FlowTriever[®] **TECH SPECS**



Model (Fig 1)	Usable Length	Outer Diameter	Inner Diameter	Guide Wire
Triever16 [®]	113 cm	16 Fr	13 Fr	0.035″
(25-101)		(5.3 mm)	(4.3 mm)	(0.9 mm)
Triever20®	90 cm	20 Fr	17 Fr	0.035"
(21-101)		(6.7 mm)	(5.7 mm)	(0.9 mm)
Triever24®	90 cm	24 Fr	21 Fr	0.035″
(22-101)		(8 mm)	(7 mm)	(0.9 mm)

FlowTriever® Catheter Size & Model (Fig 2)	Vessel Diameter Range	Guide Wire	Usable Length	Outer Diameter	Tip to Proximal Band Marker (A)	Inter-Disk Spacing (B)	Disk Segment Length (C)
S: 10-101	6-10 mm	0.035″ (0.9 mm)	115 cm	12 Fr (4 mm)	59 mm	13 mm	26 mm
M: 10-102	11-14 mm				60 mm	12 mm	26 mm
L: 10-103	15-18 mm				62 mm	14 mm	27 mm
XL: 10-104	19-25				75 mm	19 mm	38 mm





Indications: The FlowTriever® System is indicated for (1) the non-surgical removal of emboli and thrombi from blood vessels, and (2) Injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever® System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

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

See Instructions for Use for complete Indications for Use, contraindications, warnings, and precautions.

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Extracting Large Clots from Large Vessels without the need for Thrombolytics or ICU stay.



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FlowTriever[®] Retrieval/Aspiration System Indicated for Pulmonary Embolism (PE)



FlowTriever[®]

What is the FlowTriever[®]?

The FlowTriever[®] is the first mechanical thrombectomy device FDA indicated and purposebuilt for treatment of pulmonary embolism, removing large clots from large vessels, immediately restoring blood flow, and relieving right heart strain without the need for thrombolytic drugs or ICU stay.

Highlights & Clinical Benefits:

- Immediate symptom improvement
- Single session treatment
- · Eliminates the need for thrombolytics and ICU stay
- Minimizes blood loss
- Avoids Capital Equipment

Which patients are best for FlowTriever®?

Acute PE patients with significant clot burden in segmental or central pulmonary arteries. Further considerations should be made for patients with significant right heart dysfunction defined as: RV/LV >0.9, RV Hypokinesis on ECHO, or elevated cardiac biomarkers.

Mechanism of action: The FlowTriever[®]'s primary mechanism of action is rapid large bore aspiration via the Triever® (20 or 24) Catheter. This is augmented by the FlowTriever® Catheter Disks that disrupt and liberate clot from the walls to make available for retrieval. The Triever® catheters feature highly trackable, large lumens and large bore syringes designed to rapidly extract large volumes of clot while limiting blood loss. The FlowTriever® Catheter features three self-expanding nitinol mesh disks that are designed to engage, disrupt, and deliver clot to the Triever[®] (20 or 24) for extraction (see reverse).

Below: Before and after treatment with FlowTriever® and clot removed.







48-Hour Baseline

The FLARE study was a prospective, multicenter, single-arm study evaluating the FlowTriever® System in 106 patients with acute PE at 18 sites in the United States. Treatment with the FlowTriever® System was used to mechanically remove blood clots in the pulmonary arteries. The study met both of its primary safety and effectiveness endpoints, showing large and rapid reduction in right heart strain, with no device related major adverse events. Additionally, the study showed much shorter ICU and overall length of stay for patients treated with FlowTriever® compared to previous studies in which thrombolytic drugs were used.

FLARE Safety in Context

Study	Major Bleeding	Intracranial Hemorrhage		
FLARE (FlowTriever) (Tu T, et al. 2019)	1/106 (0.9%)	0/106 (0%)		
PEITHO (tPA arm) (Meyer G, et al. 2014)	58/506 (11.5%)	10/506 (2%)		
SEATTLE II (Piazza G, et al. 2014)	17/150 (11.4%)	0/150 (0%)		
OPTALYSE PE (Tapson V et al. 2018)	4/100 (4%)	2/100 (2%)		

WHY DOES LUMEN SIZE MATTER?



Flow rate increases exponentially with lumen size, leading to improved clot extraction.

THE FLARE STUDY

0 **Device Related** Major-Adverse **Events**

41.3% Required no ICU Stay

98% **Of Patients Received no** Thrombolytic Drugs