Indigo System

Peripheral Mechanical Thrombectomy

Penumbra
Aspiration of Thrombus from Subclavian Artery
Dr. Frank Arko, Atrium Health, NC

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

Indigo® System Catheters

Power Aspiration with Indigo System

<table>
<thead>
<tr>
<th>Aspiration Volume (mL in 20 sec)*</th>
<th>CAT 3</th>
<th>CAT 5</th>
<th>CAT 6</th>
<th>CAT 8</th>
<th>CAT D</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>19</td>
<td>75</td>
<td>110</td>
<td>164</td>
<td>198</td>
</tr>
</tbody>
</table>

More Efficient

Benefits of Power Aspiration

- Atraumatic tracking
- No reported bradycardia or hypotension*
- No reported risk of hypotube overtorking*
- Can retrieve distal embol
- No reported hemolysis or renal failure*

* Based on complaint information. Data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

Aspiration of Thrombus from Subclavian Artery
Dr. Frank Arko, Atrium Health, NC

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

Indigo® System Catheters

CAT 8
Arterial and venous clot in larger vessels where circumferential aspiration is desired

CAT 6
Arterial clot in larger arteries including SFA, popliteal, and viscerals

CAT 5 & 3
Smaller, distal reach for upper and lower arterial extremities

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

Aspirate, Don’t Macerate

More Efficient

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Smaller, distal reach for upper and lower arterial extremities

CAT D
50 cm length for upper and lower arm AV fistula/graft thrombus aspiration
Patients: 579

The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT 8 is advanced through sheath over a wire.

The Indigo CAT 8 is placed just proximal to the face of the clot and wire is retracted. Aspiration is applied to Indigo CAT 8 via Pump MAX until CAT 8 becomes occluded (recommend waiting at least 90 seconds).

The Indigo CAT 8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

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

**PRISM Trial Results**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>79</td>
<td>5</td>
</tr>
</tbody>
</table>

**Above Knee/Popliteal**

Successful Revascularization: XTRACT with Indigo

**Below Knee**

Successful Revascularization: Post All Interventions

**Conclusion:** XTRACT Technique Used in PRISM Trial for Arterial Occlusions

**CAT8 Tip Shapes**

- STR
- TORQ
- XTORQ

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

**Data on file at Penumbra, Inc.**
CATD | Latest Indigo® Technology

Shorter Length, Greater Aspiration Power *

Up to 8F Arterial and Venous Indication

CATD for Fistula/Graft Thrombus Aspiration

Thrombus Aspirated with Indigo System
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

### Indigo Catheters

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
<th>Proximal OD</th>
<th>Distal OD</th>
<th>Length</th>
<th>Compatible Penumbra Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>CATD</td>
<td>Indigo D + Large Lumen Aspiration Tubing</td>
<td>8.0 F</td>
<td>8.0 F</td>
<td>50 cm</td>
<td>Separator** D</td>
</tr>
</tbody>
</table>

### CAT8XTORQ115
Indigo 8 XTorq Tip | 8.0 F | 8.0 F | 115 cm | Separator 8

### CAT8TQR85
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

<table>
<thead>
<tr>
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<th>Distal OD</th>
<th>Length</th>
<th>Compatible Penumbra Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEP3</td>
<td>Separator 3</td>
<td>n/a</td>
<td>.028*</td>
<td>190 cm</td>
<td>CAT3</td>
</tr>
</tbody>
</table>

### Accessories

<table>
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<th>Distal OD</th>
<th>Length</th>
<th>Compatible Penumbra Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMX110</td>
<td>Pump MAX™</td>
<td></td>
<td></td>
<td></td>
<td>MAX Canister</td>
</tr>
<tr>
<td>IAPS2</td>
<td>MAX Canister</td>
<td></td>
<td></td>
<td></td>
<td>Pump MAX</td>
</tr>
<tr>
<td>IST3</td>
<td>Large Lumen Aspiration Tubing</td>
<td></td>
<td></td>
<td></td>
<td>All Indigo Catheters</td>
</tr>
</tbody>
</table>

### 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 coronary 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. Unintended landing 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 sterilize 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.
- 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.
- Repositioning of the Indigo Aspiration Catheter is necessary during the recanalization 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; arterial or venous dissection; distal embolization; embolus; false aneurysm formation; hemotoma or hemangio 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; emergency 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 catheter/tubing is intended for single use only. Do not re-use. Reuse may result in catheter 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.
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- To prevent fire or shock hazard, use 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.