



AGENȚIA MEDICAMENTULUI  
ȘI DISPOZITIVELOR MEDICALE

## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
1.2. Declarația de conformitate CE	Declarație de conformitate CE
1.3. Certificatul CE	Certificat CE

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			separator 8			penumbra				
DM000359383	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	SEPARATOR 8, 150CM	SEP8	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000226266	CATETER DE ASPIRAȚIE	INDIGO™	Separator 8, 150cm	39692	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226267	CATETER DE ASPIRAȚIE	INDIGO™	Separator 8, 90cm	SEPD	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	

✓ Coarexort('Producatorul','penumbra') И Coarexort('Model','separator 8')



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Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal	
			separator 3			penumbra					
DM000360526	CATETER DE ASPIRAȚIE PENTRU TROMBECTOMIE	PENUMBRA SYSTEM	SEPARATOR 3D	PSS3D	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022		
DM000359377	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	SEPARATOR 3, 190CM	SEP3	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022		
DM000360525	CATETER DE ASPIRAȚIE PENTRU TROMBECTOMIE	PENUMBRA SYSTEM	SEPARATOR 3MAX	3MAXS	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022		
DM000226644	CATETER DE ASPIRAȚIE	Penumbra System®	Separator 3MAX	3MAXS	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019		
DM000226257	CATETER DE ASPIRAȚIE	INDIGO™	Separator 3	37865	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019		
DM000226645	CATETER DE ASPIRAȚIE	Penumbra System®	Separator 3D	PSS3D	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019		
DM000226258	CATETER DE ASPIRAȚIE	INDIGO™	Separator 3S	SEP3S	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019		
DM000226264	CATETER DE ASPIRAȚIE	INDIGO™	Separator 3MAX	SEP3MAX	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019		
✓ Coșul de gună([Producatorul], 'penumbra') și Coșul de gună([Model], 'separator 3')											



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Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			separator 6			penumbra				
DM000359379	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	SEPARATOR 6, 175CM	SEP6	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000226265	CATETER DE ASPIRAȚIE	INDIGO™	Separator 6	38961	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
✓ <code>Coapozitiv('Producatorul','penumbra') И Coapozitiv('Model','separator 6')</code> <a href="#">Очистить</a>										

A detailed 3D rendering of a medical catheter, the Indigo System, against a blue background with a fine grid pattern. The catheter has a long, flexible orange shaft that curves across the frame. At the distal end, there is a dark purple, bulbous dilation catheter (DC) with a braided metal wire extending from its tip. The text "Indigo System" is prominently displayed in large, white, 3D block letters, with the orange catheter shaft passing through the letter "I".

# Indigo System

Peripheral Mechanical Thrombectomy

Penumbra 



# Indigo System Catheters



CAT  
8

Arterial, venous, and pulmonary  
clot in larger vessels where cir-  
cumferential 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



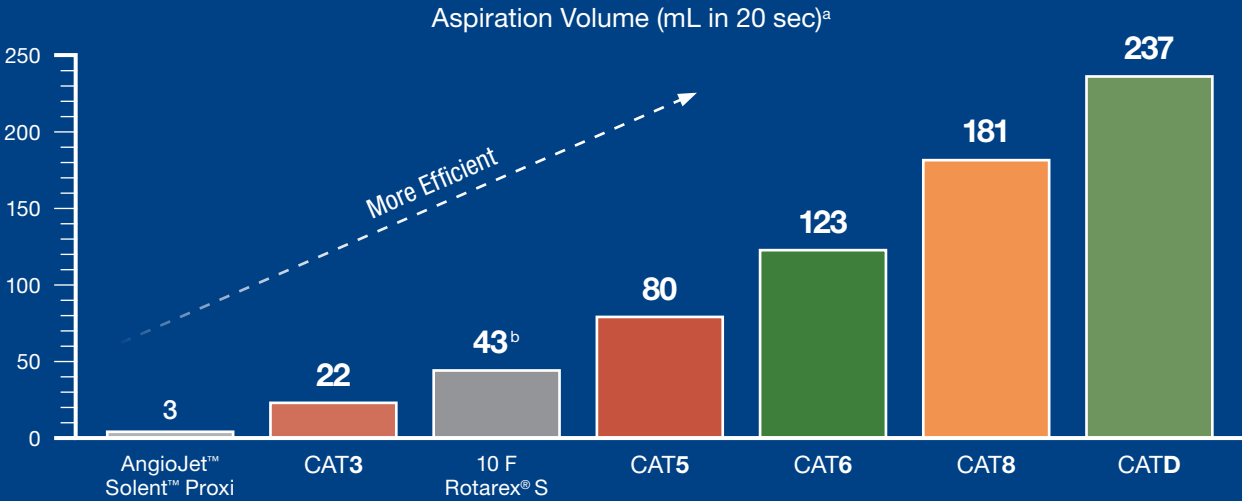
CAT  
D

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

## Aspirate, Don't Macerate

## Get the Clot Out with Indigo System

### Power Aspiration with Indigo System



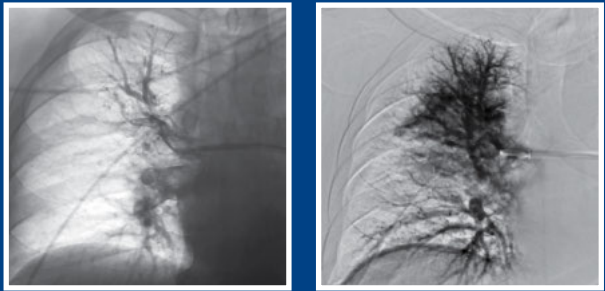
a. AngioJet setup tested with its own accessories and aspiration source per its Instructions for Use. Data for AngioJet Solent Proxi was collected in 2015.  
Indigo System setup tested with its own accessories and aspiration source per its Instructions for Use. Tests performed using water.  
b. Aspiration volume for Rotarex S Catheter was acquired from Rotarex S Catheter Instructions for Use. On file at Penumbra, Inc.

Benefits of Mechanical Power Aspiration

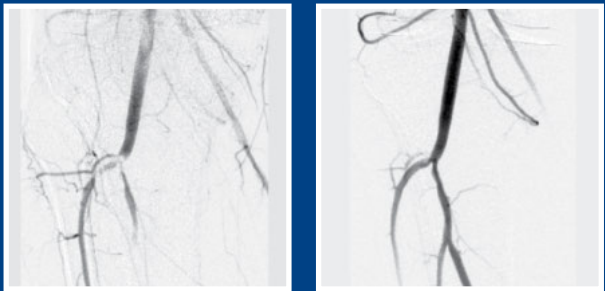
• Atraumatic tracking  
• No reported bradycardia or hypotension<sup>c</sup>

• No reported haemolysis or renal failure<sup>c</sup>  
• Can be used to retrieve distal emboli

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



Removal of Thrombus from Pulmonary  
Dr. Juan José Ciampi-Dopazo, Complejo Hospitalario de Toledo, Toledo, Spain



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





# Indigo System Features

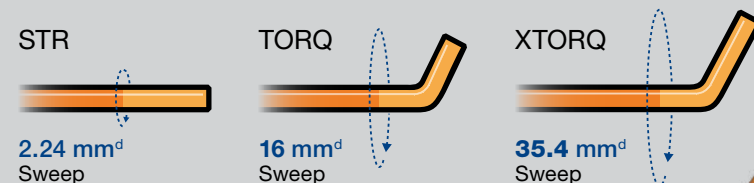
**1 Mechanical Clot Engagement**  
Proprietary Separator Technology

**2 Maximised Aspiration Power**  
Large Lumen Aspiration

**3 Advanced Tracking Technology**  
Multiple Material Transitions

**4 Tip Directionality for Circumferential Aspiration**

## CAT8 Tip Shapes



## Powered by Penumbra ENGINE

One Touch for Maximum Aspiration  
Powerful, Deep Vacuum

-29 inHg<sup>e</sup>

Live Feedback During Procedure  
Integrated Clot Catcher



Dr. Rajneesh Agrawal,  
Desert Radiology, NV, USA



Easy Setup  
Sleek, Simple Design

<sup>d</sup>. Measurement calculated using tip angle and length.  
<sup>e</sup>. Tests performed and data on file at Penumbra, Inc.  
Bench test results may not be indicative of clinical performance.

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

**79** Patients

**5** Centers

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

Above Knee/Popliteal

77.3%

Below Knee

22.8%

Successful Revascularisation  
**XTRACT with Indigo**

87.2%

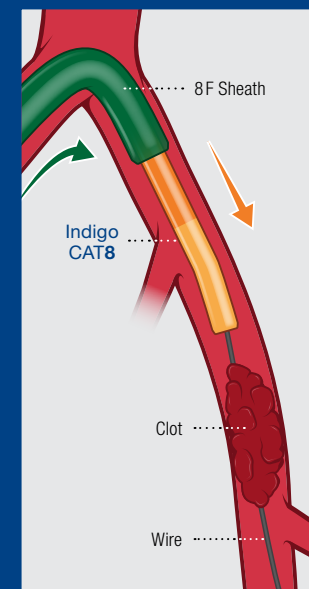
Successful Revascularisation  
**Post All Interventions**

96.2%

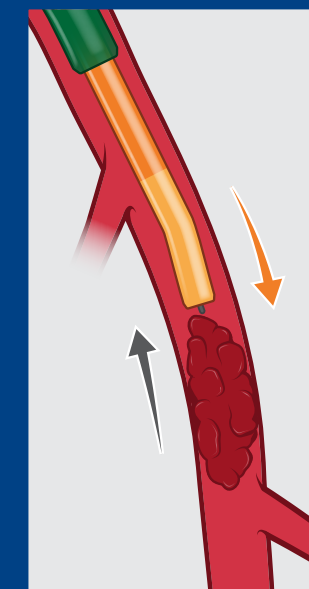
Successful Revascularisation was defined as TIMI 2-3 flow

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

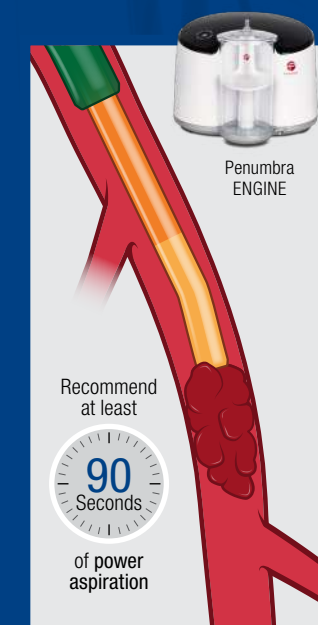
## XTRACT Technique Used in PRISM Trial for Arterial Occlusions



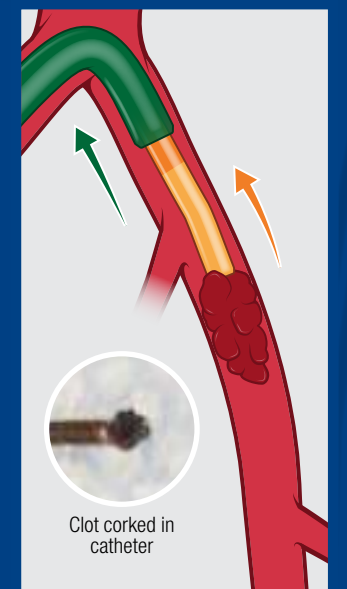
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.



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



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

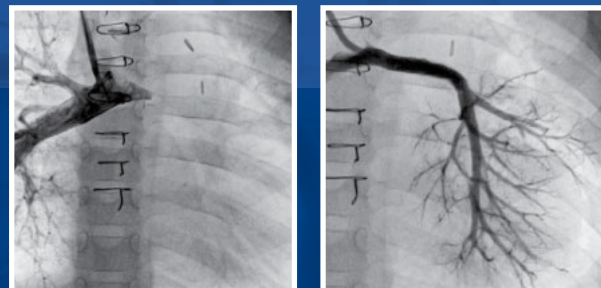


The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

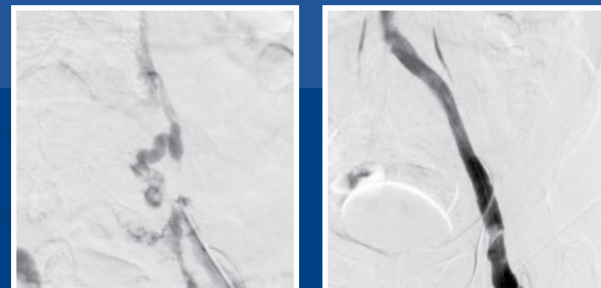
<sup>f</sup>. Saxon RR, Benenati JF, Teigen C, Adams GL, Sewall LE; PRISM Trialists. Utility of a Power Aspiration-Based Extraction Technique as an Initial and Secondary Approach in the Treatment of Peripheral Arterial Thromboembolism: Results of the Multicenter PRISM Trial. *J Vasc Interv Radio*. 2018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

The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes. Renderings for illustrative purposes only. Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment.

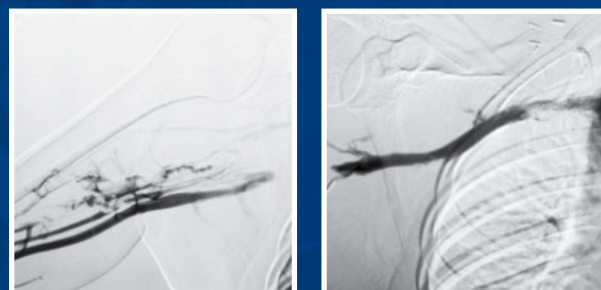




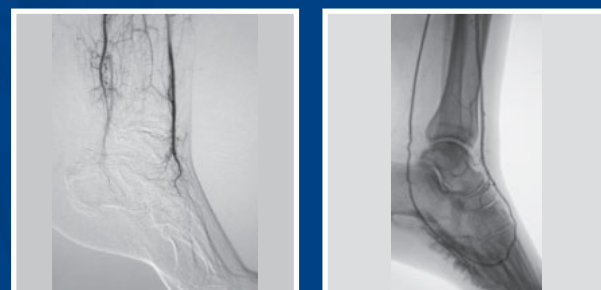
**Removal of Thrombus from Pulmonary**  
Drs. Sergio Berti, Cataldo Palmieri, and Isabella Spadoni,  
Fondazione Toscana Gabriele Monasterio, Ospedale del Cuore, Italy



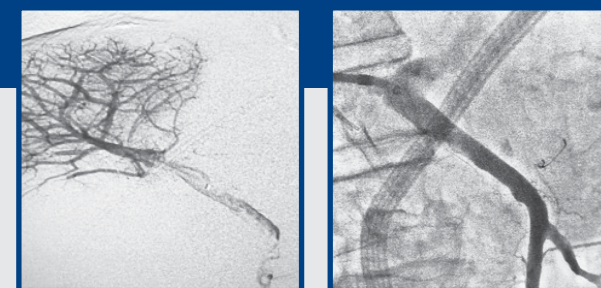
**Removal of Thrombus from Iliac & Femoral Vein**  
Dr. Michael Lichtenberg, Klinikum Arnsberg, Arnsberg, Germany



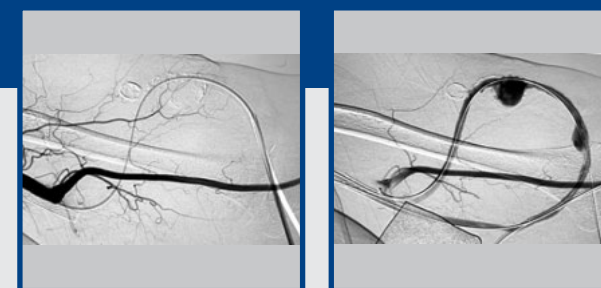
**Removal of Thrombus from Subclavian Vein**  
Dr. Frank Arko, Atrium Health, NC, USA



**Removal of Thrombus from BTA**  
Dr. Gianmarco de Donato, University of Siena, Siena, Italy



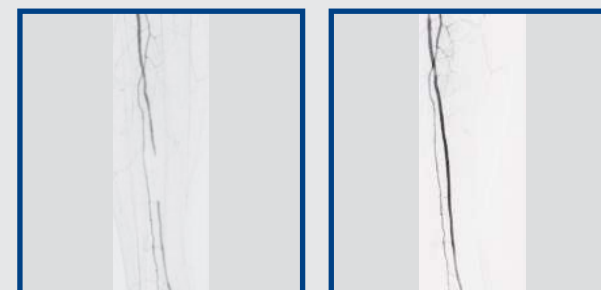
**Removal of Thrombus from Portal Vein**  
Dr. Rafik Lababidi, Largo Medical Center, FL, USA



**Removal of Thrombus from AV Fistula**  
Dr. Venkatpavel Tummala, Lakeland Regional Medical Center, FL, USA

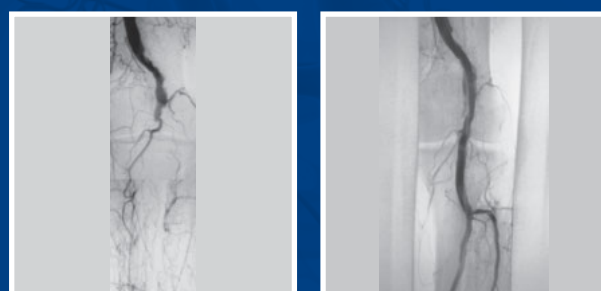


**Removal of SFA Chronic Total Occlusion**  
Dr. Branavan Umakanthan, Nevada Heart and Vascular Center, NV, USA



**Removal of Thrombus from Anterior Tibial**  
Dr. Florian Wolf, Allgemeines Krankenhaus der Stadt Wien, Vienna, Austria

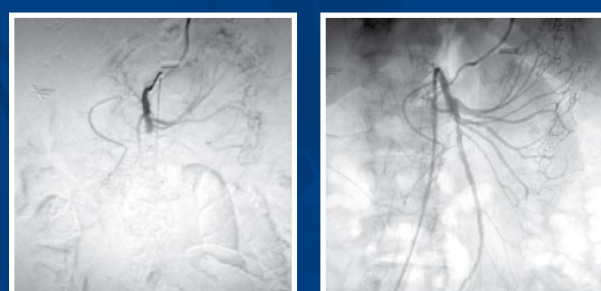
## Up to 8F Arterial, Venous, and Pulmonary Indication



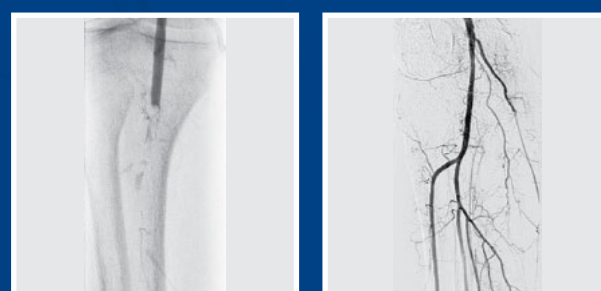
**Removal of Thrombus from Popliteal Artery**  
Dr. Theodosios Bisdas, Athens Medical Center, Athens, Greece



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



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



**Removal of Thrombus from Popliteal Artery**  
Dr. Maria Antonella Ruffino, Città della Salute e della Scienza di Torino, Torino, Italy

## Indigo System Powered by Penumbra ENGINE

### Indigo System Setup

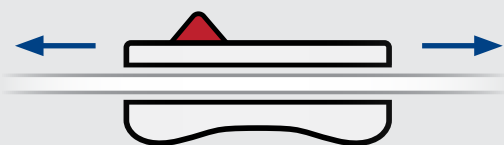
- Press down firmly to secure Penumbra ENGINE Canister
- Set Dynamic Flow Switch to **OFF**
- Attach aspiration tubing to Canister
- Power **ON** Penumbra ENGINE; 4 LEDs illuminate, indicating powerful, deep vacuum
- Attach Indigo System Aspiration Catheter to aspiration tubing



# Indigo System

## Now Packaged with Dynamic Tubing

### Ability to Slide Flow Switch



### 64% Larger Flow Switch ID<sup>g</sup>



Large Lumen  
Flow Switch



Dynamic Flow Switch

<sup>g</sup>. Compared to previous Flow Switch. Data on file at Penumbra, Inc.  
Flow Switch comparison images shown at same scale.

### Indigo Catheter Kits

Catalog Number	Description	Proximal OD	Distal OD	Compatibility (Sheath or Guide)	Working Length (cm)	Wire Platform (in.) (mm)	Compatible Penumbra Devices
<b>CAT8XTORQ115KIT – Now!</b>	Indigo 8 XTORQ Tip + Dynamic Aspiration Tubing	8 F (2.67 mm)	8 F (2.67 mm)	8 F (2.67 mm) Sheath	115	.014–.038 (.36–.97)	Separator 8
<b>CAT8TORQ85KIT – Now!</b>	Indigo 8 TORQ Tip + Dynamic Aspiration Tubing	8 F (2.67 mm)	8 F (2.67 mm)	8 F (2.67 mm) Sheath	85	.014–.038 (.36–.97)	Separator 8
<b>CAT8STR85KIT – Now!</b>	Indigo 8 Straight Tip + Dynamic Aspiration Tubing	8 F (2.67 mm)	8 F (2.67 mm)	8 F (2.67 mm) Sheath	85	.014–.038 (.36–.97)	Separator 8
<b>CAT6KIT – Now!</b>	Indigo 6 + Dynamic Aspiration Tubing	6 F (2.00 mm)	6 F (2.00 mm)	6 F (2.00 mm) Sheath	135	.014–.038 (.36–.97)	Separator 6
<b>CAT5KIT – Now!</b>	Indigo 5 + Dynamic Aspiration Tubing	6 F (2.00 mm)	5 F (1.65 mm)	6 F (2.00 mm) Sheath	132	.014–.038 (.36–.97)	Separator 5
<b>CAT3KIT – Now!</b>	Indigo 3 + Dynamic Aspiration Tubing	4.1 F (1.37 mm)	3.4 F (1.14 mm)	5 F (1.65 mm) Sheath	150	.014–.025 (.36–.64)	Separator 3
<b>CATD – Now!</b>	Indigo D + Dynamic Aspiration Tubing	8 F (2.67 mm)	8 F (2.67 mm)	8 F (2.67 mm) Sheath	50	.014–.038 (.36–.97)	Separator D

### Indigo Separators

Catalog Number	Description	Distal OD (in.) (mm)	Total Length (cm)	Compatible Penumbra Devices
<b>SEP8</b>	Separator 8	.072 (1.83)	150	CAT8
<b>SEP6</b>	Separator 6	.055 (1.40)	175	CAT6
<b>SEP5</b>	Separator 5	.045 (1.14)	175	CAT5
<b>SEP3</b>	Separator 3	.028 (.71)	190	CAT3
<b>SEPD</b>	Separator D	.072 (1.83)	90	CATD

### Accessories

Catalog Number	Description	Compatible Penumbra Devices
<b>PMXENG – Now!</b>	Penumbra ENGINE	Penumbra ENGINE Canister
<b>IAPS3 – Now!</b>	Penumbra ENGINE Canister	Penumbra ENGINE

Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use.

#### INDIGO Aspiration System – Intended Use

The INDIGO Aspiration System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems and certain central circulatory system conditions such as pulmonary emboli using continuous aspiration.

#### 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 ENGINE – Intended Use

The PENUMBRA ENGINE is intended as a vacuum source for Penumbra Aspiration Systems.



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info@penumbrainc.com

Product availability varies by country. Images used with permission. Consents on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive for all patients. Renderings for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes. Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment. Photographs taken by and on file at Penumbra, Inc. Please contact your local Penumbra representative for more information.

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18533, Rev. A 06/20 EU