Penumbra

US IFU Brief Summaries and International Risk Statements

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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.

International Risk Statement

PENUMBRA SYSTEM™ with 3D REVASCULARIZATION 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.

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™

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.

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.

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PENUMBRA SYSTEM® with 3D REVASCULARIZATION DEVICE™
(continued)

Precautions

- The PENUMBRA SYSTEM should only be used by physicians whohave 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 removethrombus. 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, burns, alopecia, or neoplasia 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 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.

Penumbra

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 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 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™ and RED 72 with SENDit™ Technology (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 to remove thrombus and restore blood flow in the neurovasculature using 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.

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PENUMBRA SYSTEM® RED®
(continued)

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 recomended.
- 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.[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.
- 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.

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.

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PENUMBRA SYSTEM® RED® 72 SILVER LABEL

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 thrombolytic drug therapy or who failed thrombolytic drug 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 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. Exercise care when manipulating the device through tortuous anatomy.
- Do not use the Penumbra System with a pump other than the Penumbra Aspiration Pump.
- The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.
- 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.
- When performing aspiration, ensure that the Penumbra Aspiration

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

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PENUMBRA SYSTEM® RED® 72 SILVER LABEL
(Continued)

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.[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.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- 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.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating 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.

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.

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PENUMBRA SYSTEM® RED® 72 with SENDit™ Technology

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 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 or SENDit Technology 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.
- When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove

International Risk Statement

PENUMBRA SYSTEM™ RED™ 72 with SENDit™ Technology (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.

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PENUMBRA SYSTEM® RED® 72 with SENDit™ Technology
(Continued)

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.[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.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- 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.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; arteriovenous fistula; death; distal embolization; device malfunction; 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; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure; vessel spasm, thrombosis, dissection, or perforation.

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.

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PENUMBRA SYSTEM® RED® 72 SILVER LABEL with SENDit™ Technology

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 thrombolytic drug therapy or who failed thrombolytic drug 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 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 or SENDit Technology 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. Exercise care when manipulating the device through tortuous anatomy.
- Do not use the Penumbra System with a pump other than the Penumbra Aspiration Pump.
- The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.
- 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.

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

U.S. IFU Brief Summaries

PENUMBRA SYSTEM® RED® 72 SILVER LABEL with SENDit™ Technology *(Continued)*

- 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 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.[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.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- 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.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating 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.

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 Statement

Penumbra

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

U.S. IFU Brief Summaries

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.
- 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.

International Risk Statement

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

U.S. IFU Brief Summaries

ACCESS25™ Delivery Microcatheter

Indications for Use
The ACCESS25 Delivery Microcatheter is indicated 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 ACCESS25 Delivery Microcatheter should only be used by physicians who have received appropriate training in interventional techniques.
- 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 the ACCESS25 Delivery Microcatheter for delivery of liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).
- Do not use automated high-pressure contrast injection equipment with the ACCESS25 Delivery Microcatheter 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 ACCESS25 Delivery Microcatheter in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the ACCESS25 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.
- 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.
- Use caution when manipulating, advancing and/or withdrawing the device through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage.
- Avoid excessive wiping of the coated device.

Potential Adverse Events
potential complications include but are not limited to: 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.

International Risk Statement

ACCESS25™ Delivery Microcatheter (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.

ACCESS25 Delivery Microcatheter – Intended Use
The ACCESS25 Delivery Microcatheter is 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
Potential complications include but are not limited to: 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.

ACCESS25™ Delivery Microcatheter (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 Delivery Microcatheters – Intended Use
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents and therapeutic devices to the vasculature.

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

Penumbra

U.S. IFU Brief Summaries

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.

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.

International Risk Statement

Penumbra Delivery Microcatheters (PX SLIM™, VELOCITY™) (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 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.

Penumbra Delivery Microcatheters (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 Delivery Microcatheters – Intended Use
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents and therapeutic devices to the vasculature.

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

Penumbra

U.S. IFU Brief Summaries

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 Statement

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.

Penumbra

U.S. IFU Brief Summaries

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 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

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.

Penumbra

U.S. IFU Brief Summaries

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.

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.

International Risk Statement

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.

Penumbra Access Catheter 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 Access Catheter System – Intended Use
The Penumbra Access Catheter System 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 vessel occlusion; access site complications such as hematoma, hemorrhage, spasm, occlusion, or compartment syndrome; air embolism; allergic reaction and anaphylaxis from contrast media or device material; arteriovenous fistula; death; emboli including foreign body embolization; inflammation; infection; intracranial hemorrhage; ischemia; nerve injury; neurological deficits including stroke; pseudoaneurysm; renal impairment or acute renal failure from contrast media; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure; vessel dissection, vessel perforation; vessel spasm; vessel thrombosis.

Penumbra

U.S. IFU Brief Summaries

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.
- 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 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.

International Risk Statement

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.

Penumbra

U.S. IFU Brief Summaries

BENCHMARK™ BMX®81 System

Indication For Use
The BENCHMARK BMX81 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 BMX81 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 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 BMX81 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 dam
- aged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the BENCHMARK BMX81 Access System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the BENCHMARK BMX81 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: access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hand dysfunction; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; pathological hand cold intolerance; radial artery spasm, radial artery occlusion and compartment syndrome; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; vessel spasm, thrombosis, dissection, or perforation.

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BENCHMARK™ BMX™81 System (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.

BENCHMARK BMX81 Access System – Intended Use
The BENCHMARK BMX81 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; radial artery spasm, radial artery occlusion and compartment syndrome; 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; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; hand dysfunction; pathological hand cold intolerance.

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BENCHMARK™ BMX®96 System

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

Contraindictions
There are no known contraindications.

Warnings
The BENCHMARK BMX96 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 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.

BENCHMARK™ BMX®96 System

Indication For Use
The BENCHMARK BMX96 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 BMX96 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 inability to access the target vasculature location; and/ or may compromise the structural integrity of the device.

International Risk Statement

BENCHMARK™ BMX™96 System (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.

BENCHMARK BMX96 System – Intended Use
The BENCHMARK BMX96 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.

BENCHMARK™ BMX™96 System (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.

BENCHMARK BMX96 System – Intended Use
The BENCHMARK BMX96 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; access site complications such as hematoma, inflammation, infection, necrosis, pain, and tenderness, granuloma; pathological hand cold intolerance; intracranial hemorrhage; infection; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; hand dysfunction; radial artery spasm, radial artery occlusion and compartment syndrome.

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BENCHMARK™ BMX®96 System
(continued)

- Do not use automated high-pressure contrast injection equipment with the BENCHMARK BMX96 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 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.
- 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; pathological hand cold intolerance; intracranial hemorrhage; infection; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; hand dysfunction; radial artery spasm, radial artery occlusion and compartment syndrome.

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MIDWAY™ Delivery Catheters

Indication for Use
MIDWAY Delivery Catheters
The MIDWAY Delivery Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Contraindications
There are no known contraindications.

Warnings
- The MIDWAY Delivery Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- 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 resulting in patient injury. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection.

- Do not use automated high-pressure contrast injection equipment with the MIDWAY Delivery Catheter because it may damage the device.
- Failure to abide by the warnings in this label might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Precautions
- Inspect catheter and packaged accessories prior to use. 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 autoclave. Exposure to temperatures above 54°C (130°F) may damage device.
- Verify catheter size is suitable for the procedure.
- Use prior to the “Use By” date.
- Use the MIDWAY Delivery Catheter in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the MIDWAY Delivery Catheter 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.
- Avoid excessive wiping of the coated 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.
- 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.
- Torquing the catheter may cause damage which would result in kinking. Should the catheter become severely kinked, withdraw the entire catheter.
- Extreme care must be taken to avoid damage to the vasculature through which the catheter travels. The catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Potential Adverse Events
Possible complications include, but are not limited to, the following: access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; acute occlusion; allergic

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MIDWAY Delivery Catheters (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.

MIDWAY Delivery Catheters – Intended Use
The MIDWAY Delivery Catheter 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: access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; acute occlusion; allergic reaction and anaphylaxis from contrast media; death; device malfunction; distal embolization; embolism (air, foreign body, plaque, thrombus); false aneurysm formation; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; use of the device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia.

MIDWAY Delivery Catheters (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.

MIDWAY Delivery Catheters – Intended Use
The MIDWAY Delivery Catheters are intended to provide a conduit for introduction of interventional devices to the peripheral and neurovascular anatomy.

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

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MIDWAY™ Delivery Catheters
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reaction and anaphylaxis from contrast media; death; device malfunction; distal embolization; embolism (air, foreign body, plaque, thrombus); false aneurysm formation; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; Use of the device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia.

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.

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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.

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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.

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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.

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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.
- 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.

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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.

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 (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 to remove tissue and/or fluid during minimally invasive neurosurgery.

Potential Adverse Events
Potential complications include but are not limited to: Allergic Reaction; Brain Injury; Cardiac Arrhythmia; Cerebral Edema; Death; Hemorrhagic Stroke (Re-bleeding); Infection; Inflammation; Intracranial hemorrhage; Ischemic Stroke; Minor Electric Shock; Neurological deficits including decreased consciousness; Residual fluid/tissue due to inability to remove fluid/tissue; Seizures; Unintended removal of tissue leading to brain injury.

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.

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INDIGO® Aspiration System

Indication for Use
INDIGO Aspiration Catheters and Separators:
As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

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

Contraindications
Not for use in the coronaries or the neurovasculature.

Warnings
- The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not advance, retract or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR™ against resistance may result in damage to the device or vessel.
- Do not use the INDIGO Aspiration System with a pump other than the Penumbra Aspiration Pump.
- Placing guidewire too distal in the pulmonary vasculature or excessive manipulation of aspiration/guiding catheter in the smaller, peripheral, and segmental pulmonary artery branches can result in vessel perforation.

Precautions
- The device is intended for single use only. Do not resterilize or reuse.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the INDIGO Aspiration System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended.
- Hemoglobin and hematocrit levels should be monitored in patients with >700 mL blood loss from the clot aspiration procedure.
- The INDIGO SEPARATOR is not intended for use as a guidewire. If repositioning of the INDIGO Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard catheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the INDIGO Aspiration Catheter because it may damage the device.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arrhythmia; arteriovenous fistula; cardiac injury; cardio-

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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 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 (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.

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.

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, and for the treatment of pulmonary embolism 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

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respiratory arrest; death; device malfunction; distal embolization; emboli; excessive blood loss; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; intimal disruption; myocardial infarction; emergent surgery; fibrillation; hypotension; hemoptysis; respiratory failure; thromboembolic events.

INDIGO® Aspiration System with LIGHTNING® Aspiration Tubing

Indication for Use
INDIGO Aspiration Catheters and Separators:
As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

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

Contraindications
There are no known contraindications.

Warnings
- Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump. Use of LIGHTNING Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of LIGHTNING Aspiration Tubing Otherwise, this could result in degradation of the performance of this equipment.

Precautions
- The device is intended for single use only. Do not resterilize or reuse.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove the thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended.
- Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- Do not use in oxygen rich environment.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media, acute occlusion, air embolism, arrhythmia/fibrillation, arteriovenous fistula, death, device malfunction, distal embolization, emergent surgery, false aneurysm

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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™ System LIGHTNING™ Aspiration Tubing (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; pneumothorax; 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: 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; pneumothorax; 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.

Penumbra

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INDIGO® Aspiration System
(continued)

formation, hematoma, hemorrhage, or blood loss at access site, hematoma, hemorrhage, or blood loss, hypotension, inability to completely remove thrombus or control blood flow, infection, ischemia, kidney damage from contrast media, myocardial infarction, neurological deficits including stroke, respiratory failure, thromboembolic events, vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

INDIGO® Aspiration System with LIGHTNING FLASH®

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 FLASH Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING FLASH 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 FLASH Aspiration Tubing. Otherwise, this could result in degradation of the performance of this equipment.
- Common emitters (such as RFID emitters, security systems, diathermy equipment, electrocautery equipment, and portable transmitters) should not be used in close proximity to LIGHTNING FLASH Aspiration Tubing as they can interfere with and result in degradation of the performance of the device. If degraded performance is observed, stop usage immediately and relocate any potential sources of interference before resuming use.

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.

International Risk Statement

INDIGO™ Aspiration System with LIGHTNING FLASH™ (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.

INDIGO Aspiration System with LIGHTNING FLASH – Intended Use
LIGHTNING FLASH Aspiration Tubing is a sterile aspiration tubing component of the INDIGO Aspiration System and is designed 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; acute occlusion; air embolism; arrhythmia/fibrillation; arteriovenous fistula; death; device malfunction; distal embolization; emergent surgery; false aneurysm formation; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or blood loss; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; myocardial infarction; neurological deficits including stroke; respiratory failure; thromboembolic events; vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

INDIGO™ Aspiration System with LIGHTNING FLASH™ (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 with LIGHTNING FLASH – Intended Use
The INDIGO Aspiration System with the LIGHTNING FLASH Aspiration Tubing is intended 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.

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; pneumothorax; 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.

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INDIGO® Aspiration System with LIGHTNING FLASH®
(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, arrhythmia/fibrillation, arteriovenous fistula, death, device malfunction, distal embolization, emergent surgery, false aneurysm formation, hematoma, hemorrhage, or blood loss at access site, hematoma, hemorrhage, or blood loss, hypotension, inability to completely remove thrombus or control blood flow, infection, ischemia, kidney damage from contrast media, myocardial infarction, neurological deficits including stroke, respiratory failure, thromboembolic events, vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

INDIGO® Aspiration System with LIGHTNING BOLT®

Indication for Use
INDIGO Aspiration Catheters and Separators:
As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

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

Contraindications
Not for use in the coronaries or the neurovasculature.

Warnings
- The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not advance, retract, or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or separator against resistance may result in damage to the device or vessel.
- Placing the guidewire too distal in the pulmonary vasculature or excessive manipulation of the aspiration/guiding catheter in the smaller, peripheral, and segmental pulmonary artery branches can result in vessel perforation.
- Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump.
- Do not pressurize the saline IV bag connected to the LIGHTNING BOLT Aspiration Tubing in set up.
- Use of LIGHTNING BOLT Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING BOLT Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly.
- Common emitters (such as RFID emitters, security systems, wireless power transfer, diathermy equipment, high frequency surgical equipment, and portable transmitters) should not be used in close proximity to LIGHTNING BOLT Aspiration Tubing as they can interfere with and result in degradation of the performance of the device. If degraded

International Risk Statement

INDIGO™ Aspiration System with LIGHTNING BOLT™ (Non-CE Mark Jurisdictions)

Prior to use, please refer to the Instructions for Use for INDIGO Aspiration System (including LIGHTNING BOLT) for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use.

Indigo Aspiration System with Lightning Bolt – Intended Use
The INDIGO Aspiration System with the LIGHTNING BOLT Aspiration Tubing is intended 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 using intermittent, continuous, or modulated 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; arrhythmia/fibrillation; arteriovenous fistula; cardiac injury; cardio-respiratory arrest; death; device malfunction; distal embolization; emboli; emergent surgery; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or excessive blood loss; hemoptysis; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; infarction leading to organ damage; neurological deficits including stroke; respiratory failure; vessel complications (including vessel spasm, thrombosis, intimal disruption, dissection, valvular damage, or perforation)

INDIGO™ Aspiration System with LIGHTNING BOLT™ (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 with LIGHTNING BOLT – Intended Use
The INDIGO Aspiration System with the LIGHTNING BOLT Aspiration Tubing is intended 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 using intermittent, continuous, or modulated aspiration.

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

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INDIGO® Aspiration System with LIGHTNING BOLT® *(continued)*

performance is observed, stop usage immediately and relocate any potential sources of interference before resuming use. Note: potential sources of interference may be concealed and therefore not readily observable.
- 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 BOLT 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.
- 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 the thrombus. Excessive aspiration or failure to stop 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.
- 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; cardiac injury; cardio-respiratory arrest; death; device malfunction; distal embolization; emboli; emergent surgery; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or excessive blood loss; hemoptysis; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; infarction leading to organ damage; neurological deficits including stroke; respiratory failure; vessel complications (including vessel spasm, thrombosis, intimal disruption, dissection, valvular damage, or perforation).

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INDIGO™ Aspiration System with LIGHTNING BOLT™ (CE Mark Jurisdictions) *(continued)*

site; hemoptysis; hemorrhage; hypotension/hypertension; infarction leading to organ damage; infection; ischemia; myocardial infarction; neurological deficits including stroke; pneumothorax; 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.

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INDIGO® Aspiration System (LIGHTNING BOLT® 6X with TraX™)

Indication for Use
INDIGO Aspiration Catheters and Separators:
As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

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

Contraindications
Not for use in the coronaries or the neurovasculature.

Warnings
- The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques.
- Do not advance, retract, or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or separator against resistance may result in damage to the device or vessel.
- Placing the guidewire too distal in the pulmonary vasculature or excessive manipulation of the aspiration/guiding catheter in the smaller, peripheral, and segmental pulmonary artery branches can result in vessel perforation.
- Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump.
- Do not pressurize the saline IV bag connected to the Lightning Bolt Aspiration Tubing in set up.
- Use of Lightning Bolt Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, Lightning Bolt Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly.
- Common emitters (such as RFID emitters, security systems, wireless power transfer, diathermy equipment, high frequency surgical equipment, and portable transmitters) should not be used in close proximity to Lightning Bolt Aspiration Tubing as they can interfere with and result in degradation of the performance of the device. If degraded performance is observed, stop usage immediately and relocate any potential sources of interference before resuming use. Note: potential sources of interference may be concealed and therefore not readily observable.
- 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 Bolt 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.
- Use the INDIGO Aspiration System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.

International Risk Statement

INDIGO™ Aspiration System (LIGHTNING BOLT™ 6X with TraX™) (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.

INDIGO Aspiration System with LIGHTNING BOLT – Intended Use
The INDIGO Aspiration System with the LIGHTNING BOLT Aspiration Tubing is intended 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 using intermittent, continuous, or modulated 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; arrhythmia/fibrillation; arteriovenous fistula; cardiac injury; cardio-respiratory arrest; death; device malfunction; distal embolization; emboli; emergent surgery; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or excessive blood loss; hemoptysis; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; infarction leading to organ damage; neurological deficits including stroke; respiratory failure; vessel complications (including vessel spasm, thrombosis, intimal disruption, dissection, valvular damage, or perforation).

INDIGO™ Aspiration System (LIGHTNING BOLT™ 6X with TraX™) (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 with LIGHTNING BOLT – Intended Use
The INDIGO Aspiration System with the LIGHTNING BOLT Aspiration Tubing is intended 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 using intermittent, continuous, or modulated aspiration.

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; pneumothorax; 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.

Penumbra

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INDIGO® Aspiration System (LIGHTNING BOLT® 6X with TraX™) *(continued)*

- 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 stop 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 or TraX because it may damage the device.
- 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; cardiac injury; cardio-respiratory arrest; death; device malfunction; distal embolization; emboli; emergent surgery; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or excessive blood loss; hemoptysis; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; infarction leading to organ damage; neurological deficits including stroke; respiratory failure; vessel complications (including vessel spasm, thrombosis, intimal disruption, dissection, valvular damage, 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.

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,

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INDIGO™ CAT™ RX Aspiration Catheters and INDIGO SEPARATOR™ 4 (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.

INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4 – Intended Use
The INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4 are intended for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

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 (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.

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

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.

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 Statement

INDIGO™ CAT™ RX Aspiration Catheters and INDIGO SEPARATOR™ 4 (CE Mark Jurisdictions) *(continued)*

INDIGO CAT RX Aspiration Catheters and INDIGO SEPARATOR 4 – Intended Use

The INDIGO Aspiration System is designed to remove emboli and thrombi from the vasculature 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; anemia; arrhythmia; arteriovenous fistula; death; emboli; emergent surgery; foreign body embolization; hematoma or hemorrhage at access site; hemorrhage; infection; inflammation; ischemia; myocardial infarction; neurological deficits including stroke; pseudoaneurysm; renal impairment or acute renal failure from contrast media; residual thrombus due to inability to completely remove thrombus; vessel dissection (intimal disruption); vessel perforation; vessel spasm; vessel thrombosis.

Penumbra

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ELEMENT™ Vascular Access System

Indication for Use
The Element™ Vascular Access System is indicated for the introduction of therapeutic or diagnostic devices into the vasculature.

Contraindications
There are no known contraindications.

Warnings
- The Element Vascular Access System should only be used by physicians who have received appropriate training in interventional techniques.
- The Element Vascular Access System is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective 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 Element Vascular Access System.
- Do not use automated high-pressure contrast injection equipment with the Element Vascular Access System because it may damage the devices.
- Failure to abide by the warnings in this labeling might result in damage to the Element Sheath coating, which may necessitate intervention or result in serious adverse events.

Precautions
- Do not use kinked or damaged Element Sheath or Dilator. 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 Element Vascular Access System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the Element System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the Element System. Unrestrained moving or torquing of the Element System against resistance may result in damage to the vessel or devices.
- Maintain a constant infusion of an appropriate flush solution.
- The maximum diameter of the device to be introduced should be determined to ensure compatibility with the Element Sheath.
- 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 Element Sheath because this may cause unpredictable changes in the coating which could affect the Element Sheath safety and performance.
- When inserting, manipulating, or withdrawing a device through the Element Sheath always maintain Element Sheath position.

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, ischemia, neurological deficits including stroke, vessel spasm, thrombosis, dissection, or perforation, radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia, blood loss, arrhythmia, cardiac injury, cardio-respiratory arrest, hemoptysis, pneumothorax, respiratory failure, valvular damage.

International Risk Statement

ELEMENT™ Vascular Access System (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.

ELEMENT Vascular Access System – Intended Use
The Element™ Vascular Access System is intended for the introduction of therapeutic or diagnostic devices into the 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; access site complications such as hematoma, inflammation, infection, necrosis, pain and tenderness, granuloma; infection; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure may lead to cataracts, skin reddening, burns, alopecia, or neoplasia; blood loss; arrhythmia; cardiac injury; cardio-respiratory arrest; hemoptysis; pneumothorax; respiratory failure; valvular damage.

ELEMENT™ Vascular Access 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.

Element Vascular Access System – Intended Use
The Element Vascular Access System is intended to provide a conduit for introduction of interventional devices to the peripheral anatomy.

Potential Adverse Events
Possible complications include, but are not limited to, the following: access site complications such as hematoma, hemorrhage, spasm, occlusion, or compartment syndrome; acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device material; arrhythmia; arteriovenous fistula; cardiac injury; cardio-respiratory arrest; death; emboli including foreign body embolization; hemoptysis; infection; inflammation; intracranial hemorrhage; ischemia; nerve injury; neurological deficits including stroke; pneumothorax; pseudoaneurysm; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure; renal impairment or acute renal failure from contrast media; respiratory failure; valvular damage; vessel dissection; vessel perforation; vessel spasm; vessel thrombosis.

Penumbra

U.S. IFU Brief Summaries

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.

International Risk Statement

RUBY™ Coil System (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.

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.

RUBY™ Coil System (GEN II) (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.

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.

RUBY™ Coil 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.

Ruby Coil System – Intended Use
The Ruby Coil System is intended to endovascularly obstruct or occlude blood flow in aneurysms or other vascular abnormalities.

Potential Adverse Events
Potential complications include but are not limited to: acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device materials; aneurysm rupture; arteriovenous fistula; coil herniation into parent vessel; death; emboli (includes foreign body embolization); pseudoaneurysm; hematoma or hemorrhage at access site; incomplete aneurysm occlusion requiring retreatment; infection; inflammation; intracranial hemorrhage; ischemia; myocardial infarction; necrosis; neurological deficits including stroke; thromboembolic events; post-embolization syndrome; recanalization; renal impairment or acute renal failure from contrast media; vessel spasm, thrombosis, dissection

Penumbra

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

RUBY™ Coil System (CE Mark Jurisdictions) *(continued)*

(intimal dissection) or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

POD™ System (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.

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 (Non-CE Mark Jurisdictions)

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.

Penumbra

U.S. IFU Brief Summaries

LP System

Indication 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 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.
- 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.

International Risk Statement

POD™ System 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.

POD System – Intended Use
The POD System is intended to endovascularly obstruct or occlude blood flow in aneurysms or other vascular abnormalities.

Potential Adverse Events
Potential complications include but are not limited to: acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device materials; aneurysm rupture; arteriovenous fistula; coil herniation into parent vessel; death; emboli (includes foreign body embolization); pseudoaneurysm; hematoma or hemorrhage at access site; incomplete aneurysm occlusion requiring retreatment; infection; inflammation; intracranial hemorrhage; ischemia; myocardial infarction; necrosis; neurological deficits including stroke; thromboembolic events; post-embolization syndrome; recanalization; renal impairment or acute renal failure from contrast media; vessel spasm, thrombosis, dissection (intimal dissection) or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

Penumbra

U.S. IFU Brief Summaries

LP Coil System (Gen II)

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.

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.
- 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 and physician 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.
- 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.

International Risk Statement

LP Coil System (Gen II) (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 LP Coil System (Gen II) – Intended 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

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.

Penumbra LP Coil 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 LP Coil System – Intended Use
LP Coil is intended to endovascularly obstruct or occlude blood flow in aneurysms or other vascular abnormalities.

Potential Adverse Events
Potential complications include but are not limited to:
acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device materials; aneurysm rupture; arteriovenous fistula; coil herniation into parent vessel; death; emboli (includes foreign body embolization); pseudoaneurysm; hematoma or hemorrhage at access site; incomplete aneurysm occlusion requiring retreatment; infection; inflammation; intracranial hemorrhage; ischemia; myocardial infarction; necrosis; neurological deficits including stroke; thromboembolic events; post-embolization syndrome; recanalization; renal impairment or acute renal failure from contrast media; vessel spasm, thrombosis, dissection (intimal dissection) or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

Penumbra

U.S. IFU Brief Summaries

RUBY® XL System

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

Contraindications
There are no known contraindications.

Warnings
- The Ruby XL 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 catheter 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 catheter is not under stress before coil detachment. Stored forces in the catheter could cause the tip to move during detachment, which could lead to lesion rupture.
- Advancing the delivery pusher beyond the catheter tip could lead to lesion rupture.

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.
- 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 and physician 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.
- 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; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; 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.

International Risk Statement

RUBY™ XL System (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.

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

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; false aneurysm formation; hematoma or hemorrhage at access site of entry; incomplete aneurysm occlusion; infection; intima dissection; 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.

Penumbra

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 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 Statement

Penumbra Delivery Microcatheters (LANTERN™) (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 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.

Penumbra Delivery Microcatheters (LANTERN™) (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 Delivery Microcatheters – Intended Use
The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents and therapeutic devices to the vasculature.

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

PENUMBRA COIL 400™, PAC400™, POD400™, and PENUMBRA SMART COIL™ System – Intended Use (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 COIL 400, PAC400, POD400, and PENUMBRA SMART COIL System – Intended Use
The PENUMBRA COIL 400, PAC400, POD400, and PENUMBRA SMART COIL System are intended to endovascularly obstruct or occlude blood flow in aneurysms or other vascular abnormalities.

Potential Adverse Events
Potential complications include but are not limited to: acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device materials; aneurysm rupture; arteriovenous fistula; coil herniation into parent vessel; death; emboli (includes foreign body embolization); pseudoaneurysm; hematoma or hemorrhage at access site; incomplete aneurysm occlusion requiring retreatment; infection; inflammation; intracranial hemorrhage; ischemia; myocardial infarction;

Penumbra

U.S. IFU Brief Summaries

Penumbra Swift™ Coil System

Indications for Use
The Penumbra Swift 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 Swift 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.

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.
- 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 and physician 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.
- 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.

International Risk Statement

PENUMBRA COIL 400™, PAC400™, POD400™, and PENUMBRA SMART COIL™ System – Intended Use (CE Mark Jurisdictions)
(continued)

necrosis; neurological deficits including stroke; thromboembolic events; post-embolization syndrome; recanalization; renal impairment or acute renal failure from contrast media; vessel spasm, thrombosis, dissection (intimal dissection) or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

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 Swift™ Coil System (Non-CE Mark Jurisdictions)

Penumbra Swift Coil System – Intended Use
The Penumbra Swift 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

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.

Penumbra SwiftPAC™ (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 swiftPAC – Intended Use
Penumbra swiftPAC Coil is intended to endovascularly obstruct or occlude blood flow in aneurysms or other vascular abnormalities.

Potential Adverse Events
Potential complications include but are not limited to: acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media or device materials; aneurysm rupture; arteriovenous fistula; coil herniation into parent vessel; death; emboli (includes foreign body embolization); pseudoaneurysm; hematoma or hemorrhage at access site; incomplete aneurysm occlusion requiring retreatment; infection; inflammation; intracranial hemorrhage; ischemia; myocardial infarction; necrosis; neurological deficits including stroke; thromboembolic events; post-embolization syndrome; recanalization; renal impairment or acute renal failure from contrast media; vessel spasm, thrombosis, dissection (intimal dissection) or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

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International Risk Statement

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