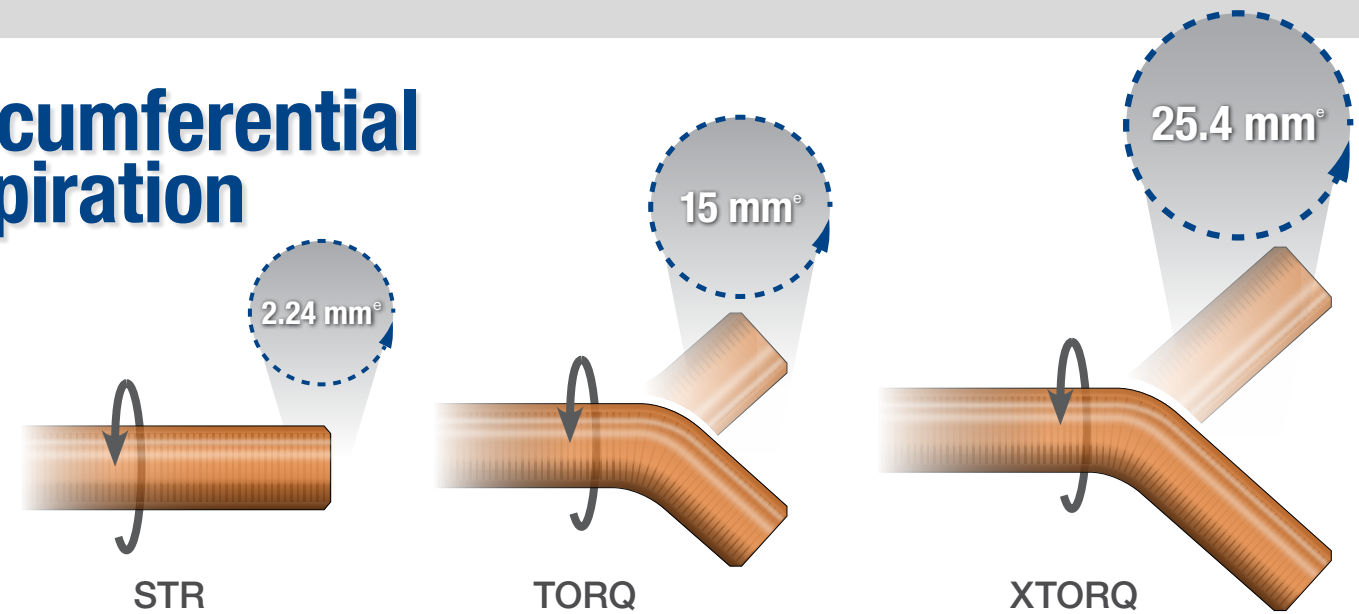


More Aspiration

Aspiration Volume (mL in 20 sec)^c



Circumferential Aspiration



a. Data on file at Penumbra, Inc.
c. Data on file at Penumbra, Inc.

b. Data on file at Penumbra, Inc. Based on testing with CAT5.
d. Data on file at Penumbra, Inc. e. Data on file at Penumbra, Inc.



Ordering Information

| Catalog Number | Description | Proximal OD | Distal OD | Length | Compatible Penumbra Devices |
|--------------------------|-------------------------------|-------------|-----------|----------------|-----------------------------|
| 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 | |
| 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 Pump MAX.

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 opened 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 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 neurovascular 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 micro-catheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Indigo Aspiration Catheter because it may damage the device.

Indigo 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 Penumbra Aspiration Systems.

Contraindications

There are no known contraindications.

Warnings/Precautions

- The canister/tubing is intended for single use only. Do not reuse. Reuse 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 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 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 service life of the pump. Use only water-base solvents for cleaning.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.



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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 the 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. Please contact your local Penumbra representative for more information.

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