FlowSaver® Blood Return System

Highlighting safety profile and clinical importance of minimizing blood loss

INARI MEDICAL®

Executive summary

- Minimizing blood loss and transfusions is important, particularly in PE patients due to their negative clinical impact and significant economic ramifications.
- FlowTriever® retrieval/aspiration system and FlowSaver were intentionally engineered for seamless, simple, and safe autologous blood return.
- **Beginning with FDA clearance in 2021, the safety and benefits of FlowSaver are well established by rigorous independent safety data, multiple clinical studies, and 70,000+ PE patients treated with excellent clinical outcomes.**

Summary of safety profile of autologous blood return w/ FlowSaver device

FlowTriever/FlowSaver are intentionally designed for safe blood return

- **Short vacuum time, without narrow tubing,** prevents shear stresses.
- Autologous return of blood removed directly from vessels, using sterile components, is routine across interventional procedures.
- In contrast, continuous vacuum across long-narrow tubing set may risk hemolysis.

FDA cleared device with results of independent safety research[1]

- **<0.1% increase in hemolysis for the sample of blood filtered 5x** with FlowSaver compared to control.[1]
- **No difference in CBC parameters or serum potassium levels** vs. control.[1]
- **Additional testing confirmed negligible hemolysis with Triever aspiration**.[2]

1. Third party testing conducted by NAMSA showed no biologically significant differences as compared to control. Data on file
2. Data on file

Clinical safety supported by 70,000+ patient experience w/FlowSaver[3]

- **25,000+** patients with 4+ FlowSaver filtrations/ reinfusions.
- **There have been no signs of elevated risk of hemolysis:** anemia (low hemoglobin/ hematocrit), dark urine, jaundice, elevated markers (LDH, bilirubin), renal failure (elevated Cr), or signs of poor cardiac output.

3. Data on file

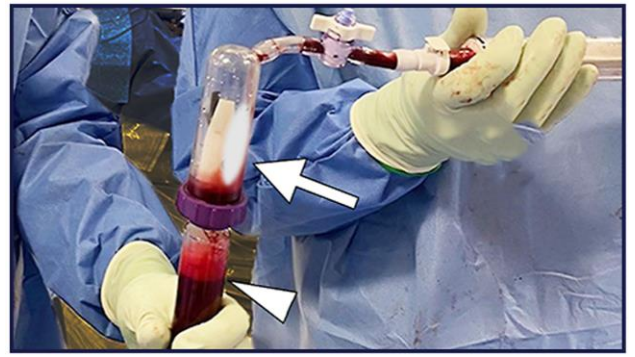
Clinical research confirms efficacy and safety of FlowSaver

- **FLASH registry** patients treated **with** FlowSaver had reduced hemoglobin drop vs. those treated **without** FlowSaver.[4]
- **Independent publication** also demonstrated reduced hemoglobin and fewer transfusions when FlowSaver was used.[5]

4. Toma, et al. European Heart Journal 43.Supplement_2 (2022): ehac544-1893
5. Bitar, et al., Journal of Vascular and Interventional Radiology, 2024

The importance of reducing blood loss and transfusions

- PE physiology makes patients sensitive to significant changes in blood volume.
- In patients with critical illness, blood loss is associated with an increased risk of mortality and hospital length of stay[1,2]
- An analysis of 19,219 inpatient VTE encounters where RBC transfusions were required with a mechanical thrombectomy procedure found:[3]
  - 3x increase in mortality (12.4% vs. 3.7%)
  - Increase in avg LoS (16.8 vs 6.9 days) and avg ICU LoS (5.6 v 1.5 days)
  - 39% higher 30-day readmission rate (9.2% vs. 6.6%)
  - Nearly double the costs for initial hospital stay ($47K median vs. $24k)
- Unnecessary RBC transfusions significantly increase hospital costs by an average of $9,779 USD per patient[4]



FlowSaver keeps blood loss to a minimum:

100 mL

median EBL

FLASH PE registry (n=79)[5]

50 mL

median EBL

FLAME high-risk PE study (n=10)[6]

1. Corwin HL, et al. Crit Care Med. 2004. doi: 10.1097/01.CCM.0000104112.34142.79
2. Damluji, et. al. Int J Cardiol 2016 Nov 1;222:531-537. doi: 10.1016/j.ijcard.2016.07.264.
3. Premier PINC AI database Q4 2015 to Q2 2022
4. Saporito A., et al. Perioperative inappropriate red blood cell transfusions significantly increase total costs in elective surgical patients, representing an important economic burden for hospitals. Frontiers in Medicine. doi: 10.3389/fmed.2022.956128
5. Toma C, et al. EuroIntervention 2023;18:1201-1212.
6. Silver, M J, et al. Circ. Cardiovasc. Interv. 2023 Oct 17

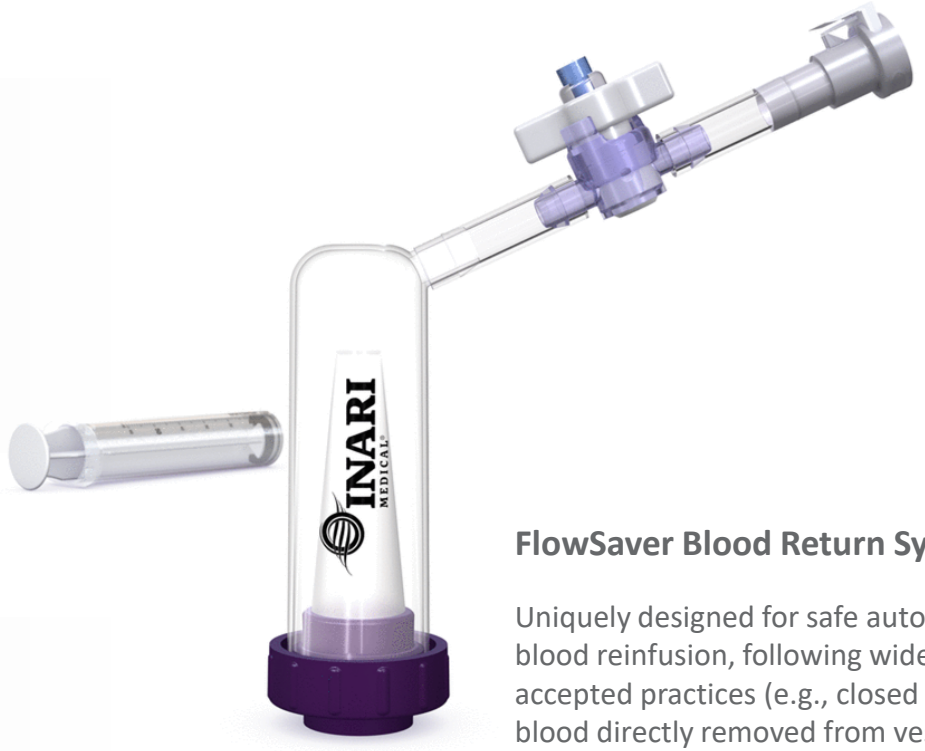
FDA cleared device with rigorous independent testing[1]

Rigorous testing protocol:

- **Same sample of blood filtered 5X** with FlowSaver prior to testing
- **3rd party testing conducted by NAMSA®**, an ISO biocompatibility certified lab*

Confirmed no biologically significant differences vs. control:

- **<0.1% increase in hemolysis** compared to control
- **No difference in CBC parameters or serum potassium levels** compared to control



FlowSaver Blood Return System

Uniquely designed for safe autologous blood reinfusion, following widely accepted practices (e.g., closed system, blood directly removed from vessels) commonly used in interventional procedures.

1. 3rd party testing conducted by NAMSA showed no biologically significant differences as compared to control. Data on file.
* https://namsa.com/about/our-accreditations-certifications/

Clinical research and commercial experience confirm benefits and safety of FlowSaver blood return system

FLASH PE registry sub-analysis

Conclusions:
Patients treated with FlowSaver had reduced hemoglobin drop vs. those treated without FlowSaver.

Toma, et al. European Heart Journal 43.Supplement_2 (2022): ehac544-1893

Independent Yale publication

Conclusions:
FlowSaver resulted in reduced hemoglobin drop, fewer transfusions, and no increase in adverse events. Results suggest the FlowSaver is both safe and effective to reduce procedure-related blood loss.

Bitar, et al., Effect of Filtered Blood Return on Outcomes of Pulmonary Aspiration Thrombectomy. Journal of Vascular and Interventional Radiology, 2024

70,000+ patients treated commercially with FlowSaver

There have been no signs of elevated risk of hemolysis:
anemia, dark urine, jaundice, elevated markers (LDH, bilirubin), renal failure, or signs of poor cardiac output.

Data on file

Conclusions

- **PE patients are particularly sensitive to blood loss, making autologous blood return highly valuable** from a clinical and economic perspective.
- **FlowSaver has been a critical advancement in the treatment of PE patients,** allowing for life-saving, effective FlowTriever thrombectomy, while effectively eliminating the blood loss tradeoff.
- **The FlowTriever system with FlowSaver blood return has demonstrated excellent immediate results and long-term clinical outcomes** across extensive commercial experience and several Inari and independent publications.
- **Inari is committed to improving patient outcomes and developing innovative technologies,** backed by scientific rigor and high-quality clinical evidence.

Indications for use:

The FlowTriever Retrieval/Aspiration System is indicated for (1) The non-surgical removal of emboli and thrombi from blood vessels. (2) Injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters are indicated for (1) The non-surgical removal of emboli and thrombi from blood vessels. (2) Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. Triever Catheters are intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters are also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters. The FlowTriever2 catheter is indicated for (1) The non-surgical removal of emboli and thrombi from peripheral blood vessels. (2) Injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel. FlowTriever2 is intended for use in the peripheral vasculature. The Triever20 Curve is used coaxially within the Triever24 for (1) The non-surgical removal of emboli and thrombi from blood vessels. (2) Injection, infusion, and/ or aspiration of contrast media and other fluids into or from a blood vessel. The Triever20 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever20 Curve Catheter is not indicated for use with FlowTriever Catheters. Triever20 Curve is also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters. Triever20 Curve must be used within the Triever24. The Triever16 Curve is indicated for (1) The non-surgical removal of emboli and thrombi from blood vessels. (2) Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The Triever16 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever16 Curve is not indicated for use with FlowTriever Catheters. The Triever16 Curve is also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters. The FlowSaver Blood Return System is used with Inari Medical catheters and sheaths for autologous blood transfusion.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for complete indications for use, contraindications, warnings, and precautions.

For all non-Inari products, please refer to manufacturer Instructions for Use/Intended Purpose for complete indications for use, contraindications, warnings and precautions.