INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Imperative Care Zoom RDL Radial Access System (Zoom RDL Radial Access System) consists of the Zoom RDL Radial Access Catheter and a 6F dilator, intended to provide vascular access to the treatment site using a direct puncture transradial access approach. The Zoom RDL Radial Access Catheter is advanced over a 6F dilator and guidewire which support the catheter as it is advanced through the wrist and directly into the radial artery. Once in place, the catheter allows for the introduction and exchange of other interventional devices into the coronary, peripheral and neuro vasculatures.

The Zoom RDL Radial Access Catheter is a single lumen, braid and coil reinforced, variable stiffness catheter. The catheter features a standard luer hub on the proximal end, an atraumatic angled tip with a radiopaque marker on the distal end, and a lubricious hydrophilic coating on the distal 21 cm portion of the catheter shaft. The catheter has a proximal outer diameter of 0.110" (2.8 mm) and is offered in working lengths of 95 cm, 103 cm, 105 cm and 110 cm. The 6F dilator has a minimum inner diameter of 0.039" and an outer diameter range of 0.083" – 0.086". Additional dimensions are included on the individual device labels.

The Zoom RDL Radial Access Catheter and 6F dilator are compatible with ≤ 0.038" diameter guidewires and standard luer lock devices (e.g., syringes). A compatible RHV can be attached to the proximal hub of the catheter and used to control hemostasis during use with other devices. A support catheter may also be used to assist in accessing the target vasculature

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 Step 8 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

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

- 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

DEVICE PREPARATION AND USE

1. Select an appropriate Zoom RDL Radial Access System (includes Zoom RDL Radial Access Catheter and 6F dilator) based on distance from the access site to the target anatomy and the vessel diameters.

2. Select an appropriate support catheter based on the dimensions of the Zoom RDL Radial Access Catheter being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. 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.
4. Select a compatible RHV for the procedure.
5. Remove the 6F dilator from the packaging card by removing the hub from the card tabs before gently removing the dilator shaft.
6. Inspect each of the components of the Zoom RDL Radial Access System for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

USE STEPS FOR THE ZOOM RDL RADIAL ACCESS SYSTEM

7. Attach the RHV to the luer of the Zoom RDL Radial Access Catheter.
8. Hydrate the outer surface of the Zoom RDL Radial Access 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 through short immersion in a bath of heparinized saline.
9. Flush the 6F dilator lumen and wet the outer surface of the dilator with heparinized saline.
10. Insert the 6F dilator completely through the RHV and tighten the RHV.
11. Gain primary radial access using standard technique and insert a ≤0.038" diameter guidewire into the vessel.
12. Holding the guidewire in place, apply pressure to the puncture site until the Zoom RDL Radial Access Catheter and 6F dilator are inserted into the vasculature.
13. Thread the Zoom RDL Radial Access Catheter and 6F dilator assembly over the guidewire, grasping the Zoom RDL Radial Access Catheter close to the skin to prevent buckling. Using a rotating motion, advance the assembly through the tissue into the vessel.
14. Under fluoroscopy, advance the Zoom RDL Radial Access Catheter and 6F dilator assembly over the 0.038" guidewire (always ensure the distal wire extends in front of the dilator tip) until a safe flushing position is achieved.
15. Detach the 6F dilator from the Zoom RDL Radial Access Catheter by loosening the RHV. Withdraw the 6F dilator.
16. Open the RHV and advance a support catheter over the 0.038" guidewire into the Zoom RDL Radial Access Catheter until the distal tip of the support catheter is well past the distal tip of the Zoom RDL Radial Access 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.
17. Under fluoroscopy, advance the device assembly into the patient's vasculature using conventional catheterization techniques.

    Note: If injection through the Zoom RDL Radial Access Catheter is necessary, remove the support catheter and guidewire and aspirate the Zoom RDL Radial Access Catheter lumen prior to injection.
18. After gaining access to the desired vessel with the support catheter and guidewire, advance the Zoom RDL Radial Access Catheter over the support catheter to the desired position.
19. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.
20. The Zoom RDL Radial Access Catheter can be used as a conduit for other interventional devices and diagnostic agents to access the target vascular site and distal vessels.
21. After the procedure has been completed, remove the Zoom RDL Radial Access Catheter per standard procedure.
22. Discard the Zoom RDL Radial Access System appropriately per facility procedure.

PACKAGING

Zoom RDL Radial Access System includes the Zoom RDL Radial Access Catheter and a 6F dilator. The Zoom RDL Radial Access Catheter is placed inside a protective HDPE tube and then the 6F dilator is secured to a HDPE packaging card. The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The Zoom RDL Radial Access System is sterilized using Ethylene Oxide (EtO). The Zoom RDL Radial Access System will remain sterile unless the pouch is opened, damaged, or the "Use By" date has passed.

MATERIALS

The Zoom RDL Radial Access System 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
	Consult electronic instructions for use
	Catalogue number
	Sterilized using ethylene oxide and contained with single sterile barrier system
	Sterilized using ethylene oxide
	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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