Indigo™ System | Mechanical Thrombectomy

Lightning™
Intelligent Aspiration

When the **Indigo System** is in thrombus, aspiration is continuous.
When in patent flow, aspiration is intermittent.

Clot Detection

Designed to help operator identify thrombus location

Designed for Blood Loss Reduction[a]

18:1 fluid loss reduction with Lightning vs. Dynamic Tubing

Lightning ON/OFF Switch

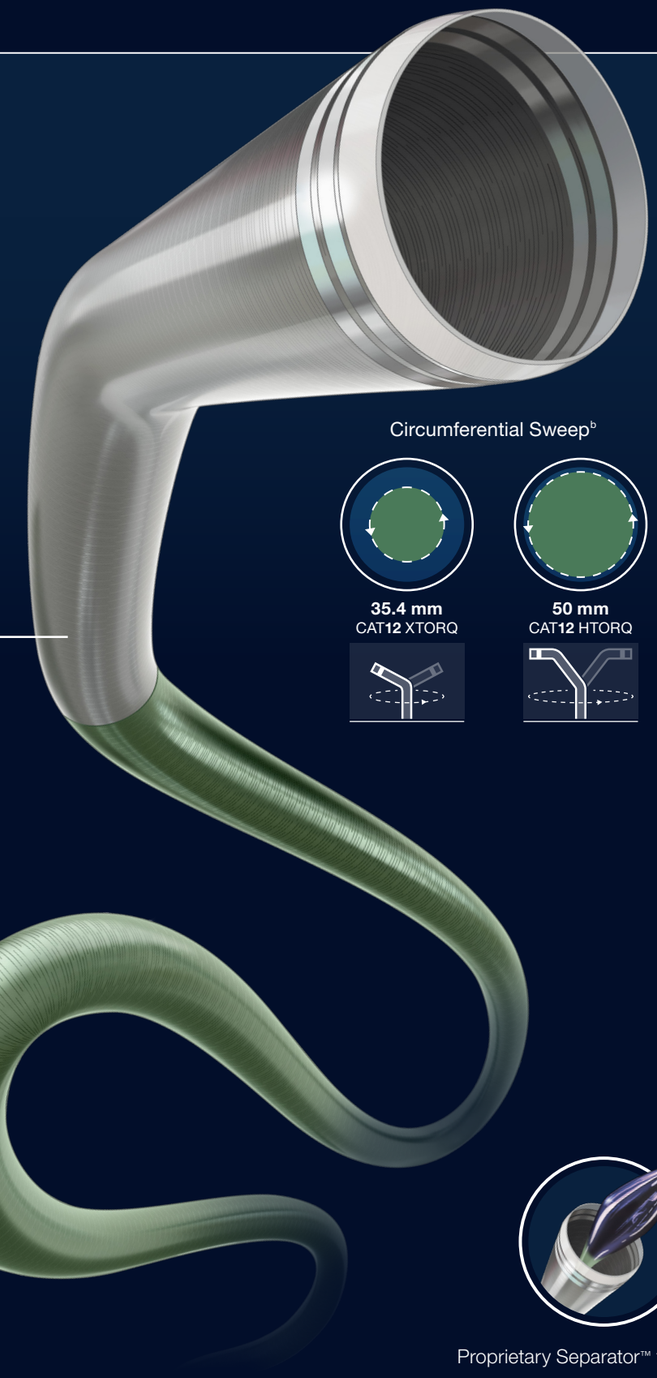
Powered by Penumbra ENGINE

a. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Tests performed using water. Renderings for illustrative purposes only.

CAT™12
Maximised Thrombus Engagement

Size and sweep enables operator to engage and remove thrombus

Multi-pitch, laser-cut, stainless steel hypotube for 1:1 torque transfer and advanced deliverability



Circumferential Sweep[b]

35.4 mm
CAT**12** XTORQ

50 mm
CAT**12** HTORQ

Proprietary Separator™ technology

b. Measurements calculated using tip angle and length. Data on file at Penumbra, Inc. Photographs taken by and on file at Penumbra, Inc.

Ordering Information

Indigo™ System Lightning™ Kits

Catalog Number	Description	Proximal OD	Distal OD	Compatibility	Working Length (cm)	Wire Platform (in.) (mm)	Compatible Penumbra Devices
LITNG12HTORQ115 – *Now!*	**Indigo 12 HTORQ Tip + Lightning Aspiration Tubing**	**12 F (4.04 mm)**	**12 F (4.04 mm)**	**12 F Sheath**	**115**	**.014–.038 (.36–.97)**	**Separator™ 12**
LITNG12HTORQ100 – *Now!*	**Indigo 12 HTORQ Tip + Lightning Aspiration Tubing**	**12 F (4.04 mm)**	**12 F (4.04 mm)**	**12 F Sheath**	**100**	**.014–.038 (.36–.97)**	**Separator 12**
LITNG12XTORQ100 – *Now!*	**Indigo 12 XTORQ Tip + Lightning Aspiration Tubing**	**12 F (4.04 mm)**	**12 F (4.04 mm)**	**12 F Sheath**	**100**	**.014–.038 (.36–.97)**	**Separator 12**

Indigo Separators

Catalog Number	Description	Distal OD (in.) (mm)	Total Length (cm)	Compatible Penumbra Devices
SEP12 – *Now!*	Separator **12**	.110 (2.79)	150	CAT™**12**

Accessories

Catalog Number	Description	Compatible Penumbra Devices
PMXENGN	Penumbra ENGINE™	Penumbra ENGINE Canister
IAPS3	Penumbra ENGINE Canister	Penumbra ENGINE

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.

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. • 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 – 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.

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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.

Product availability varies by country. Please contact your local Penumbra representative for more information.

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