



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE QSA 252.711
I.3. Certificatul CE	Certificat CE DE 252.962
I.3. Certificatul CE	Certificat CE QSA 252.761
I.3. Certificatul CE	Certificat CE QSA 252.934
I.3. Certificatul CE	Certificat CE QSA 252.885
I.3. Certificatul CE	Certificat CE TDA MDR 739880 R000
I.3. Certificatul CE	Certificat CE DE 252.969
I.3. Certificatul CE	Certificat CE QSA 252.807
I.3. Certificatul CE	Certificat CE QSA 252.949
I.3. Certificatul CE	Certificat CE QSA 252.901

Страница 1 из 3 (Всего элементов: 24)

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000359344	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 80CM	CAT6MP80	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359407	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 30CM - KIT	CAT6MP30KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359327	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, STRAIGHT, 50CM	CAT6STR50	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359406	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, STRAIGHT, 135CM - KIT	CAT6KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359341	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 50CM	CAT6MP50	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359334	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, STRAIGHT, 115CM	CAT6STR115	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359345	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 90CM	CAT6MP90	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359342	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 60CM	CAT6MP60	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359326	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, STRAIGHT, 40CM	CAT6STR40	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359411	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 6, MP, 70CM - KIT	CAT6MP70KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	

Словослит(Nr_catalog, 'CAT6')



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000359319	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 3, STRAIGHT, 150CM 081454801INDCAT5M	CAT3	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359387	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 3, STRAIGHT, 150CM - KIT 081454801INDKIT7M	CAT3KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000226286	CATETER DE ASPIRAȚIE	INDIGO™	3MAX - KIT	CAT3MAXKIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226172	CATETER DE ASPIRAȚIE	INDIGO™	3MAX	CAT3MAX	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226279	CATETER DE ASPIRAȚIE	INDIGO™	3 - KIT	CAT3KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226165	CATETER DE ASPIRAȚIE	INDIGO™		CAT3	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	

✓ [Code export\({Nr_catalog},_CAT3\)](#) Oprește



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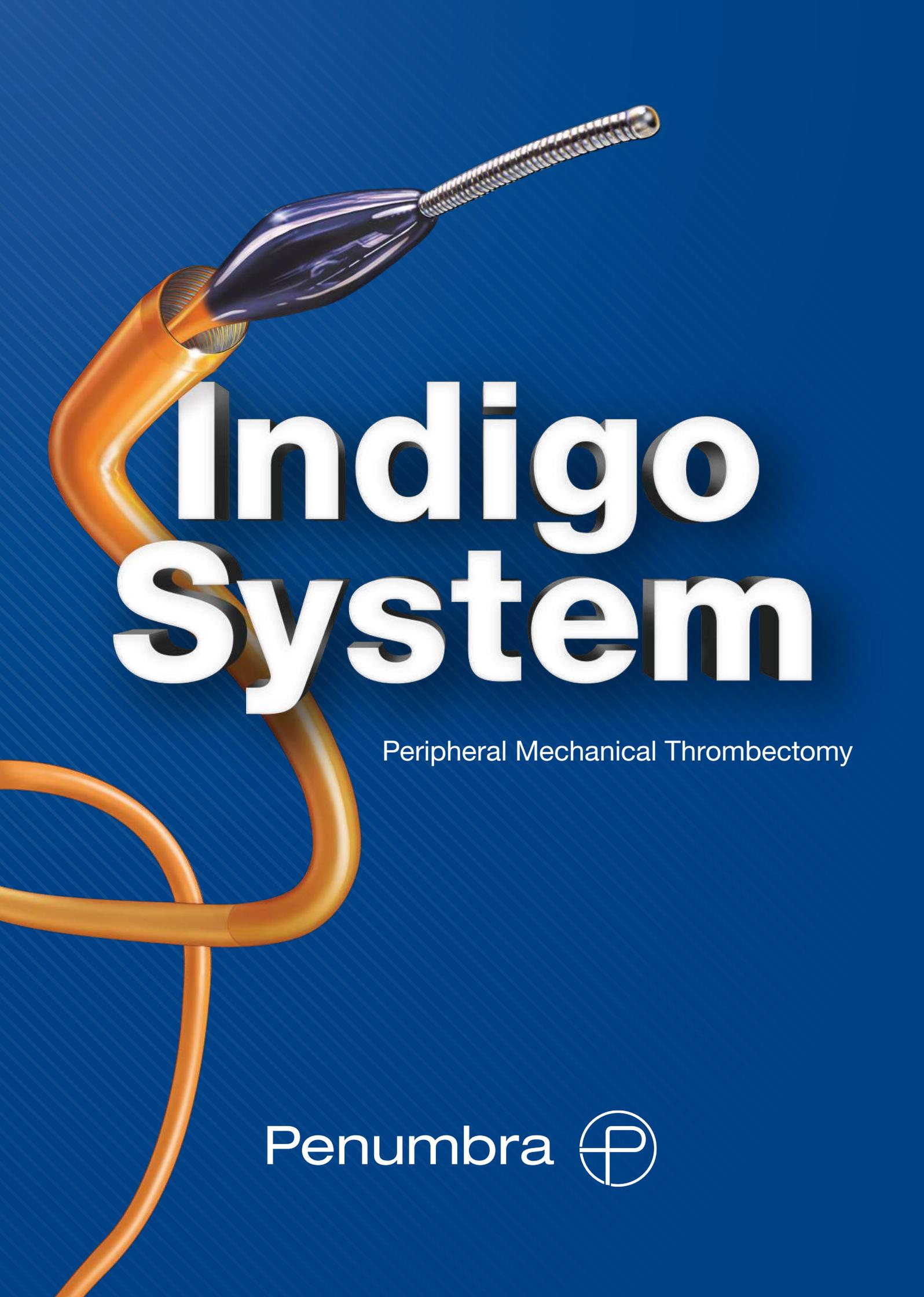
Страница 1 из 3 (Всего элементов: 24)

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				CAT8						
DM000359442	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, TORQ, 30CM - KIT	CAT8TORQ30KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359439	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, STRAIGHT, 100CM - KIT	CAT8STR100KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359376	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, XTORQ, 115CM	CAT8XTORQ115	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359448	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, TORQ, 85CM - KIT	CAT8TORQ85KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359432	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, STRAIGHT, 50CM - KIT	CAT8STR50KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359372	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, TORQ, 95CM	CAT8TORQ95	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359444	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, TORQ, 50CM - KIT	CAT8TORQ50KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359430	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, STRAIGHT, 30CM - KIT	CAT8STR30KIT	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359358	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, STRAIGHT, 80CM	CAT8STR80	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359357	SISTEM DE ASPIRAȚIE	INDIGO™ SYSTEM	ASPIRATION CATHETER 8, STRAIGHT, 70CM	CAT8STR70	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	

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☑ `Сортировка(Nr. catalog), 'CAT8'`



Indigo System

Peripheral Mechanical Thrombectomy

Penumbra 

Indigo System Catheters



CAT
8

Arterial, venous, and pulmonary 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

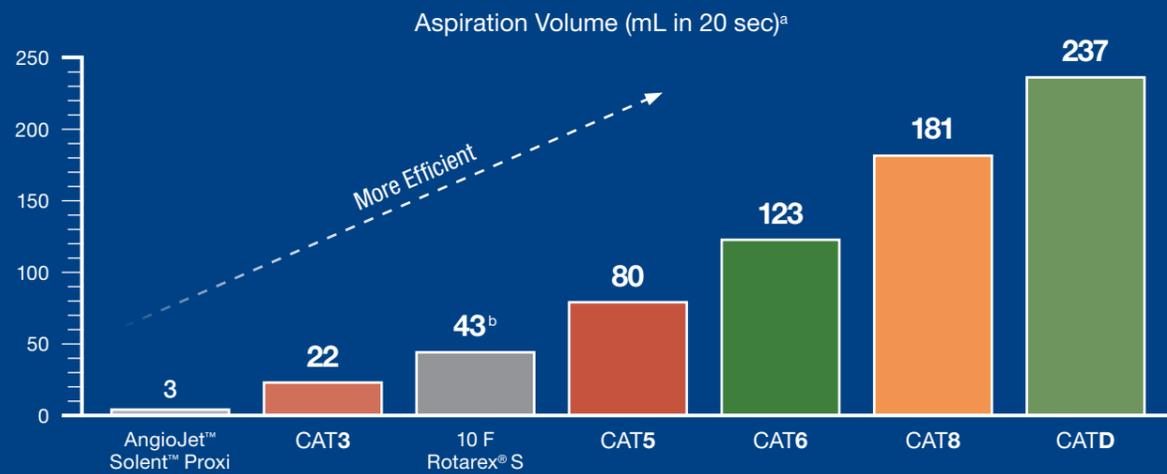


CAT
D

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

Aspirate, Don't Macerate

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.

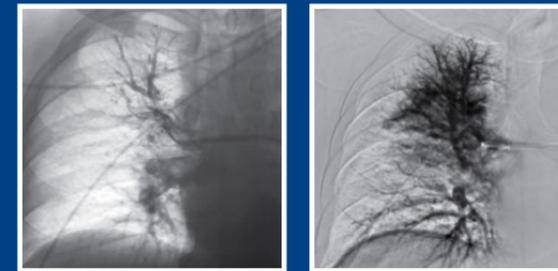
Benefits of Mechanical Power Aspiration

- Atraumatic tracking
- No reported haemolysis or renal failure^c
- No reported bradycardia or hypotension^c
- Can be used to retrieve distal emboli

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

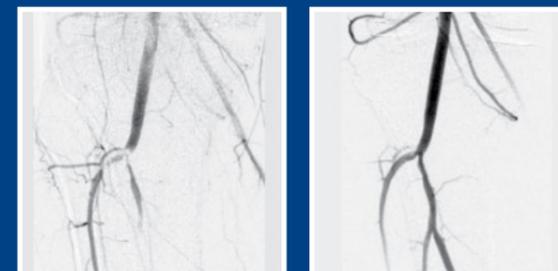
Indigo System Catheters

Get the Clot Out with Indigo System



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



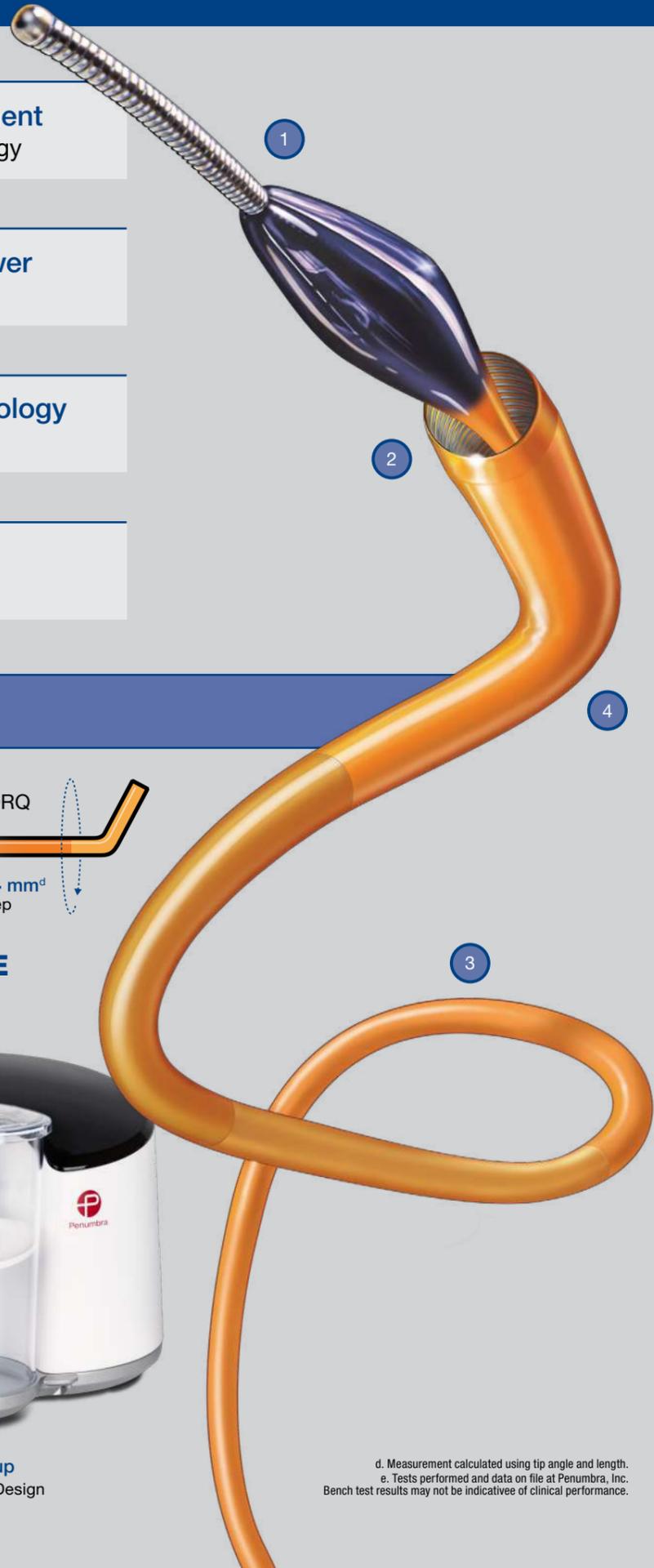
Indigo System Features

1 Mechanical Clot Engagement
Proprietary Separator Technology

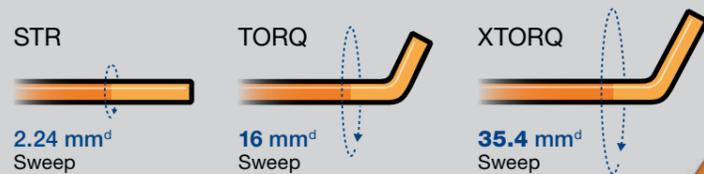
2 Maximised Aspiration Power
Large Lumen Aspiration

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^e

Live Feedback During Procedure
Integrated Clot Catcher



Dr. Rajneesh Agrawal,
Desert Radiology, NV, USA



Easy Setup
Sleek, Simple Design

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

PRISM Trial Results^f

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



Below Knee



Successful Revascularisation
XTRACT with Indigo



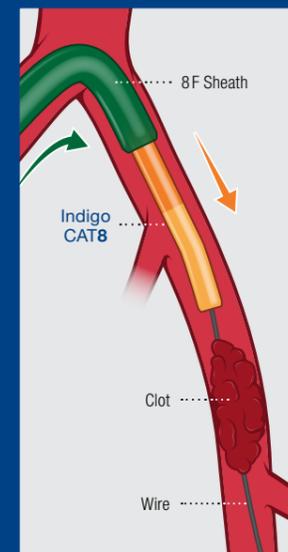
Successful Revascularisation
Post All Interventions



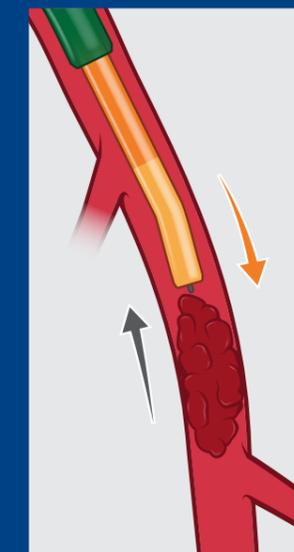
Successful Revascularisation was defined as TIMI 2–3 flow

Conclusion: XTRACT Technique with Indigo System is Safe and Effective

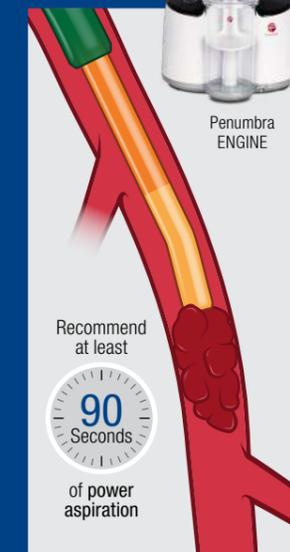
XTRACT Technique Used in PRISM Trial for Arterial Occlusions



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.



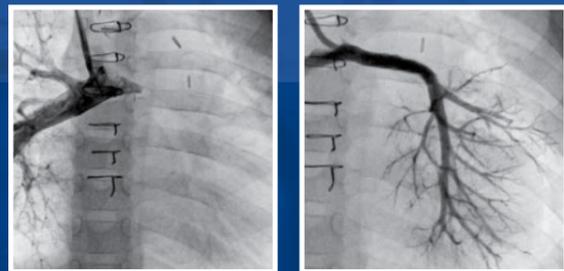
Aspiration is applied to Indigo CAT8 via Penumbra ENGINE until CAT8 becomes occluded (*recommend waiting at least 90 seconds*).



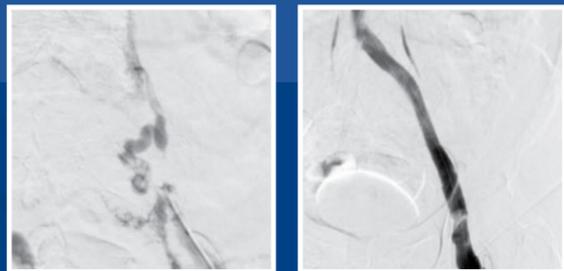
The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

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

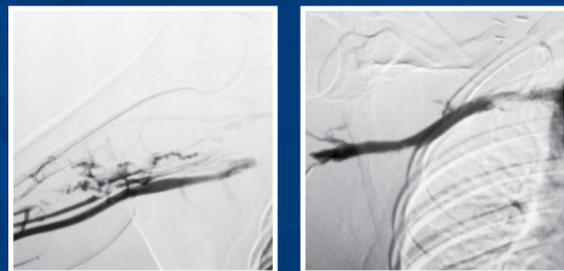
The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes. Renderings for illustrative purposes only. Procedural and operative techniques 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



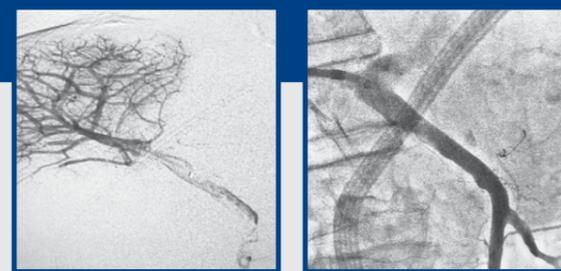
Removal of Thrombus from Iliac & Femoral Vein
 Dr. Michael Lichtenberg, Klinikum Arnsberg, Arnsberg, Germany



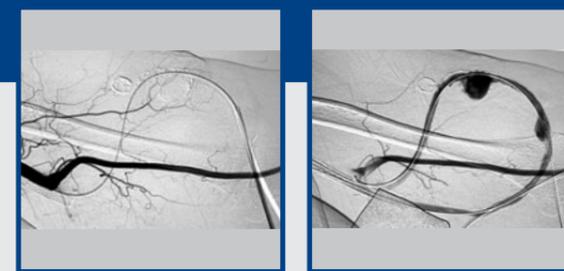
Removal of Thrombus from Subclavian Vein
 Dr. Frank Arko, Atrium Health, NC, USA



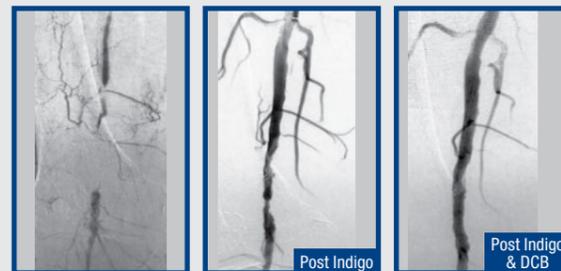
Removal of Thrombus from BTA
 Dr. Gianmarco de Donato, University of Siena, Siena, Italy



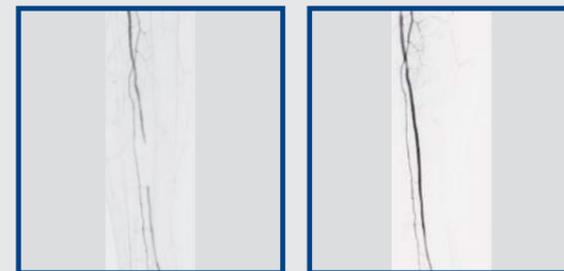
Removal of Thrombus from Portal Vein
 Dr. Rafik Lababidi, Largo Medical Center, FL, USA



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

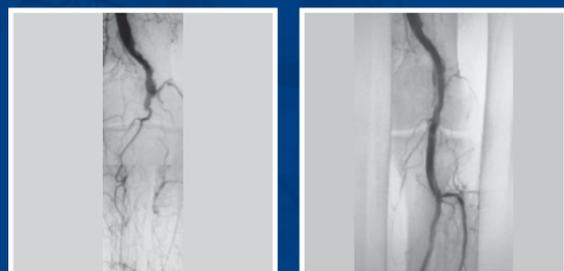


Removal of SFA Chronic Total Occlusion
 Dr. Branavan Umakanthan, Nevada Heart and Vascular Center, NV, USA



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

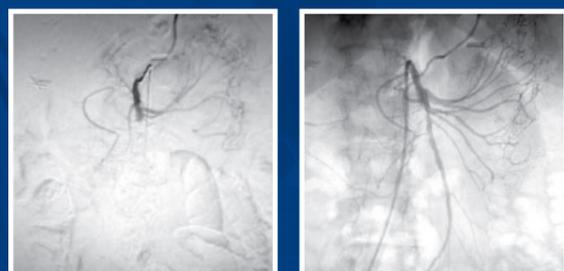
Up to 8F Arterial, Venous, and Pulmonary Indication



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

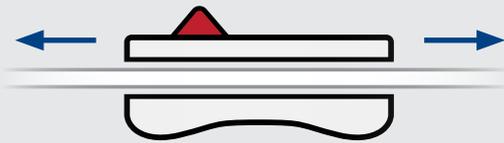
- A** Press down firmly to secure Penumbra ENGINE Canister
- B** Set Dynamic Flow Switch to **OFF**
- C** Attach aspiration tubing to Canister
- D** Power **ON** Penumbra ENGINE; 4 LEDs illuminate, indicating powerful, deep vacuum
- E** Attach Indigo System Aspiration Catheter to aspiration tubing



Indigo System

Now Packaged with Dynamic Tubing

Ability to Slide Flow Switch



64% Larger Flow Switch ID^g



Large Lumen Flow Switch



Dynamic Flow Switch

g. 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
CAT8XTORQ115KIT - Now!	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
CAT8TORQ85KIT - Now!	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
CAT8STR85KIT - Now!	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
CAT6KIT - Now!	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
CAT5KIT - Now!	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
CAT3KIT - Now!	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
CATD - Now!	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
SEP8	Separator 8	.072 (1.83)	150	CAT8
SEP6	Separator 6	.055 (1.40)	175	CAT6
SEP5	Separator 5	.045 (1.14)	175	CAT5
SEP3	Separator 3	.028 (.71)	190	CAT3
SEPD	Separator D	.072 (1.83)	90	CATD

Accessories

Catalog Number	Description	Compatible Penumbra Devices
PMXENGN - Now!	Penumbra ENGINE	Penumbra ENGINE Canister
IAPS3 - Now!	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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F +49 30 2005 676-10
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F 1.510.748.3232
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info@penumbrainc.com

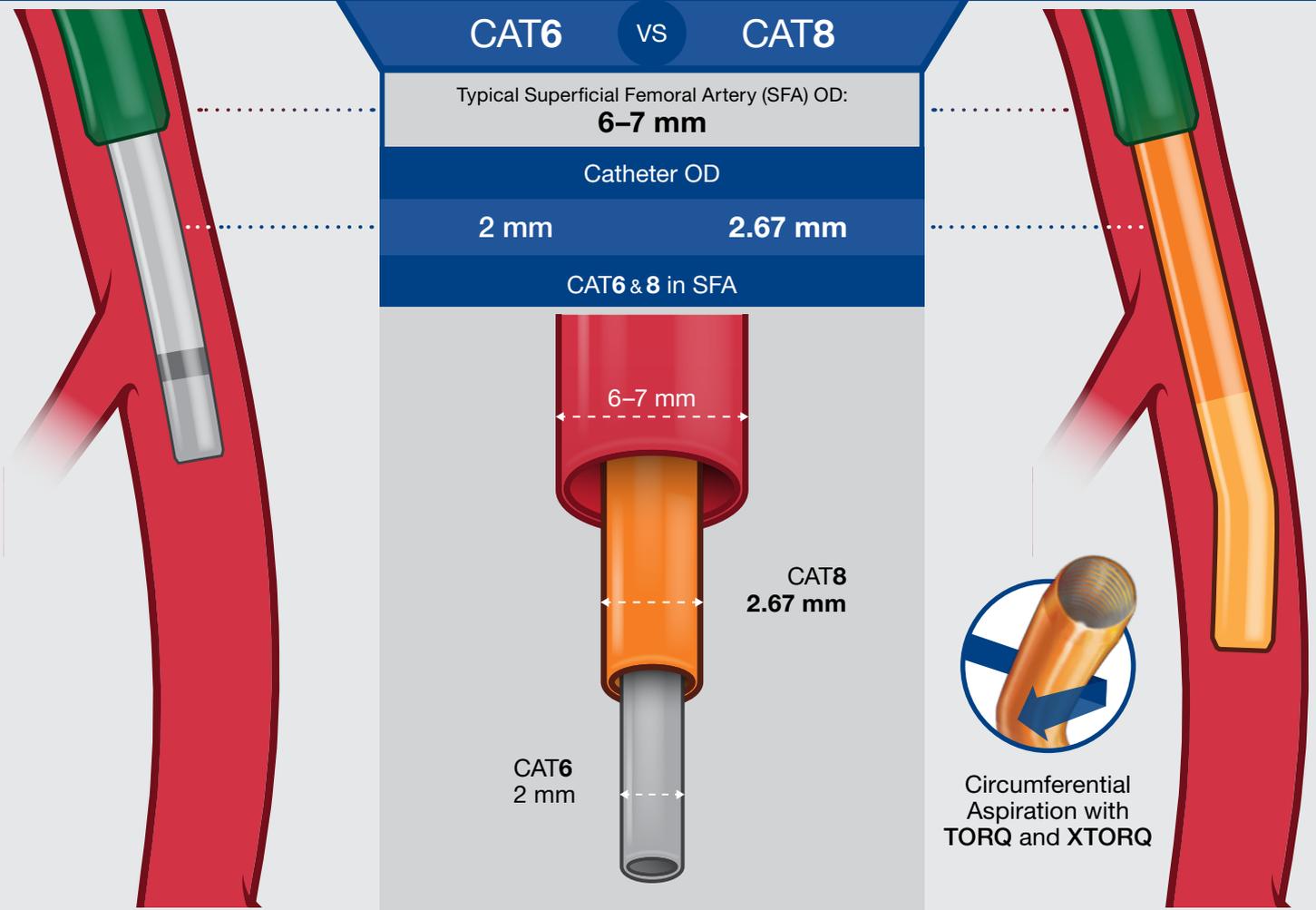
Product availability varies by country. Images used with permission. Consents on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. 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

Indigo System

Power Aspiration with CAT8



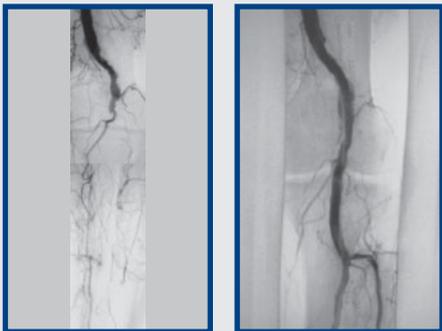
Use largest non-occlusive catheter for **maximum power aspiration**

.63 mm difference in puncture hole size

CAT6	●	●	CAT8
2.82 mm			3.45 mm

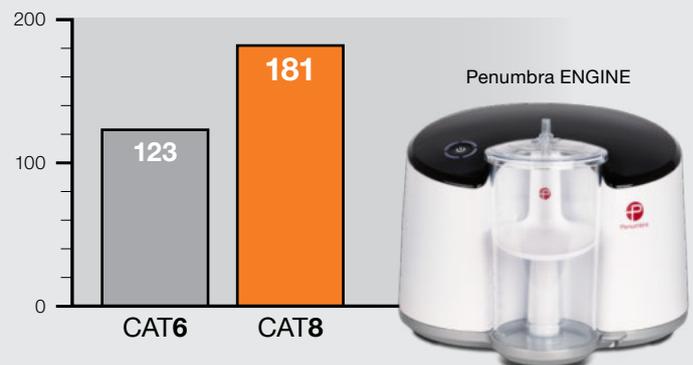
CAT8 has ~150% the power of CAT6^a

Aspiration of Thrombus from Popliteal with CAT6 & 8



Dr. Theodosios Bisdas, Athens Medical Center, Athens, Greece

Aspiration Volume (mL in 20 sec)^a



^a Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

Vessel diameters used are common clinical measurements. Renderings are for illustrative purposes only. The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Images used with permission. Consent on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes.

Ordering Information

Indigo Catheter Kits							
Catalog Number	Description	Proximal OD	Distal OD	Compatibility (Sheath or Guide)	Working Length (cm)	Wire Platform (in.) (mm)	Compatible Penumbra Devices
CAT8XTORQ115KIT – Now!	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
CAT8TORQ85KIT – Now!	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
CAT8STR85KIT – Now!	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
CAT6KIT – Now!	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
CAT5KIT – Now!	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
CAT3KIT – Now!	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
CATD – Now!	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
SEP8	Separator 8	.072 (1.83)	150	CAT8
SEP6	Separator 6	.055 (1.40)	175	CAT6
SEP5	Separator 5	.045 (1.14)	175	CAT5
SEP3	Separator 3	.028 (.71)	190	CAT3
SEPD	Separator D	.072 (1.83)	90	CATD

Accessories		
Catalog Number	Description	Compatible Penumbra Devices
PMXENGN – Now!	Penumbra ENGINE	Penumbra ENGINE Canister
IAPS3 – Now!	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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