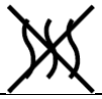
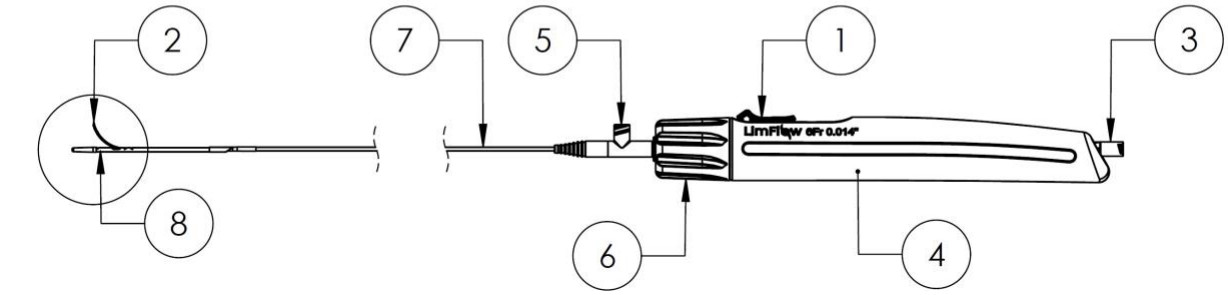
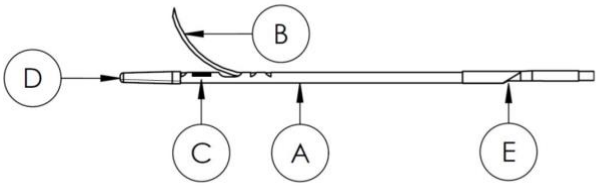
LimFlow ARC® Instructions for Use

Explanations of symbols on labels and packaging	
	Manufacturer
	Sterilized using ethylene oxide
	Do not resterilize
	Do not re-use
	Catalogue number
	Lot number
	Use-by date
	Consult electronic instructions for use
	Non-Pyrogenic
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Unique device identifier
	Prescription only
	No latex
	Single Sterile Barrier System
	Caution when operating the device

1. DEPLOYMENT SLIDE RELEASE BUTTON
2. CANNULA TIP EMERGING FROM CANNULA EXIT
3. CANNULA WIRE PORT
4. DEPLOYMENT HANDLE
5. FLUSH PORT
6. ROTATING KNOB WITH HEMOSTATIC SEAL
7. CATHETER SHAFT
8. CANNULA NOSECONE WITH CANNULA EXIT PORT





A. CATHETER SHAFT
B. CANNULA (GUIDE)
C. DIRECTIONAL MARKER AND NOSECONE
D. DISTAL END PORT
E. PROXIMAL RAPID EXCHANGE PORT

ARC Catalog Number	AC-US-21 AC-US-23

Caution: Federal (USA) law restricts this device to sale by or on order of a physician

I. DESCRIPTION

The LimFlow ARC® is a 6 Fr compatible catheter designed to facilitate placement and positioning of guidewires within the peripheral vasculature. The LimFlow ARC is comprised of three primary elements: 1) Cannula, 2) Catheter shaft, and 3) Deployment handle with deployment control slide.

II. CONTENTS

One (1) LimFlow ARC

III. INDICATIONS FOR USE

The LimFlow ARC is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The LimFlow ARC is not intended for use in the coronary or cerebral vasculature

IV. CONTRAINDICATIONS

The LimFlow ARC is not intended for use in the coronary or cerebral vasculature.

V. WARNINGS

- Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For Single Use. Do not resterilize.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and/or resterilization after initial use. Re-use of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose the LimFlow ARC to organic solvents (e.g., alcohol). Do not use if package is opened or damaged.
- Do not use after the last day of the month noted on the "Use By" date on the package.

VI. PRECAUTIONS

- Store in a cool, dry, and dark place.
- This catheter should only be used by physicians trained in peripheral percutaneous interventional techniques in a fully equipped catheterization laboratory.
- Do not use without completely reading and understanding this document.
- The LimFlow ARC should be kept straight during flushing, preparation steps, and during guidewire loading. A sterile gauze sponge with heparinized saline may be used to wipe the catheter (with the cannula in the retracted position) going from the proximal hub to the distal tip. Do not tug or otherwise overstretch the catheter to straighten it.
- Confirm visualization of the targeted distal vessel via contrast injection and fluoroscopy prior to using the catheter. Avoid contrast injection in the sub-intimal space.
- Minimize sub-intimal dissection tract beyond point of reconstitution.
- To maintain guidewire position during device exchanges, an exchangeable length guidewire is recommended.
- Prior to use, carefully read the instructions packaged with the crossing guidewire that is to be used with the LimFlow ARC. See Table 1 for a list of recommended crossing guidewires. Failure to use recommended crossing guidewire may result in damage to the guidewire, such as abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the LimFlow ARC over the crossing guidewire.

- Always visualize tracking of the catheter tip.
- If strong resistance is felt during catheter manipulation/delivery, determine the cause of the resistance before proceeding further. Consider using a 3-4 mm balloon at low ATM to dilate points of resistance, as needed, along delivery track. If the cause cannot be determined, withdraw the LimFlow ARC.
- Excessive rotation, bending, or kinking of LimFlow ARC may affect its performance. Withdraw the LimFlow ARC if it becomes excessively kinked.
- If the crossing guidewire kinks, carefully attempt to remove the wire and replace with a new one. Stop if any resistance is felt when removing wire from the LimFlow ARC. If resistance is encountered, retract the cannula tip back into the shaft and then remove the LimFlow ARC and wire together from the vasculature.
- Excessive calcification at the site of re-entry may impair performance.
- Do not rotate more than 360 degrees in any one direction as this may cause wrapping of the tracking guidewire around the catheter shaft.

VII. POTENTIAL COMPLICATIONS

This product is designed for use by physicians trained in and familiar with peripheral percutaneous interventional techniques. Possible complications may include, but are not limited to, the following:

- Vessel dissection, perforation, or injury
- Embolism
- Vessel spasm
- Pseudoaneurysm
- Vascular thrombosis
- Hemorrhage
- Ischemia

VIII. DIRECTIONS FOR USE

1. Use sterile technique to carefully remove the LimFlow ARC from the packaging. Inspect the catheter for damage.
2. Flush the LimFlow ARC thoroughly, at the flush port (5), the cannula wire port (3), and distal end port (D) with sterile heparinized saline until the solution exits the distal end of the catheter.
3. Ensure proper function of the LimFlow ARC by 1) retracting and advancing the cannula tip via proximal and distal movement of the deployment slide, and 2) rotating the Rotating Knob which rotates the catheter shaft/ nosecone.
4. Fully retract the cannula tip via proximal retraction of the handle deployment slide until it stops. Prior to insertion into the body, ensure that the cannula tip is fully retracted into the catheter lateral port and the handle deployment slide is locked in the most proximal position. If not, repeat flushing sequence as defined in "2" above.
5. Insert a standard 300 cm 0.014” tracking guidewire through the introducer sheath and advance until it is beyond target crossing location.
6. Select a 0.014" crossing guidewire from the list of recommended crossing guidewires in Table 1. If desired, the crossing wire may be pre-loaded through the cannula wire port prior to device insertion.

The following crossing guidewires are recommended for use with the LimFlow ARC cannula. Failure to use a recommended guidewire may result in damage to the guidewire, such as, abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the LimFlow ARC over the guidewire.

Table 1: Recommended Crossing Guidewires

Crossing Guidewires
Boston Scientific™ Thruway 0.014"
Medtronic Nitrex™ 0.014"
Terumo Runthrough™ 0.014"

7. After gaining vascular access, introduce the LimFlow ARC and crossing guidewire into the vasculature. Verify that the cannula tip is fully retracted back into the shaft and the catheter is straight. Back load the 0.014" tracking guidewire into the LimFlow ARC through the distal end port (D) of the nosecone. Confirm the exit of the guidewire from the proximal rapid exchange port (E).
8. Introduce the LimFlow ARC into the 6 French or greater introducer sheath. While tracking the LimFlow ARC over a guidewire, always ensure the cannula tip is fully retracted inside the catheter lateral port and the handle deployment slide is locked in the most proximal position. Always track the LimFlow ARC over a guidewire. Do not track the LimFlow ARC in the vasculature without a guidewire.
9. Track the LimFlow ARC over the guidewire to the desired vascular site. Torque the LimFlow ARC as needed during delivery via the handle Rotating Knob, but not more than 360 degrees in any one direction. Further or continued rotation in the same direction will result in the rapid exchange guidewire wrapping around the LimFlow ARC device.
10. Rotate the image intensifier so the distal housing of the LimFlow ARC eclipses the target crossing/re-entry site when visualized using fluoroscopy.
11. Once this initial orientation is confirmed, rotate the image intensifier to a ninety-degree orthogonal fluoroscopic view and/or to maximal distance between the ARC device and the crossing/re-entry target. Confirm that the distal housing of the LimFlow ARC is positioned "in line" with target re-entry site.
12. Using the radiopaque marker as a guide, orientate the cannula exit port of the LimFlow ARC towards the desired vascular target site via rotation of the Rotating Knob (**Figure 1**). The flat radiopaque marker is offset from the center of the ARC in the direction of the cannula. When the radiopaque marker appears thinnest, offset in the direction of the crossing/re-entry site, the cannula is aimed correctly at the target location.

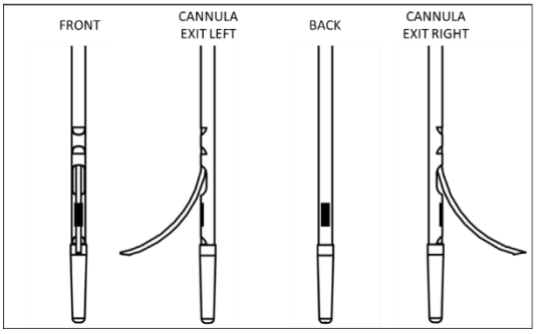


Figure 1: Cannula Nosecone with Cannula Exit Port

13. If additional orientation adjustments are necessary, this can be achieved via rotation of the Rotating Knob. A confirming orthogonal view should be considered after each new adjustment of the catheter towards the crossing/re-entry target.
14. Release any stored torque in the LimFlow ARC shaft once the cannula tip is properly positioned. Ensure the radiopaque marker is oriented toward the desired vascular location (target site) prior to actuation of the handle deployment slide.
15. Depress handle deployment slide release button and incrementally advance the slide, as appropriate, to extend the cannula tip from the LimFlow ARC lateral port and position it at the vascular target site.
16. Maintain gentle forward pressure on the LimFlow ARC shaft at the sheath. If resistance is felt during deployment, do not apply unnecessary forward push on the LimFlow ARC. It may result in damage to the cannula tip and or separation of the cannula tip.
17. Advance the crossing guidewire through the cannula tip to position it as desired at the vascular target site. If, after advancing the crossing guidewire distally, it is desired to retract the guide wire and resistance is experienced, first retract the cannula fully into the LimFlow ARC, then proceed with retraction of the crossing guidewire.
18. Retract the cannula tip into the LimFlow ARC by fully retracting the handle deployment slide until it stops. Release the handle deployment slide button to lock the deployment slide in the retracted position. Ensure the cannula tip is fully retracted into the catheter lateral port, and the handle deployment slide is locked, prior to withdrawing the catheter over both tracking and crossing guide wires.
19. Carefully retract the LimFlow ARC over the guidewires, leaving the crossing guidewire in place for subsequent therapeutic procedures.

IX. PATENT INFORMATION

Please see www.LimFlow.com/patents

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