Zoom™ 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.

INDICATIONS FOR USE
The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), 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, basilar, and vertebral arteries) within 8 hours of last known well.

Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS
- Verify aspiration pump is appropriate before use.

  The Zoom System catheter(s) have been verified for use with the Zoom Aspiration Tubing, Zoom POD Aspiration Tubing, and Zoom Aspiration Pump. 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.
- The Zoom System 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 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.
- Extreme caution should be used if it is required that the catheters 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 the catheters 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 catheters has a lubricious hydrophilic coating and should be hydrated per preparation Step 6 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 in a bath of heparinized saline.
- Do not use automated high-pressure contrast injection equipment with the Zoom System as it may damage the device.
- When performing aspiration, ensure that the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing clamp 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 Zoom Aspiration Tubing or Zoom POD Aspiration Tubing clamp when aspiration is complete can result in serious patient injury.
- Do not perform more than 3 clot retrieval attempts with the Zoom System.
- Do not stop aspiration if the thrombus is engaged with the Zoom System. Stopping aspiration while thrombus is engaged can result in distal embolization and serious patient injury.
- The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.
- The Zoom System catheters are not recommended for use in combination with stent-retrievers.
- Direct aspiration using the LDP Catheters (Zoom 88 LDP, Zoom 88 LDP Support, TracStar LDP) alone is not supported by the Imperative Trial due to insufficient data. Aspiration through the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) must be performed in conjunction with a Zoom (7X, 71, 55, 45, 4S, or 35) Catheter.

PRECAUTIONS
- The 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 the catheters and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Zoom System 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.
- 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 catheter 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. This may result in adverse events requiring additional intervention.
- Do not use if the labeling is incomplete or illegible.
- When removing the device from the pouch card, be sure to remove the catheter in line with the protective tubing to reduce the risk of damaging the catheter.
- Use of an access site introducer sheath is necessary to introduce the LDP Catheter into the patient's vasculature. A support catheter + guidewire are required when advancing the LDP Catheter into the hemostasis valve on the access site introducer sheath. Attempting to introduce the LDP Catheter without these accessories can result in kinking or other damage to the device.

POTENTIAL ADVERSE EVENTS

- Possible 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.

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

Imperative Care, Inc.
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Zoom™ 88 Large Distal Platform™ (Zoom 88)
Zoom™ 88 Large Distal Platform™ Support (Zoom 88)

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.

INDICATIONS FOR USE
The Zoom 88 Large Distal Platform and Zoom 88 Large Distal Platform Support are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS
- The Zoom 88 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 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.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the Zoom 88 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 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 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 torqueing 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 is necessary to introduce the Zoom 88 into the patient's vasculature. Attempting to introduce the catheter without this introducer 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 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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Imperative Care Zoom™ RDL Radial 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.

INDICATIONS FOR USE
The Imperative Care Zoom RDL Radial 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 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
- Do not place an 8 French or larger inner diameter sheath in the radial artery, but instead advance the Zoom RDL Radial Access System over a guidewire through the arterial puncture.
- Do not use the Zoom RDL Radial Access System for delivery of liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).
- The Zoom RDL Radial Access System 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 RDL Radial Access System 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
- If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient.
- 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.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g., diameter and length) of the Zoom RDL Radial Access System 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 prior to use through short immersion in a bath of heparinized saline.
- 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.
- Use the Zoom RDL Radial Access System 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 performing direct puncture and/or manipulating the device through tortuous anatomy. Do not apply excessive force, or advance or withdraw the Zoom RDL Radial Access System 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 torqueing 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
- 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 RDL Radial Access System 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 (radial artery spasm, radial artery perforation, infection, necrosis, pain and tenderness, compartment syndrome, radial artery occlusion, 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. allergic reaction)
- Coagulopathy
- Renal insufficiency/failure
- Hand dysfunction
- Pathological hand cold intolerance

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

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.

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

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.

INDICATIONS FOR USE
The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (71, 55, 45, 4S, 35) Catheter and the TracStar LDP Large Distal Platform, the Zoom 88 Large Distal Platform, or the Zoom 88 Large Distal Platform Support to the Zoom Canister of the Zoom Aspiration Pump (or equivalent vacuum 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
- Potential adverse events associated with the Zoom Aspiration Tubing and Zoom POD 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.

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Zoom™ Canister

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.

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.

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Zoom™ 6F Insert Catheters (Zoom SIM, Zoom VRT, Zoom VTK)

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.

INDICATIONS FOR USE
The Zoom 6F Insert Catheters are indicated for use in delivering radiopaque media to selected sites in the peripheral vascular system in conjunction with routine diagnostic procedures.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS
- The Zoom 6F Insert Catheters should only be used by physicians who have received appropriate training in angiographic techniques, device manipulation and observation under fluoroscopy, and are proficient in using introducer sheaths and guide catheters.
- This device is intended for single use only. Do not reuse, reprocess, or re-sterilize. 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 the Zoom 6F Insert Catheter be advanced near or through any aneurysms or other vascular malformations.
- Exercise care when manipulating the device through tortuous anatomy and use fluoroscopy for visual confirmation of distal motion. Do not apply excessive force, or advance or withdraw the Zoom 6F Insert Catheter 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. Do not torque the device more than one full revolution.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to wipe down the Zoom 6F Insert Catheter.
- Before starting infusion, verify that the catheter has not been kinked or blocked. Failure to abide by this warning may cause the catheter to break/rupture/separate, resulting in damage to the vessel.
- The maximum permissible pressure for the Zoom 6F Insert Catheter is 1200 psi (8274 kPa). Do not exceed the maximum injection pressure as it may damage the device or injure the patient.
- The Zoom 6F Insert Catheters are not intended for use in the coronary arteries or in the neurovasculature bed distal to the cervical segment of the internal carotid artery and the cranium.

PRECAUTIONS
- Use prior to the “Use By” date specified on the product package.
- Do not use if the labeling is incomplete or illegible.
- Do not use if the packaging is open or damaged.
- All agents to be infused must be used according to the manufacturer’s instructions for use.
- Exercise care when removing the pouch card from the product pouch to prevent damage to the device.
- Prior to use, ensure that the tip shape and dimensions (e.g., diameter and length) of the Zoom 6F Insert Catheter and dimensions of adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Zoom 6F Insert Catheter 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.
- 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.
- 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 attempt to heat or reshape the catheter tip curve; the catheter tip is made from a heat-sensitive material.
- Contrast media should be injected at 37°C.

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Ikon™ Guidewire

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.

INDICATIONS FOR USE
The Ikon Guidewire is indicated for general intravascular use within the peripheral and neuro vasculature to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS AND PRECAUTIONS
- This guidewire should be used only by physicians trained in percutaneous interventional techniques and procedures.
- The safety and effectiveness of the device has not been established in the coronary vasculature.
- This device is coated with a hydrophilic coating at the distal end of the device. Refer to package label for hydrophilic coating length. Please refer to the Preparation for Use and Instruction for Use Sections for further information on how to prepare and use this device to ensure it performs as intended. 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.
- Ikon Guidewires are not safe for use in or near Magnetic Resonance Imaging (MR) equipment. Use prior to the "Use By" date specified on the product package. This device is intended for single-patient use only.
- Do not reuse, re- sterilize or reprocess. After use, dispose of device in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use if package is open or damaged.
- Do not use if the labeling is incomplete or illegible.
- Confirm the compatibility of the guidewire with the catheter(s) and any other interventional devices prior to use.
- Avoid wiping the device as this may damage the device coating.
- Do not wipe the device with a dry gauze.
- Do not use 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.
- Use caution when manipulating, advancing and/or withdrawing the guidewire through any 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. This may result in adverse events requiring additional intervention.
- Altering the shape of devices by bending, twisting, or similar methods beyond instructed methods may compromise the coating integrity. This potential damage to the coating may not always be noticeable to the naked eye.
- Failure to create a tip shape per use steps could negatively impact tracking performance and may result in vessel trauma.
- Use fluoroscopy to monitor guidewire movement. Be sure to observe distal tip movement whenever the proximal portion is moved or rotated. Always advance, retract, or rotate the guidewire slowly and carefully. *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, torque or withdraw the Ikon Guidewire 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 guidewire, damage to the other interventional devices and/or patient injury.
- The torque device, the introducer, and the shaping mandrel are included to aid in the use of the guidewire and are not intended to enter the patient's body.
- Securely fasten the torque device onto the guidewire during use to prevent the torque device from slipping and damaging the guidewire and/or its coating.
- Maintain a constant heparinized saline flush between the catheter and the guidewire during a procedure.

POTENTIAL ADVERSE EVENTS
Possible complications include, but are not limited to, the following:

- Aneurysm perforation/rupture
- Death
- Embolus
- Hemorrhages
- Infarct
- Infection
- Ischemia
- Pseudoaneurysm
- Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA)
- Tissue necrosis
- Thrombosis/Thrombus
- Vasospasm
- Vessel trauma/occlusion/perforation/dissection
- Other procedural complications including but not limited to, anesthetic and contrast media risks, hemodynamic compromise, renal insufficiency, sterile inflammation or granulomas at access site and access site complications

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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