Deep Vein Thrombosis (DVT)

Diagnosis

If your doctor suspects a blood clot in the deep veins, they may:

Ask about your signs and symptoms and when they began

Ask you or a family member about your medical history

Conduct a physical examination

Your doctor may order one or more of the following tests:

- A **D-dimer** test measures a type of protein in the blood that the body produces to break down a blood clot.
- **Duplex ultrasonography** is a test that uses sound waves to look at the flow of blood in the veins. It can detect blockages or blood clots in the deep veins.
- **Contrast venography** is an X-ray that uses a special dye to take pictures of blood flow through veins.
- **Magnetic resonance imaging (MRI)** uses radio waves and a magnetic field to create images of the body.
- **Computed tomography (CT) scan** uses a combination of X-rays and computer technology to produce images of the body. CT with contrast dye enhances the image of the organ or tissue under study.

Treatment

If your doctor suspects a blood clot in the deep veins, they may recommend the following:

Anticoagulants are medications that are commonly called "blood thinners." They do not dissolve the clot, but prevent new blood clot from forming. They may also be given during your hospital stay and for several months after.

Thrombolytic therapy. A doctor may recommend an injectable medication (i.e., "clot-busting" medication) to dissolve blood clots, for patients with a low risk of bleeding.

Mechanical thrombectomy is a minimally-invasive procedure that physically removes clot from blocked arteries and veins.

Compression stockings are often recommended as part of standard treatment. These are prescribed to help reduce leg pain and swelling.

Sources: CDC, NHLBI, AHA, NLM

Renderings for illustrative purposes only.

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Penumbra

Prescribing Information

INDIGO Aspiration System CAT12 – Indication for Use
INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. **INDIGO Aspiration Tubing:** As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump:** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** Not for use in the coronaries or the neurovasculature. **Warnings** • The safety and effectiveness of this device for use in the treatment of pulmonary embolism (PE) has not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention. • The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques. • Do not advance, retract or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR against resistance may result in damage to the device or vessel. • Do not use the INDIGO Aspiration System with a pump other than the Penumbra Aspiration Pump. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the INDIGO Aspiration System in conjunction with fluoroscopic visualization. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the INDIGO Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing valve when aspiration is complete is not recommended. • The INDIGO SEPARATOR is not intended for use as a guidewire. If repositioning of the INDIGO Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard microcatheter and guidewire techniques. • Do not use automated high-pressure contrast injection equipment with the INDIGO Aspiration Catheter because it may damage the device. **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.

LIGHTNING Aspiration Tubing – Indication for Use
INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Contraindications** There are no known contraindications. **Warnings** • Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump. • Use of LIGHTNING Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly. • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of LIGHTNING Aspiration Tubing. Otherwise, this could result in degradation of the performance of this equipment. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove the thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended. • Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide. • Do not use in oxygen rich environment. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arrhythmia/fibrillation; arteriovenous fistula; death; device malfunction; distal embolization; emergent surgery; false aneurysm formation; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or blood loss; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; myocardial infarction; neurological deficits including stroke; respiratory failure; thromboembolic events; vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

INDIGO Aspiration System with LIGHTNING Aspiration Tubing – Indication for Use
INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are 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. **INDIGO Aspiration Tubing:** As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump:** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no known contraindications. **Warnings** • Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump. • Use of LIGHTNING Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly. • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of LIGHTNING Aspiration Tubing. Otherwise, this could result in degradation of the performance of this equipment. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove the thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arrhythmia/fibrillation; arteriovenous fistula; death; device malfunction; distal embolization; emergent surgery; false aneurysm formation; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or blood loss; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; myocardial infarction; neurological deficits including stroke; respiratory failure; thromboembolic events; vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

INDIGO Aspiration System – Indication for Use
INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are 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. **INDIGO Aspiration Tubing:** As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump:** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** Not for use in the coronaries or the neurovasculature. **Warnings** • The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques. • Do not advance, retract or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR against resistance may result in damage to the device or vessel. • Do not use the INDIGO Aspiration System with a pump other than the Penumbra Aspiration Pump. • Placing guidewire too distal in the pulmonary vasculature or excessive manipulation of aspiration/guiding catheter in the smaller, peripheral, and segmental pulmonary artery branches can result in vessel perforation. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the INDIGO Aspiration System in conjunction with fluoroscopic visualization. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended. • Hemoglobin and hematocrit levels should be monitored in patients with >700 mL blood loss from the clot aspiration procedure. • The INDIGO SEPARATOR is not intended for use as a guidewire. If repositioning of the INDIGO Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard catheter and guidewire techniques. • Do not use automated high-pressure contrast injection equipment with the INDIGO Aspiration Catheter because it may damage the device. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arrhythmia; arteriovenous fistula; cardiac injury; cardio-respiratory arrest; death; device malfunction; distal embolization; emboli; excessive blood loss; 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; hemoptysis; respiratory failure; thromboembolic events.

PENUMBRA ENGINE – Indication for Use
The PENUMBRA ENGINE is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no contraindications. **Warnings/Precautions** • The canister is intended for single use only. Do not reuse. Reuse may result in canister cracking or vacuum filter blockages, which may result in the inability to aspirate. • Do not block bottom air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow. • To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth. • Do not position the PENUMBRA ENGINE so that it is difficult to remove the power cord. The means of mains disconnect is to remove the power cord. • Only use replacement fuse with correct rating (see Table 1 for fuse rating). • Remove and service the PENUMBRA ENGINE if liquids or solids have been drawn into the PENUMBRA ENGINE. • Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide. • Do not use in an oxygen rich environment. • To prevent fire or shock hazard, use a replacement power cord of equal rating. • Do not re-infuse blood or fluid from the canister back into the patient. • Do not use petroleum based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the PENUMBRA ENGINE. Use only water-based solvents for cleaning. • Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the PENUMBRA ENGINE. Otherwise, this could result in degradation of the performance of this equipment. • Common emitters (such as RFID emitters, security systems, diathermy equipment, and portable transmitters) should not be used in close proximity to the PENUMBRA ENGINE as they can interfere with and result in degradation of the performance of the equipment. • Equipment is not safe for MR use. • No modification of this equipment is allowed.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. 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. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Renderings for illustrative purposes only. Photographs taken by and on file at Penumbra, Inc. Please contact your local Penumbra representative for more information.

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Deep Vein Thrombosis

What is Deep Vein Thrombosis?

Deep Vein Thrombosis (DVT) is a blood clot that stops or slows blood flow through a vein deep in the body, usually the lower leg, thigh, or pelvis. One-third of people can have complications due to the damaging effects clot can have on vein function. DVT also puts people at a higher risk of a Pulmonary Embolism (PE), a blood clot in the lungs. PE is a life-threatening condition that can occur when clot breaks free from its original location, like in the lower leg, and travels to an artery in the lungs.

Risk Factors

Almost anyone can have a DVT. However, certain factors, such as health conditions, lifestyle, age, and family history, can increase your risk. The more risk factors a person has, the higher the chance of developing a DVT. Risk factors may include the following:

Not moving for long periods (e.g., prolonged sitting, bed rest)

Cancer and cancer treatments

Family history of DVT or PE

Estrogen-based medicine (e.g., hormone therapy, birth control pills)

50% of blood clots happen during or after a stay in the hospital

Pregnancy (including up to 3 months after delivery)

Major surgery (particularly of the pelvis, abdomen, hip, knee)

Injury to a vein that may have been caused by a broken bone or severe muscle injury

Long-term diseases (e.g., heart and lung conditions, or diabetes)

Inherited clotting disorders

Overweight or obesity

Older age

Symptoms

Only about half the people who have DVT experience symptoms. When present, symptoms in the affected limb may include:

Swelling (sometimes suddenly)

Pain or tenderness

Feeling of increased warmth

Redness or discoloration of the skin

Renderings for illustrative purposes only.

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Penumbra

Indigo System | Computer Assisted Vacuum Thrombectomy

Penumbra's Indigo® Aspiration System, launched in 2014, is designed to remove clot from arteries and veins in the peripheral vasculature, and for the treatment of pulmonary embolism.

A minimally-invasive device, Indigo System enables the restoration of blood flow in such cases as acute limb ischemia and venous thrombus.

The Indigo System utilizes the Penumbra ENGINE® Aspiration Source capable of delivering nearly pure, continuous vacuum (-29 inHg or 98.2 kPa) to our catheters, enabling thrombus removal in vessels of various sizes.

The Indigo System with Lightning® Aspiration Tubing is a computer assisted vacuum thrombectomy system powered by Penumbra ENGINE®.

LIGHTNING FLASH

Designed for Accelerated Clot Detection and Removal Proprietary thrombus removal algorithms with intraprocedural audio-visual cues designed for:

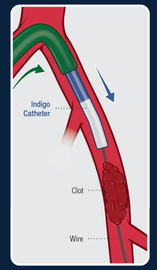
- Quicker clot detection
- Quicker patent flow detection to reduce potential blood loss

MaxID Technology

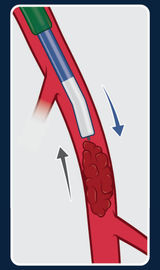
- Comparable to IDs of large-bore catheters while maintaining a lower profile
- Laser-cut stainless steel hypotube

Indigo System | Computer Assisted Vacuum Thrombectomy

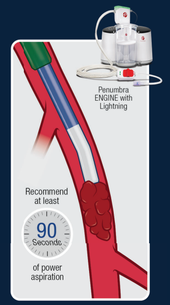
XTRACT Technique



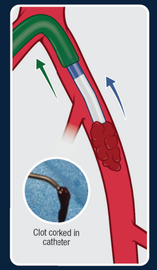
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo Aspiration Catheter is advanced through sheath over a wire.



The Indigo Aspiration Catheter is placed just proximal to the face of the clot and wire is retracted.



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



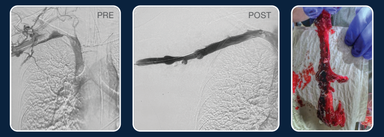
The Indigo Aspiration Catheter is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

Computer Assisted Vacuum Thrombectomy for Venous Thrombus

Estimated Device Time[a] 1½ min

Removal of Thrombus from the Subclavian Vein

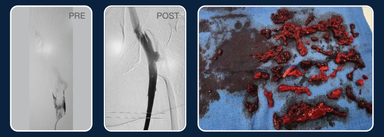
Dr. James Vogler, Saint Anthony's Hospital, FL



Estimated Device Time[a] 8 min

Removal of Thrombus from Lower Extremity

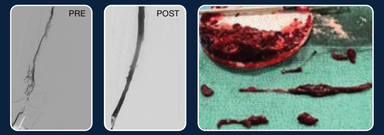
Dr. Matthew Hegewald, St. Michael Medical Center in Silverdale, WA



Estimated Device Time[a] 8 min

Removal of Thrombus from Lower Extremity

Dr. Frank Arko, Atrium Health, NC



a. Estimated device time is the estimated amount of time Lightning Flash was used during the featured case.

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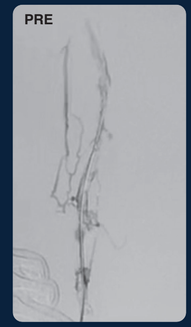
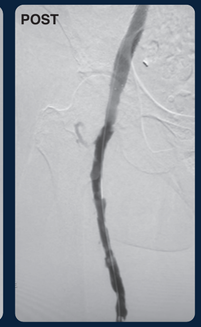
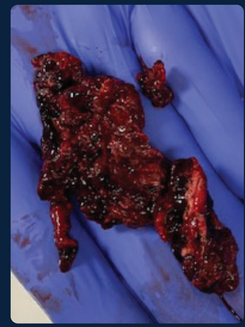
Lightning 12 for Restoration of Flow in Iliofemoral Vein

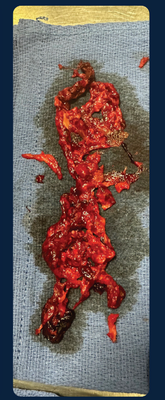




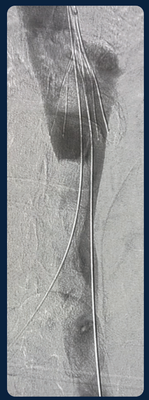


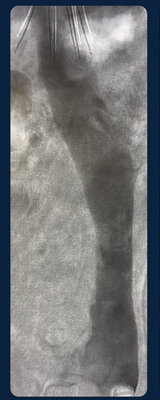
Thrombus removed with Lightning 12 & SEP12

Removal of Thrombus from IVC Filter with the Lightning Flash System



Post Lightning 12





Post Lightning Flash

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