Penumbra

U.S. IFU Brief Summaries

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 Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- 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.
- The use of fluoroscopy may present potential risks from radiation exposure. The probability of adverse events due to radiation exposure increases with the total amount of radiation observed, the number of procedures and total procedure time.

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 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.

International Risk Statements

Penumbra 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.

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.

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Penumbra System with 3D Revascularization Device
(continued)

Precautions

- 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- 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.
- Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Limit the usage of Reperfusion Catheters to arteries larger than the catheter’s outer diameter. Refer to the Reperfusion Catheter labeling for dimensional information.

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.

1. Adams, et al., Guidelines for the Early Management of Adults with Ischemic Stroke: A Guideline from the AHA/ASA Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists, Stroke May 2007; 38:1655-1711.

International Risk Statements

Penumbra

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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 (30cm) 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.

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.

International Risk Statements

Penumbra Pump MAX

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

Penumbra

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Penumbra Pump MAX *(continued)*

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 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.

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 Statements

Penumbra Delivery Microcatheters (PX SLIM, Velocity)

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 agents, such as occlusion coils to the peripheral and neuro vasculature.

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.

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Penumbra Delivery Microcatheters (PX SLIM, Velocity)
(continued)

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.

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.

International Risk Statements

Penumbra SMART 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.

Penumbra Smart Coil System – Intended Use
The Penumbra Smart Coil System is intended 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.

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Penumbra Coil System

Indication for Use
The Penumbra Coil System is indicated 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.

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 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
Potential complications include, but are not limited to: 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; 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.

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 neuro vasculature.

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.

International Risk Statements

Penumbra 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.

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; 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; 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.

Neuron Intracranial Access 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 Intracranial Access System – Intended Use
The Neuron Intracranial Access 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.

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Neuron Intracranial Access System *(continued)*

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 neuro vasculature.

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.

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 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.

International Risk Statements

BENCHMARK Intracranial Access 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.

Benchmark Intracranial Access System – Intended Use
The Benchmark Intracranial Access 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.

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BENCHMARK Intracranial Access System *(continued)*

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.

Penumbra Distal Delivery Catheters (DDC)

Indication for Use
The Penumbra Distal Delivery Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Contraindications
There are no known contraindications.

Warnings
The Penumbra Distal Delivery Catheter 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.
- 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 Penumbra Distal Delivery Catheter in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the Penumbra Distal Delivery Catheter 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; 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.

International Risk Statements

Penumbra Distal Delivery Catheters (DDC)

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 Distal Delivery Catheter – Intended Use
The Penumbra Distal Delivery Catheter is intended for the introduction of interventional devices into the peripheral and neuro vasculature.

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

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.

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Neuron MAX System *(continued)*

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.

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.
- 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 intraprocedural image-guidance.
- Do not use in an oxygen rich environment.

International Risk Statements

Neuron MAX System *(continued)*

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 (Non-EU)

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.

Artemis Neuro Evacuation Device (EU)

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.

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.

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Artemis Neuro Evacuation Device *(continued)*

Precautions

- 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.

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.

Precautions

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the Indigo Aspiration System in conjunction with fluoroscopic visualization.

International Risk Statements

Indigo Aspiration 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.

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 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.

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Indigo Aspiration System *(continued)*

Precautions

- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Indigo Aspiration Tubing valve is open for only the minimum time needed to remove thrombus.
- Excessive aspiration or failure to close the Indigo Aspiration Tubing valve when aspiration is complete is not recommended.
- The Indigo Separator is not intended for use as a guidewire. If repositioning of the Indigo Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard microcatheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Indigo Aspiration Catheter because it may damage the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; intimal disruption; myocardial infarction; emergent surgery; fibrillation; hypotension; respiratory failure; peripheral thromboembolic events.

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.

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.

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Indigo CAT RX Aspiration Catheters and Indigo Separator 4 *(continued)*

Warnings

- 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.
- Indigo Aspiration Tubing valve when aspiration is complete is not recommended.

Precautions

- 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.

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.

International Risk Statements

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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 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 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
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.

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.

International Risk Statements

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; 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; 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.

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 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

Penumbra

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POD System *(continued)*

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.

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 neuro vasculature.

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.

International Risk Statements

POD System *(continued)*

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.

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 neuro vasculature.

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.

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U.S. IFU Brief Summaries

Penumbra Delivery Microcatheters (LANTERN) *(continued)*

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.

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