

LIGHTNINGTM

Intelligent Aspiration Powered by Penumbra ENGINETM

Computer-Aided Mechanical Aspiration
Thrombectomy
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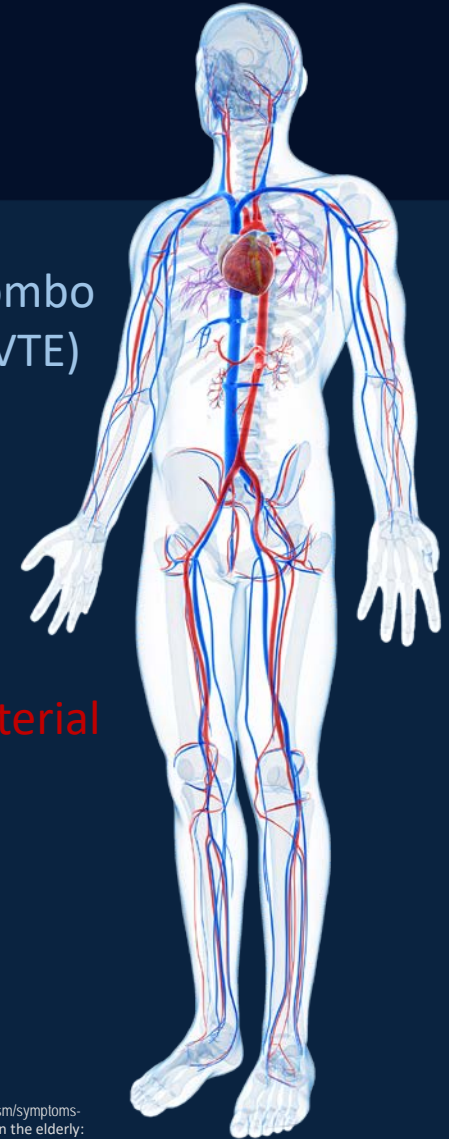


Peripheral Arterial & Venous Disease

- **Thrombus and embolism producing conditions**
- **Peripheral Arterial Disease (PAD)**
 - **Affects over 8.5 million Americans¹**
- **Venous Thromboembolism (VTE) –**
 - **VTE = Deep Vein Thrombosis (DVT) & Pulmonary Embolism (PE)**
 - **Approximately 900,000 annual VTE events in U.S.²**
 - **60% of all VTE events occur in those aged 70 years or older³**
- **COVID-19 patients are at high risk for thrombotic arterial and venous occlusions⁴**

Venous Thrombo
Embolism (VTE)

Arterial



Sources:

Centers for Disease Control and Prevention. Venous Thromboembolism (Blood Clots). Venous Thromboembolism: Impact of Blood Clots on the United States - Infographic. <http://www.cdc.gov/ncbddd/dvt/infographic-impact.html>. Accessed October 5, 2015.; <https://www.mayoclinic.org/diseases-conditions/pulmonary-embolism/symptoms-causes/syc-20354647>; <https://www.worldthrombosisday.org/issue/vte/pe/>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5220207/>; ¹ <https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-resources>; Engbers, M. J., Van Hylckama Vlieg, A., & Rosendaal, F. R. (2010). Venous thrombosis in the elderly: incidence, risk factors and risk groups. *Journal of Thrombosis and Haemostasis*, 8(10), 2105-2112. doi:<https://doi.org/10.1111/j.1538-7836.2010.03986.x>; ² Blood clots: a serious but preventable medical condition what you need to know to protect yourself. www.cdc.gov/ncbddd/dvt/documents/blood-clots-fact-sheet.pdf (2018, accessed 2 July 2019); ³ Zuo, Y., Estes, S. K., Ali, R. A., Gandhi, A. A., Yalavarthi, S., Shi, H., . . . Knight, J. S. (2020). ⁴ Prothrombotic autoantibodies in serum from patients hospitalized with COVID-19. *Science Translational Medicine*, eabd3876. doi:10.1126/scitranslmed.abd3876 Anatomical diagram is for illustrative purposes only. Image used under license from www.shutterstock.com.

Current Endovascular Clot Removal Medical Devices

- Manual Aspiration Catheters (various manufacturers)
 - Simple manual aspiration using syringe
- Inari Flowtriever (indicated for pulmonary embolism),
 - Uses self-expanding nitinol mesh disks that deliver clot to the catheter for extraction; aspiration is provided via syringe
- Inari clottriever (non-PE thrombectomy)
 - Utilizes a coring element and a braided collection bag, designed to collect clot for extraction from ClotTrievers Sheath, if aspiration is utilized, it is via syringe
- Angiovac
 - Utilizes an extracorporeal bypass circuit that is created outside the body consisting of an outflow line, a centrifugal pump, a filter and an inflow line

Lightning Intelligent Mechanical Aspiration Thrombectomy

- Unlike existing endovascular clot removal products, Lightning uses a mechanical pump to generate a vacuum for aspiration and smart technology to enhance clot removal and prevent blood loss.
- The Lightning system is used as a complete system to evacuate clot burden from peripheral arterial and venous vessels as well as the pulmonary circulation.
- The system is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.
 - Likely disease states are the following: Venous Embolism and Thrombosis (I82), Arterial Embolism and Thrombosis (I74), Acute Limb Ischemia (M62.25,.26.27.28), Pulmonary Embolism (I26).
- The Lightning device uses a proprietary algorithm that adjusts the parameters of the system allowing it to distinguish when the catheter is in free flow versus when it is aspirating clot. The smart device (Lightning) senses this flow and closes the valve in less than 50 milliseconds, versus manual actuation which typically takes a minimum of 2 seconds. This system therefore allows the system to aspirate a large amount of thrombus in a short period of time with minimal blood loss.

Lightning Intelligent Mechanical Aspiration Thrombectomy System

- The complete system is comprised of a catheter and Lightning device tubing (all connected to an aspiration pump). The intelligent or smart component (Lightning) consists of 2 sensors, a switch, a valve, and a microprocessor with a proprietary algorithm. The system is single-use, temporary and removed immediately post-procedure. The system is sold & packaged together (the pump is provided separately). Only one device is routinely used per surgical procedure.
 - The catheter part of the system is identifiable in the chargemaster via a C-code (C1757), the procedure and device name should be documented and identifiable in the operative notes/record.

Lightning Device and INDIGO System

Intelligent Aspiration Powered by Penumbra ENGINE



Microprocessor with proprietary
thrombus removal algorithm

Automatic valve control



Lightning ON/OFF Switch

Lightning Intelligent Mechanical Aspiration Thrombectomy

- Mechanical aspiration thrombectomy is a percutaneous, image guided procedure.
- The procedure is primarily an inpatient procedure.
- The procedure using the Lightning Intelligent Mechanical Aspiration Thrombectomy System is a standalone procedure, but can be used in conjunction with other procedures.
- There have been no complications/sequela/adverse events associated with the Lightning Device.

Intelligent Mechanical Aspiration Thrombectomy - Procedural Steps

- Vessels are accessed percutaneously at various sites.
- The aspiration catheter may or may not be introduced over a guidewire and then advanced to the site of the thrombus.
- Once at the site of the thrombus, the physician initiates aspiration to the catheter with the pump via the Lightning smart device.
- Lightning turns on aspiration when the catheter is in thrombus and shuts it off when not in thrombus.
- If appropriate, the separator is advanced through the catheter to assist with clearing the catheter lumen.
- A final angiogram and hemodynamic evaluation if indicated is conducted post-Indigo device removal and post-procedure.

ICD-10-PCS Code to Describe Mechanical Aspiration Thrombectomy Using AI Assistance

- There is no unique ICD-10-PCS code to describe extirpation of matter from peripheral arterial and venous systems using a mechanical thrombectomy aspiration device with smart technology to detect when the catheter is in thrombus or patent flow to reduce blood loss.
- New codes need to be created to accurately describe procedures performed with this new technology to allow for:
 - Differentiation from mechanical thrombectomy that does not involve aspiration or AI assistance
 - Accurate reporting and outcomes tracking associated with reduced blood loss and better clot removal

Thank You