

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Zoom™ 4S 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 and luer hub on the proximal end. Additional dimensions are included on the device labels. The following device sizes are available.

TABLE 1 – CATHETER SIZES

Model Number	Product Name	Distal Diameter		Proximal Diameter		Maximum Outer Diameter	Nominal Working Length	Hydrophilic Coating Length
		Inner	Outer	Inner	Outer			
ICRC04S125	Zoom 4S, 125 cm	0.045"	0.056"	0.045"	0.060"	0.062"	125 cm	65 cm
ICRC04S144	Zoom 4S, 144 cm	0.045"	0.056"	0.045"	0.060"	0.062"	144 cm	65 cm
ICRC04S160	Zoom 4S, 160 cm	0.045"	0.056"	0.045"	0.060"	0.062"	160 cm	65 cm

TABLE 2 – CATHETER COMPATIBILITY

Model Number	Product Name	Guide Sheath Minimum Inner Diameter	Microcatheter Maximum Outer Diameter	Guidewire Diameter
ICRC04S125	Zoom 4S, 125 cm	0.071"	0.040"	0.014" – 0.035"
ICRC04S144	Zoom 4S, 144 cm	0.071"	0.040"	0.014" – 0.035"
ICRC04S160	Zoom 4S, 160 cm	0.071"	0.040"	0.014" – 0.035"

The Zoom™ 4S Catheter is recommended for use in vessels with a minimum diameter of 2.5mm to avoid vessel injury, dissection, or perforation.

The Zoom™ 4S Catheter is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the Zoom™ 4S Catheter and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The Zoom™ 4S Catheter is indicated for the introduction of interventional devices into the neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zoom™ 4S Catheter should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- 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 Zoom™ 4S 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 Zoom™ 4S 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 in a bath of heparinized saline.
- Do not use automated high-pressure contrast injection equipment with the Zoom™ 4S Catheter as it may damage the device.
- The safety and effectiveness of the Zoom™ 4S Catheter has only been evaluated via transfemoral access.
- The Zoom™ 4S 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 Zoom™ 4S 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™ 4S 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.
- 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.
- 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.
- 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.
- 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.
- 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, 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.

DEVICE PREPARATION AND USE

1. Select an appropriate Zoom™ 4S Catheter based on the distance from the access site to the target anatomy (see Table 1). Ensure that the diameter of the Zoom™ 4S Catheter is appropriate for the vasculature.
 - Select an appropriate guide catheter based on the dimensions of Zoom™ 4S Catheter being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
2. Open the 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 Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the Zoom™ 4S 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™ 4S Catheter and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.
5. Attach the provided RHV to the luer of the Zoom™ 4S Catheter.
6. Hydrate the outer surface of the Zoom™ 4S Catheter and flush the lumen of the catheter and RHV 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 in a bath of heparinized saline.

Use Steps for the Zoom™ 4S Catheter

7. Gain primary access to the target vessel using a compatible guide catheter (≥ 0.071 " inner diameter).
8. Open the RHV attached to the luer of the Zoom™ 4S Catheter and advance a compatible microcatheter and/or guidewire (0.014"-0.035" diameter) into the Zoom™ 4S Catheter until the distal tip of the microcatheter and/or guidewire is well past the distal tip of the Zoom™ 4S Catheter and then tighten the RHV to secure the microcatheter and/or guidewire in place. Do not overtighten the RHV as it could deform the microcatheter and/or guidewire.

9. Gently insert the Zoom™ 4S Catheter with the microcatheter and/or guidewire assembly (device assembly) into the guide catheter.
Note: Follow the guide catheter manufacturer's instructions for use when performing this step.
10. Under fluoroscopy, advance the device assembly through the guide catheter and into the patient's vasculature using conventional catheterization techniques.

Note: If injection through the Zoom™ 4S Catheter is necessary, remove the microcatheter and/or guidewire and aspirate the Zoom™ 4S Catheter lumen prior to injection.
11. After gaining access to the desired vessel with the microcatheter and/or guidewire, advance the Zoom™ 4S Catheter over the microcatheter and/or guidewire to the desired position.
12. Once the desired position is achieved, remove the microcatheter and, if necessary, the guidewire.
13. The Zoom™ 4S Catheter can be used as a conduit for other interventional devices and diagnostic agents (i.e. contrast) to access the target vascular site and distal vessels.
14. After the procedure has been completed, obtain a post-treatment angiogram to verify procedural results and remove the Zoom™ 4S Catheter through the guide catheter per standard procedure.
15. Discard the Zoom™ 4S Catheter appropriately per facility procedure.

PACKAGING

The Zoom™ 4S Catheter is placed inside a protective high-density polyethylene (HDPE) tube and then secured to a HDPE packaging card. A Rotating Hemostasis Valve (RHV) is included in the packaging. The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The Zoom™ 4S Catheter is sterilized using Ethylene Oxide (EtO).

The Zoom™ 4S Catheter will remain sterile unless the pouch is opened, damaged, or the "Use By" date has passed.

MATERIALS

The Zoom™ 4S 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, labeling and information to be supplied - Part 1: General requirements, §5 Symbols

Symbol	Definition
	Manufacturer
	Lot number
	Use-by date

	Attention - See instructions for use for safety information and symbols glossary
	Catalogue number
	Sterilized using ethylene oxide and contained with single sterile barrier system with protective packaging outside
	Non-pyrogenic
	*Caution: Federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Do not re-use
	*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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