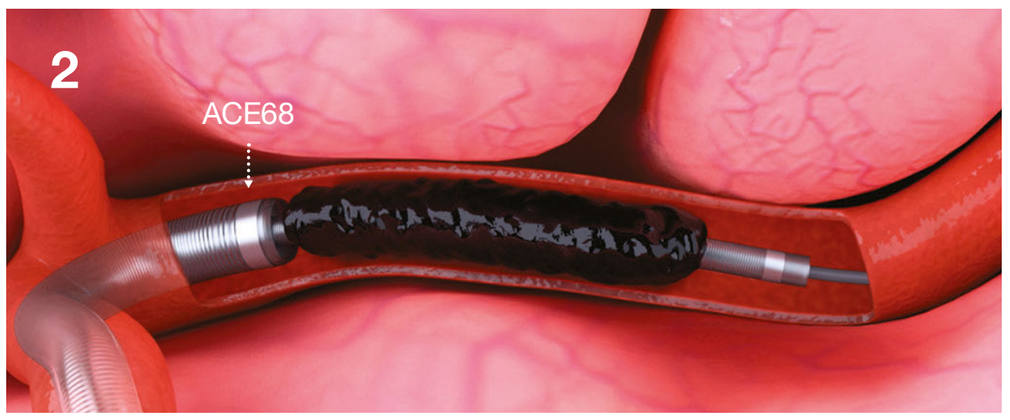
Penumbra

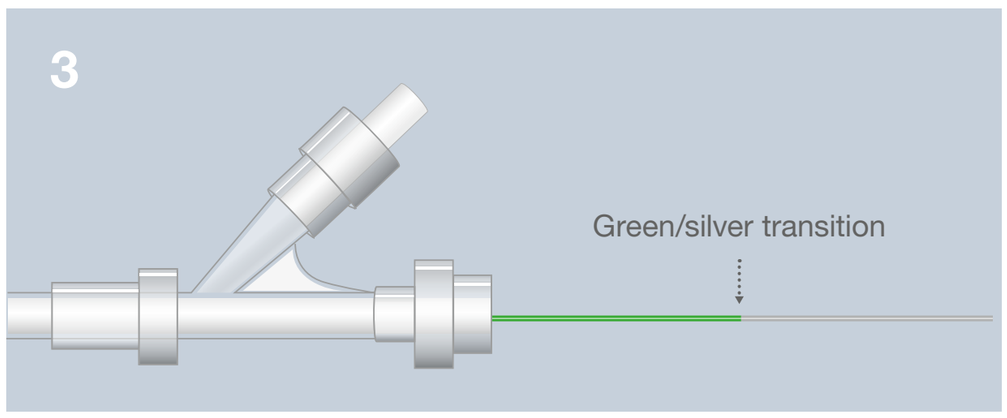
3D

REVASCULARIZATION DEVICE

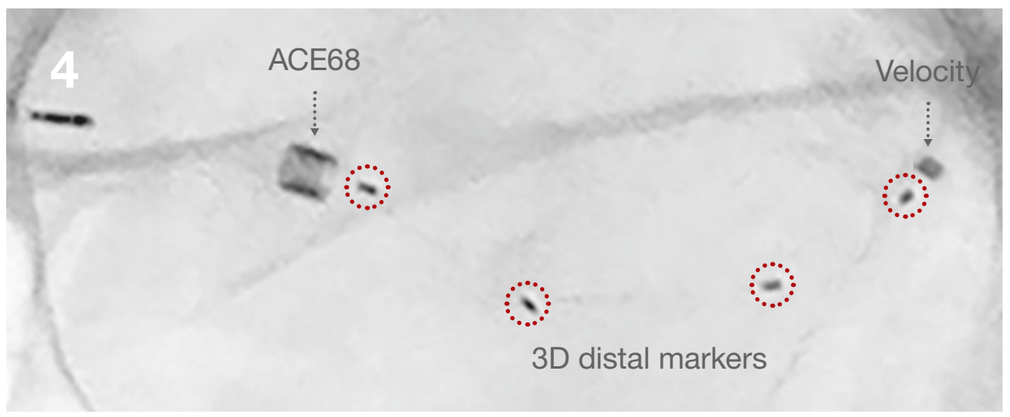
Advance Velocity Microcatheter
past distal edge of clot.



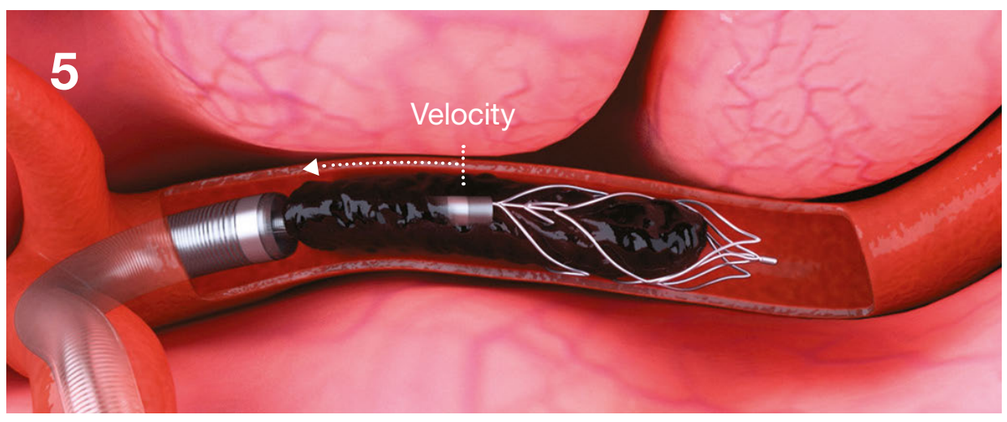
Position ACE68 Reperfusion Catheter
at the proximal edge of occlusion.



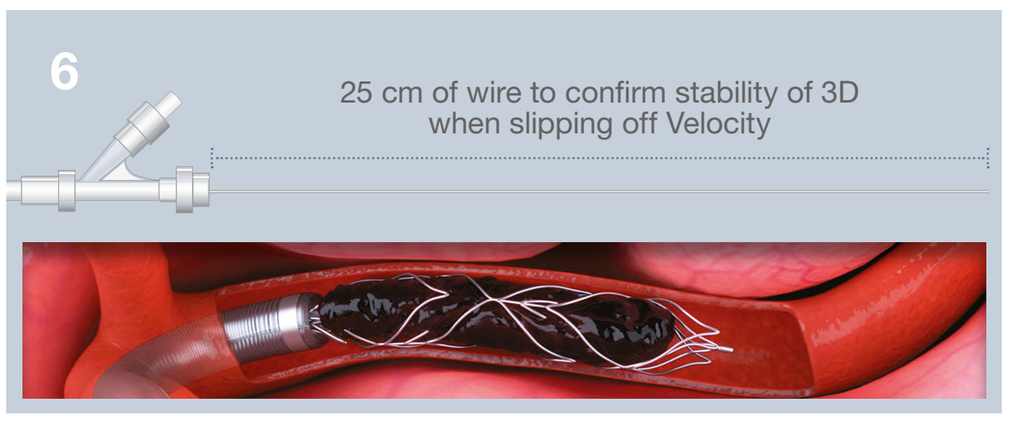
Activate fluoro at green/silver transition.



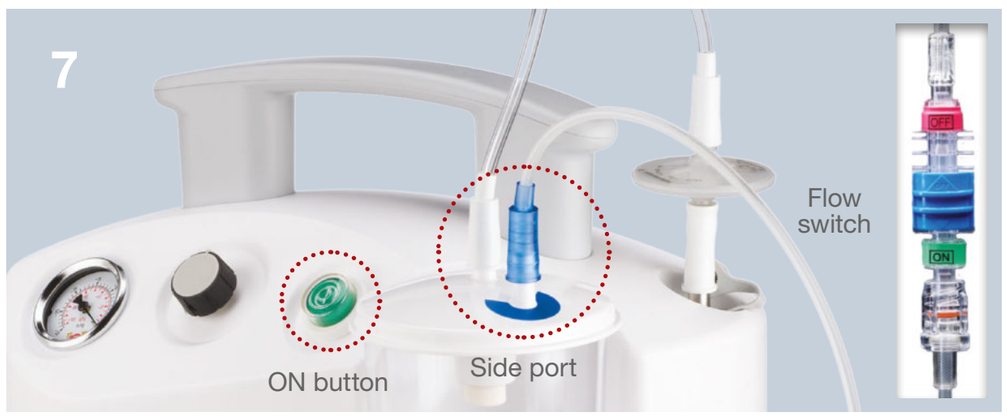
Advance distal marker of 3D to tip of Velocity.
Ensure all 4 distal markers exit ACE68.



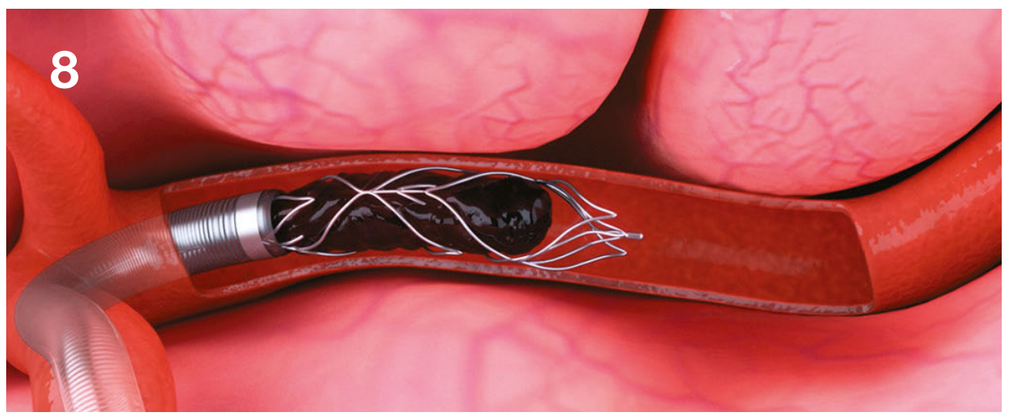
Slowly unsheath 3D.



Slip off Velocity for maximum aspiration power.

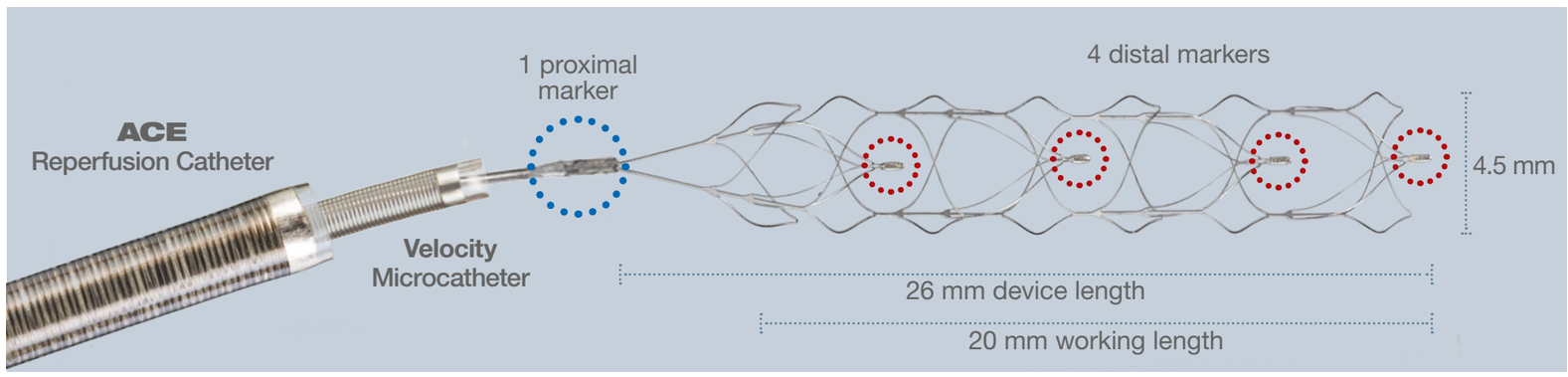


Attach aspiration tubing and turn ON Pump MAX.
Turn flow switch ON and aspirate 90 seconds *(recommended*)*.



Slowly withdraw 3D into ACE under continuous aspiration.
If resistance is met, withdraw 3D and ACE as a unit.

COMPATIBILITY



Deliver with Velocity Microcatheter.
Aspirate with ACE68, ACE64, ACE60, 5MAX, or 4MAX.

***Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment.**

Product availability varies by country. Prior to use, please refer to the Instructions for Use for Penumbra System with 3D Revascularization Device, Penumbra System, Penumbra Pump MAX, and Penumbra Delivery Microcatheters for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please refer to the back of this chart for IFU summaries. Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes. Image used with permission. Consent on file at Penumbra, Inc. Please contact your local Penumbra representative for more information.

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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 Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Do not advance, retract or use any component of the Penumbra System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter, revascularization device, or Separator against resistance may result in damage to the device or vessel.
- Do not use the Penumbra System with a pump other than the Penumbra Aspiration Pump.
- The Penumbra 3D Revascularization Device has not been evaluated in patients with angiographic evidence of pre-existing arterial injury.

Precautions

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.
- The Penumbra Separator is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[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.
- Limit the usage of Reperfusion Catheters to arteries larger than the catheter’s outer diameter.

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.

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.

Penumbra System Reperfusion Catheters and Separators – Indication For Use

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.

Penumbra Aspiration Tubing – Indication For Use

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

Contraindications

There are no known contraindications.

Warnings

- The Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Do not advance, retract or use any component of the Penumbra System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter 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.

Precautions

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the “Use By” date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure 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.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
- The total time allowed to achieve patient revascularization is 120 minutes of using the Penumbra System.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- Limit the usage of Reperfusion Catheters in arteries larger than the catheter’s outer diameter.

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

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.

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.

Penumbra Delivery Microcatheters – Indication For Use

The Penumbra Delivery Microcatheters are 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 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 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

Product availability varies by country. Prior to use, please refer to the Instructions for Use for Penumbra System with 3D Revascularization Device, Penumbra System, Penumbra Pump MAX, and Penumbra Delivery Microcatheters for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes. Image used with permission. Consent on file at Penumbra, Inc. Please contact your local Penumbra representative for more information.

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