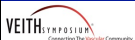



Time To Perfusion In ALL: Which Is Faster, Lightning Bolt 7 (Penumbra) Or Open Surgical Embolectomy: When Is Open Surgery Necessary In 2024

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Professor & Chairman
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Disclosures

- Consultant: BD, Boston Scientific, Contego Medical, Cordis, Endologix, Inspire MD, Medtronic, Rapid Medical, Shockwave, Penumbra, Vivasure, Nectero, Reflow
- Stock options: Inspire MD and Centerline Biomedical, Reflow
- VIVA Physicians, Board Member
- Research Studies: Abbott, Endologix, Surmodics, W.L. Gore, Terumo Aortic, NIH, Boston Scientific, Merit, Contego Medical, Inspire MD, Reva Medical, Penumbra, Medalliance, Nectero

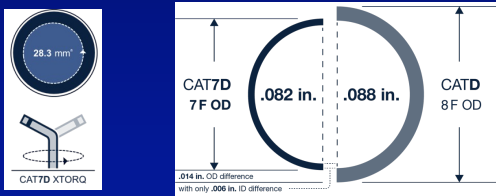



Why Indigo?



- Enables thrombus removal similar to surgical embolectomy
 - Underlying lesion can then be Rx during same procedure
- Enables access to vessels below-the-knee (BTK)
- Potentially eliminates the need for lytics
- Preserves adjunctive treatment options


CAT 7 & 7D





CAT 7 & 7D is 93% the size of CATD

Lightning Bolt 7





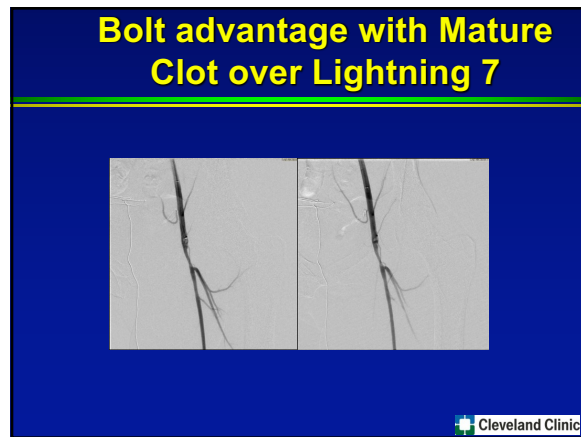
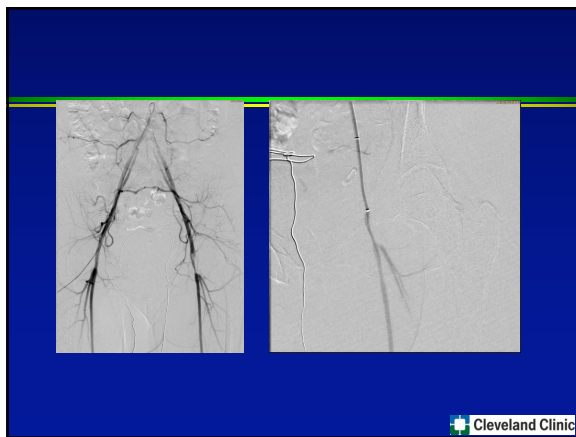
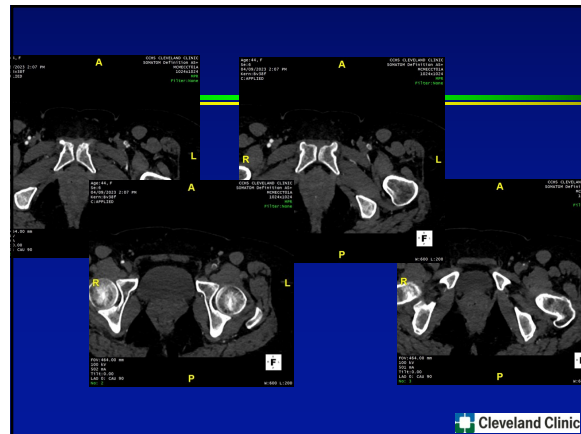
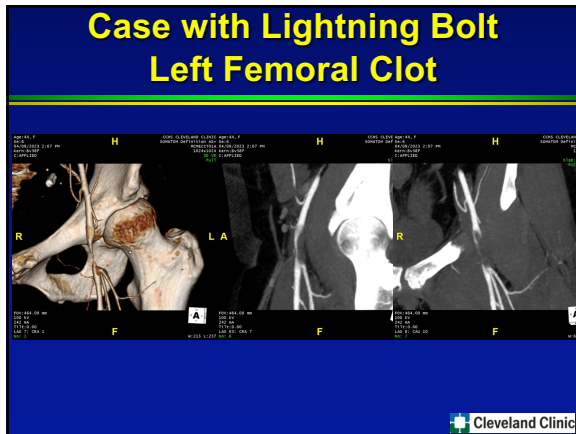
Lightning Bolt 7
High Power, Low Profile

Lightning Bolt 7



- Lightning Bolt 7 designed for accelerated thrombus removal
- Offers a frontline thrombus removal option for multiple clot lesions, above and below-the-knee
- Enables thrombus removal similar to Fogarty embolectomy
- Underlying stenosis can then be addressed at same procedure
- Potentially reduces the need for lytics
- Preserves adjunctive treatment options





6 Month Follow Up

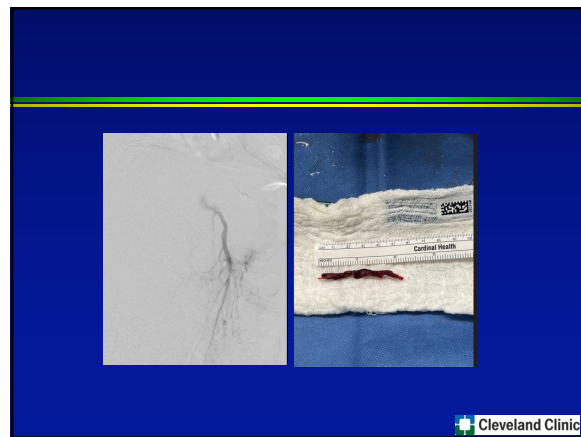
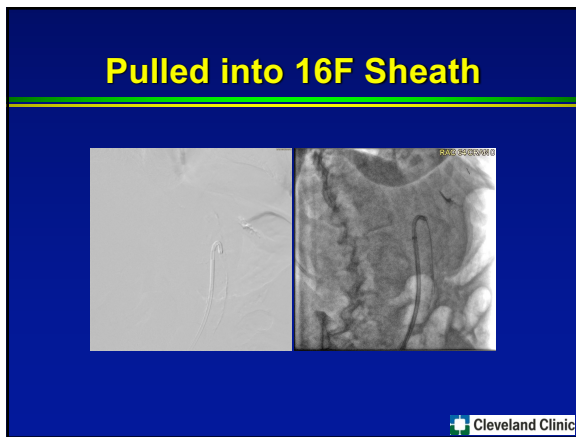
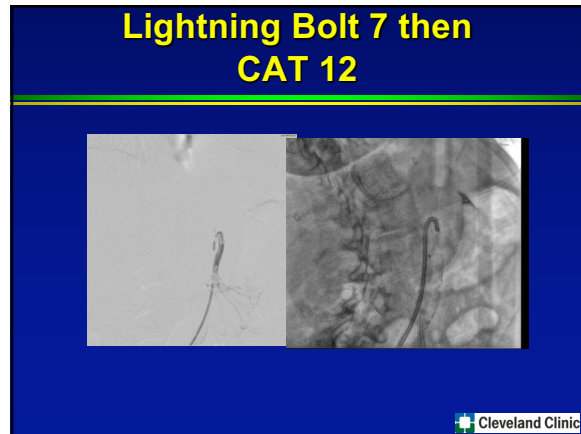
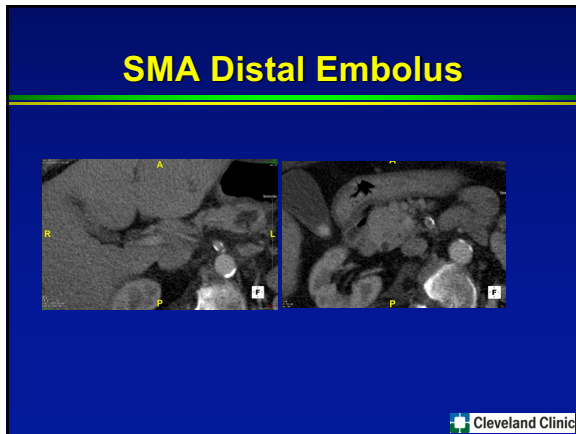
- ABI 1.0
- Duplex without residual stenosis
- No recurrent events
- Maintained on Coumadin

Acute Mesenteric Ischemia

- 64 yo WF with hemorrhagic shock to GI bleed held AC for Afib
- Congenital Heart baby
 - Blalock shunt chronic hypoxia and pulmonary HTN
- Metastatic breast cancer
- Acute onset abdominal pain
- 7.41/36/30 Plts 34K



Stride Eligibility

Inclusion Criteria

- Patient age ≥18
- Patient presents with acute (≤14 days) occlusion of lower limb artery(ies) (below inguinal ligament)
- Patient with a Rutherford Category I, IIa or IIb score
- Frontline treatment with Indigo Aspiration System
- Informed consent is obtained from either patient or legally authorized representative (LAR)

Exclusion Criteria

- Life expectancy <1 year
- Target vessel size <3 mm
- LE AJ secondary to dissections, vasculitis, and/or target vessel trauma
- Amputation in the ipsilateral limb
- Pregnancy or positive pregnancy test according to site specific standards of care
- Absolute contraindication to contrast admin.
- Patient is unwilling or unable to comply with protocol follow up schedule and/or based on the investigator's judgment the patient is not a good study candidate
- Currently participating in an investigational drug or device clinical trial that may confound the study endpoints.
- Target thrombus in a saphenous vein bypass graft

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Data Supports

Frontline Thrombus Removal with Indigo

Target Limb Salvage at 30 days

Treatment	Target Limb Salvage at 30 days
STRIDE Study Indigo System	98.2%
Open Surgical Revascularization ^{1,2}	83%

Mortality at 30 days

Treatment	Mortality at 30 days
STRIDE Study Indigo System	3.4%
Open Surgical Revascularization ^{1,2}	13.2%

Cleveland Clinic

Conclusions

- Indigo Family of Devices
 - Single session thrombectomy without lytics
 - Lightning Smart Aspiration limits blood loss
 - Bolt mechanism devours chronic clot
 - Catheters tracks well in arteries without a wire
 - Used for mesenterics, SFA pop and proximal tibial
 - Open Surgery rarely needed

