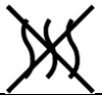
Explanations of symbols on labels and packaging	
	Manufacturer
	Sterilized using ethylene oxide
	Do not resterilize
	Do not re-use
	Catalogue number
	Lot number
	Use-by date
	Consult electronic instructions for use
	Non-Pyrogenic
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Unique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

CAUTION: US federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

I. DEVICE DESCRIPTION

The LimFlow V-CEIVER® is a percutaneous snaring device with a luer on the proximal end and a snaring basket at the distal end. The basket is composed of nitinol for shape memory and visibility with radiopaque markers on either end of the basket for added visibility. The coaxial sheathing system is used to re-constrain the basket once a guide wire is captured.

II. INTENDED USE / INDICATIONS FOR USE

The LimFlow V-Ceiver is intended for use in the cardiovascular system to manipulate and retrieve guidewires specified in the IFU.

III. CONTRAINDICATIONS

None known.

IV. WARNINGS

- This product contains nitinol, a nickel titanium alloy. Allergic reactions to nickel should be considered.
- The LimFlow V-Ceiver should only be used to snare the following 0.014" guidewires: Boston Scientific Thruway™, Medtronic Nitrex™, and Terumo Runthrough™

V. PRECAUTIONS

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular sheaths, angiographic catheters, and guide wires should be employed.
- Manipulation of the product requires fluoroscopic control.
- Excessive force should not be used to manipulate or retrieve a foreign object.
- Do not attempt to shape the catheter tip or snare, as doing so may damage the device. Damage may include, but not limited to, separation of the nitinol snare from the catheter.
- The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for the reproductive and development affects.

VI. POTENTIAL ADVERSE EVENTS

Potential adverse procedural events related to foreign body manipulation and retrieval in the vasculature can include, but are not limited to:

- Embolization
- Stroke
- Pulmonary embolism
- Myocardial infarction
- Vessel perforation
- Device entrapment

VII. SPECIFICATIONS

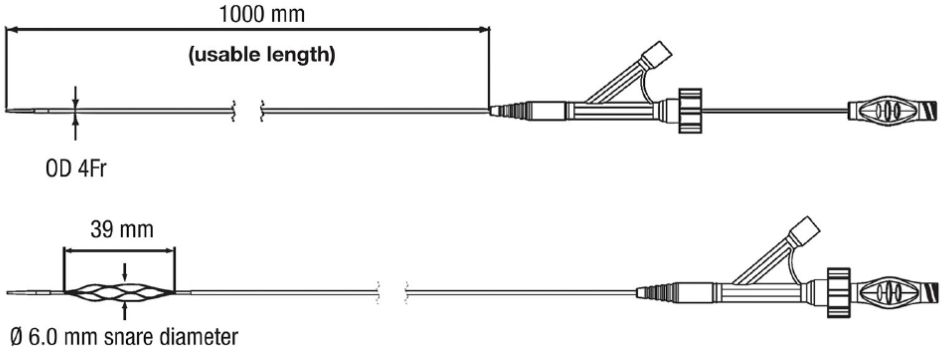


Figure 1: LimFlow V-Ceiver - Closed/Open Configuration

Table 1: V-Ceiver Product Specification

Catalog Number	Useable Length	Catheter Diameter	Maximum Basket Diameter	Maximum Guidewire Diameter
VC-US-21	1000 mm	4 Fr	6.0 mm	0.014 inch

VIII. DIRECTIONS FOR USE

1. After removing product from the package, the device should be flushed with heparinized saline.
2. Gain vascular access using standard interventional techniques and a 4Fr sheath.
3. Introduce a standard 0.014" guidewire to the desired location.
4. Tighten the hemostasis valve and flush both luer connections with saline and introduce the snare catheter over the guide wire and advance to the desired location.
5. Loosen the hemostasis valve and retract the outer sheath to expose the snaring basket. Do not reposition the snare catheter while the basket is exposed. Instead, recapture the basket prior to adjusting catheter position.
6. Retract the 0.014" guide wire to maximize the available space for the snaring procedure. Note: The LimFlow V-Ceiver should only be used to snare wires specified in the Warnings section above.
7. Once the foreign object (guide wire) is captured/surrounded by the struts of the snaring basket, advance the outer sheath to capture the snaring basket and the guide wire together. The outer sheath should completely enclose the snaring basket and distal (or floppy) portion of the guide wire. In cases where the snaring basket cannot be fully enclosed, confirm visually via fluoroscopy that the wire is sufficiently captured to initiate withdrawal.
8. Tighten the hemostasis valve and carefully remove the snare catheter and externalize the foreign object (guide wire).
9. After retrieval, hospital standard of care should be followed for removing the sheath and providing hemostasis to prevent bleeding at vascular access site.

IX. HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one time single use. The product is sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a cool, dry, and dark location. Upon removal from package, inspect the product to ensure no damage has occurred.

X. REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local LimFlow sales representative for information on available literature.

XI. PATENT INFORMATION

Please see www.LimFlow.com/patents

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