

# Safety Profile of the ClotTriever System

# The excellent safety profile of ClotTrievers is supported by a wealth of basic science, clinical data, and commercial experience



1. ClotTrievers was studied extensively in animal vein models. Pathologic analysis of veins treated with ClotTrievers demonstrated no evidence of endothelial or valve damage.<sup>1</sup>
2. Independent histology study of extracted DVT thrombus found no valve or vessel tissue<sup>2</sup>
3. CLOUT, our real-world registry of DVT patients treated with ClotTrievers, showed patent duplex ultrasound at 6 months in 90% of patients. No incidence of valve injury.<sup>3</sup>
4. CLOUT data has been consistent with the large ClotTrievers patient series published in high impact peer reviewed journals by well known, highly respected physicians from large academic centers.<sup>4-11</sup>
5. We have treated over 35,000 patients commercially with excellent safety outcomes.
6. Building on this evidence, the CLOUT 500-patient analysis and a CLOUT propensity score analysis are planned to be presented in Sept/Oct. AND Inari is announcing the first DVT RCT comparing mechanical thrombectomy to anticoagulation.

1. JVIR • Scientific e-Posters Abstract No. 676.

2. Silver, et al. Catheter Cardiovasc Interv. 2021 Jun 1;97(7):1422-1429

3. Dexter, et al. J Vasc Surg Venous Lymphat Disord. 2022 Jul;10(4):832-840

4. Benarroch-Gamble, J. J Vasc Surg Venous Lymphat Disord. 2020 Mar;8(2):174-181

5. Zia, S. J Vasc Surg. 2020 July; volume 72 issue 1, E243

6. Irshad, A. J Vasc Surg. 2020 July; volume 72, issue 1, E60-60

7. Raskin, A. JACC Case Rep. 2021 Mar 17;3(3):415-420

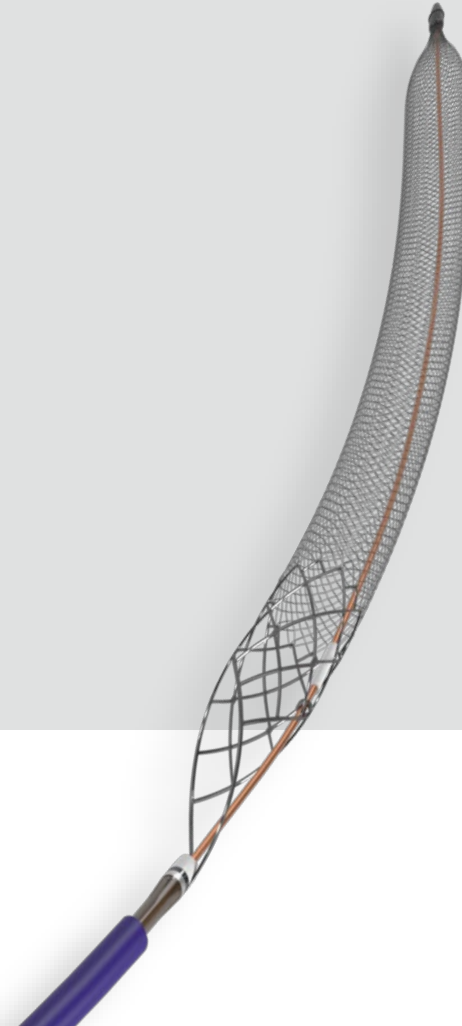
8. Shah, N. J Vasc Surg Venous Lymphat Disord. 2021 May;9(3):615-620

9. Wadhwa, V. Arab J Intervent Radiol 2021 Feb;5:71-75

10. Jolly, M. J Vasc Surg Venous Lymphat Disord. 2022 Jun 9:S2213-333X(22)00250-5

11. Weissler, et al. Ann Vasc Surg. 2022 Aug 22:S0890-5096(22)00500-3.

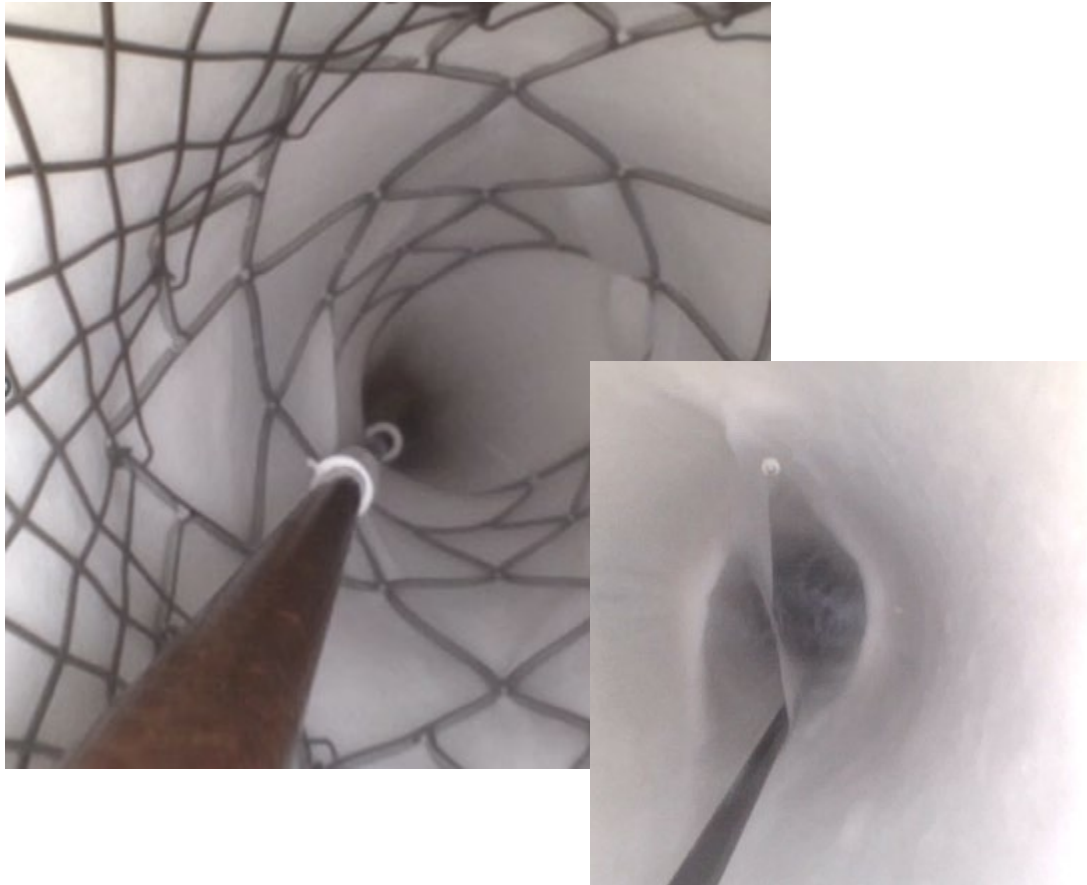
- Non-abrasive, **atraumatic nitinol coring element** engages acute to chronic clot<sup>1</sup>
- Angled leading struts **designed to preserve valve function**
- **0.35 atm of pressure on vessel walls** (20 times less than the 10 atm by most balloons)<sup>2</sup>



1. Thrombus Chronicity Sub-analysis of Mechanical Thrombectomy for Deep Vein Thrombosis in Real-World Patients: Six-month Outcomes from the CLOUT Registry. Presented at AVF 2022 by Dr. David Dexter
2. Data on file

# ClotTriever and ClotTriever BOLD ex vivo example demonstrating intact valve function

ClotTriever ex vivo example /  
Bovine Valves 6-8 mm ID



ClotTriever BOLD ex vivo example /  
Bovine Valves 6-8 mm ID



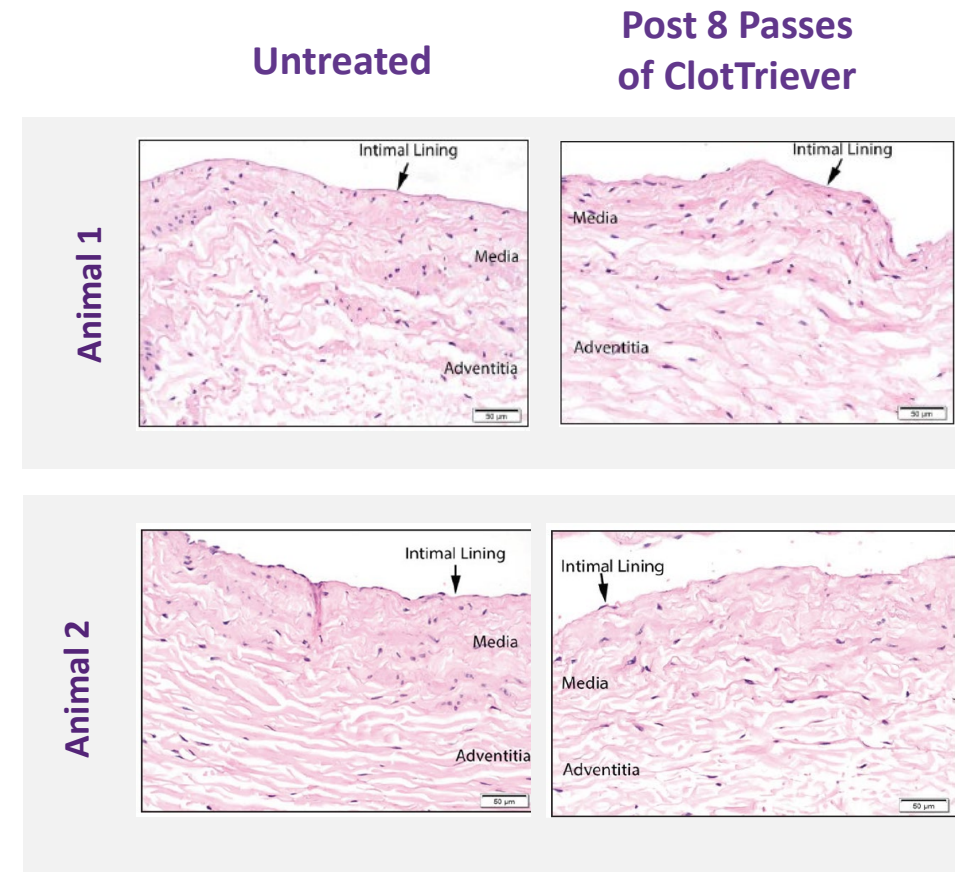
# Published evaluation of ovine veins after 8 passes of ClotTriever demonstrated NO vessel or valve damage

JVIR published abstract

## Tu, et al. Evaluation of venous valve anatomy after ClotTriever treatment in an ovine model<sup>1</sup>

*Jugular veins of 2 animals exposed to 8 passes of the ClotTriever System, while control veins remained untreated. During the procedure, venograms were performed. Post-procedure, test and control veins were collected and evaluated.*

- ClotTriever “**did not impair valve functionality**”
- “All microscopically assessed sections were **graded as normal**”
- Veins showed “**no discernable macroscopic or microscopic changes** post treatment with ClotTriever”



**Figure 1. The unchanged morphologic appearance of ovine vein wall as confirmed by hematoxylin and eosin (H&E) staining.**



# Peer reviewed, published histopathologic report of extracted thrombi shows NO venous wall or valve tissue



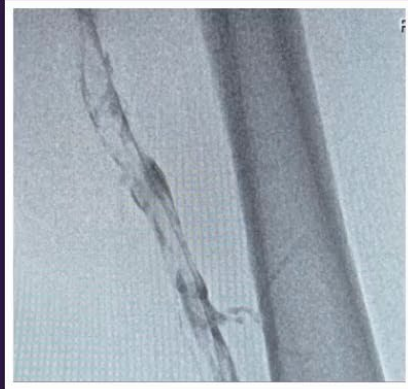
Catheter Cardiovasc Interv. 2021

## Silver, et. al. Histopathologic analysis of extracted thrombi from deep venous thrombosis and pulmonary embolism: Mechanisms and timing<sup>1</sup>

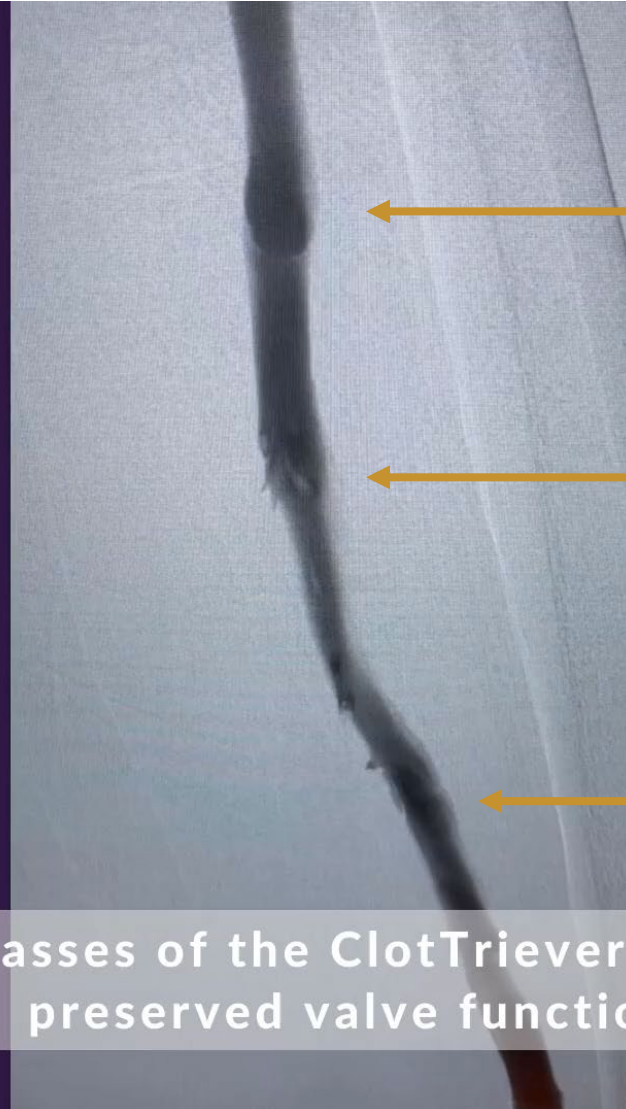
*Thrombus retrieved using a catheter-based thrombectomy system (ClotTriever for lower extremity DVT and FlowTriever for PE) from the 17 patients (7 DVT cases and 10 PE cases) were histologically evaluated.*

**“Light microscopy of DVT samples did not demonstrate venous wall components or venous valve tissue.”**

# Post-ClotTrievers imaging consistently shows functioning valves after multiple passes<sup>1</sup>



Pre-Venogram

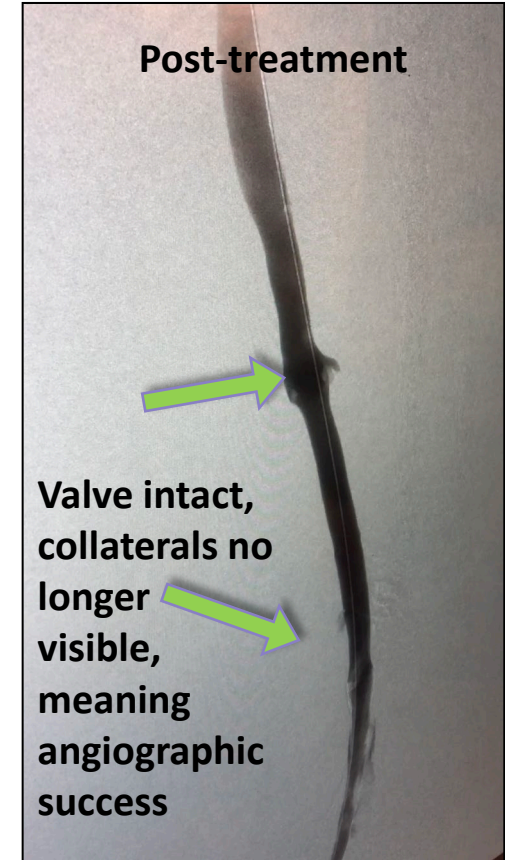
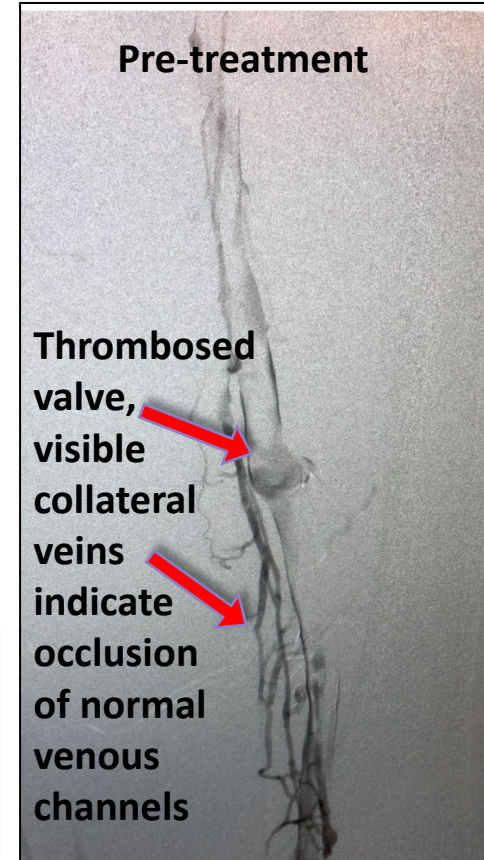
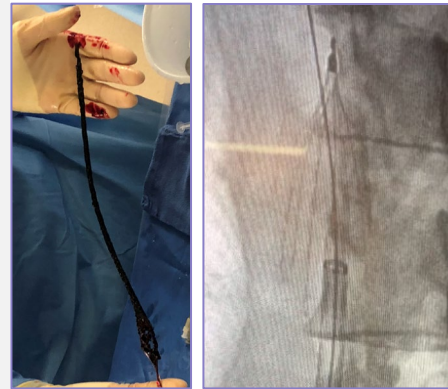


Fully functioning venous valves after 4 ClotTrievers passes

Venogram after 4 passes of the ClotTrievers System demonstrating preserved valve function

# Case Example: 8 ClotRiever passes; patency restored, valve intact, collaterals no longer visible

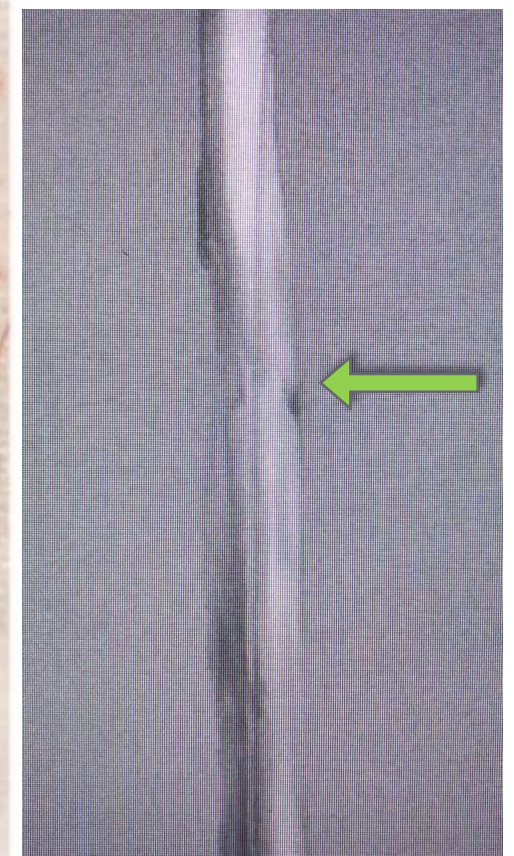
- Clot extending bilaterally from IVC filter to tibials
- ClotRiever cleared iliacs to popliteals in 8 device passes
- No lytics administered
- **90% clot removal achieved; patency restored; valves intact**





# Case Example: 3 ClotTriever passes; patency restored, valves intact

- Clot extending from Icfv TO pv
- ClotTriever cleared leg in 3 passes
- **90% clot removal achieved; patency restored; valves intact**



# ClotTriever has demonstrated excellent short and longer-term results



CLOUT registry interim results - ClotTriever System in Iliofemoral DVT Patients (N=250)

## Lytic-free, Mechanical Thrombectomy

Procedural Results

**99.6%**

Single-session treatment

**50.0mL**

Median estimated blood loss

**0mg**

Thrombolytics used

## Significant Thrombus Removal

Across DVT Chronicity

**85.8%**

Complete or near complete thrombus removal\*

**90.8%** Acute<sup>2</sup>

**81.9%** Subacute<sup>2</sup>

**83.8%** Chronic<sup>2</sup>

\*≥75% THROMBUS REMOVAL DETERMINED BY INDEPENDENT CORE LABORATORY-ADJUDICATED MARDER SCORES.

## Positive Safety Outcomes

At 30 Days\*

**0.0%**

Vessel/Valve damage

**0.0%**

Acute renal injury

**0.4%**

Device-related SAEs

\*ADJUDICATED BY AN INDEPENDENT MEDICAL MONITOR

## Long-term Patient Benefits

At 6 months

**90.1%**

Flow via duplex ultrasound

**100%**

Median reduction in pain

**91.2%**

Free of moderate or severe PTS symptoms\*

**94.2%** Acute<sup>2</sup>   **88.2%** Subacute<sup>2</sup>   **90.9%** Chronic<sup>2</sup>

Significant improvement in rVCCS and EQ-5D QoL scores

\*24.4% OF PATIENTS HAD PTS SYMPTOMS AT 6 MONTHS

1. Dexter DJ, et al. Interim outcomes of mechanical thrombectomy for deep vein thrombosis from the All-Comer CLOUT Registry. J Vasc Surg Venous Lymphat Disord. 2022 Jul;10(4):832-840.e2.  
2. Thrombus Chronicity Sub-analysis of Mechanical Thrombectomy for Deep Vein Thrombosis in Real-World Patients: Six-month Outcomes from the CLOUT Registry. Presented at AVF 2022 by Dr. David Dexter

# Multiple independent peer reviewed studies at reputable institutions confirm the excellent results from the CLOUT registry



Annals of Vascular Surgery 2022

Duke Health | 18 DVT patients

## Restoring venous patency with the ClotTriever following deep vein thrombosis

Weissler, et al. DOI:<https://doi.org/10.1016/j.avsg.2022.07.031>

- Venous flow was re-established in all 18 patients
- No bleeding complications.
- All patients with available follow-up, except 1, retained patency of the treated venous segments and most had mild post-thrombotic syndrome or none at all.
- These findings suggest that the ClotTriever is a safe and effective way to treat extensive ilio caval/femoral DVT

J Vasc Surg Venous Lymphat Disord 2022

OhioHealth Riverside Methodist Hospital | 96 DVT patients

## Outcomes from a tertiary care center using a catheter thrombectomy system for managing acute iliofemoral deep vein thrombosis

Jolly, et al. J Vasc Surg Venous Lymphat Disord 2022;:-:1-7

- No mortality, major bleeding, or device-related complications
- 93 patients (97%) had  $\geq 75\%$  thrombus removal
- 97% had normal flow at 30 days
- 100% had normal or partial compressibility at 30 days

# ClotTriever is the most studied mechanical thrombectomy system for the treatment of DVT



Data as of August 2022.

\*Includes 250 patients enrolled in the CLOUT registry in whom results have not yet been reported.

1. Benarroch-Gamble, J. J Vasc Surg Venous Lymphat Disord. 2020 Mar;8(2):174-181
2. Zia, S. J Vasc Surg. 2020 July; volume 72 issue 1, E243
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# Summary: ClotTriever unmatched safety results



## 70+ peer reviewed publications, and **ZERO** reports of valve or vessel damage

0

Reported cases of valve or vessel damage in the **CLOUT registry**<sup>1</sup>

0

Reports of valve or vessel damage in multiple **independent peer-reviewed publications**<sup>2,3</sup>

0

Vessel or valve damage detected on **animal histology study vs. controls**<sup>4</sup>

0

Valve or venous wall components in **independent report of extracted thrombi**<sup>5</sup>

## Excellent short and longer-term outcomes (CLOUT results in 250 patients)<sup>1</sup>

86%

Complete or near complete **thrombus removal**

90%

**Normal flow** on duplex ultrasound at **6 months**

91%

**Freedom from moderate-severe PTS symptoms** at **6 months**

1. Dexter, et al. J Vasc Surg Venous Lymphat Disord. 2022 Jul;10(4):832-840

2. Weissler, et al. Ann Vasc Surg. 2022 Aug 22:S0890-5096(22)00500-3.

3. Jolly, et al. J Vasc Surg Venous Lymphat Disord 2022;:-1-7

4. JVIR • Scientific e-Posters Abstract No. 676

5. Silver, et al. Catheter Cardiovasc Interv. 2021 Jun 1;97(7):1422-1429.

# Inari's commitment to high-quality clinical evidence continues



- **35,000+** patients treated, **70+** peer reviewed publications, and **more than 700** ClotTriever patients studied to date
- **2 new ClotTriever data releases** planned for Sept/Oct (CLOUT 500 analysis, CLOUT propensity score analysis)
- Planned enrollment of **the first ever DVT RCT** comparing mechanical thrombectomy to anticoagulation

## INDICATIONS

The ClotTriever Thrombectomy System is indicated for the non-surgical removal of thrombi and emboli from blood vessels. Injection, infusion, and /or aspiration of contrast media and other fluids into or from a blood vessel. The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).

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

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