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Joint press release from Society of Interventional Radiology and Society for Vascular Surgery

Medical societies to launch large-scale study on vein filter use Society of Interventional Radiology and Society for Vascular Surgery form new foundation, collaborate on multicenter trial to improve patient care

FAIRFAX, Va.—The Society of Interventional Radiology and Society for Vascular Surgery jointly will launch PRESERVE—the first large-scale, multispecialty prospective study to evaluate the use of inferior vena cava (IVC) filters and related follow-up treatment.

The study—along with the formation of the IVC Filter Study Group Foundation—are direct actions taken to address the August 2010 FDA medical alert detailing the possibility that retrievable IVC filters could move or break, potentially causing significant health risks for patients. SIR and SVS are in the process of determining a framework for the PRESERVE (**PRE**dicting the **S**afety and **E**ffectiveness of **I**nferio**R** **V**ena Cava Filters) study, with the goal of obtaining a functional view of all filters placed in the United States.

“PRESERVE data will allow a systematic, functional view, representative of all filters placed in the United States, thus, all stakeholders—individuals, health care professionals, insurers and government regulators—will be armed with the knowledge they need on patient risk and, subsequently, quality improvement in filter placement, management and retrieval,” said SIR President Marshall E. Hicks, M.D., FSIR. “This is a paradigm-shifting initiative: interventional radiologists and vascular surgeons collaborating to launch a large-scale prospective study evaluating inferior vena cava filters reveals a lot about each specialty’s focus—and that focus is on patients, first and foremost,” noted SVS President Peter Głowiczki, M.D.

The five-year study will evaluate the overall safety and efficacy of filters placed by doctors and intends to enroll 1,800 patients at approximately 50 centers in the United States. Members of the IVC Filter Study Group Foundation collectively discussed ways to respond to the FDA’s stated concerns. SIR and SVS are in the process of making a final decision for a contract research organization, completing protocol development and submitting the study for investigational device exemption (IDE) study with HIPAA (Health Insurance Portability and Accountability Act) compliance. Study directors are Matthew S. Johnson, M.D., FSIR, Indiana University School of Medicine, Indianapolis, Ind., and David L. Gillespie M.D., FACS, University of Rochester School of Medicine and Dentistry, Rochester, N.Y. Most filter manufacturers have agreed to participate in the study.

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. IVC filters are placed inside patients by vascular specialists to prevent blood clots from breaking free and traveling to the lungs or heart and causing a pulmonary embolism. FDA recommendations are that physicians remove the filters, which are designed to be retrievable, once the threat of pulmonary embolism has passed. The FDA warning said that all physicians were encouraged to consider the benefits and health risks of IVC filter removal for each patient.

Members of the IVC Filter Study Group Foundation board of directors are SVS President Peter Głowiczki, M.D., Mayo Clinic College of Medicine, Rochester, Minn. (president); SIR President Marshall E. Hicks, M.D., FSIR, University of Texas MD Anderson Cancer Center, Houston (vice president); SVS Executive Director Rebecca M. Maron, CAE (secretary); SIR Executive Director Susan E. Sedory Holzer,

MA, CAE (treasurer); John A. Kaufman, M.D., MS, FSIR, Dotter Interventional Institute, Portland, Ore. (SIR representative); and Peter Lawrence, M.D., UCLA Medical Center, Santa Monica (SVS representative).

Learn more about the Society of Interventional Radiology at www.SIRweb.org and the Society for Vascular Surgery at www.vascularweb.org.

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About the Society of Interventional Radiology

Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-ray, MRI and other imaging to advance a catheter in the body, such as in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine. Today, interventional oncology is a growing specialty area of interventional radiology. Interventional radiologists can deliver treatments for cancer directly to the tumor without significant side effects or damage to nearby normal tissue.

Many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. This year, [SIR celebrates 40 years](#) of innovation and advances in interventional radiology. Visit www.SIRweb.org.

About the Society for Vascular Surgery

The Society for Vascular Surgery® (SVS) is a not-for-profit professional medical society, composed primarily of vascular surgeons, that seeks to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness. SVS is the national advocate for 4,000 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease. Visit its website at www.VascularWeb.org.