IVC Filters - Why Is The FDA So Concerned

the FDA warning of August 2010 (12) reported 146 cases of filter migration and 56 filter fractures among a variety of filter designs, currently available studies have not pointed to these potential more severe complications of filter placement. The FDA communication expressed the concern that these mechanical failures may be associated with the long-term placement of retrievable filters.

IVC Filters - Why Is The FDA So Concerned

Given the potential severe consequences of
- filter fracture
- filter embolization
- vena cava penetration of filter parts
- the marked growth in their use

the SVS/SIR have designed this PS-IDE study to better understand the current use of venous filters and the adverse events associated with their use.

IVC Filters - Why Is The FDA So Concerned

The overall goals
- Characterize current practice
  - the indications
  - filter type
  - frequency and success of filter removal
- safety of placement initially and in the long term
  - filter mechanical stability
  - caval patency
  - frequency of subsequent episodes of pulmonary embolism
  - recurrence of deep vein thrombosis

The first steps are to identify the characteristics of use in a broad range of clinical practice settings in the US.

Trial Leadership

Sponsor: IVC Filter Study Group Foundation
  Society of Interventional Radiology
  Society for Vascular Surgery

Steering Committee:
  David Gillespie, MD, Co-Chair
  Matthew Johnson, MD, Co-Chair
  Jeanne Laberge, MD
  James Spies, MD
  Rodney White, MD

Contract Research Organization:
  New England Research Institutes, Inc
The PRESERVE Trial

Supporting Manufacturers & Devices

- ALN Implants Chirurgicaux
- Argon Medical Devices, Inc./Rex Medical
- B. Braun Interventional Systems, Inc.
- Bard Peripheral Vascular, Inc.
- Cook Incorporated
- Cordis Corporation
- Volcano Corporation
- ALN Vena Cava Filters
- Option Elite® Retrievable Vena Cava Filter
- VirtuTech® II Vena Cava Filter
- DELE® Vena Cava Filter System
- Günther Tulip VCF
- OptEase®/TrapEase® VCF
- Crux Vena Cava Filter

The PRESERVE Trial

The study is a multi-center, prospective, open-label, non-randomized investigation of all commercially available inferior vena cava filters placed in subjects for the prevention of death from fatal or symptomatic PE.

This study will enroll approximately 1800 IVC filter subjects at up to 60 sites in the United States.

All treated subjects will be evaluated at procedure, 3-months, 6-months, 12-months, 18-months (phone), and 24-months post-procedure.

All subjects in whom the IVC filter is removed will be followed for 1-month post-retrieval.

Primary Safety Endpoint is a composite endpoint at 12-months that includes:

- Freedom from clinically significant perforation after successful filter placement;
- Freedom from filter embolization;
- Freedom from caval thrombotic occlusion;
- Freedom from new deep vein thrombosis (DVT); and
- Freedom from serious adverse events (SAEs) within the peri-operative period

Primary Effectiveness Endpoint is a composite endpoint at 12-months in-situ or 1-month post-retrieval (whichever comes first) that includes:

- Procedural and technical success
- Freedom from clinically significant pulmonary embolism (PE)

Secondary endpoints include the following:

- Mechanical Stability, defined by the absence of the following at the time of retrieval or at each follow up:
  - Migration cephalad movement of the filter >20mm relative to fixed anatomic landmarks compared to the time of placement
  - Migration caudal migration of the filter >20mm relative to fixed anatomic landmarks compared to the time of placement
  - Perforation >5mm outside apparent cava wall as determined by CT or perforation of adjacent viscer or major vessel
  - Filter fracture: any loss of a filter's structural integrity (i.e. breakage or separation) documented by imaging or autopsy
  - Filter embolization: post-deployment movement of the filter or its components to a distant anatomic site completely out of the target zone

Secondary endpoints include the following:

- Procedure-related complications, in the judgment of the Principal Investigator at 3-months
- Major adverse events (composite and individual components) defined as death, PE, caval thrombotic occlusion, DVT, clinically significant perforation, retroperitoneal hematoma, or adjacent organ penetration at 3-months, 6-months, 12-months, 18-months, and 24-months
- Filter tilting >15° at any time-point as determined by appropriate imaging.
Enrollment Accrual

Trial Enrollment

Enrollment by Filter Type

Thank you