

**What is New with Penumbra Indigo Clot Aspiration Systems:
Improved Catheter and Computer Based Clot Removal**

**Lightning Bolt: How it Works and Why it Improves Clot Removal
in Various Vascular Beds – Is Open Surgery Ever Needed**

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DISCLOSURES

CMO PENUMBRA INC

Innovation of CAVT


Lightning 7 & 12

1st Generation CAVT
Single pressure differential based algorithm designed to mitigate blood loss




Lightning Flash[®] 1.0

Algorithms: for quicker clot detection and patent flow detection"
Flash Mode, Extraction Mode, and Sampling Mode



Lightning Flash 2.0 with Select +[™]


Enhanced algorithmic sensitivity and optimized valve cadence with **"Gallop Mode"**



Lightning Bolt[®]
Modulated Aspiration designed to rapidly ingest clot at the tip of the catheter

Lightning Bolt 6[®] with TraX[™]
Modulated Aspiration with TraX[™] for below-the-knee (BTK) navigation

Lightning Bolt 12:
Bolt 2.0 software engineered for improved clot removal efficiency



Introduction of CAVT

Lightning Flash 2.0 with Select +[™]

Enhanced algorithmic sensitivity and optimized valve cadence with **"Gallop Mode"**



Lightning Bolt[®]
Modulated Aspiration designed to rapidly ingest clot at the tip of the catheter

Lightning Bolt 12:
Modulated Aspiration 2.0 now for VTE

Recently FDA cleared



Next-Gen Software
for Arterial and Venous Thrombus Removal


Designed for:

SPEED




Optimized valve cadence for thrombus removal
"Gallop Mode" & Bolt Mode

SAFETY



Versatile catheter sizing with MaxID design paired with Next-Gen CAVT Algorithms

SIMPLICITY



Streamlined audio-visual cues prompted by Dual Clot Detection Algorithms

Lightning Bolt 12 with Bolt 2.0
Modulated Aspiration now for Venous Thrombus PE and arterial clot

Speed:


- Optimized valve cadence for thrombus removal
- "Gallop Mode" & Bolt Mode**

Safety:

- Versatile catheter sizing with MaxID design paired with Next-Gen CAVT Algorithms

Simplicity:

- Streamlined audio-visual cues prompted by Dual Clot Detection Algorithms



Improved Clot Removal Efficiency

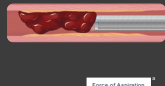
- 3x faster** than Lightning 12/SEP 12
- 22% Increase** in aspiration tubing size
- 60% less saline usage** when compared to Bolt 1.0
- Automatic backflush designed to streamline aspiration

Designed for Speed

Bolt Mode


Modulated Aspiration Designed to Rapidly Remove Thrombus and Restore Flow

Fricion builds between large thrombus and the catheter when under continuous aspiration



Force of Friction Force of Aspiration

Bolt Mode modulates between full aspiration and ambient pressure to break the friction and ingest the clot

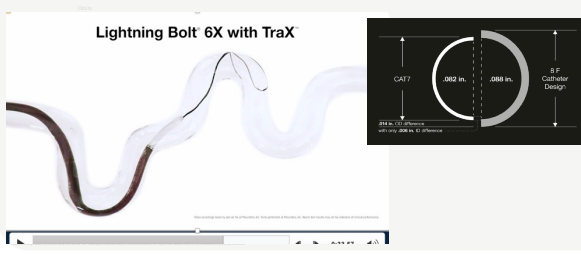


Force of Friction Force of Aspiration

Bolt Mode

The Next Generation of CAVT

Lightning Bolt 6X with TraX



Lightning Bolt 6X with TraX

CAT7: 202 in. 288 in. 8 F Catheter Design

Historical control surgical outcomes vs. STRIDE

Outcome	Open Surgery	STRIDE ^a
Target Limb Salvage at 30 days	83.1% ^[R,2]	98.2%^[1] (108/111)
Target Limb Salvage at 365 days	77.3% ^[R,2]	88.5%^[1] (77/87)
Patency at 30 days	78.6% ^[3]	89.4%^[1] (101/113)
Mortality at 30 days	13.2% ^[4]	3.4%^[5] (4/119)
Mortality at 365 days	33.8% ^[4]	12.0%^[1] (12/100)
Major bleeding	21.0% ^[R,4]	4.2%^[5] (5/119)


a. STRIDE study was a randomized, controlled, single-blind, parallel-to-specific publication to evaluate safety for selected patient and data collection methods for open surgical vascularization. 1. N Engl J Med. 2023;389(10):1011-1021. 2. N Engl J Med. 2019;381(10):1011-1021. 3. JAMA. 2019;321(10):1011-1021. 4. N Engl J Med. 2019;381(10):1011-1021. 5. N Engl J Med. 2023;389(10):1011-1021.

STRIDE II Study Overview

Purpose	To collect and evaluate clinical evidence supporting the safety and performance of the Indigo Aspiration System in a patient population with lower extremity acute limb ischemia (LEALI).
Study Design Features	Post-market, prospective, acute LEALI; up to 300 limbs; up to 50 global sites. Approximately 50 limbs with LEALI due to an acute thrombus in a previously placed stent will be enrolled as a subgroup.
Key Endpoints	Primary: Target Limb Salvage at 30d Secondary: TIPI 2/3 Flow; Patency 30d; Device-related major bleeding; Device-related SAEs; Device-related distal embolization; All-cause mortality at 30d and 180d Follow-up at Discharge and/or 7d, 30d, and 180d
Product	Indigo Aspiration System (Lightning Bolt 7, Lightning Bolt 12, Lightning Bolt 6X w TraX and CAT RX)
National PI	Daniel Clair Vascular Surgeon Vanderbilt University Medical Center Dierk Scheinert Angiology Germany
Independent Medical Reviewer	Bret Wichmann Interventional Radiology Vascular & Interventional Physicians

New Technology: Lightning Flash™

SUBGROUP FROM 300 PATIENT INTERIM ANALYSIS



Penumbra ENGINE™ pump with Lightning Flash™ Aspiration Tubing attached

Lightning Flash™ (16F catheter)

Periprocedural Characteristics; mean (SD), median [IQR], or % (n)	Lightning Flash (N = 86)
Thrombectomy time, min [†]	23 [19-35]
Primary endpoint: Percent reduction in RV/LV ratio, baseline to 48 h	27.8% (14.1%) [†]
Percent reduction in sPAP	24.5% (18.5%)
Reduction in Borg dyspnea scale score, baseline to discharge	3 [2-7]

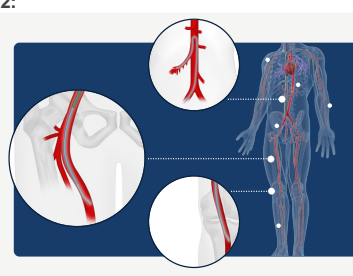
† First Indigo device insertion to last Indigo device removal. 19 of 82. 8 Access site hematoma.

Lightning Bolt 6X, 7, 12:

Arterial Applications

Arterial Thrombus Applications

- Upper Extremity
- Lower Extremity
- Popliteal
- Below-the-Knee
- A-fib Emboli
- In-Stent Thrombosis
- Bypass Graft Occlusions
- Visceral Occlusions



Lightning Bolt: How it Works and Why it Improves Clot Removal in Various Vascular Beds – Is Open Surgery Ever Needed

- Significant advancements to improve ease of use, safety and efficiency of clot removal
- Clinical data with excellent outcomes supports this technology as the best non surgical option for clot management
- Need for surgery in ALI is reduced in large percentage of cases with outcomes that are either better or equal to conventional surgery