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.

The overall goals

- Characterize current practice
  - 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.

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 vena filters
- and the adverse events associated with their use.

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
- VenaTech U2 Vena Cava Filter
- DENALI Vena Cava Filter System
- Günther Tulip VCF
- OptEase/TrapEase VCF
- Crux Vena Cava Filter

The PRESERVE Trial

A Prospective, Single Arm, Evaluation of the Safety and Effectiveness of Inferior Vena Cava Filters

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 2,100 IVC filter subjects at up to 60 sites in the United States. All treated subjects will be evaluated at procedure, 3-months, 6-months (phone), 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 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-retieval (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 viscera 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;
The PRESERVE Trial

Secondary endpoints include the following:
• Filter retrieval at any time
  - Attempted retrieval
  - Successful retrieval
  - Failed retrieval
  - Percentage of retrieval success
  - Complications associated with filter retrieval
  - Reasons for failed retrieval
• Secondary Effectiveness Endpoint will be calculated for each individual filter and includes freedom from PE at 12 months.

Start-up Status

60 Sites Selected
• Specialty Distribution as Contact PI
  - 36 Interventional Radiologist as Contact PIs
  - 18 Vascular Surgeons as Contact PIs
  - 1 Trauma Surgeon as Contact PI
  - 5 Undetermined Contact PIs
• Fairly Even Geographic Distribution across the US
• Equitable Distribution of Sites using Filters from Participating Manufacturers

Activation Status

4 Sites Activated!
- Indiana Univ.
- Harbor UCLA
- RI Hospital
- Rochester Regional
- 58 Sites in various stages of Start-up
- 11 Sites – Have both IRB approval and Executed CTA, minor outstanding items for activation remain
- 29 Sites – Have IRB approval, awaiting executed CTA and minor outstanding items
- 12 Sites – Have executed CTA, awaiting IRB approval and minor outstanding items
- 6 Sites – Still awaiting IRB approval, CTA execution, training, and regulatory document collection

Enrollment Status

First Patient In – 13/Oct/2015!

4 Patients Enrolled as of 09/Nov/2015

Visit our public website for more information:
www.preservetrial.com

Thank you