# Table of Contents

- Penumbra System with 3D Revascularization Device 2
- Penumbra System RED 4
- Penumbra ENGINE 6
- Penumbra Pump MAX 7
- Penumbra Delivery Microcatheters (PX SLIM, Velocity) 7
- Penumbra SMART COIL System 8
- Penumbra Coil System 9
- Neuron Intracranial Access System 10
- BENCHMARK Intracranial Access System 10
- BENCHMARK BMX96 System 11
- Penumbra Distal Delivery Catheters 12
- Neuron MAX System 13
- Artemis Neuro Evacuation Device 13
- Indigo Aspiration System 14
- Indigo Aspiration System with Lightning 16
- Indigo CAT RX Aspiration Catheters and Indigo Separator 4 17
- Ruby Coil System 19
- POD System 20
- LP System 21
- Penumbra Delivery Microcatheters (LANTERN) 22
**PENUMBRA SYSTEM™ with 3D REVASCULARIZATION DEVICE™**

**Indication for Use**

**Penumbra Reperfusion Catheters and Separators**
As part of the PENUMBRA SYSTEM, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

**Penumbra 3D Revascularization Device**
As part of the PENUMBRA SYSTEM, the Penumbra 3D REVASCULARIZATION DEVICE is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

**Penumbra Aspiration Tubing**
As part of the PENUMBRA SYSTEM, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion 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**
- 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 neuro 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information.
- Do not advance, retract or use any component of the PENUMBRA 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, revascularization device, or SEPARATOR™ against resistance may result in damage to the device or vessel.
- Do not use the PENUMBRA SYSTEM with a pump other than the Penumbra Aspiration Pump.
- The Penumbra 3D REVASCULARIZATION DEVICE has not been evaluated in patients with angiographic evidence of pre-existing arterial injury.

**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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

**PENUMBRA SYSTEM™ (CE Mark Jurisdictions)**

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.

**Penumbra System – Intended Use**
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

**International Risk Statement**

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.

**PENUMBRA SYSTEM – Intended Use**
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

**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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening or burns from x-ray exposure.

**PENUMBRA SYSTEM™ (PENUMBRA JET™ 7 Reperfusion Catheter with Standard Tip, Non-CE Mark Jurisdictions)**

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.

**PENUMBRA SYSTEM – Intended Use**
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

**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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening or burns from x-ray exposure.
U.S. IFU Brief Summaries

**PENUMBRA SYSTEM® with 3D REVASCULARIZATION DEVICE™**

(continued)

**Precautions**

- The PENUMBRA SYSTEM should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Use prior to the “Use By” date.
- Use the PENUMBRA SYSTEM in conjunction with fluoroscopic visualization.
- As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.
- The Penumbra SEPARATOR is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.1 Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.

**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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening or burns from x-ray exposure.


International Risk Statement

**PENUMBRA SYSTEM™ (PENUMBRA JET™, CE Mark Jurisdictions)**

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.

**PENUMBRA SYSTEM – Intended Use**
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

**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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening or burns from x-ray exposure.
U.S. IFU Brief Summaries

PENUMBRA SYSTEM RED®

Indication for Use
Penumbra Reperfusion Catheters and Separators
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra Aspiration Tubing
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion 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
- 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 neurovasculature 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Confirm vessel diameter, and select appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information.
- Do not advance, retract or use any component of the Penumbra 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 Penumbra System with a pump other than the Penumbra Aspiration Pump.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Precautions
- The Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Use prior to the “Use By” date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
- Maintain a constant infusion of appropriate flush solution.

International Risk Statement

PENUMBRA SYSTEM RED™ (Non-CE Mark Jurisdictions)
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.

PENUMBRA SYSTEM – Intended Use
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

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; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

PENUMBRA SYSTEM RED™ (CE Mark Jurisdictions)
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.

PENUMBRA SYSTEM – Intended Use
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media or device material; acute vessel occlusion; air embolism; arrhythmia; arteriovenous fistula; death; foreign body embolization; emboli; pseudoaneurysm; hematoma or hemorrhage at access site; residual thrombus due to inability to completely remove thrombus; infection; inflammation; intracranial hemorrhage; ischemia; renal impairment or acute renal failure from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.
Precautions

- When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.

- The Penumbra Separator is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such reposition should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.

- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines. Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.

- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.

- Avoid using alcohol, antiseptic solutions, or other solvents to pretreat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.

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
- intracranial hemorrhage
- ischemia
- kidney damage from contrast media
- neurological deficits including stroke
- vessel spasm, thrombosis, dissection, or perforation
- radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure

**U.S. IFU Brief Summaries**

**PENUMBRA ENGINE®**

**Indication for Use**
The PENUMBRA ENGINE is indicated as a vacuum source for PENUMBRA Aspiration Systems.

**Contraindications**
There are no contraindications.

**Precautions/Warnings**
- 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.

---

**International Risk Statement**

**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.

**Penumbra ENGINE – Intended Use**
The Penumbra ENGINE is intended as a vacuum source for Penumbra Aspiration Systems.
Penumbra Pump MAX®

**Indication for Use**
The Penumbra Pump MAX is indicated as a vacuum source for the Penumbra Aspiration Systems.

**Contraindications**
There are no contraindications.

**Warnings/Precautions**
- The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate.
- Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Remove and service the pump if liquids or solids have been drawn into the vacuum pump.
- Do not use in the presence of a flammable anaesthetic mixture with air or nitrous oxide.
- Do not use in an oxygen rich environment.
- To prevent fire or shock hazard, use replacement fuses of equal size and rating.
- 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 patient.
- Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the pump. Use only water-base solvents for cleaning.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.

Penumbra Delivery Microcatheters (PX SLIM™, Velocity™)

**Indication for Use**
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral and neuro vasculature.

**Contraindications**
There are no known contraindications.

**Precautions**
- The devices are 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 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 Penumbra Delivery Microcatheters in conjunction with fluoroscopic visualization.

Penumbra Pump MAX™

**Indication for Use**
The Penumbra Pump MAX is intended as a vacuum source for the Penumbra Aspiration Systems.

**Contraindications**
There are no contraindications.

**Warnings/Precautions**
- The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate.
- Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the pump so that it is difficult to operate the power cord disconnection device.
- Remove and service the pump if liquids or solids have been drawn into the vacuum pump.
- Do not use in the presence of a flammable anaesthetic mixture with air or nitrous oxide.
- Do not use in an oxygen rich environment.
- To prevent fire or shock hazard, use replacement fuses of equal size and rating.
- 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 patient.
- Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the pump. Use only water-base solvents for cleaning.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.
Precautions

• Do not advance or withdraw the Penumbra Delivery Microcatheters against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Moving or torquing the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.
• If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; hematoma or hemorrhage at access site; death; intracranial hemorrhage; hemorrhage; infection (at access site); distal embolization; ischemia (cardiac and/or cerebral); embolus (air, foreign body, thrombus, plaque); aneurysm perforation; false aneurysm formation; neurological deficits including stroke; vessel spasm, thrombosis, dissection, perforation or rupture; air embolism; emboli.

Penumbra SMART COIL® System

Indication for Use
The Penumbra Smart Coil System is indicated for the embolization of:
• Intracranial aneurysms
• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
• Arterial and venous embolizations in the peripheral vasculature

Contraindications
There are no known contraindications.

Warnings
The Penumbra Smart Coil System should only be used by physicians who have received appropriate training in interventional techniques.

Precautions
• The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness, or death.
• Do not use kinked or damaged devices. Do not use opened or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
• Standard and Soft configurations of Smart Coils are designed with Nitinol wire inside the platinum outer coil. The safety and effectiveness of this device has not been evaluated in patients with Nitinol allergy.
• Use prior to the “Use By” date.
• Use device in conjunction with fluoroscopic guidance.
• Do not advance or withdraw the device against resistance without careful assessment of the cause using fluoroscopy.
• Moving or torquing the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.
Penumbra SMART COIL® System (continued)

Potential Adverse Events
Potential complications include but are not limited to: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection or perforation.

Penumbra Coil System

Indication for Use
The Penumbra Coil System is indicated for the embolization of:
• Intracranial aneurysms.
• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
• Arterial and venous embolizations in the peripheral vasculature.

Contraindications
There are no known contraindications.

Warnings
The Penumbra Coil System should only be used by physicians who have received appropriate training in neuro-interventional techniques.

Precautions
• The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness, or death.
• Do not use kinked or damaged devices. Do not use opened or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
• Use prior to the “Use By” date.
• Use device in conjunction with fluoroscopic guidance.
• Do not advance or retract the device against resistance without careful assessment of the cause using fluoroscopy.
• Moving or torque the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture/access site/site of entry; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection or perforation.

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.

Penumbra Coil System – Intended Use
The Penumbra Coil System is intended for the endovascular embolization of:
• Intracranial aneurysms
• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
• Arterial and venous embolizations in the peripheral vasculature

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.
NEURON® Intracranial Access System

Indication for Use
The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neurovasculature.

Contraindications
There are no known contraindications.

Warnings
The Neuron Intracranial Access System should only be used by physicians who have received appropriate training in interventional techniques.

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; and/or may compromise the structural integrity of the device.
• 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 Neuron Intracranial Access System in conjunction with fluoroscopic visualization.
• Do not advance or withdraw the Neuron Intracranial Access System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.
• If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

BENCHMARK™ Intracranial Access System

Indication for Use
The BENCHMARK Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neurovasculature.

Contraindications
There are no known contraindications.

Warnings
• The BENCHMARK Intracranial Access System should only be used by physicians who have received appropriate training in interventional techniques.
• The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient.
• 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
BENCHMARK™ Intracranial Access System (continued)

- Inability to access the target vasculature location; and/or may compromise the structural integrity of the device.
- Do not use automated high-pressure contrast injection equipment with the Benchmark Intracranial Access System because it may damage the device.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Precautions
- 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 BENCHMARK Intracranial Access System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the BENCHMARK Intracranial Access System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Prior to beginning radial artery access, conduct screening, such as an Allen test, to ensure that radial access is appropriate for the patient.
- As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
- acute occlusion;
- air embolism;
- death;
- distal embolization;
- emboli;
- false aneurysm formation;
- access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma, infection;
- intracranial hemorrhage;
- ischemia;
- neurological deficits including stroke;
- vessel spasm, thrombosis, dissection, or perforation;
- radial artery spasm, radial artery occlusion and compartment syndrome;
- radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia;
- hand dysfunction;
- pathological hand cold intolerance.

BENCHMARK™ BMX™96 System

Indication For Use
The BENCHMARK BMX96 System is indicated for the introduction of interventional devices into the peripheral, coronary, and neurovasculature.

Contraindications
There are no known contraindications.

Warnings
The BENCHMARK BMX96 System should only be used by physicians who have received appropriate training in interventional techniques.

BENCHMARK™ BMX™96 System (Non-CE Mark Jurisdictions)

Prior to use, please refer to the Instructions for Use for complete product indications, contradictions, warnings, precautions, potential adverse events, and detailed instructions for use.

BENCHMARK BMX96 System – Intended Use
The BENCHMARK BMX96 System is intended for the introduction of interventional devices into the peripheral, coronary, and neurovasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
- acute occlusion;
- air embolism;
- death;
- distal embolization;
- emboli;
- false aneurysm formation;
- hematoma or hemorrhage at puncture site;
- infection;
- intracranial hemorrhage;
- ischemia;
- neurological deficits including stroke;
- vessel spasm, thrombosis, dissection, or perforation.
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; and/or may compromise the structural integrity of the device.
- 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 BENCHMARK BMX96 System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the BENCHMARK BMX96 System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

Potential Adverse Events

Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.
U.S. IFU Brief Summaries

Penumbra Distal Delivery Catheters (DDC) (continued)

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; false aneurysm formation; ischemia; air embolism; death; hematoma or hemorrhage at puncture site; neurological deficits including stroke; distal embolization; infection; emboli; intracranial hemorrhage; vessel spasm, thrombosis, dissection, or perforation.

Neuron MAX System

Indication for Use
The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Contraindications
There are no known contraindications.

Warnings
The Neuron MAX System should only be used by physicians who have received appropriate training in interventional techniques.

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; and/or may compromise the structural integrity of the device.
• 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 Neuron MAX System in conjunction with fluoroscopic visualization.
• Do not advance or withdraw the Neuron MAX System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.
• If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

Artemis™ Neuro Evacuation Device

Indication for Use
The Artemis Neuro Evacuation Device is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum in conjunction with a Penumbra Aspiration Pump.

Penumbra Aspiration Pump:
The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.

Contraindications
• The Artemis Neuro Evacuation Device is not recommended during surgery of the brainstem, cerebellum, epidural or subdural spaces.
• Do not use fibrinolytic therapy during the procedure.

International Risk Statement

Penumbra Distal Delivery Catheters (DDC) (continued)

Neuron MAX System

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.

Neuron MAX System – Intended Use
The Neuron MAX System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

Artemis™ Neuro Evacuation Device (CE Mark Jurisdictions)

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.

Artemis Neuro Evacuation Device – Intended Use
The Artemis Neuro Evacuation Device is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum for patients age 18 or older in conjunction with a Penumbra Aspiration Pump.

Penumbra Aspiration Pump:
The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.
**U.S. IFU Brief Summaries**

**Artemis™ Neuro Evacuation Device (continued)**

- Do not use the Artemis Neuro Evacuation Device with a non-Penumbra recommended aspiration pump. The safety and effectiveness of its use with a non-Penumbra recommended aspiration pump has not been established and can lead to patient injury or death.

**Warnings**
- The Artemis Neuro Evacuation Device should only be used by physicians who have received appropriate training to perform image-guided neurosurgical procedures.

**Precautions**
- The Artemis Neuro Evacuation Device is intended for single use only. Do not resterilize or reuse. Resterilization or reuse could lead to infection or ineffective removal of tissue and/or fluid.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the Artemis Neuro Evacuation Device in conjunction with a Penumbra aspiration system, and for the treatment of pulmonary embolism.
- Do not use in an oxygen rich environment.
- Do not advance or use the Artemis Neuro Evacuation Device against resistance without careful visual assessment of the cause. If the cause cannot be determined, withdraw the device. Unrestrained torqueing or forced insertion of the device against resistance may result in damage to the device, which may lead to tissue damage and/or device breakage.

**Potential Adverse Events**

Possible complications include, but are not limited to, the following: hematoma expansion, fever, headaches, vomiting, hyperglycemia, edema, re-bleeding, death, bleeding, increased blood pressure, infections, seizures, intraventricular hemorrhage, hydrocephalus, thromboembolic events, decreased consciousness, craniotomy, unintended removal of tissue leading to neurological and/or sensory deficit.

**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.

**International Risk Statement**

**Artemis™ Neuro Evacuation Device (CE Mark Jurisdictions) (continued)**

**Potential Adverse Events**

Possible complications include, but are not limited to, the following: hematoma expansion, fever, headaches, vomiting, hyperglycemia, edema, re-bleeding, death, bleeding, increased blood pressure, infections, seizures, intraventricular hemorrhage, hydrocephalus, thromboembolic events, decreased consciousness, craniotomy, unintended removal of tissue leading to neurological and/or sensory deficit.

**Artemis™ Neuro Evacuation Device (Non-CE Mark Jurisdictions)**

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.

**Artemis Neuro Evacuation Device – Intended Use**

The Artemis Neuro Evacuation Device is intended for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.

**Potential Adverse Events**

Possible complications include, but are not limited to, the following: hematoma expansion, fever, headaches, vomiting, hyperglycemia, edema, re-bleeding, death, bleeding, increased blood pressure, infections, seizures, intraventricular hemorrhage, hydrocephalus, thromboembolic events, decreased consciousness, craniotomy, unintended removal of tissue leading to neurological and/or sensory deficit.

**Penumbra Pump MAX – Intended Use**

The Penumbra Pump MAX is intended as a vacuum source for the Penumbra Aspiration Systems.

**INDIGO™ Aspiration System (CE Mark Jurisdictions)**

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 – Intended Use**

The Indigo Aspiration System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems and certain central circulatory system conditions such as pulmonary emboli using continuous aspiration.

**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.
INDIGO® Aspiration System (continued)

- 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; arteriovenous fistula; death; device malfunction; distal embolization; embolii; 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 arrest; respiratory failure; thromboembolic events.
U.S. IFU Brief Summaries

INDIGO® Aspiration System with LIGHTNING®

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, anemia; arrhythmia; arteriovenous fistula; cardiac injury, cardiac perforation, cardiac tamponade; cardio-respiratory arrest; compartment syndrome; death; emboli; emergent surgery; foreign body embolization; hematoma or hemorrhage at access site; hemoptysis; hemorrhage; hypotension/hypertension; infarction leading to organ damage; infection; ischemia; myocardial infarction; neurological deficits including stroke; pneumonia; pseudaneurysm; renal impairment or acute renal failure from contrast media; residual thrombus due to inability to completely remove thrombus or control blood flow; respiratory failure; valvular damage; vessel spasm, thrombosis, dissection (intimal disruption), or perforation.

International Risk Statement

INDIGO™ LIGHTNING™ Aspiration Tubing Risk Statement (CE Mark Jurisdictions)
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 System Lightning Aspiration Tubing – Intended Use
Lightning Aspiration Tubing is a sterile aspiration tubing component of the INDIGO Aspiration System and is intended to serve as a conduit to assist in thrombus removal and restoration of blood flow in the peripheral vasculature and for the treatment of pulmonary embolism.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device material; anemia; arrhythmia; arteriovenous fistula; cardiac injury, cardiac perforation, cardiac tamponade; cardio-respiratory arrest; compartment syndrome; death; emboli; emergent surgery; foreign body embolization; hematoma or hemorrhage at access site; hemoptysis; hemorrhage; hypotension/hypertension; infarction leading to organ damage; infection; ischemia; myocardial infarction; neurological deficits including stroke; pneumonia; pseudoaneurysm; renal impairment or acute renal failure from contrast media; residual thrombus due to inability to completely remove thrombus or control blood flow; respiratory failure; valvular damage; vessel spasm, thrombosis, dissection (intimal disruption), or perforation.

INDIGO™ Aspiration System (CE Mark Jurisdictions)
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 – Intended Use
The INDIGO Aspiration System is intended to serve as a conduit to assist in thrombus removal and restoration of blood flow in the peripheral vasculature and for the treatment of pulmonary embolism.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
allergic reaction and anaphylaxis from contrast media or device material; anemia; arrhythmia; arteriovenous fistula; cardiac injury, cardiac perforation, cardiac tamponade; cardio-respiratory arrest; compartment syndrome; death; emboli; emergent surgery; foreign body embolization; hematoma or hemorrhage at access site; hemoptysis; hemorrhage; hypotension/hypertension; infarction leading to organ damage; infection; ischemia; myocardial infarction; neurological deficits including stroke; pneumonia; pseudoaneurysm; renal impairment or acute renal failure from contrast media; residual thrombus due to inability to completely remove thrombus or control blood flow; respiratory failure; valvular damage; vessel spasm, thrombosis, dissection (intimal disruption), or perforation.
**U.S. IFU Brief Summaries**

**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® CAT™ RX Aspiration Catheters and INDIGO SEPARATOR™ 4**

**Indication for Use**

The Indigo CAT RX Aspiration Catheters and Indigo Separator 4: As part of the Indigo Aspiration System, the Indigo CAT RX Aspiration Catheters and Indigo Separator 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

**International Risk Statement**

| 17 |
The INDIGO Aspiration Tubing:
As part of the Indigo Aspiration System, the Indigo Sterile Aspiration Tubing is indicated to connect the Indigo CAT RX 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
The Indigo Aspiration System is contraindicated in:
• The removal of fibrous, adherent or calcified material (e.g. chronic clot, atherosclerotic plaque)
• The cerebral vasculature

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 Aspiration 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 safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) 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 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 4 is not intended for use as a guidewire. If repositioning of the Indigo CAT RX Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard guidewire techniques.
• Do not use Indigo Separator 4 to macerate or retrieve thrombus distal to the catheter tip. Indigo Separator 4 is intended to be used with Indigo CAT RX Aspiration Catheter to clear the distal end of the catheter lumen should it be blocked with thrombus.
• Do not use automated high-pressure contrast injection equipment with the Indigo CAT RX Aspiration Catheter because it may damage the device.
U.S. IFU Brief Summaries

INDIGO® CAT™ RX Aspiration Catheters and INDIGO SEPARATOR™ 4 (continued)

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.

RUBY® Coil System

Indication for Use
The RUBY Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

Contraindications
There are no known contraindications.

Warnings
The RUBY Coil System should only be used by physicians who have received appropriate training in interventional techniques.

Precautions
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness, or death.
- 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 device in conjunction with fluoroscopic guidance.
- Do not advance or retract the device against resistance without careful assessment of the cause using fluoroscopy.
- Moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.

Potential Adverse Events
Possible complications include, but are not limited to:
- acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.

International Risk Statement

RUBY™ Coil System

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.

Ruby Coil System – Intended Use
The RUBY Coil System is intended for arterial and venous embolizations in the peripheral vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
- acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at puncture/access site/ site of entry; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; thromboembolic episodes; neurological deficits including stroke and possibly death; vascular thrombosis; post-embolization syndrome; revascularization; recanalization; inadequate occlusion; aneurysm rupture; parent artery occlusion; incomplete aneurysm filling.

RUBY™ Coil System (GEN II)

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.

Ruby Coil System – Intended Use
The RUBY Coil System is intended for arterial and venous embolizations in the peripheral vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
- acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.
Intracranial aneurysms.

- Do not advance or retract the device against resistance without careful assessment of the cause using fluoroscopy. If POD cannot be advanced or retracted, withdraw the device as a unit with the microcatheter.
- Moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.

Potential Adverse Events

- Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.

U.S. IFU Brief Summaries

POD™ System

Indication for Use

For POD Coils with nominal sizes ≤ 6 mm:
The POD System is indicated for the embolization of:
- Intracranial aneurysms.
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Arterial and venous embolizations in the peripheral vasculature.

For POD Coils with nominal sizes > 6mm:
The POD System is indicated for arterial and venous embolizations in the peripheral vasculature.

Contraindications

There are no known contraindications.

Warnings

The POD System should only be used by physicians who have received appropriate training in interventional techniques.

Precautions

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness, or death.
- Do not use kinked or damaged devices. Do not use opened or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Do not advance or retract the device against resistance without careful assessment of the cause using fluoroscopy. If POD cannot be advanced or retracted, withdraw the device as a unit with the microcatheter.
- Moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.

Potential Adverse Events

Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.

International Risk Statement

POD™ System

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.

POD System – Intended Use

The POD System is indicated for the embolization of:
- Intracranial aneurysms.
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Arterial and venous embolizations in the peripheral vasculature.

Potential Adverse Events

Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.

POD™ System (GEN II)

For POD Coils with nominal sizes ≤ 6 mm – Intended Use

The POD System is indicated for the embolization of:
- Intracranial aneurysms.
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Arterial and venous embolizations in the peripheral vasculature.

For POD Coils with nominal sizes > 6 mm – Intended Use

The POD System is intended for arterial and venous embolizations in the peripheral vasculature.

Potential Adverse Events

Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.
LP System

Indications for Use
The Penumbra LP Coil System is indicated for the embolization of:

- Intracranial aneurysms.
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Arterial and venous embolizations in the peripheral vasculature.

Contraindications
There are no known contraindications.

Warnings
- The Penumbra LP Coil System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not use kinked or damaged devices. Do not use opened or damaged packages. Return damaged devices and packaging to the manufacturer/distributor.
- Do not advance or withdraw the device against resistance without careful assessment of the cause using fluoroscopy.
- If resistance is encountered when withdrawing the coil, withdraw the microcatheter until the resistance subsides.
- Do not rotate the delivery pusher during use. Rotating the delivery pusher may result in premature detachment, which could lead to coil damage, incorrect positioning, or vessel damage.
- Verify repeatedly that the microcatheter is not under stress before coil detachment. Stored forces in the microcatheter could cause the tip to move during detachment, which could lead to lesion rupture.
- Advancing the delivery pusher beyond the microcatheter tip could lead to lesion rupture.
- The device is intended for single use only. Do not sterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness or death.
- Use prior to the “Use By” date.
- Use device in conjunction with fluoroscopic guidance.
- As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
- Moving or torquing the device against resistance may result in damage to the vessel or device.

Precautions
- Maintain a constant infusion of an appropriate flush solution.
- The device may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective lesion treatment.

Potential Adverse Events
Potential complications include but are not limited to: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; aneurysm rupture; arteriovenous fistula; coagulopathy; coil herniation into parent vessel; death; device malfunction; distal embolization; emboli; embolic stroke and other cerebral ischemic events; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; intracranial hemorrhage; ischemia; myocardial infarction; neurological deficits including stroke; parent artery occlusion; peripheral thromboembolic events; post-embolization syndrome; premature device detachment; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure; recanalization; renal failure; respiratory failure; revascularization; thromboembolic episodes; vessel spasm, thrombosis, dissection, or perforation.
U.S. IFU Brief Summaries

Penumbra Delivery Microcatheters (LANTERN™)

Indication for Use
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils to the peripheral and neurovasculature.

Contraindications
There are no known contraindications.

Warnings
The Penumbra Delivery Microcatheters should only be used by physicians who have received appropriate training in interventional techniques.

Precautions
• The devices are 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 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 Penumbra Delivery Microcatheters in conjunction with fluoroscopic visualization.
• Do not advance or withdraw the Penumbra Delivery Microcatheters against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Moving or torquing the device against resistance may result in damage to the vessel or device.
• Maintain a constant infusion of an appropriate flush solution.
• If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

International Risk Statement

Penumbra Delivery Microcatheters (LANTERN™)

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.

Penumbra Delivery Microcatheters – Intended Use
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils to the peripheral and neurovasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; hematoma or hemorrhage at access site; death; intracranial hemorrhage; hemorrhage; infection (at access site); distal embolization; ischemia (cardiac and/or cerebral); embolus (air, foreign body, thrombus, plaque); aneurysm perforation; false aneurysm formation; neurological deficits including stroke; vessel spasm, thrombosis, dissection, perforation or rupture; air embolism; emboli.

Product availability varies by country. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician.

Copyright ©2018–2022 Penumbra, Inc. All rights reserved. The Penumbra P logos, Penumbra System, RED, 3D, 3D Revascularization Device, Penumbra JET, Penumbra ENGINE, MAX, PX SLIM, Velocity, SMART COIL, Penumbra SMART COIL, Neuron, BENCHMARK, BMX, BMX96, Neuron MAX, Artemis, Indigo, CAT, Lightning, Separator, Ruby, POD, and LANTERN are registered trademarks or trademarks of Penumbra, Inc. in the USA and other countries. 14628, Rev. T 09/22