INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Zoom™ 7X Catheter is a single lumen, braid and coil reinforced, variable stiffness catheter with a radiopaque marker and a lubricious hydrophilic coating on the distal portion of the catheter (Table 1). The Zoom 7X Catheter has a luer hub on the proximal end. Dimensions for the Zoom 7X Catheter are included on the individual device label. The Zoom 7X Catheter is compatible with 0.014" – 0.018" guidewires. An additional support catheter may also be used to assist in accessing the target vasculature. The Zoom 7X Catheter is intended to be used in conjunction with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing and the Zoom Aspiration Pump (or equivalent vacuum pump) to aspirate thrombus. The Zoom 7X Catheter is packaged with the accessories listed in Table 1. The Rotating Hemostasis Valve (RHV) is intended to be attached to the proximal hub of the Zoom 7X Catheter and used to control hemostasis during use with other devices. The introducer sheath is intended to facilitate insertion of the Zoom 7X Catheter into a guide catheter or RHV.

TABLE 1 – ZOOM 7X CATHETER SIZE

Model Number	Product Name	Accessories	Nominal Inner Diameter (in)		Max Outer Diameter (in)		Nominal Working Length	Hydrophilic Coating Length
			Distal	Proximal	Distal	Proximal		
ICRC07X137	Zoom 7X Catheter	- RHV - Introducer Sheath (2x)	0.071	0.071	0.085	0.086	137 cm	35 cm

TABLE 2 – CATHETER VESSEL SIZING GUIDELINES

Device Distal Inner Diameter	Device Distal Outer Diameter (mm)	Recommended Vessel Diameter (mm)
0.071"	2.1	> 3.5

TABLE 3 – CATHETER COMPATIBILITY

Product Name	Guide Sheath or Introducer Sheath / Minimum Inner Diameter	Microcatheter or Intermediate Catheter / Maximum Outer Diameter
Zoom 7X Catheter	6F / 0.088"	5F / 0.061"

The Zoom Aspiration Tubing, Zoom POD Aspiration Tubing, and Zoom Aspiration Pump are packaged and sold separately from the catheters. Refer to the individual *Instructions for Use* for more information.

INDICATIONS FOR USE

The Zoom 7X Catheter, with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing, and 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

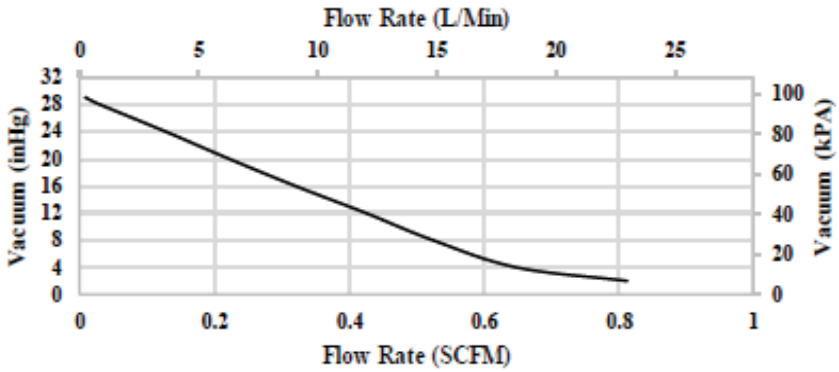
There are no known contraindications.

WARNINGS

- **Verify aspiration pump is appropriate before use.**

  The Zoom 7X Catheter has been verified for use with the Zoom Aspiration Tubing, Zoom POD Aspiration Tubing, and the Zoom Aspiration Pump. The Zoom Aspiration Pump is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 1. 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 (Figure 1).

FIGURE 1 – PUMP PRESSURE-FLOW PERFORMANCE CURVE FOR THE ZOOM ASPIRATION PUMP



- The Zoom 7X Catheter 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 catheter 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 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. 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 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 by immersing in a bath of heparinized saline.
- Do not use automated high-pressure contrast injection equipment with the catheter 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 7X Catheter.
- Do not stop aspiration if the thrombus is engaged with the Zoom 7X Catheter. 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 7X Catheter is not recommended for use in combination with stent-retrievers.

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 the catheter and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Zoom 7X 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.
- 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 catheters 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.
- 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.
- Do not use if the labeling is incomplete or illegible.

POTENTIAL ADVERSE EVENTS

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

- 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)
- Acute occlusion, ischemia
- 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.

DEVICE PREPARATION AND USE

1. Select an appropriate introducer sheath or guide sheath per Table 3 to access the appropriate cerebral artery proximal to the thrombus occlusion site.

   Note: Follow the introducer sheath or guide sheath Instructions for Use when performing this step.
2. Open the Zoom 7X Catheter product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.

3. Remove the accessories from the pouch card by removing them from the card tabs before gently lifting the Zoom 7X Catheter luer from the pouch card tab and removing the catheter shaft from the protective tubing.

   Note: Remove the catheter in parallel with the protective tubing. Do not remove the catheter perpendicular to the tubing to prevent damage to the catheter.

4. Inspect the Zoom 7X Catheter and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.
5. Hydrate the introducer sheath(s) with heparinized saline.
6. Hydrate the outer surface of the Zoom 7X Catheter and flush the lumen of the catheter with heparinized saline.

   Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated by submerging in a bath of heparinized saline.

7. Gently insert the catheter tip into the flared end of the provided introducer sheath.
8. Attach the provided RHV to the luer of the Zoom 7X Catheter.
9. Open the RHV on the Zoom 7X Catheter and advance a guidewire (0.014" - 0.018" diameter, per physician discretion) or support catheter + guidewire into the Zoom 7X Catheter until the distal tip of the support catheter is past the distal tip of the Zoom 7X Catheter and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
10. Gently insert the Zoom 7X Catheter with introducer sheath over the accessory devices (e.g., guidewire and support catheter, as necessary) into the access site introducer sheath or guide sheath.
11. Once the catheter is inserted, retract and remove the introducer sheath.
12. Under fluoroscopy, continue advancing the device assembly towards the target vessel.

    Note: If injection through the Zoom 7X Catheter is necessary, remove the support catheter and guidewire and aspirate the Zoom 7X Catheter lumen prior to injection.

THROMBECTOMY USING THE ZOOM 7X CATHETER

13. Position the Zoom 7X Catheter proximal to the thrombus. Remove the support catheter and the guidewire.
14. Ensure the clamp on the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing is in the closed position and attach the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing to the aspiration pump. Turn on the aspiration pump (refer to the aspiration pump Instructions for Use). Allow the aspiration pump to run until the aspiration gauge reads at least -20 inHg.
15. Connect the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing directly to the Zoom 7X Catheter or to the side port of the RHV.
16. To begin aspiration, open the clamp on the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing. To stop aspiration, close the clamp on the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing and turn off the aspiration pump.
17. Using a 5 cc or 10 cc syringe, aspirate approximately 5 cc of blood from the Zoom 7X Catheter to remove any thrombus that may remain in the catheter.
18. Obtain a post-treatment angiogram to verify that the thrombus has been removed.
19. After the procedure has been completed, remove the Zoom 7X Catheter per standard procedure.

    Note: While removing the Zoom 7X Catheter, aspirate through the catheter lumen to collect any fibrin that may have been deposited within or at the tip of the catheter.

20. Discard the Zoom 7X Catheter appropriately per facility procedure.

PACKAGING

The Zoom 7X Catheter is placed inside a protective high-density polyethylene (HDPE) tube and then secured to an HDPE packaging card. A Rotating Hemostasis Valve (RHV) is included in the Zoom 7X Catheter packaging. Two introducer sheaths are included in the Zoom 7X Catheter packaging. The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The Zoom 7X Catheter is sterilized using ethylene oxide (EO).

The Zoom 7X Catheter will remain sterile unless the pouch is opened, damaged, or the "Use by" date has passed.

MATERIALS

The Zoom 7X Catheter is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Except where indicated with an asterisk (*), Standard Reference: ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements, §5 Symbols.

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary
	Catalogue number
	Single sterile barrier system with protective packaging outside. Sterilized by ethylene oxide.
	Nonpyrogenic
	*Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	*Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry
	Medical device

WARRANTY

Imperative Care, Inc. (“Imperative Care”) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.

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℞ Only

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