

Zoom™ Aspiration Catheters (Zoom 71, Zoom 55, Zoom 45, Zoom 35)

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The Zoom Aspiration Catheters, with the Zoom Aspiration Tubing Set and Zoom Aspiration Pump (or equivalent vacuum pump), 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.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zoom Aspiration Catheters have been verified for use with the Zoom Aspiration Pump and Tubing Kit. The Zoom Aspiration Pump is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use. If using a vacuum pump other than the Zoom Aspiration Pump, carefully review the vacuum pump performance parameters to ensure it can achieve the same operating vacuum pressures between -20 inHg and -29.9 inHg and corresponds to the same flow rate ranges.
- Zoom should only be used by physicians who have received appropriate training in interventional techniques and treatment of acute ischemic stroke.
- This device is intended for single use only. Do not sterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Extreme caution should be used if it is required that Zoom be advanced near or through any aneurysms or other vascular malformations.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw Zoom or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per steps in the IFU with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Do not use automated high-pressure contrast injection equipment with Zoom as it may damage the device.
- When performing aspiration, ensure that the Imperative Care Aspiration Tubing valve is open for only the minimum time needed to remove the thrombus. Do not aspirate for more than 60 continuous seconds when no clot is engaged with the catheter. Excessive aspiration or failure to close the aspiration tubing valve when aspiration is complete can result in serious patient injury.
- Do not perform more than 3 clot retrieval attempts with the Zoom Aspiration Catheter.

PRECAUTIONS

- Use prior to the “Use By” date specified on the product package.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of Zoom and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use Zoom in conjunction with fluoroscopic visualization.
- Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use if the labeling is incomplete or illegible.

POTENTIAL ADVERSE EVENTS

- Possible complications include, but are not limited to, the following:
 - Acute occlusion, Ischemia
 - Unstable angina
 - Arrhythmia, including ventricular fibrillation
 - Death
 - Distal embolization including to a previously uninvolved territory
 - Emboli
 - False aneurysm formation
 - Fever
 - Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas)
 - Infection, Sepsis
 - Intracranial hemorrhage
 - Hypotension/Hypertension
 - Acute myocardial infarction
 - Infarction/Necrosis
 - Neurological defects including stroke
 - Vessel spasm, thrombosis, dissection, perforation, rupture
 - Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

US Federal Law restricts this device to use by or on the order of a physician.



TracStar™ LDP Large Distal Platform (TracStar LDP)

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The TracStar LDP is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The TracStar LDP should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the TracStar LDP be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per steps in the IFU with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not sterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the TracStar LDP and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Use the TracStar LDP in conjunction with fluoroscopic visualization.
- Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the TracStar LDP or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath and Catheter Introducer are necessary to introduce the TracStar LDP into the patient's vasculature. Attempting to introduce the catheter without these introducers can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the TracStar LDP as it may damage the device.

POTENTIAL ADVERSE EVENTS

- Acute occlusion, Ischemia
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Fever
- Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas)
- Infection, Sepsis
- Intracranial hemorrhage
- Hypotension/Hypertension
- Acute myocardial infarction
- Infarction/Necrosis
- Neurological defects including stroke
- Vessel spasm, thrombosis, dissection, perforation, rupture
- Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

US Federal Law restricts this device to use by or on the order of a physician.



Zoom™ 88-T Large Distal Platform (Zoom 88-T LDP)

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The Zoom 88-T LDP is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zoom 88-T LDP should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the Zoom 88-T LDP be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per steps in the IFU with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the Zoom 88-T LDP and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Use the Zoom 88-T LDP in conjunction with fluoroscopic visualization.
- Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the Zoom 88-T LDP or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath and Catheter Introducer are necessary to introduce the Zoom 88-T LDP into the patient's vasculature. Attempting to introduce the catheter without these introducers can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the Zoom 88-T LDP as it may damage the device.

POTENTIAL ADVERSE EVENTS

- Acute occlusion, Ischemia
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Fever
- Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas)
- Infection, Sepsis
- Intracranial hemorrhage
- Hypotension/Hypertension
- Acute myocardial infarction
- Infarction/Necrosis
- Neurological defects including stroke
- Vessel spasm, thrombosis, dissection, perforation, rupture
- Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

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Zoom™ Aspiration Pump

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The Zoom Aspiration Pump is intended for general suction use in hospitals and clinics.

CONTRAINDICATIONS

There are no contraindications.

WARNINGS/PRECAUTIONS

- The pump should only be used by healthcare professionals.
- The air vent(s) should not be blocked. Blocked vents may cause the pump to overheat and shut off or fail to restart.
- To avoid risk of electric shock the pump should be connected to a properly grounded outlet.
- Do not position the device so that it is difficult to access the power supply cord (disconnecting device).
- If using the pump for specific suction purposes, such as pharyngeal and thoracic suction, user should review the IFU for the specific aspiration device prior to operation.
- Replace the pump in the situation of accidental entry of fluids or solids into the vacuum pump.
- Do not use device in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- Do not use in an oxygen-rich environment.
- In order to prevent fire or shock hazards, replace the fuse with equal size and rating as specified on the pump label and replace the power cord of equal rating as specified in the IFU.
- Do not use petroleum-based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. Failure to comply with this will reduce the operating life of the pump.
- Do not modify the pump.
- Do not use portable and mobile RF communications equipment (including cables and accessories) closer than 12 inches (30 cm) to any part of the pump.
- Use of other cables and accessories which are not supplied may result in non-compliance and negatively affect electromagnetic compatibility.
- The Zoom Aspiration Pump utilizes inches of Mercury (inHg) for Vacuum pressure measurement. This measurement unit is significantly different from millimeters of Mercury (mmHg) which can be found in other suction pumps (1 inHg = 25.4 mmHg). Please ensure you are utilizing the correct measurement unit when selecting your desired Vacuum pressure levels.
- When used incorrectly, a high-flow, high-suction vacuum can cause hemorrhaging and soft tissue, muscle, and vital organ damage that can lead to serious injury and/or death. Please ensure you are using the correct accessories, connections and settings before starting Vacuum pressure.

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Zoom™ Aspiration Tubing

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The Zoom Aspiration Tubing Set is intended to connect the Zoom Aspiration Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- Contents are supplied sterile using ethylene oxide (EO) and are non-pyrogenic. Prior to use, inspect the packaging and the entire product for damage. Never use a device that has damage to either the packaging or the product.
- This device is designed and intended for single patient use. Do not re-sterilize and/or reuse this device.

PRECAUTIONS

- Only physicians familiar with standard endovascular interventional techniques should use this device.
- Tubing should be flushed with sterile saline prior to use.
- Ensure all connections are secure before use. Do not over-tighten the male luer connector, as excessive force may damage the product.

POTENTIAL ADVERSE EFFECTS

- The Zoom Aspiration Tubing is used to connect the Zoom Aspiration Catheter to the Zoom Canister of the Zoom Aspiration Pump. Potential adverse events associated with the Zoom Aspiration Tubing could occur due to improper use of sterile handling technique and include, but are not limited to, the following: fever, infection, sepsis, and death.

US Federal Law restricts this device to use by or on the order of a physician.



Zoom™ Canister

See IFU packaged with product for complete instructions on device usage

INDICATIONS FOR USE

The Zoom Canister is intended to collect aspirated fluids for disposal and prevent fluid ingress from damaging the Zoom Aspiration Pump.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- Use prior to the "Use By" date specified on the product package.
- Do not use if the packaging is open or damaged.
- Do not use if the labeling is incomplete or illegible.
- This device is intended for single use only. Do not sterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.

PRECAUTIONS

- Prior to use, ensure that the Zoom Canister is not cracked.
- If flow through the device becomes restricted, remove and replace the device.

US Federal Law restricts this device to use by or on the order of a physician.

