LimFlow Vector® Instructions for Use

Explanation 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**
	**Caution: Federal (USA) law restricts this device to sale by or on order of a physician**
	**Product is not made with natural rubber latex**
	**Single Sterile Barrier System**
	**Unique device identifier**
	**Caution when operating the device**

I. DESCRIPTION

The LimFlow VECTOR® is used to cut venous valves during vascular peripheral bypass procedures. The cutting basket of the LimFlow Vector self-centers in the vessel and prevents the valve-cutting blades from damaging the vessel wall. The size of the cutting basket and cutting blades adjust to the internal diameter of the vein as the LimFlow Vector is being advanced through the vessel.

II. INDICATION FOR USE

The LimFlow Vector is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

III. CONTRAINDICATIONS

1. Endarterectomy procedures
2. Thrombolysis procedures
3. Vein stripping procedures
4. Embolectomy procedures
5. Vascular dilation procedures

IV. WARNINGS

1. Do not use if the package or device is damaged.
2. Do not use if inner packaging is opened outside a sterile environment.
3. Do not insert the LimFlow Vector into a vessel or extract from a vessel in the open position.
4. Do not open or close the LimFlow Vector while in a coiled configuration.
5. Do not use device for valvulotomy unless the target vein is fully distended by arterial blood flow (due to anastomosis of artery to vein) or by saline injection.
6. Do not pass the LimFlow Vector through a vessel in an open position that has undergone synthetic grafting or contains implants.
7. The LimFlow Vector is to be used by a qualified physician.
8. The LimFlow Vector should not be used without first reading and understanding these directions in their entirety.
9. The LimFlow Vector must be flushed with heparinized saline only.
10. The LimFlow Vector should not be used with guidewires larger than 0.018" in outer diameter.
11. The interventional removal of venous valves must take place under imaging procedures (fluoroscopy inspection, endoscopy, venography). The result should be (angiographically) documented.
12. In case of increased resistance, the cause must be determined and removed at once. If required, the valvulotomy must be interrupted. Application of higher force may damage the surrounding structures.
13. The LimFlow Vector device must not be pushed forward against strong resistances. Before the procedure can be continued, the cause of the resistance must be determined under fluoroscopy and measures of retraction must be considered.
14. Always make sure that the stopcock is closed when you are starting with the procedure.
15. Ensure that the cutting element (cutting basket) is fully retracted, prior to and during device advancement, withdrawal and rotation.

V. PRECAUTIONS

1. United States Federal and other law restricts this device to sale on or by the order of a physician.
2. Do not use device past the expiration date printed on the labeling.
3. Do not expose catheters to strong solvents.
4. Protect the catheters and the catheter tips from impact and excessive force at all times. Do not attempt to reshape the catheter, catheter tip or the nitinol needle, since reshaping may damage internal components of the device.
5. The LimFlow Vector is single use only. Do not re-use, reprocess, or resterilize (reference "Resterilization/Repackaging" section of this document for further details).
6. Keep any dissected portion of the vein straight and avoid twisting the vein during valvulotomy.
7. Advancement, manipulation, withdrawal of catheter should always be performed under fluoroscopic guidance, if resistance is met during manipulation.

VI. POTENTIAL COMPLICATIONS

- Vessel wall perforation

- Intima disruption
- Entrapment of cutting blades in branches or anastomoses
- Inadequate valve disruption
- Vein stricture
- Thrombus formation
- Post-procedure wound necrosis
- Vessel damage
- Vessel occlusion/stenosis
- Hematoma
- Hemorrhage
- Infections
- Erythema
- Entrapment of cutting blades
- Embolism

VII. ADDITIONAL REQUIRED ITEMS

1. 4Fr Introducer sheaths
2. 0.018" guidewire
3. Contrast for visualization

VIII. SPECIFICATIONS

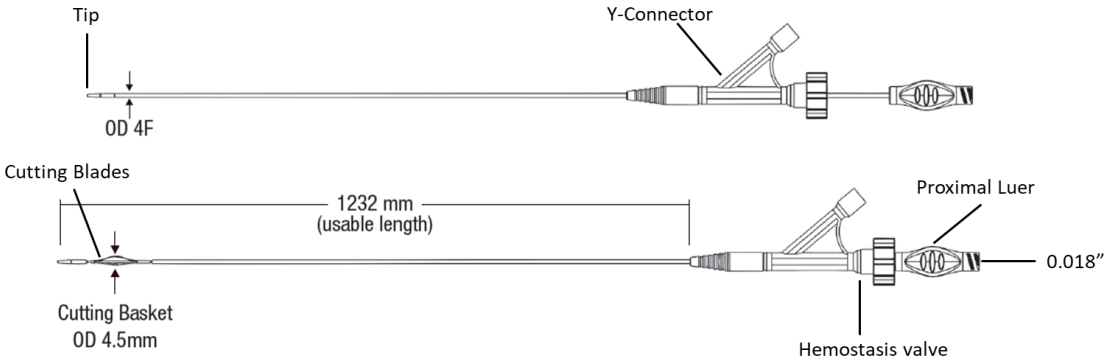

Figure 1: LimFlow Vector Open Configuration

Table 1: Vector Product Specifications

Catalog Number	Useable Length	Catheter Diameter	Maximum Cutting Basket Diameter	Maximum Guidewire Diameter
VT-US-21	1232 mm	4 Fr	4.5 mm	0.018 inch

IX. TO OPEN PACKAGE

1. Open box and remove sealed sterile unit.
2. Inspect packaging for damage and verify expiration date.
3. Open sealed sterile unit and present contents to personnel in sterile environment.
4. Carefully remove device from primary packaging.
   Caution: Remove product from packaging with care to ensure that device is not damaged.

X. PRE-USE CHECK

1. Inspect the device for bends and other damage.

XI. DIRECTIONS FOR USE

1. Flush guidewire lumen through proximal luer port with saline before use.
2. Open the one-way stopcock.
3. Using female luer port of the Y-connector, flush the lumen between inner and outer catheter shaft.

Note: Ensure the tuohy-borst valve (hemostasis valve) is tightened, to prevent movement.

4. Close the one-way stopcock.
5. Under imaging control via x-ray fluoroscopy, insert the LimFlow Vector in the closed position into the vein over the guidewire.
6. Place the LimFlow Vector distal to the vein valve to be cut.
7. To open the self-expanding cutting basket, pull back the outer catheter to the proximal luer of the inner catheter.
   Note: Loosen tuohy-borst valve at the Y-connector to allow inner catheter to move within the outer catheter, close the tuohy-borst valve to avoid blood loss.
   Note: When opening the cutting basket, the cutting blades are released automatically. The three basket brackets with the cutting blades center the LimFlow Vector in the vessel.
8. Tighten the tuohy-borst valve to secure the cutting blades in the open position.
9. Using fluoroscopic guidance, push the entire LimFlow Vector (both inner and outer catheters) slowly forward to perform the valvulotomy of the opening valve.
10. Repeat the procedure for each valve that needs to be cut.
    Note: The LimFlow Vector must not be inserted into the vessel in the open condition. This will cause the outer catheter to lose its safety function.
    Note: The LimFlow Vector utilizing the cutting basket and cutting blades, cuts valves only when in open condition during movements in the forward direction.
11. Close the LimFlow Vector cutting basket by pushing the outer catheter with flushing port forward until you can notice the basket close.
    Note: The LimFlow Vector can be closed at any time by pushing the outer catheter forward.
12. Pass the device through the vein an additional 1-2 times.
13. To remove the LimFlow Vector, loosen the tuohy-borst valve, close the cutting blades with the catheter, and tighten the tuohy-borst valve. Verify the cutting basket is closed under fluoroscopic imaging prior to removal.
14. Steps 7 through 11 may be repeated as necessary.
15. Confirm the free flow of blood through the vein.

XII. STORAGE

Store in a cool, dry, and dark location.

XIII. RESTERILIZATION/REPACKAGING

These devices are single use only. Do not re-use, reprocess, or resterilize. The cleanliness and sterility of the re-processed device cannot be assured. Re-use of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or resterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only. If for any reason this device must be returned to LimFlow Inc., place it in the original packaging and return it to the address listed on the box.

XIV. SAFE HANDLING AND DISPOSAL

This device is single use and disposable device. Do not implant. Please return the used device only at the time that the device has not performed as intended or the device is related to an adverse event. In other situations, the device should not be returned but disposed according to local regulations.

If serious medical incidents should arise during use of this medical device, users should notify both LimFlow Inc. and the applicable regulatory agency.

This product contains no heavy metals or radio isotopes and is not infectious or pathogenic. Please consult local regulations to verify proper disposal of sharps.

XV. PACKAGING

1. Devices should be sealed and packed in a manner that minimizes potential for breakage, contamination of the environment, or exposure to those handling such packages during transit. For devices capable of penetrating or cutting skin or packaging material, the primary packaging must be capable of maintaining the product without puncture of the packaging under normal conditions of transport.
2. The sealed primary container should be placed inside watertight secondary packaging. The secondary packaging should be labeled with an itemized list of the contents of the primary receptacle. Cleaning methods should be detailed if

possible.

3. Both primary and secondary packaging of single use disposable devices should be labelled with an ISO 7000-0659 Biohazard symbol.
4. Primary and secondary packaging must then be packaged inside an outer package, which must be a rigid, fiberboard box. The outer shipping container must be provided with sufficient cushioning material to prevent movement between the secondary and outer containers.
5. Shipping paper and content marking for the outer shipping container are not required.

XVI. PATENT INFORMATION

Please see www.LimFlow.com/patents

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