



Enrollment begins for PRESERVE, large study of IVC filters

# Enrollment begins for PRESERVE, large study of IVC filters

Patient enrollment begins for PRESERVE, a large study of retrievable IVC filters

As of mid-December, researchers have activated the first 10 medical sites and enrolled the first nine patients in a study that will determine the safety and effectiveness of inferior vena cava filters, small, cage-like devices implanted to prevent life-threatening blood clots from reaching the heart or lungs.

Over the course of the five-year study, 2,100 patients are expected to participate through a total of 60 different medical sites around the U.S.

According to the U.S. Surgeon General, between 350,000 and 600,000 people each year in the United States are affected by blood clots and between 100,000 and 180,000 people die of pulmonary embolism (a blood clot that travels to the lungs) each year. Approximately 250,000 patients a year receive IVC filters.

While vein filters have been in use for years, PRESERVE (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters), is the first large-scale, multispecialty, prospective clinical research trial that will evaluate their real world safety and effectiveness. The inferior vena cava is the main vessel returning blood from the lower half of the body to the heart.

The project is overseen by the IVC Filter Study Group Foundation, sponsored jointly by the Society for Vascular Surgery (SVS) and the Society of Interventional Radiology (SIR). All stakeholders came together over a shared concern for the safety and effectiveness of an increasingly popular treatment for life-threatening conditions.

The use of inferior vena cava filters has undergone revolutionary changes through the years and trauma patients are likely to be treated in an emergency setting and may not follow up with their physician to get the implants removed. The PRESERVE study is enlisting patients who agree to have their medical care followed for three years.

“The treatment of deep vein thrombosis in trauma patients has challenged physicians to know the best way to take care of those patients,” said co-principal investigator Dr. David Gillespie, chief of vascular and endovascular surgery at Southcoast Health System, Fall River, Mass. “There are a lot of devices from different manufacturers to choose from. Physicians have been using the retrievable filters with the idea they will retrieve them, but for many reasons they often don’t.”

“SIR and SVS have been engaged in ongoing dialogue with the FDA for several years to gather additional data and

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better understand IVC filter safety and effectiveness,” said co-principal investigator Dr. Matthew S. Johnson, FSIR and professor of radiology and surgery at Indiana University School of Medicine. “Our foremost commitment is to patient safety, and this study will help determine how well filters prevent pulmonary embolism and how they function over the course of their implantation.”

The PRESERVE study is unusual because:

- More typically, studies follow one or two devices. Studying filters produced by seven different manufacturers at once is an enormous undertaking. The trial will follow 300 patients per device.
- The protocol instructs participating physicians to manage the patient exactly as they would if there were no study going on, so that “real world” outcomes can be assessed.
- The trial is a joint venture of two medical associations working together in an unusual, paradigm-shifting initiative that brings together the FDA, the medical profession and multiple device manufacturers.
- Gillespie and Johnson note that all these aspects make PRESERVE a monumental study that took more than five years to get all entities on board.

Learn more about this trial at [www.PRESERVEtrial.com](http://www.PRESERVEtrial.com) .

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## About the Society for Vascular Surgery

The Society for Vascular Surgery advances the care and knowledge of vascular disease, which affects the veins and arteries of the body, to improve lives everywhere. It counts more than 6,000 medical professionals worldwide as members, including surgeons, physicians and nurses. For more information about vascular health and the society, please visit [www.vascular.org](http://www.vascular.org) .

## About the Society of Interventional Radiology

The Society of Interventional Radiology is a nonprofit, professional medical society representing more than 6,000 practicing interventional radiology physicians, scientists and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies. For more information about SIR, please visit [sirweb.org](http://sirweb.org) .

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## PRESERVE Quick Facts

- PRESERVE: Nickname for **PRE**dicting the **S**afety and **E**ffectiveness of Inferior **V**ena Cava Filters
- Patients enrolled as of Dec. 15: 9
- Active sites as of Dec. 15: 10
- Patients expected: 2,100
- Expected sites: 60
- Study duration: Five years; each patient will stay in the study for three years, or until one month after the filter is removed
- Collaborators: Society of Interventional Radiology (SIR), Society of Vascular Surgery (SVS) which formed the

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- IVC Filter Study Group Foundation, a 501©(3) not-for-profit entity that sponsors and oversees PRESERVE
- Trial website: [www.PRESERVEtrial.com](http://www.PRESERVEtrial.com)

### Participating Manufacturers:

- ALN Implants Chirurgicaux (ALN Vena Cava Filters)
- Argon Medical Devices, Inc. (Option™ Elite Retrievable Vena Cava Filter designed and manufactured by Rex Medical)
- B. Braun Interventional Systems Inc. (VenaTech® LP Vena Cava Filter)
- Cook Incorporated (Cook Günther Tulip Vena Cava Filter)
- CR Bard Peripheral Vascular, Inc. (DENALI® Vena Cava Filter System)
- Cordis Corporation (Cordis OptEase® Retrievable Vena Cava Filter / Cordis TrapEase® Vena Cava Filter)
- Volcano Corporation (Crux® Vena Cava Filter System)

### Principal investigators:

- Dr. David L. Gillespie, Southcoast Health System, Fall River, Mass.
- Dr. Matthew S. Johnson, Indiana University School of Medicine, Indianapolis, Ind.

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