



Indigo System

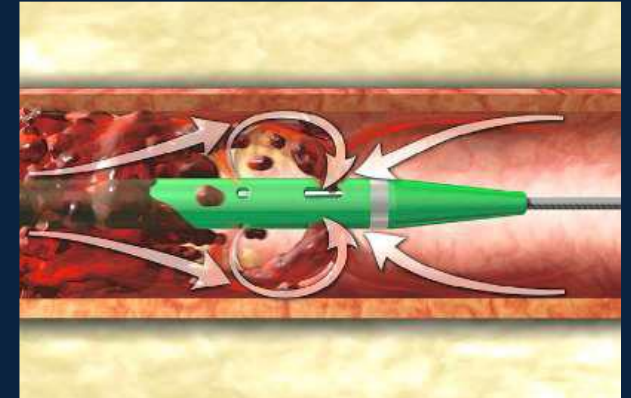
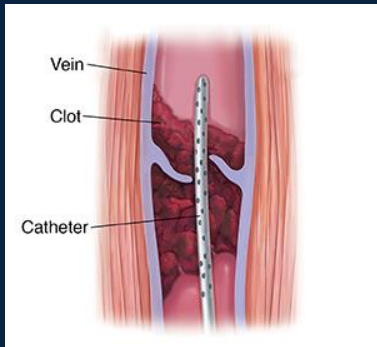
Applications

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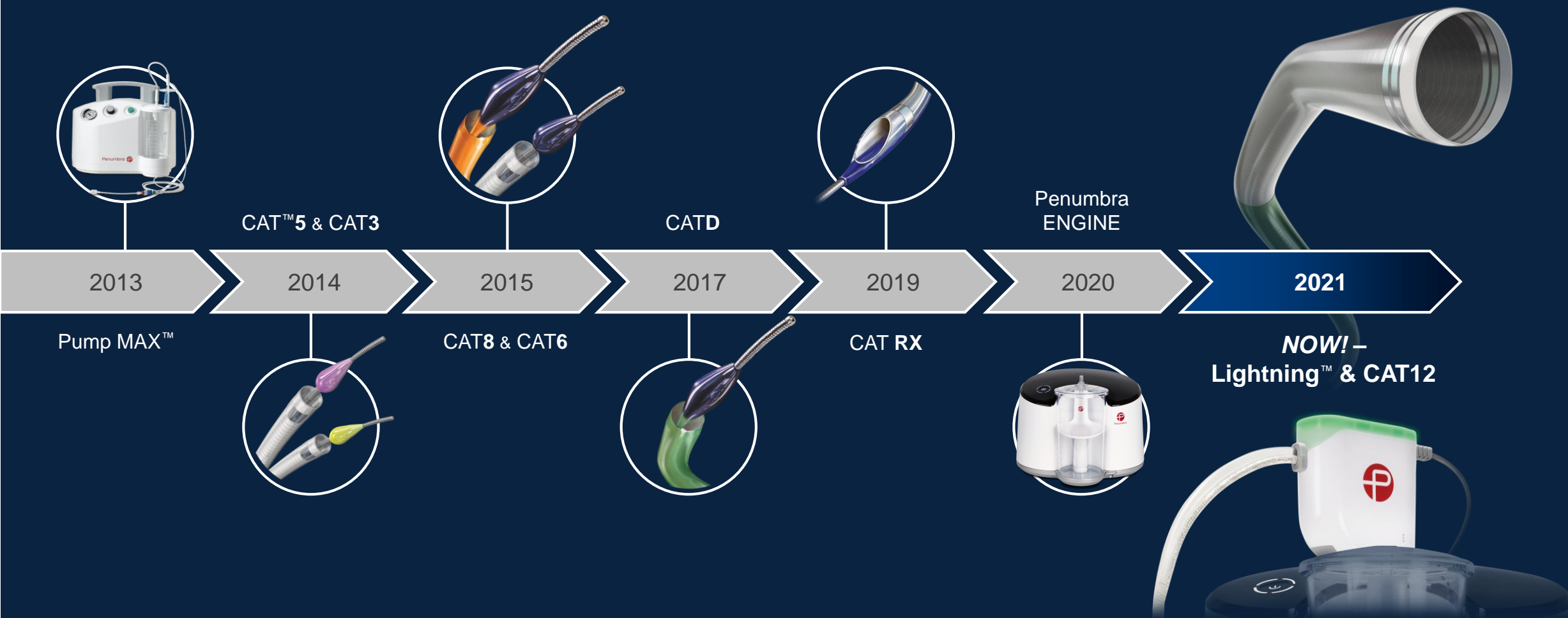
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טיפול בחסימות כלי דם

מבחינה היסטורית הטיפול בחסימות כלי דם כתוצאה מקרשי דם התבצע באמצעות מגוון טכנולוגיות כגון הכנסת קטטר פוגרטי-אמבולקטומי, טרומבקטומיה מכנית סיבובית, הזרקת והזלפה של חומרים טרומבוליטיים (אורוקינז וסטרפטוקינז), אנגיופלסטיה באמצעות בלון וסטנט, ניתוח מעקפים ועוד.



אבולוציה של של שאיבת קרישי דם באמצעות מערכת Indigo



As part of the Indigo Aspiration System, the Indigo CAT RX Aspiration Catheters and Indigo Separator™ 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

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חדשנות של קטטרים ומגוון רב - Indigo System

					
CAT	3	5	6	8	D
Compatibility (Sheath/Guide)	5 F (1.65 mm) Compatibility	6 F (2.00 mm) Compatibility	6 F (2.00 mm) Compatibility	8 F (2.67 mm) Compatibility	8 F (2.67 mm) Compatibility
Working Length	150 cm	132 cm	135 cm	85 cm (Straight and TORQ Tips) & 115 cm (XTORQ Tip)	50 cm
Wire Platform	.014-.025" (.36-.64 mm)	.014-.038" (.36-.97 mm)	.014-.038" (.36-.97 mm)	.014-.038" (.36-.97 mm)	.014-.038" (.36-.97 mm)
Compatible Penumbra Devices	Separator 3	Separator 5	Separator 6	Separator 8	Separator D

תכונות הקטטר

יכולת שאיבה מקסימלית , במגוון גדול של, אורכים וקטרים

אפשרות סיבוב קצה הקטטר
המאפשרת הגדלת שטח
השאיבה באמצעות שאיבה
מעגלית

טכנולוגיית מעקב מתקדמת
המתאפשרת באמצעות מבנה
ייחודי של הקטטר הבנוי ממספר
רב של פלחים בקשיחויות שונות

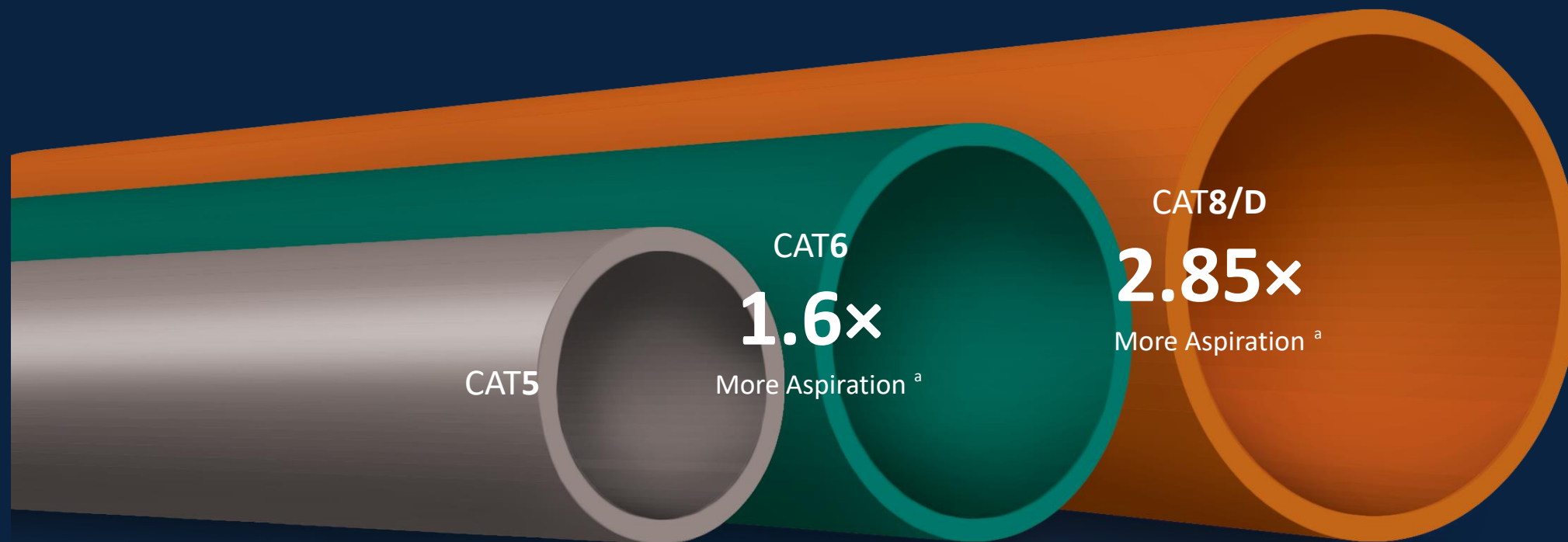
שאיבה מכאנית של קרישים בנוסף לטכנולוגיה
ייחודית של הפרדת הקריש מכלי הדם
ומשיכתו לתוך הקטטר תוך כדי הפעלת
שאיבה מתמדת



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גודל מוגדל של הקטטר = יותר כוח שאיבה



^a Compared to CAT5. Data on file at Penumbra, Inc.
Renderings for illustrative purposes only.

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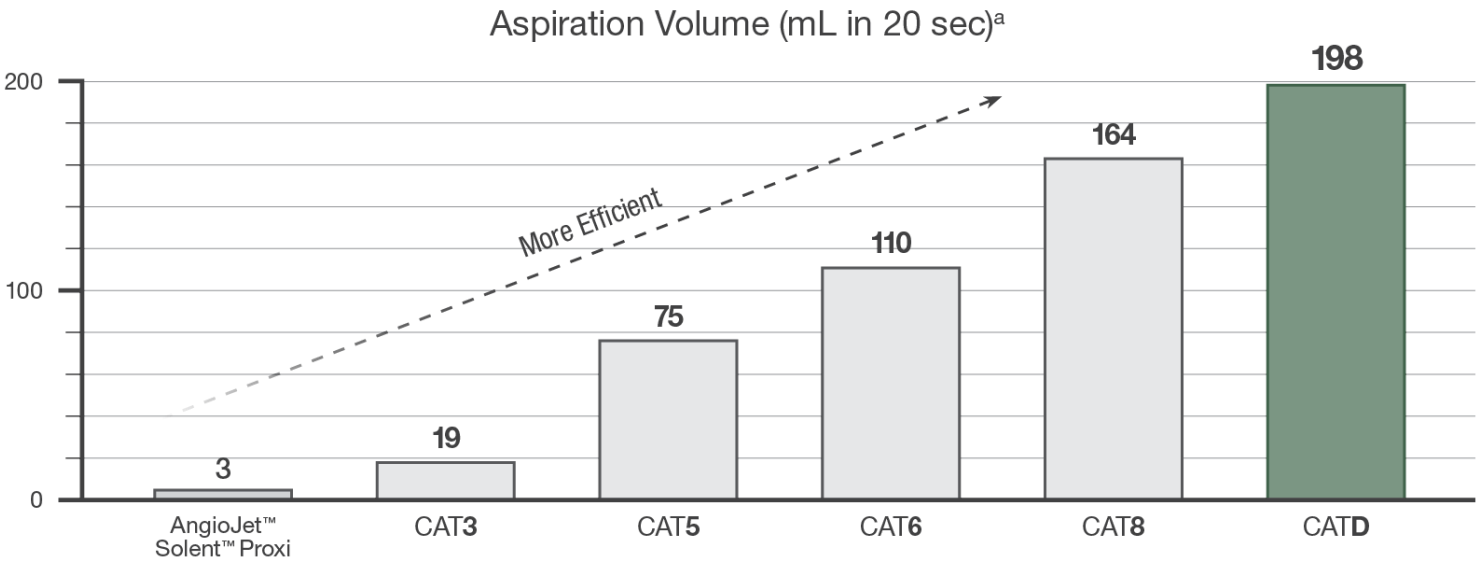
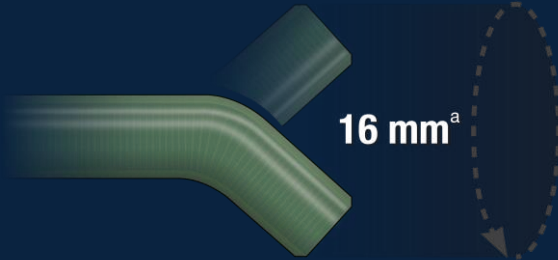
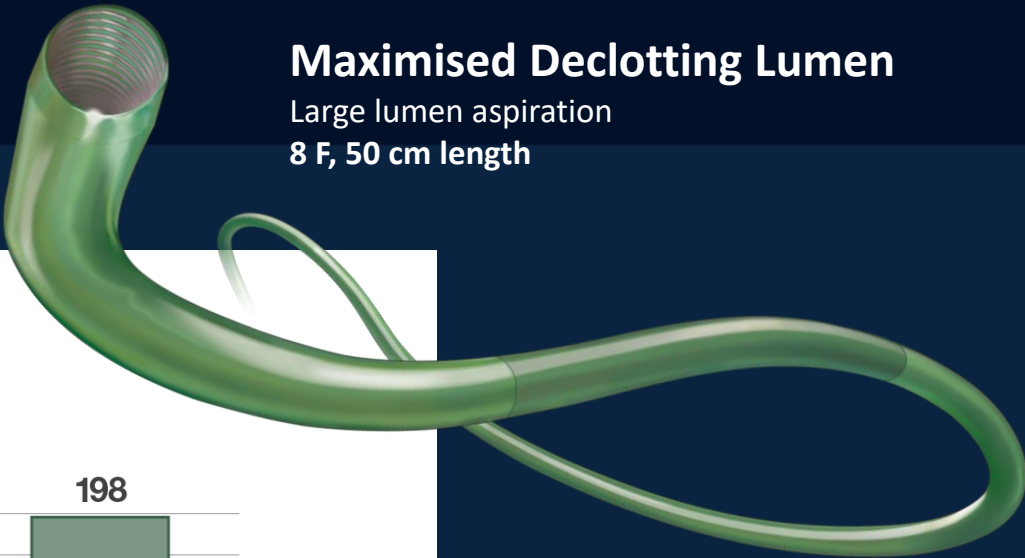
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הוצאת הקרישים במהירות

Indigo System-CAT D

Maximised Declotting Lumen
Large lumen aspiration
8 F, 50 cm length



a. AngioJet™ setup tested with its own accessories and aspiration source per its Instructions for Use. Indigo System setup tested with its own accessories and aspiration source per its Instructions for Use. Flow rate testing conducted using water. Data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Product availability varies by country. 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. Please contact your local Penumbra representative for more information. Copyright ©2021 Penumbra, Inc. All rights reserved. The Penumbra P logos, Indigo, Lightning, Penumbra ENGINE, MAX, CAT, Separator, and ACE are registered trademarks or trademarks of Penumbra, Inc. in the USA and other countries. All other trademarks are the property of their respective owners. 21123, Rev. A 08/21 OUS

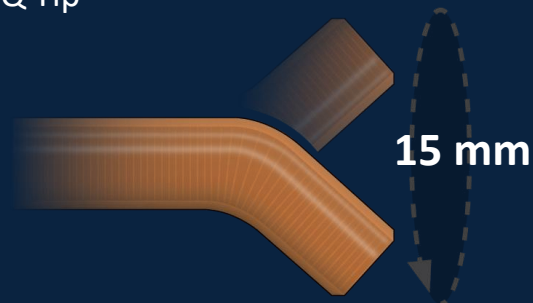
שאיבה היקפית (צנטריפוגלית) מגדילה שטח פני השאיבה

Straight (STR) Tip



Available in 85 cm (CAT8)

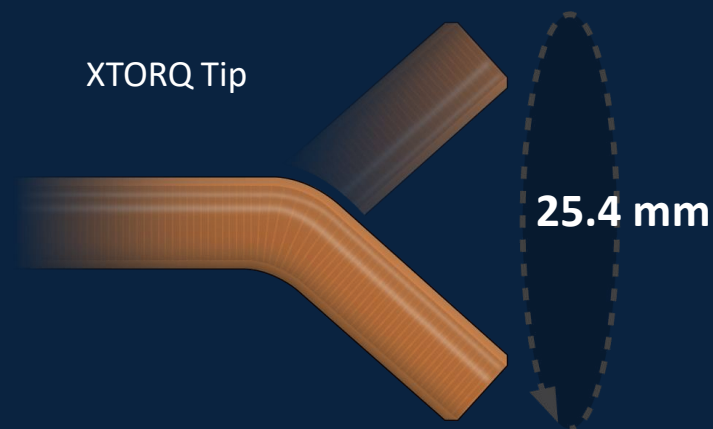
TORQ Tip



Available in 85 cm (CAT8)
and 50 cm (CATD)

Angle: 20–45°
Tip length: 1 cm

XTORQ Tip



Available in 115 cm (CAT8)

Angle: 20–45°
Tip length: 1.8 cm

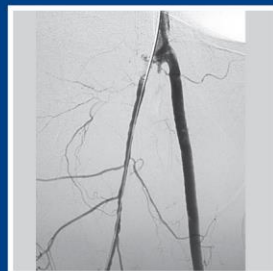
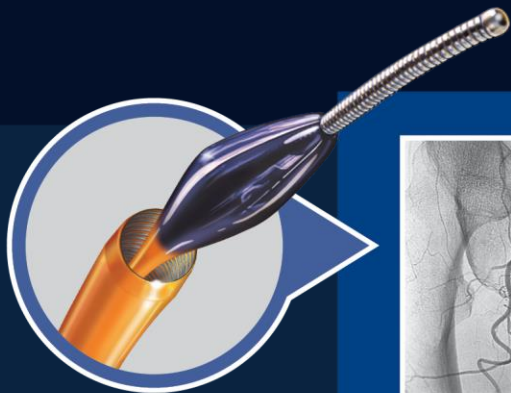
Measurements calculated using tip angle and length. Data on file at Penumbra, Inc.

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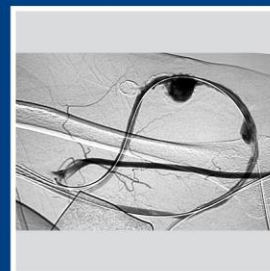
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אינדיקציה ורידית ועורקית של מערכת אינדיגו

CAT
8



Aspiration of Thrombus from Occluded Fem-Pop Graft
Dr. Corey Teigen, Sanford Health, ND, USA



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

CAT
D



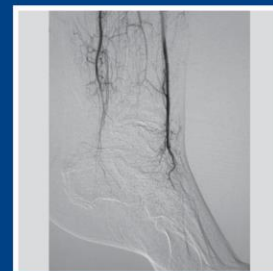
CAT
6



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



**Penumbra
ENGINE**



Aspiration of Thrombus from BTA Vessels
Dr. Gianmarco de Donato, Azienda Ospedaliera Universitaria Senese, Siena, Italy

CAT
5&3



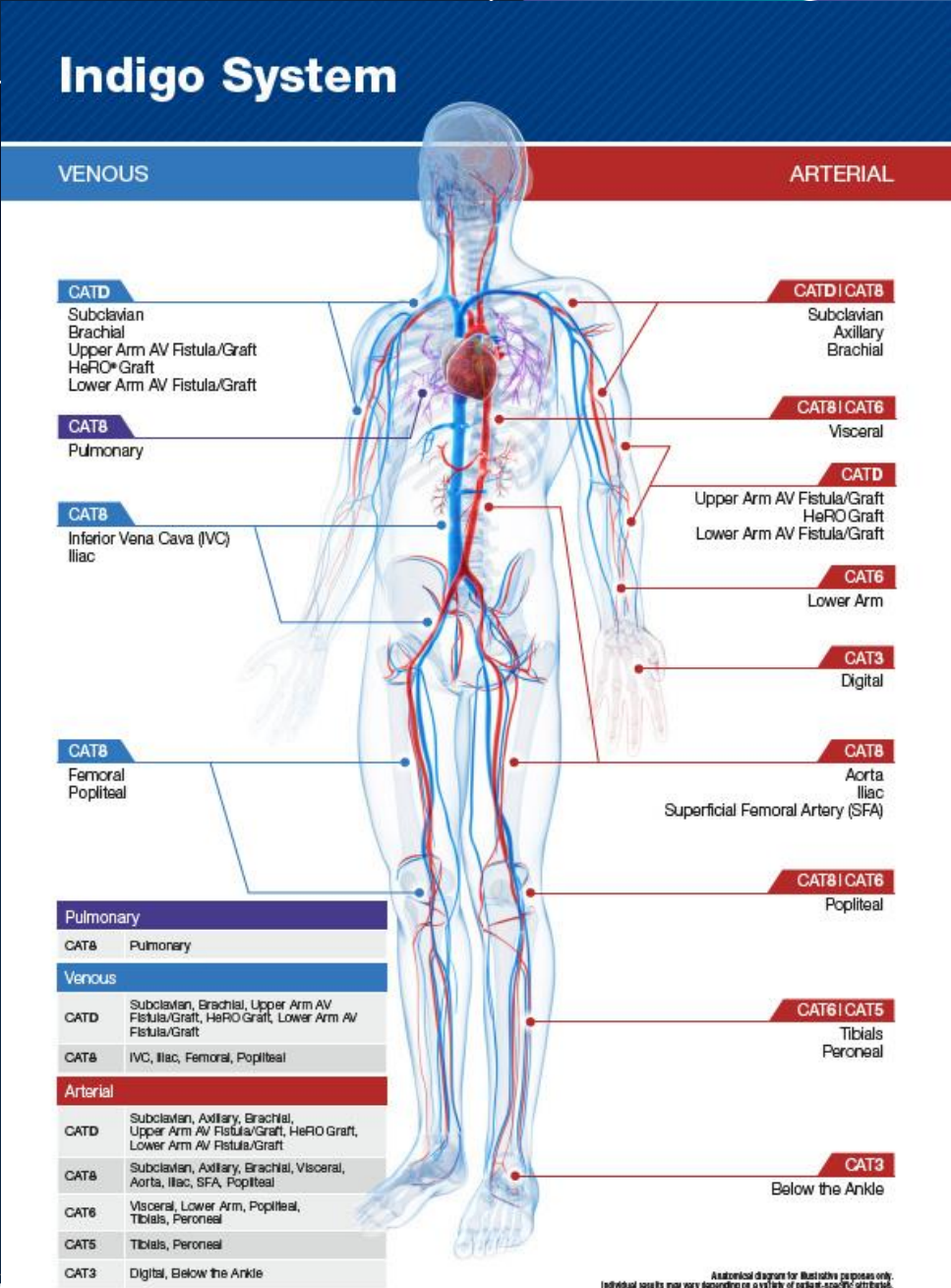
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מערכת שאיבה אחת
זהה הן בעורקים והן
בוורידים



Science of Aspiration

✓ מערכת INDIGO מתוצרת פנומברה מיועדת לשאיבת קרישים בשיטת תת לחץ.

✓ המערכת עובדת על עקרון של **שאיבה קבועה ומתמשכת** בתת לחץ של 29- מ"מ כספית.

✓ המערכת מיועדת לשאיבת קרישים רכים אשר גילם אינו עולה על שלושה שבועות .

✓ המערכת המאושרת FDA מיועדת לשאיבה בעורקים הפריפריים, IN-STENT, STENOSIS, ורידים- מערכת שטחית ועמוקה, **Pulmonary Embolism** - שאיבת תסחיף ריאתי וכן ממערכת העורקים הכליליים- **coronary artery**

Science of Aspiration

✓ מעבר לרעיון הפשטני והיעיל, הקטטרים הם גולת הכותרת מבחינת יכולת העבירות באנטומיות המורכבות ביותר.

✓ מגוון של קטטרים ישרים וכאלה עם סיומת זוויתית של בין 20-45 מעלות, למניפולציות סמוכות לאינטימה.

✓ המערכת של פנומברה החלה את דרכה בטיפול בשבץ מוחי בכלי הדם המוחיים ומאוחר יותר תוכננה לשאיבת קרישי דם ממערכת כלי הדם הפריפריים.

Science of Aspiration

✓ אחת מהאינדיקציות החשובות ולמעשה מצילות חיים ביניהם בטיפול בתסחיף ריאתי-PE pulmonary embolism הוא מצב שבו נחסם עורק ראשי של הריאה או אחד מסעיפיו, על ידי חומר (למשל, קריש דם או תסחיף שומני) שזרם בדם דרך מחזור הדם. לרוב מדובר בקריש דם שהגיע לריאה מווריד הרגליים ואז נקרא תהליך מסוג זה בשם Venous Thrombo Embolism או VTE. בחולים אלו נדרשת מעורבות משולבת של מחלקות קרדיולוגיה, טיפול נמרץ, רדיולוגיה פולשנית וכירורגיית כלי דם.



the Instructions for Use for

cautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

בחירת השרוולית

CAT8

CAT6

Company	Sheath Name	Valve Type	Length	French	Manufacturer Part Number
Terumo®	Pinnacle® Destination® with Tuohy (RHV)	Tuohy (RHV)	45 cm 65 cm 90 cm	≥ 8 F	54-84506 54-86506 54-89006
Cook®	Flexor® Shuttle® with Tuohy (RHV)	Tuohy (RHV)	90 cm	≥ 8 F	KSAW-8.0-38-90-RB-SHTL-HC
Terumo	Pinnacle Destination with Tuohy (RHV)	Tuohy (RHV)	45 cm	≥ 6 F	54-64506

Note: Sheaths with pin hole valves or Check-Flo® valves may NOT be compatible or may damage the tip of the Indigo Catheters. Sheaths with removable cross-cut valves or Tuohy (RHV), such as listed above, are recommended.

Penumbra ENGINE™ Setup

Video recordings taken by and on file at Penumbra, Inc.

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20445, Rev. A 02/21 EU



Science of Aspiration

✓ לאחר שהתמקמנו בסמוך לקריש הדם , רצוי ומומלץ לבצע את השאיבה ללא מוביל (gw) על מנת לשמר את יכולת השאיבה המקסימלית בהסתמך על שטח הפנים הגדול של הקטטר.

✓ במידה וחייבים לשמור על המיקום, רצוי להשתמש במוביל דק ככל הניתן (0.014") על מנת לאפשר שאיבה מקסימלית .

✓ בהתאם לצורך, לגיל הקריש ורמת צמיגותו, לייעול השאיבה ניתן להשתמש במוביל - Separator אשר בקצהו המרוחק יש תוספת מעובה בצורת זית המסייעת בהזזת הקריש מדפנות העורק\וריד ומאפשרת להעבירו ביעילות ובמהירות לתוך הקטטר .



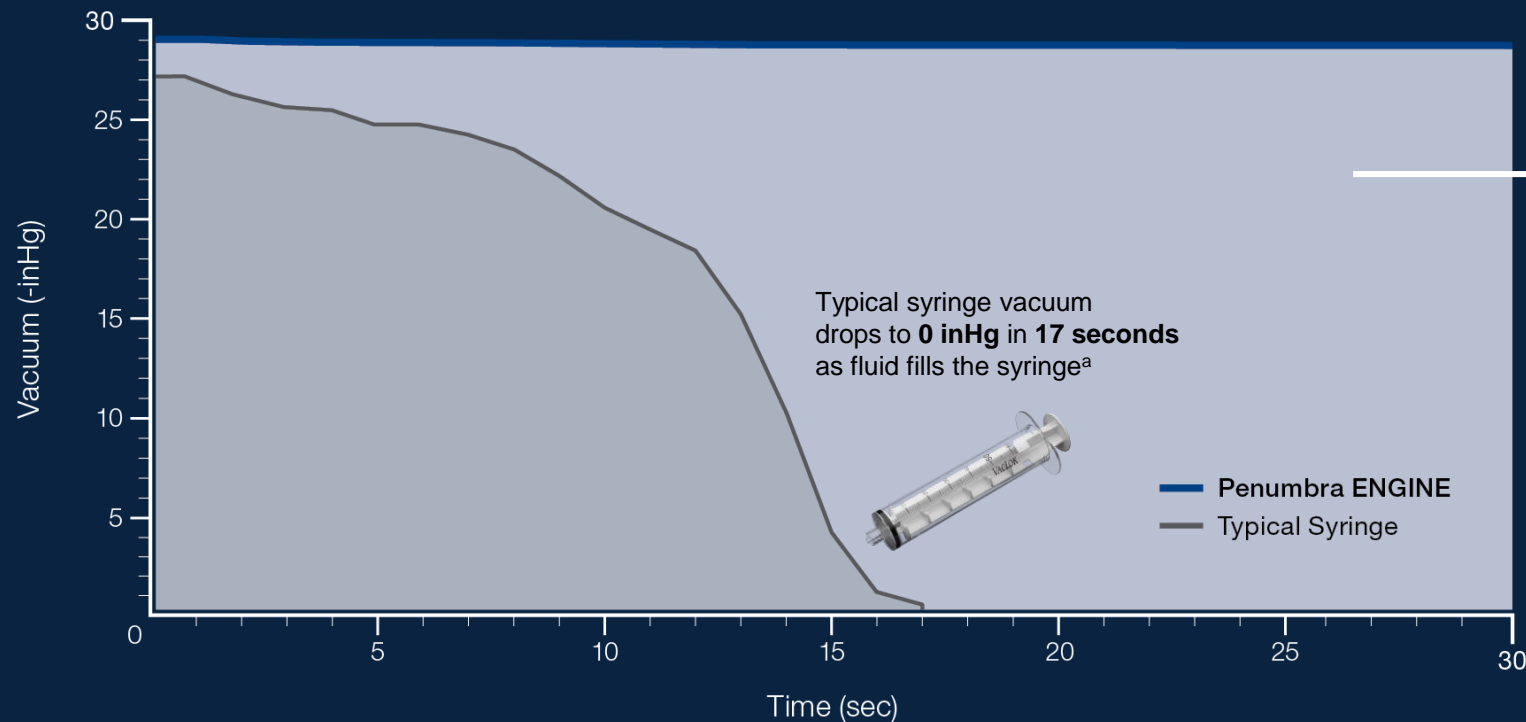
Science of Aspiration

✓ בעת השאיבה מעת לעת יש צורך לשטוף של הקטטר או הצנרת המחוברת למיכל השאיבה ועל כן יש להקפיד לפקח שהמערכת ממשיכה לשאוב תוך התבוננות מתמדת על הצנרת השקופה ומיכל השאיבה - CANISTE

✓ במידה והקטטר עמוס בקרישים ונדרש ניקוי של הקטטר, ניתן להוציאו באופן פשוט בו מושכים את הקטטר מכלי הדם תוך כדי שאיבה להצמדת הקריש לקטטר, סוגרים את השאיבה ומנקים את חלקי הקטטר באמצעות שאיבת נוזל סליין לתוך מיכל האיסוף, במקרים עיקשים יש לבצע ניתוק כל חלקי המערכת וביצוע שטיפה בלחץ ע"י מזרק 5 סמ"ק.

✓ בשאיבה עורקית כיוון השאיבה מומלץ מפרוקסימל לדיסטל תוך הקפדה על שאיבה מתמשכת גם בהוצאת הקטטר לשם ניקוי למניעת נדידת מיקרו קרישים לאזורים מרוחקים.

Penumbra ENGINE vs. Syringe-Based Aspiration



Penumbra ENGINE stays at full vacuum for duration of procedure^b



a. Tests performed and data on file at Penumbra, Inc. Data obtained using a 60 cc syringe connected to Penumbra ACE™60 5.4 F catheter with vacuum gauge attached to proximal barrel of syringe and continuous filling of syringe. Bench test results may not be indicative of clinical performance. Test performed using water.

b. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Test performed using water.

Photographs taken by and on file at Penumbra, Inc.

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Penumbra ENGINE

One Touch for Maximum Aspiration

Powerful, Deep Vacuum

-29 inHg^a

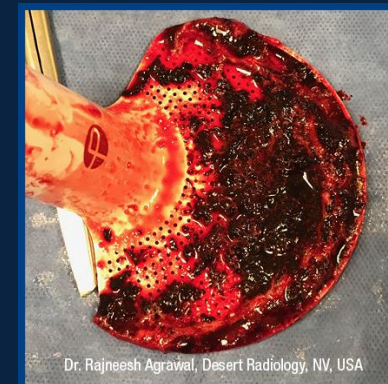
Easy Setup

Sleek, Simple Design



Live Feedback During Procedure

Integrated Clot Catcher

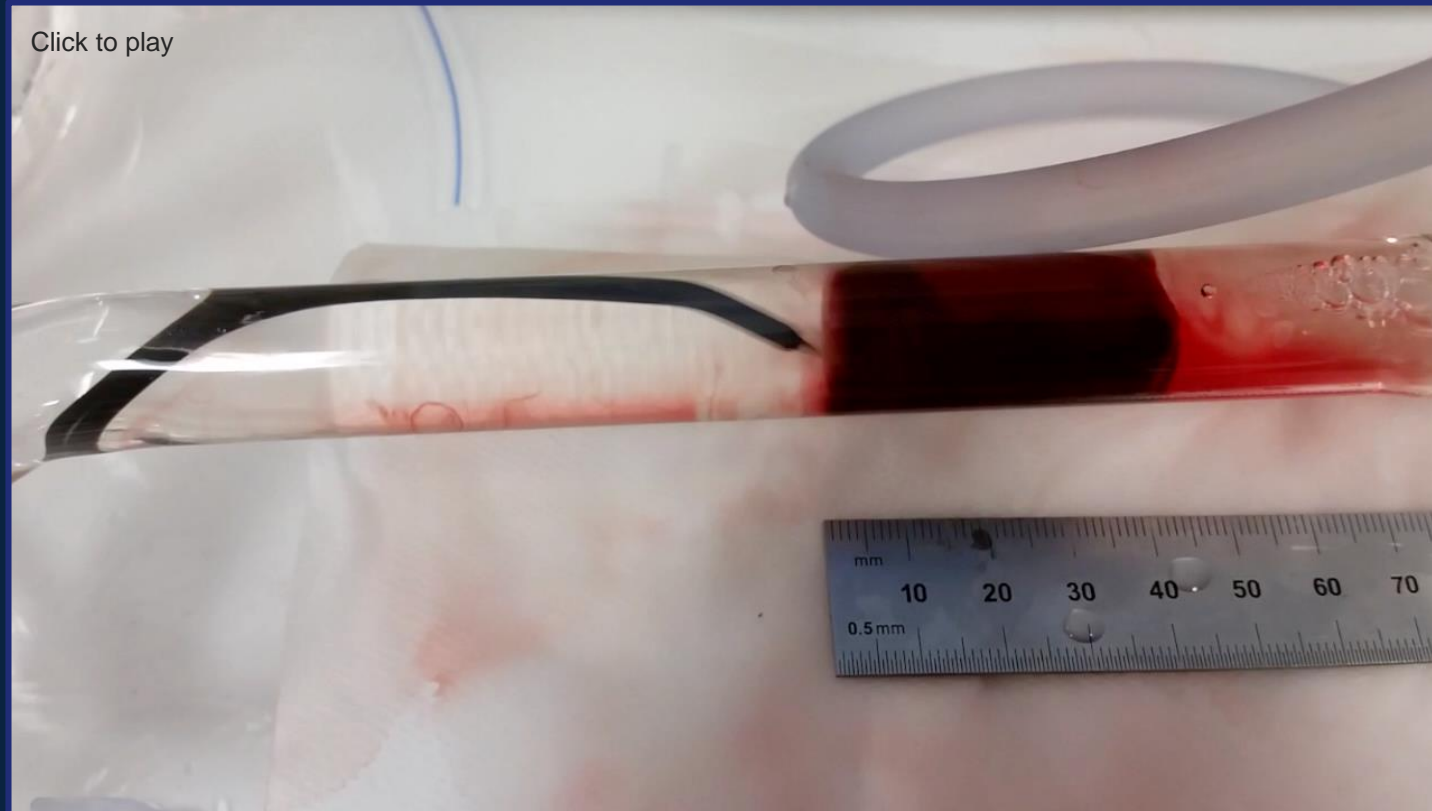


^a Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Images used with permission. Consents on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes.

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CAT8 XTORQ with SEP8



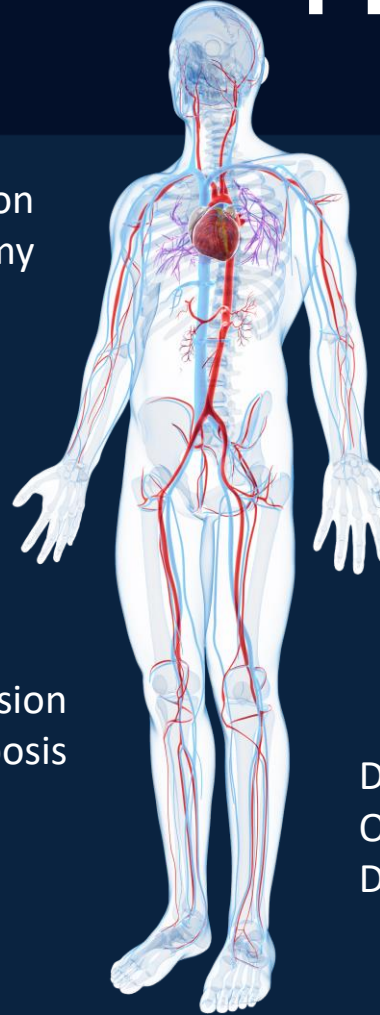
Video recording taken by and on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

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Indigo System Arterial Applications

Subclavian Artery Occlusion
Axillary Artery Thrombectomy



Superior Mesenteric Artery Thrombosis Occlusion

Superficial Femoral Artery Occlusion
In-Stent Thrombosis

Distal Popliteal Thrombosis
Occlusion of Tibial-Peroneal Trunk
Distal Emboli from Atherectomy in Tibial-Peroneal Trunk

Anatomical diagram is for illustrative purposes only. Image used under license from Shutterstock.com.

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Distal Popliteal Thrombosis



Patient Profile:

- Smoker, Diabetic, Resting leg pain
- Presented in the ER

Pre-Intervention Angiogram: Distal Popliteal Thrombosis

Dr. Corey Teigen, Sanford Health, ND, USA

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Distal Popliteal Thrombosis



Pre-Intervention Angiogram



Indigo System with CAT6



Distal triple vessel run-off to
anterior tibial artery, peroneal
artery, posterior tibial artery



Thrombus removed from
Distal Popliteal with
Indigo System

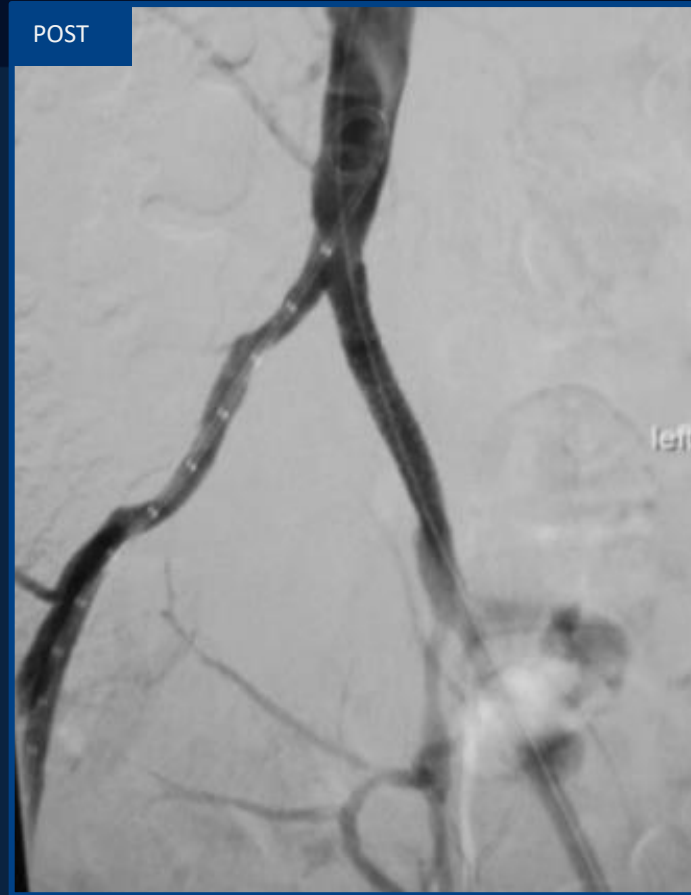
Dr. Corey Teigen, Sanford Health, ND, USA

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Common Iliac Occlusion



Dr. Paul Perkowski, Baton Rouge General, LA, USA

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Femoral-Popliteal Bypass Occlusion

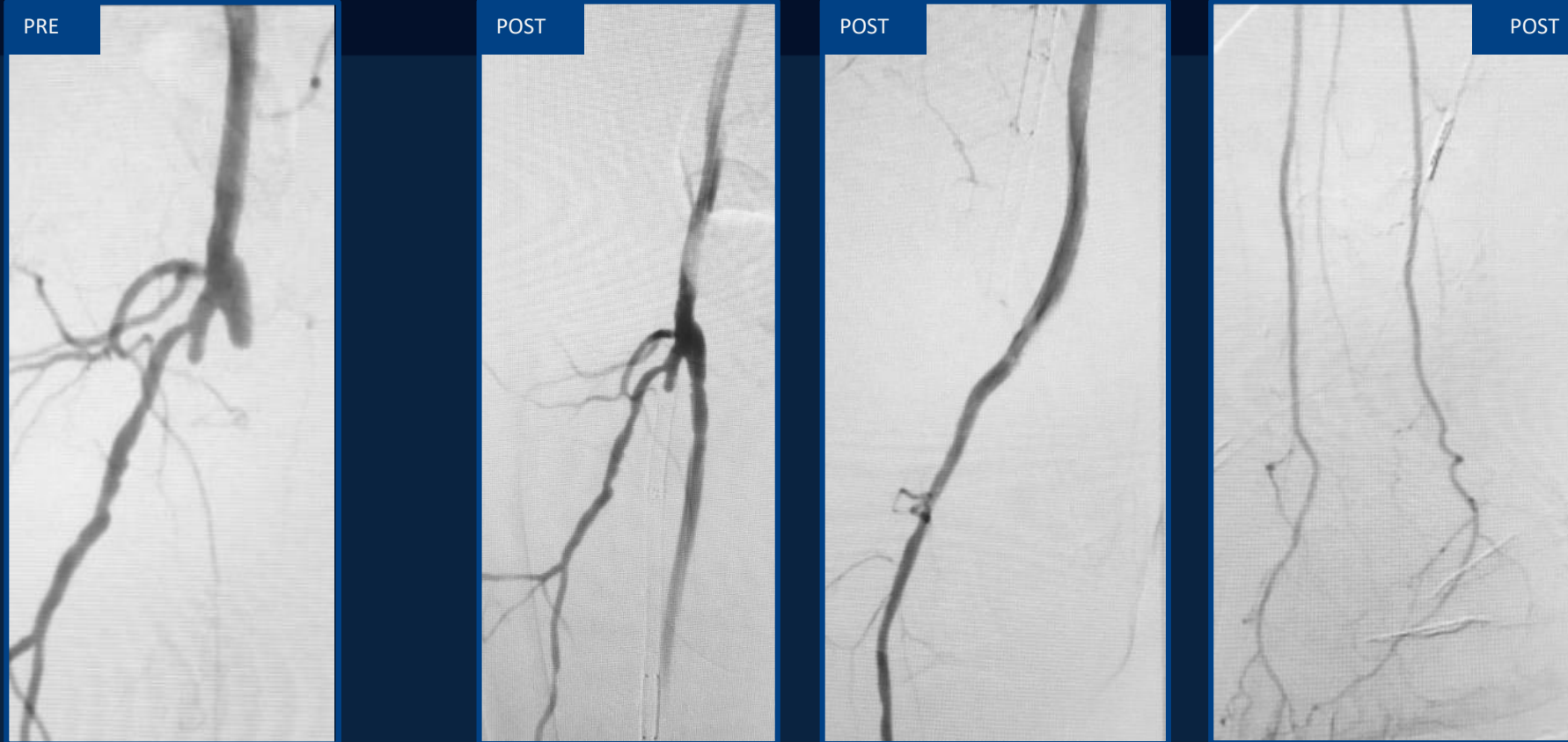


Pre-Intervention Angiogram: Femoral-Popliteal Occlusion

Dr. Timothy Yates, Mount Sinai Medical Center, FL, USA

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Femoral-Popliteal Bypass Occlusion



Dr. Timothy Yates,
Mount Sinai Medical Center,
FL, USA

Removal of Thrombus from Femoral-Popliteal Bypass Graft: Distal flow established to the foot

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Superior Mesenteric Artery Occlusion



Dr. Frank Vandy, Metropolitan Heart and Vascular Institute, MN, USA

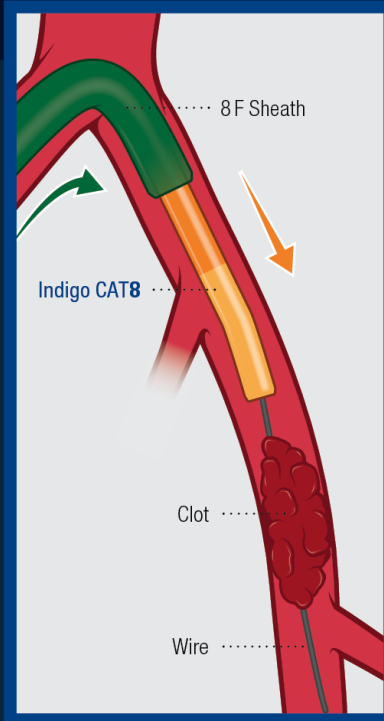
Indigo System with CAT8 XTORQ: thrombus removed and flow restored to SMA

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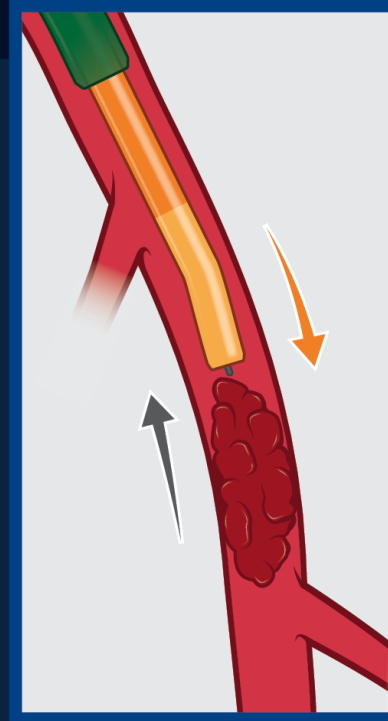
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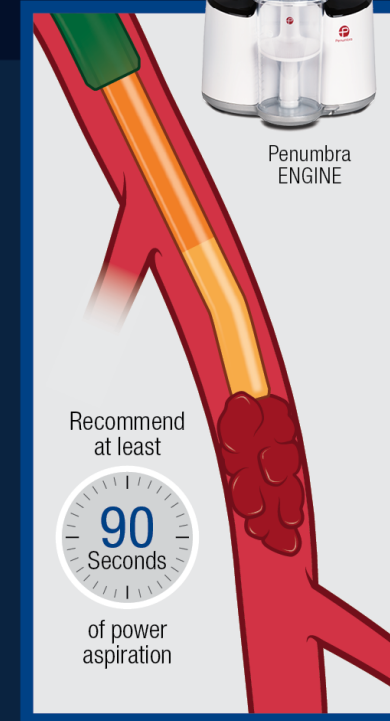
XTRACT Technique Used in PRISM Registry



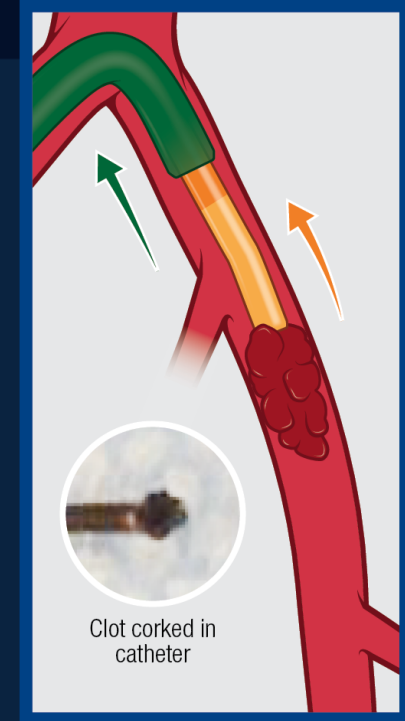
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.



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.

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Science of Aspiration

✓ בשאיבה של פקקת ורידים עמוקה DVT או בשאיבת תסחיף ריאתי מומלץ לעבור את הקריש עם הקטטר ותהליך השאיבה יהיה הפוך, כלומר, מדיסטאל לפרוקסימל על מנת ליצור ערוצי מעבר לדם וניקוי יעיל יותר לכמות משמעותית מאוד של הקרישים.

✓ בהתאם לצורך, ניתן לשלב בתחילת השאיבה, או בסיומה מתן טיפול תרומבוליטי מקומי שמסייע לרכך את הקריש ולקצר את משך הפעולה.

✓ מומלץ בעיקר בוורידים בהם כמות הקרישים היא מאוד משמעותית כגון בטיפול ב-DVT

✓ יש לבצע את פעולת השאיבה באופן מחזורי, פעמים מספר ולוודא יעילות באמצעות הזרקות חומר ניגוד דרך מחבר ה-Y.

Indigo System Venous Applications

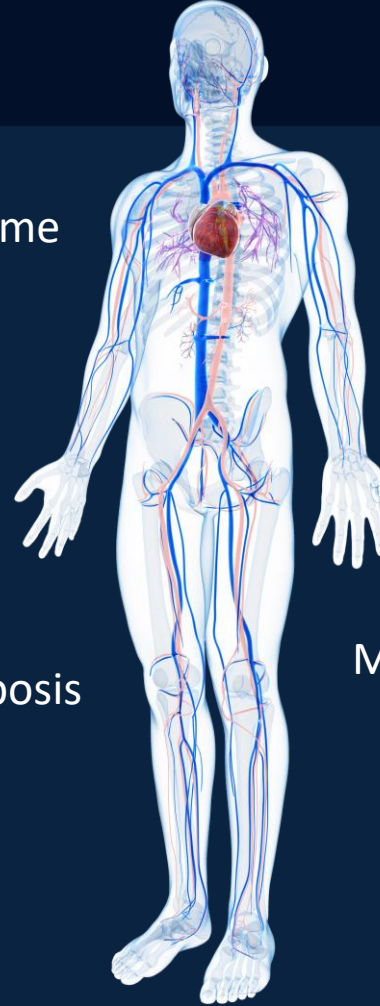
Paget-Schroetter Syndrome

Cephalic Vein Thrombus
AV Fistula
Aneurysmal Fistula

Iliofemoral Deep Vein Thrombosis

Inferior Vena Cava Occlusion
Inferior Vena Cava Filter Occlusion

May-Thurner Syndrome



Anatomical diagram is for illustrative purposes only. Image used under license from Shutterstock.com.

ATTRACT Showed that tPA is Not the Conservative Option.^a

Goal is to Reduce Dose and Duration of tPA.^a

Turbo Pulse Technique



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^a. As presented at VEITH 2017 by Dr. James Benenati,
Miami Cardiac and Vascular Institute, FL, USA.

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Iliofemoral Deep Vein Thrombosis



Patient profile:

- 87 year old, Female
- Left leg swelling and pain
- Access Site: Internal Jugular Vein

Pre-Intervention Angiogram: Left Iliofemoral deep vein thrombosis

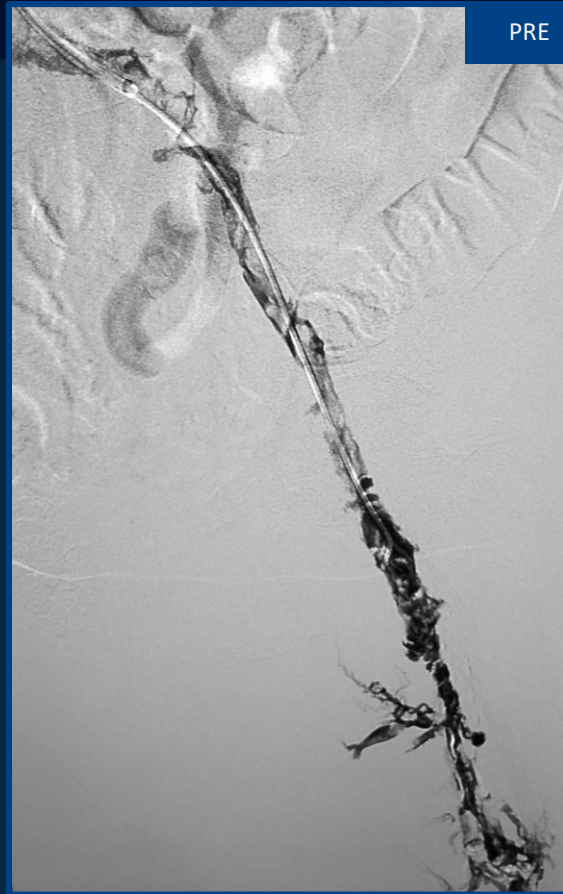
Dr. Corey Teigen, Sanford Health, ND, USA

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Iliofemoral Deep Vein Thrombosis



- **Indigo System** with CAT8 115 cm **XTORQ** and SEP8
- Thrombus removed in Iliofemoral vein
- Only 70 cc of blood loss

Dr. Corey Teigen, Sanford Health, ND, USA

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May-Thurner Syndrome



May-Thurner syndrome (MTS) הוא מצב רפואי לא תקין, שבו וריד באזור האגן (iliac vein) נמעך בידי העורק שעובר בסמוך לו. לכן, מצב זה מכונה גם iliac vein compression syndrome. למעשה, תופעה זו עלולה להתרחש במקומות נוספים בגוף, אך היא נפוצה במיוחד באזורי האגן (שם היא מכונה תסמונת או סינדרום מיי טרנר)

- Patient Symptoms: Left leg swelling, left leg pain
- Access Site: Internal Jugular

Pre-Intervention Angiogram: Left Iliofemoral Vein Occlusion

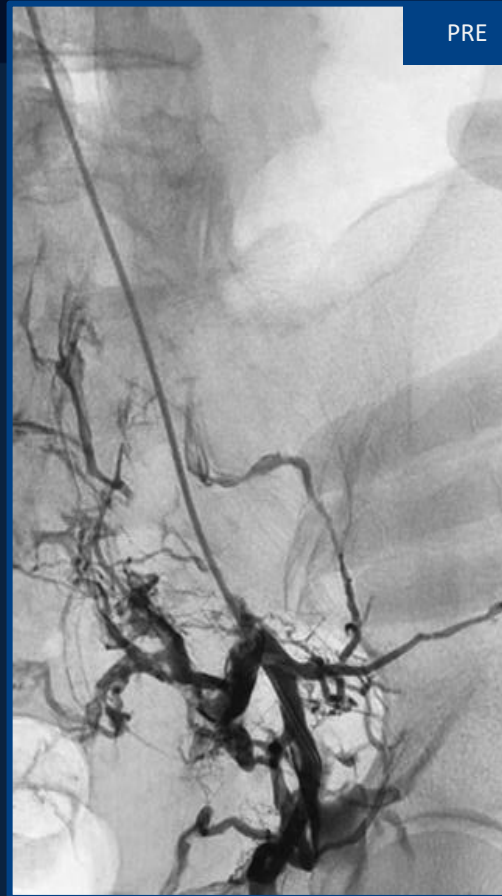
Dr. Corey Teigen, Sanford Health, ND, USA

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May-Thurner Syndrome



Thrombus removed and
flow established in left
iliofemoral vein

**Indigo System with
CAT8 XTORQ 115 cm**

Dr. Corey Teigen, Sanford Health, ND, USA

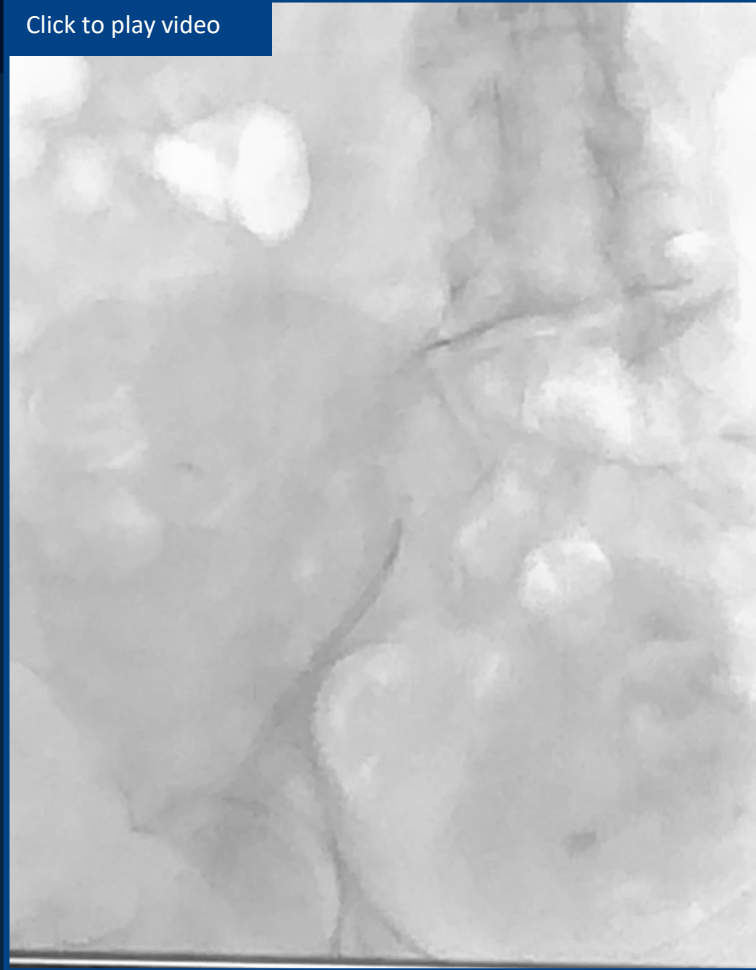
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Coring Clot Technique

Click to play video



Using macro movements to
core clot with CAT8 and SEP8

Dr. David Medina, Dignity Health, AZ, USA

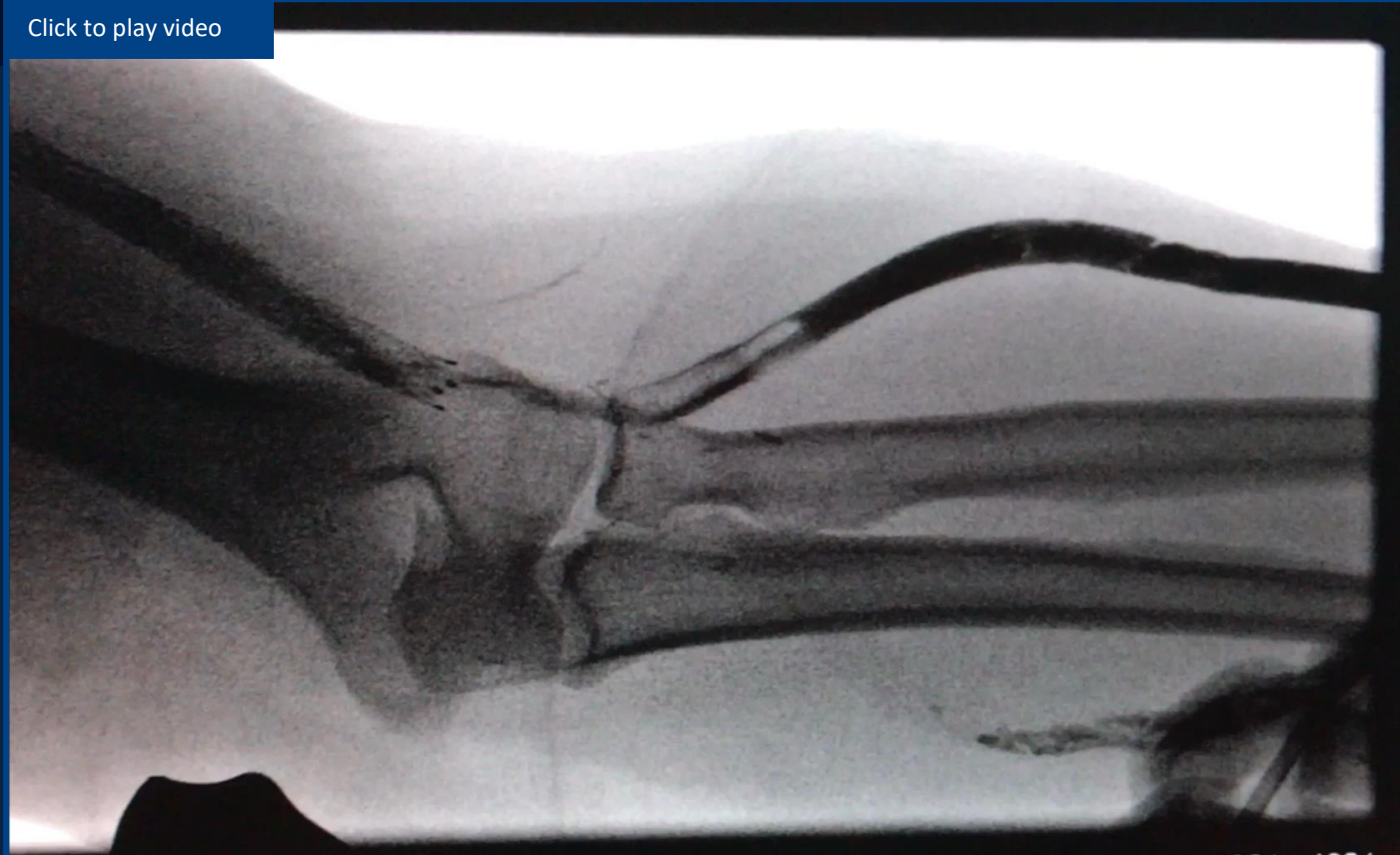
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AV Graft

Click to play video



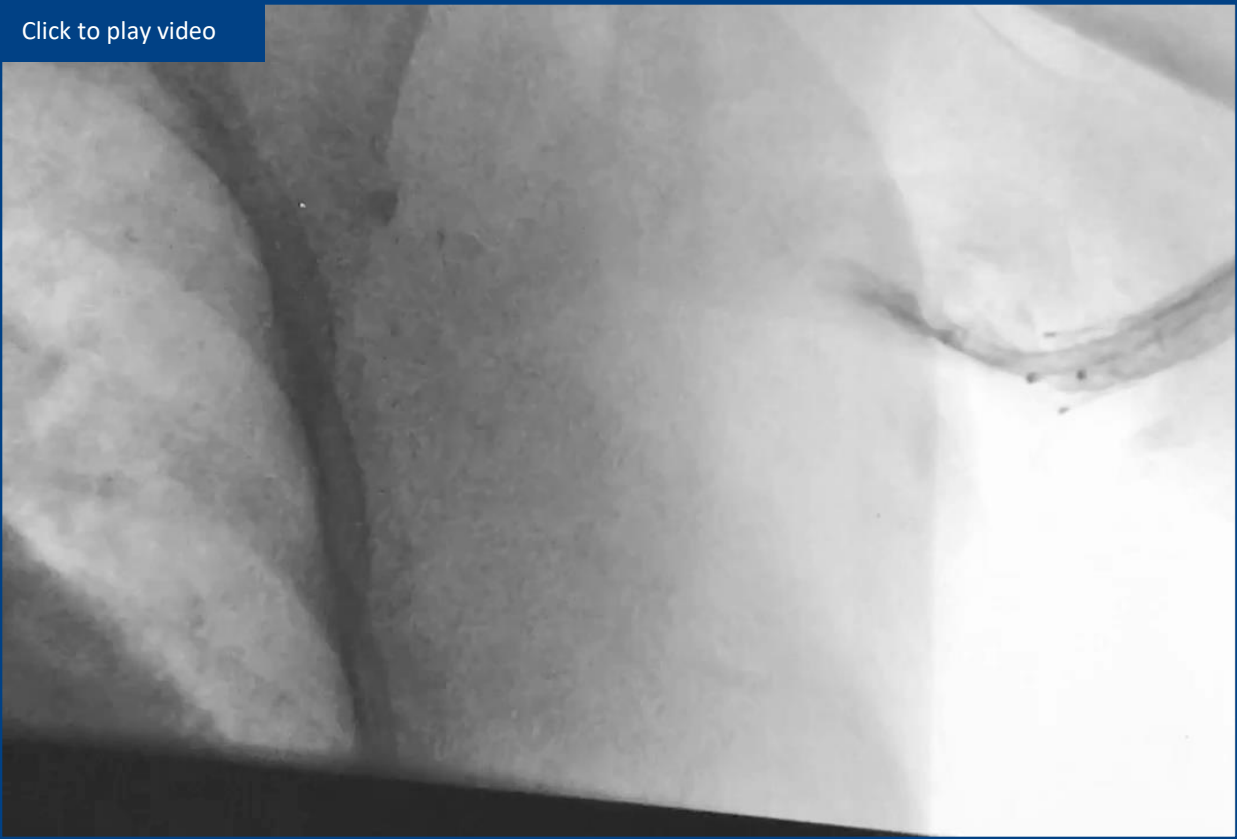
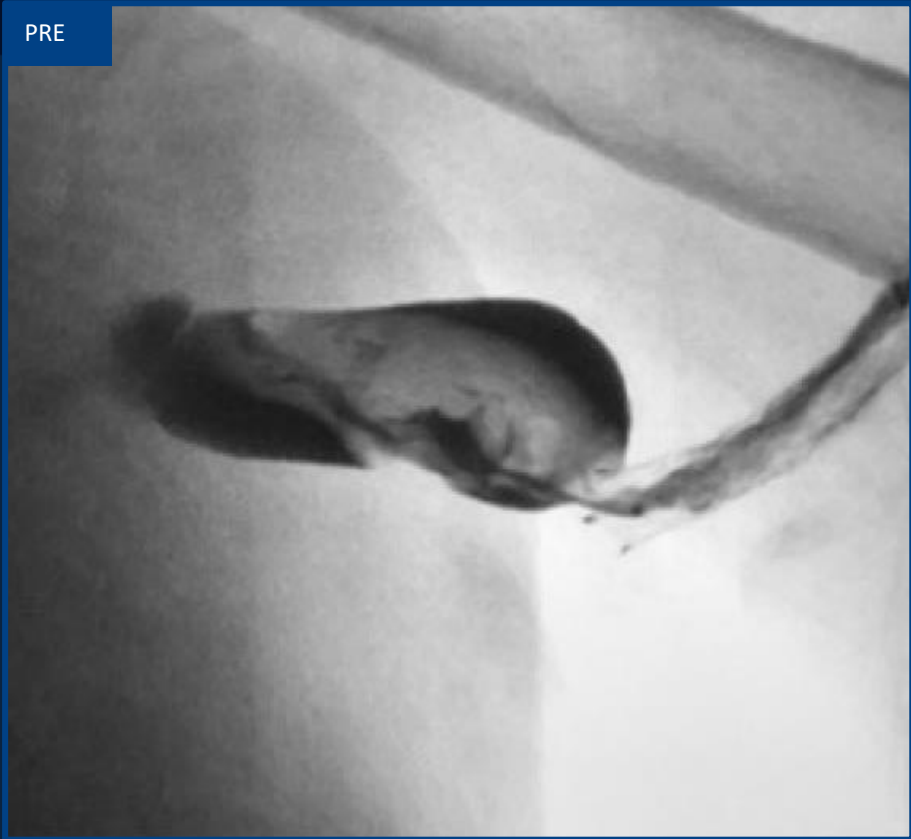
Dr. Steve Lemons, University of Kansas, KS, USA

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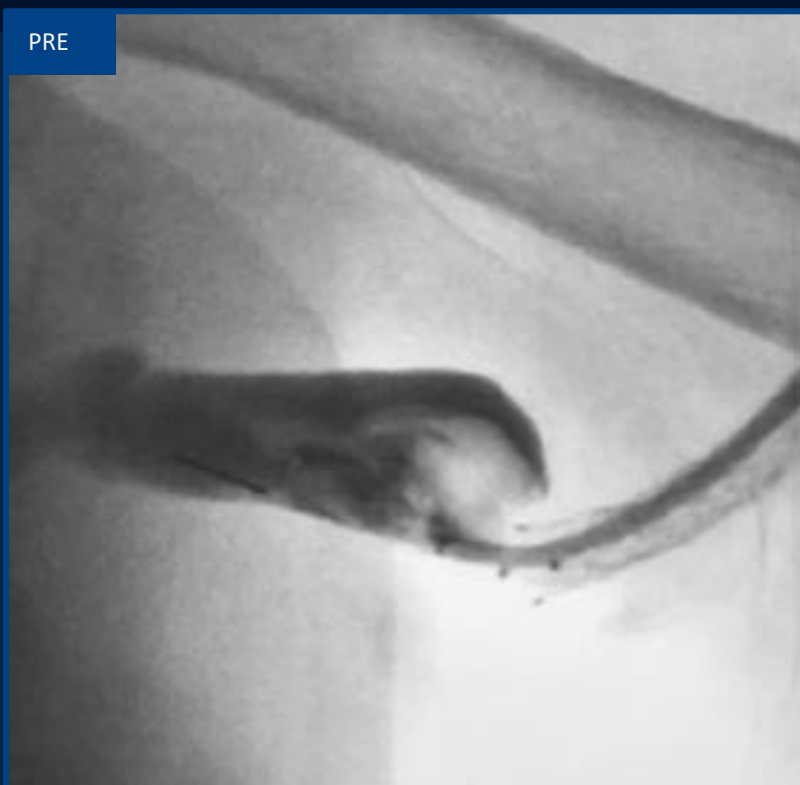
AV Fistula Thrombus



Dr. Paul Perkowski, Baton Rouge General, LA, USA

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AV Fistula Thrombus



Dr. Paul Perkowski, Baton Rouge General, LA, USA

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Treatment of Pulmonary Embolism



Dr. Amir Darki,
Loyola Medicine Gottlieb Memorial Hospital, IL



PE Trial Data Overview

	Primary Efficacy (change in RV/LV ratio at 48 hrs)	Primary Safety	Major Bleeding ¹	All-Cause Mortality (30 days)	Device Time	Hospital Length of Stay ² (Days (± SD))	PE Recurrence Rate (30 days)
EXTRACT-PE^a (N=119) Penumbra Indigo System	27.3%	Major Adverse Events within 48 hrs: 1.7% ³	Within 48 hrs: 1.7%	2.5%	37 min (median)	3.7 ± 2.5	0%
SEATTLE II^b (N=150) EkoSonic™ Endovascular System	24% ⁴	Major Bleeding within 72 hrs: 10%	Within 72 hrs: 10%	2.7%	12–24 hrs	8.8 ± 5	n/a

1. Definitions of major bleeding differed for each trial. Please refer to the specific publications for further information.

2. Length of hospital stay is defined as procedure to discharge.

3. 2 patients experienced 3 events (groin access site bleeding, hemoptysis, death due to sustained ventricular tachycardia post-procedure).

4. Percent reduction calculated for subjects that had CT scan completed within 48 +/- 6 hrs.

a. Sista AK, Horowitz JM, Tapson VF, et al. Indigo aspiration system for treatment of pulmonary embolism: results of the EXTRACT-PE trial. *J Am Coll Cardiol Cardiovasc Interv.* 2021 Feb 8; 14(3): 319–329. doi:10.1016/j.jcin.2020.09.053.

Trial device used was Indigo Aspiration System and catheter was limited to the Indigo System CAT8 used in conjunction with the SEP8 on a per case basis. Lightning 12 was not available at time of trial.

b. Piazza G, Hohlfelder B, Jaff MR, et al. A prospective, single-arm, multicenter trial of ultrasound-facilitated, catheter-directed, low-dose fibrinolysis for acute massive and submassive pulmonary embolism: the SEATTLE II study. *JACC Cardiovasc Interv.* 2015 Aug 24;9(10):1382–1392. doi:10.1016/j.jcin.2015.04.020.

Clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors.

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Science of Aspiration

בקרב...חידושים

LIGHTNING™

Intelligent Aspiration Powered by Penumbra ENGINE™





Lightning

Intelligent Aspiration Powered by Penumbra ENGINE



Clot Detection

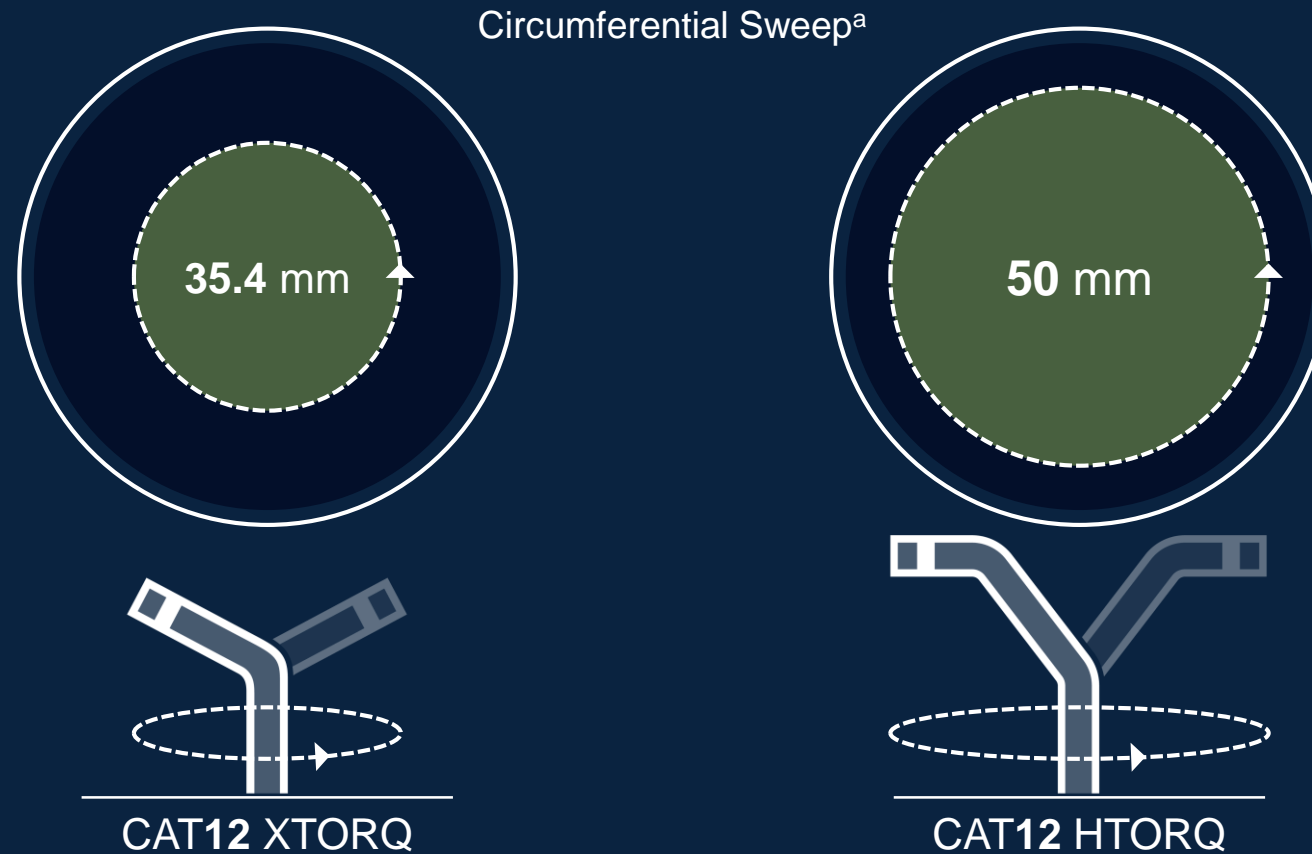
• נועד לעזור למצנתר לזהות את מיקום הפקקת

– הלחיצה תפסיק להתריע בפני המצנתר כאשר יזוהה קריש הדם, מה שעשוי להגביר את יעילות הפעולה וקיצור משך זמן הפעולה.



Click to play

Maximised Aspiration – Size and Sweep



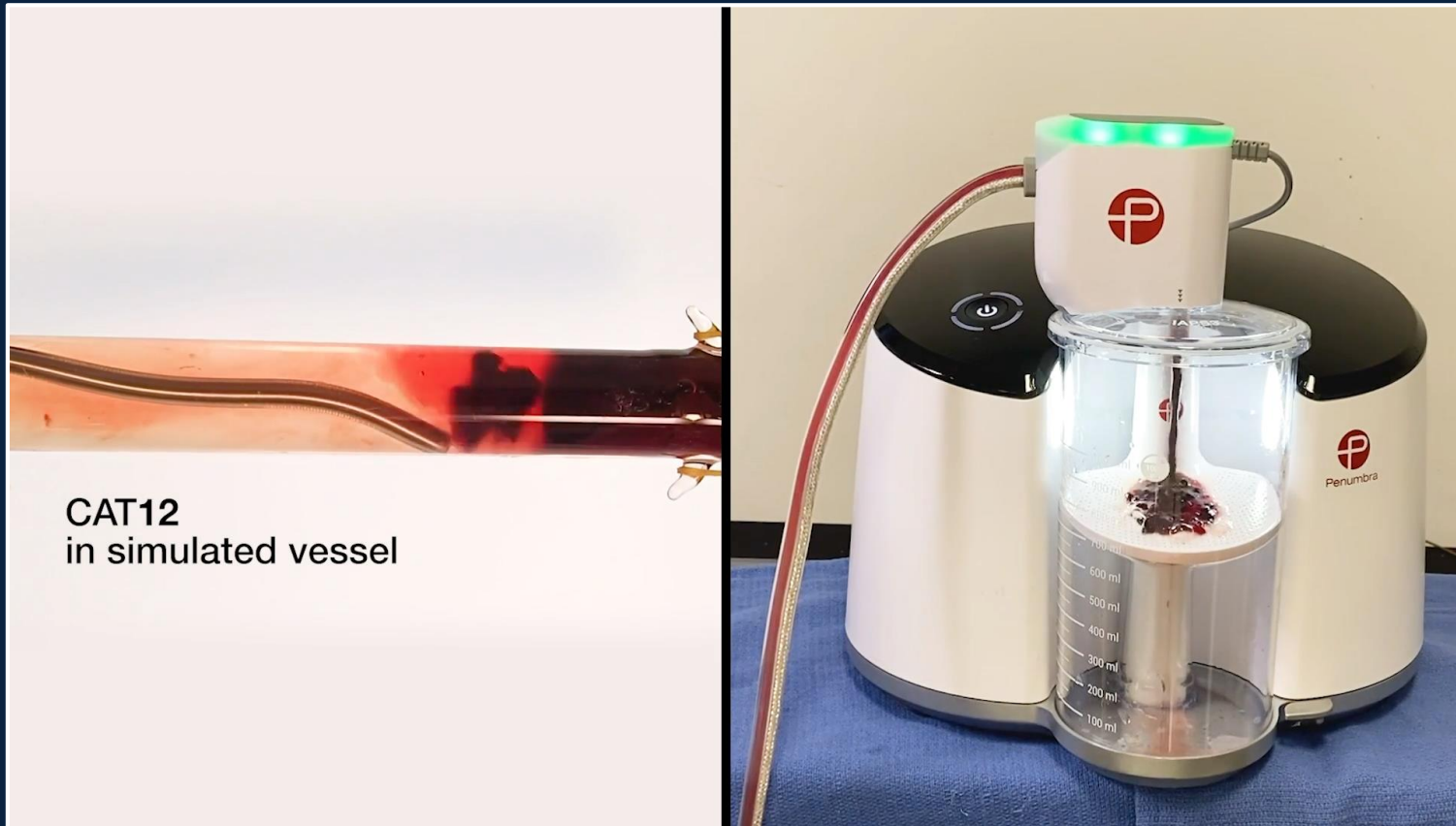
^a Measurements calculated using tip angle and length. Data on file at Penumbra, Inc.
Renderings for illustrative purposes only. Comparison images not shown to scale.

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Lightning 12 Aspiration

Click to play



CAT12
in simulated vessel

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Penumbra ENGINE

**One Touch for
Maximum Aspiration**
Powerful, deep vacuum

-29 inHg^a

Easy Setup
Sleek, simple design



**Live Feedback
During Procedure**
Integrated clot catcher



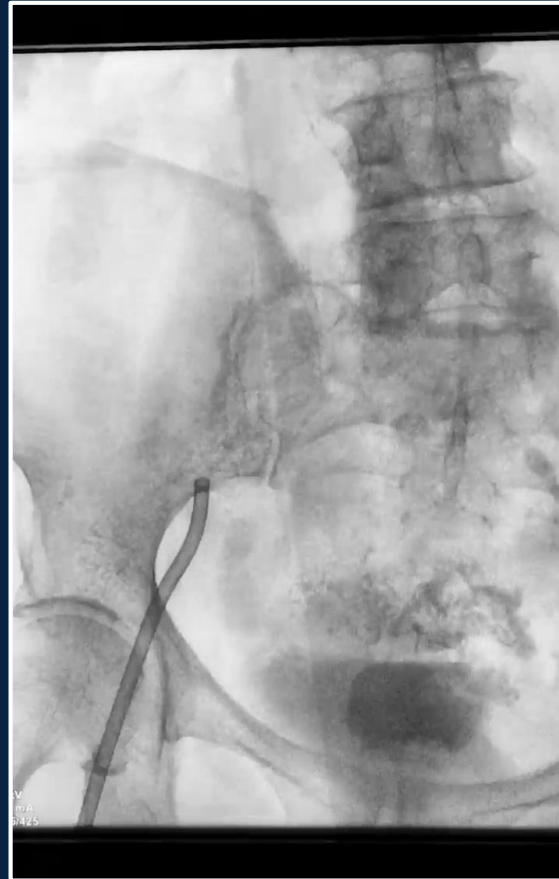
Dr. Brian Schiro,
Miami Cardiac and
Vascular Institute, FL, USA



Dr. Jay Mathews,
Manatee Memorial
Hospital, FL, USA

Coring Clot Technique

[Click to play video](#)



Using macro movements to
core clot with Lightning 12

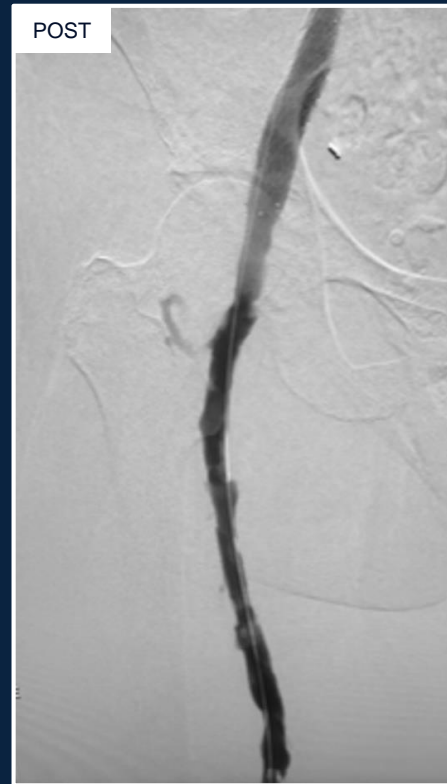
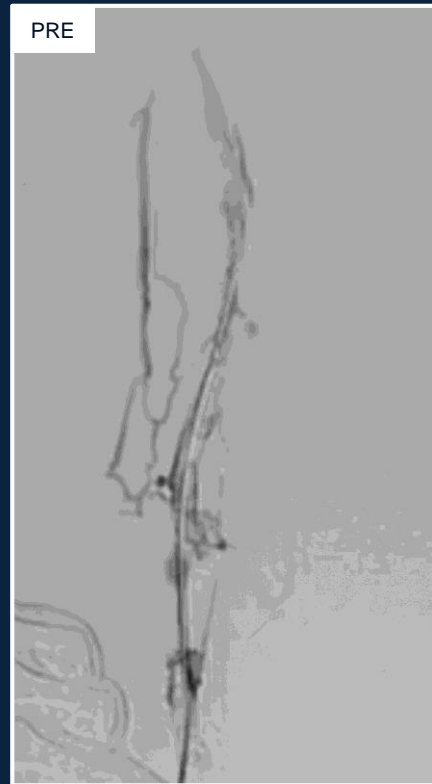
Dr. Gregory Schnier, Alamance Regional Medical Center, NC, USA

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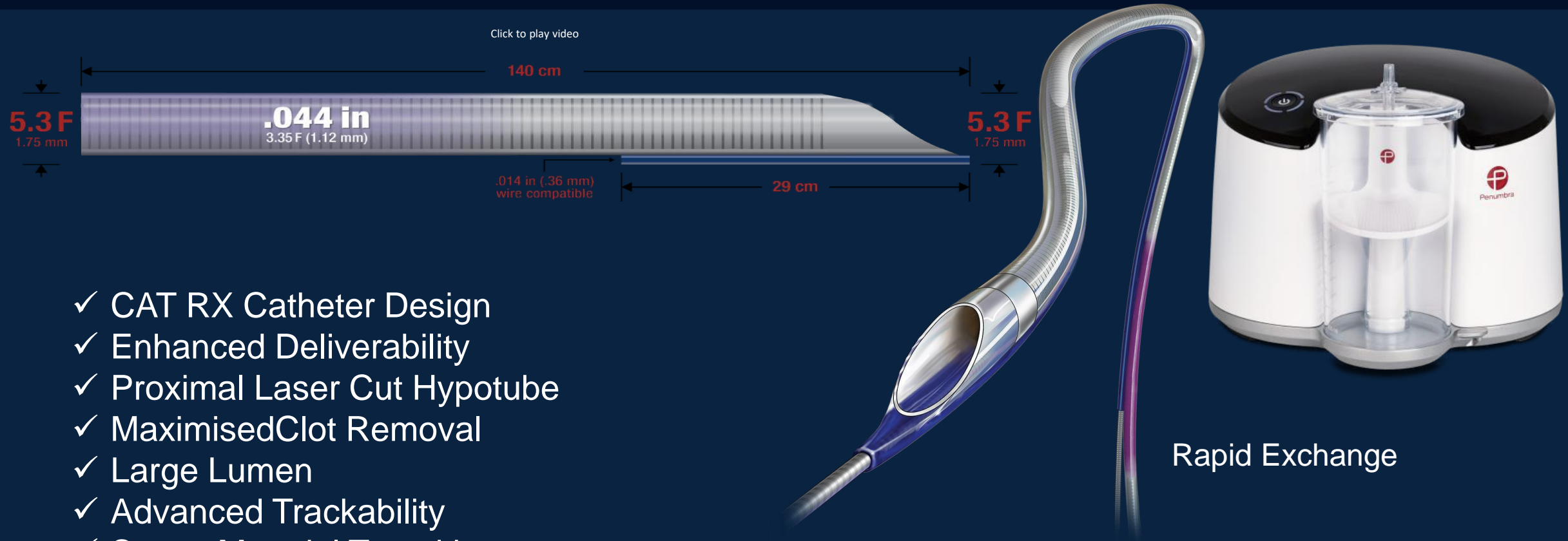
Restoration of Flow in Iliofemoral Vein



Thrombus removed with
Lightning **12** & SEP**12**

Drs. Aaron Kulwicki & Patrick Muck, Bethesda North Hospital, OH, USA

Indigo System | CAT RX Mechanical Thrombectomy



- ✓ CAT RX Catheter Design
- ✓ Enhanced Deliverability
- ✓ Proximal Laser Cut Hypotube
- ✓ Maximised Clot Removal
- ✓ Large Lumen
- ✓ Advanced Trackability
- ✓ Seven Material Transitions

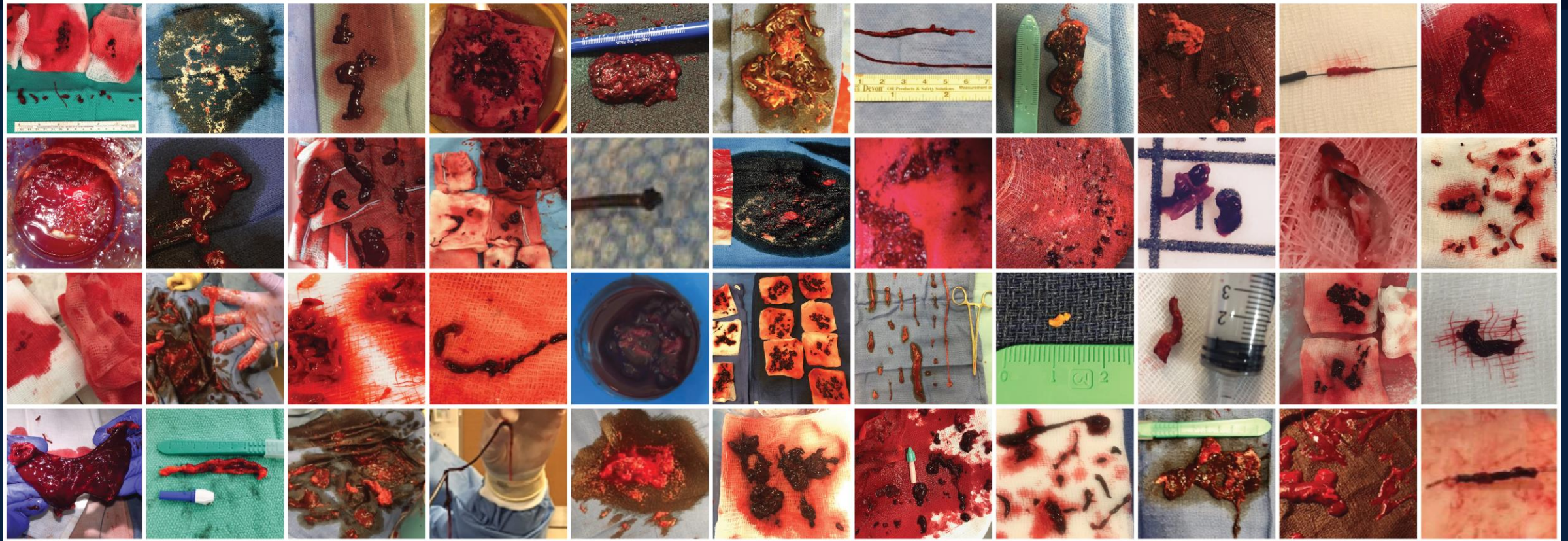
Dr. Gregory Schnier, Alamance Regional Medical Center, NC, USA

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Get the Clot Out with Indigo System



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תודה רבה

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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 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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