


# Indigo System



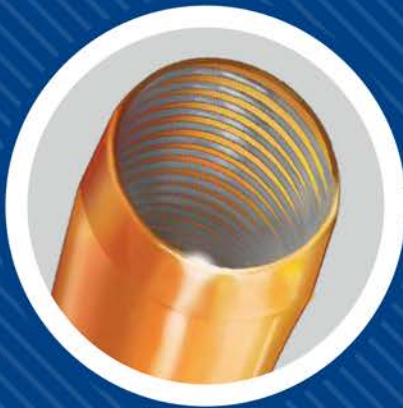
Penumbra 

**Mechanical  
Clot Engagement**



**Proprietary Separator  
Technology**

**Maximised  
Aspiration Power**

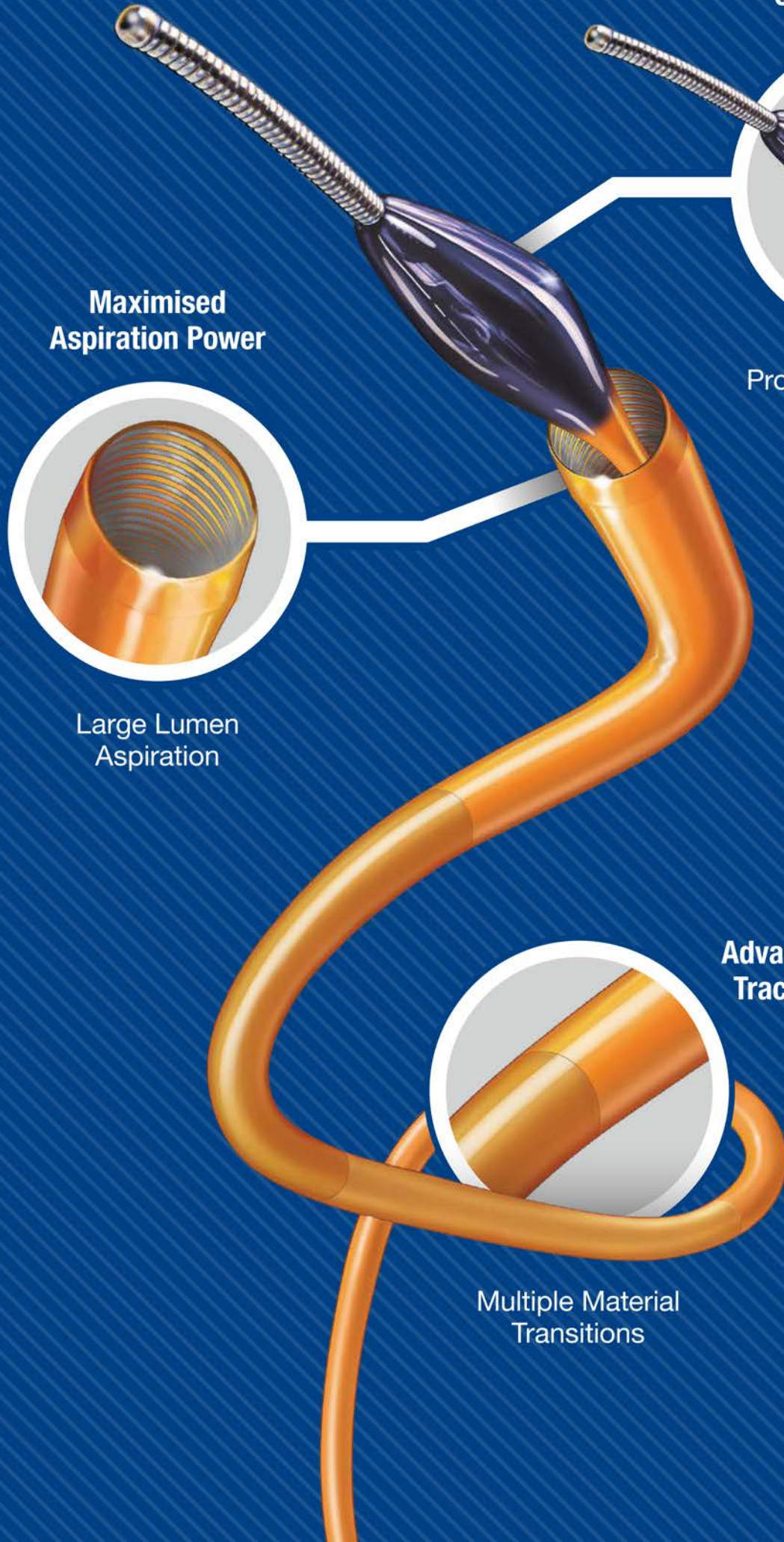


**Large Lumen  
Aspiration**

**Advanced  
Tracking Technology**



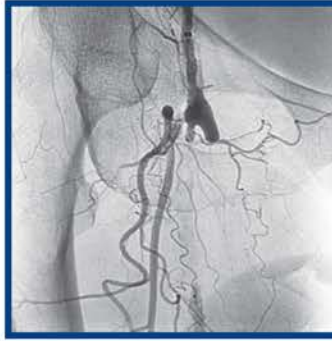
**Multiple Material  
Transitions**



**CAT  
8**



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



**Aspiration of Thrombus from Occluded Fem-Pop Graft**

Dr. Corey Teigen, Sanford Health, ND, USA

**CAT  
6**



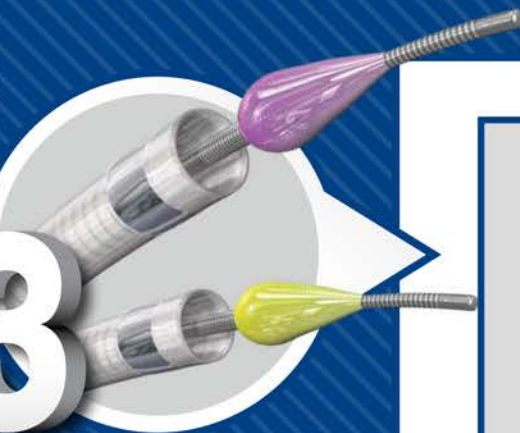
Arterial clot in larger arteries including SFA, popliteal and viscerals



**Aspiration of Thrombus from Popliteal Artery**

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

**CAT  
53  
& 3**

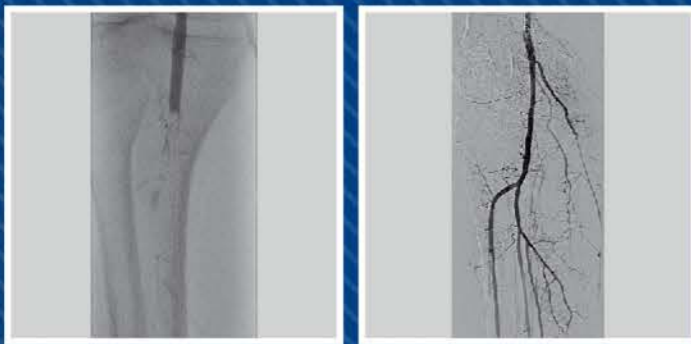


Smaller, distal reach for upper and lower arterial extremities cases



**Aspiration of Thrombus from Anterior Tibial**

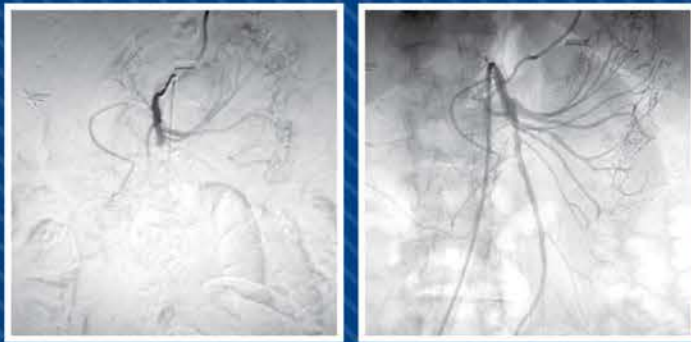
Dr. Florian Wolf, Allgemeines Krankenhaus der Stadt Wien, Vienna, Austria



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



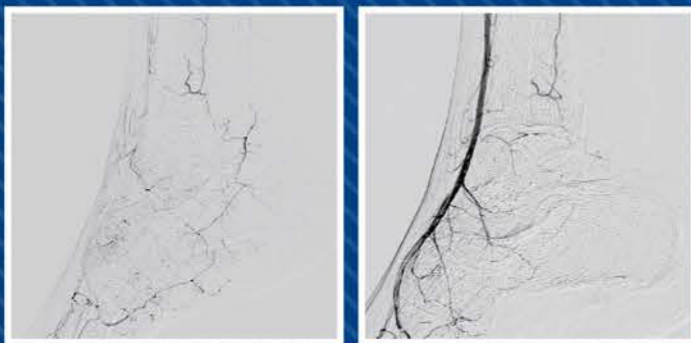
**Aspiration of Thrombus from SFA Stent**  
Dr. George Adams, REX/UNC Healthcare, NC, USA



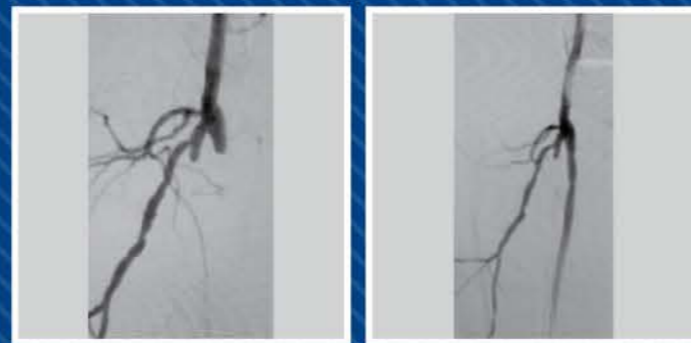
**Aspiration of SMA Embolus**  
Drs. Rahul Patel & Robert Lookstein, Mount Sinai Hospital, NY, USA



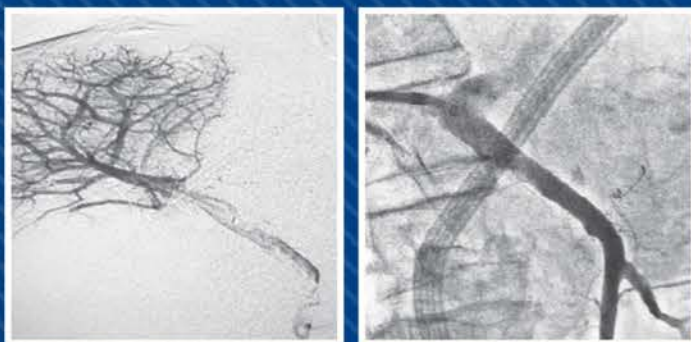
**Renal Artery Occlusion Post Chimney Endograft**  
Dr. Theodosios Bisdas, St. Franziskus-Hospital, Münster, Germany



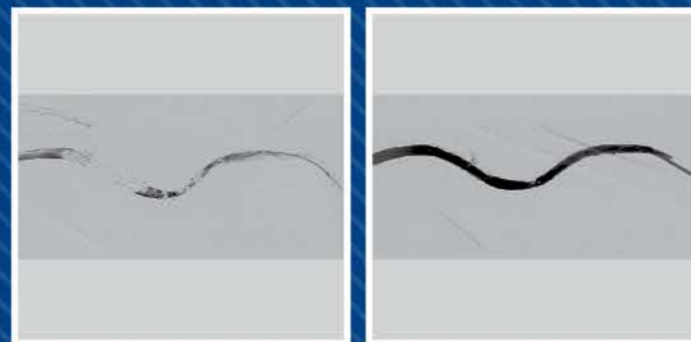
**Aspiration of Thrombus from Anterior Tibial**  
Dr. Maria Antonella Ruffino, Città della Salute e della Scienza di Torino, Italy



**Aspiration of Thrombus from Femoral-Popliteal**  
Dr. Timothy Yates, Mount Sinai Medical Center, FL, USA

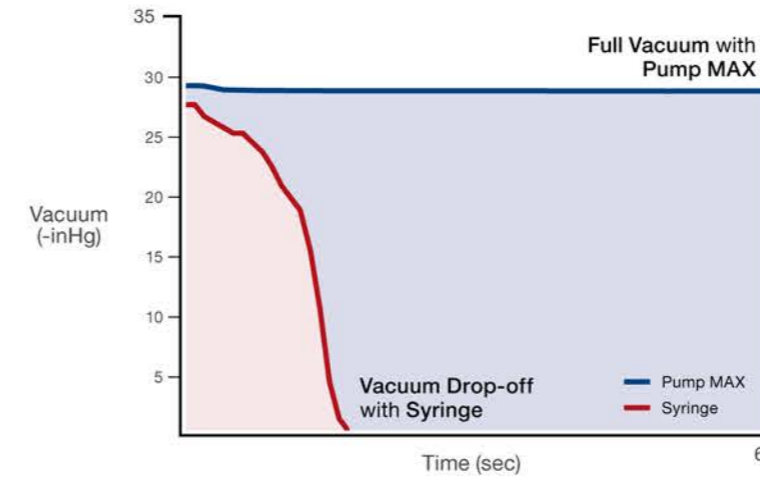


**Aspiration of Thrombus from Portal Vein**  
Dr. Rafik Lababidi, Largo Medical Center, FL, USA

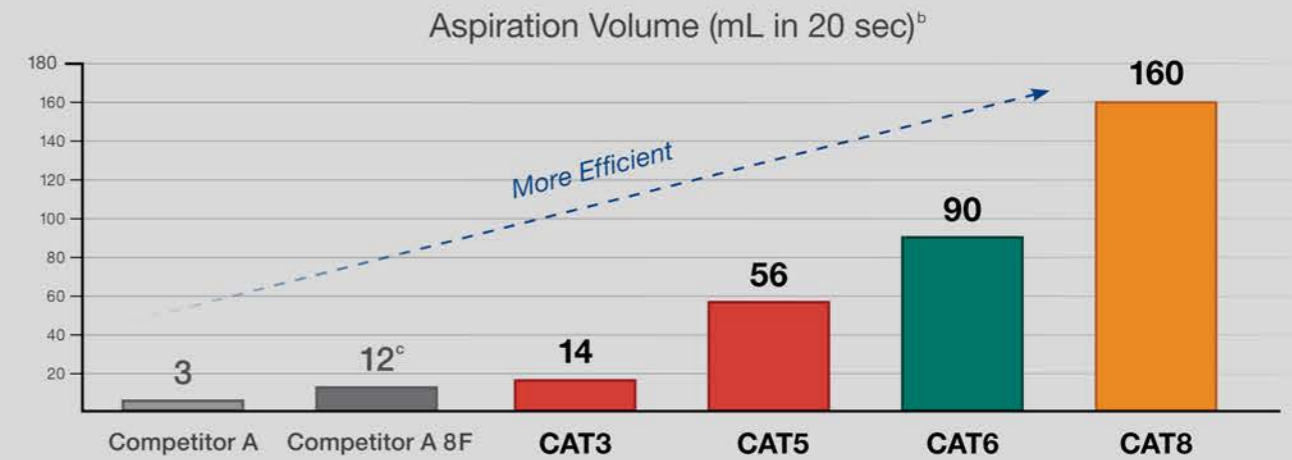


**Aspiration of Thrombus from Hemodialysis Access Graft**  
Drs. Yann Le Bras & François Petitpierre, Groupe Hospitalier Pellegrin, Bordeaux-Cedex, France

## Full Vacuum<sup>a</sup>



## Power Aspiration



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

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

a, b, c. Tests performed and data on file at Penumbra, Inc.  
Bench test results may not be indicative of clinical performance.  
d. Based on clinical data and complaint information. Data on file at Penumbra, Inc.



# Ordering Information

Catalog Number	Description	Proximal OD	Distal OD	Length	Compatible Penumbra Devices
<b>Indigo Catheters</b>				Working	
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
<b>Indigo Separators</b>				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
<b>Accessories</b>					
PMX110	Pump MAX 110V				MAX Canister
PMX220	Pump MAX 220V				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.



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Product availability varies by country. 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.