

# ***IVC Filters***

***“The Good, The Bad, and The Avoidable”***



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2018 OOA Convention



## ***Relevant Disclosure***

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Under the Oklahoma State Medical Association CME guidelines disclosure must be made regarding relevant financial relationships with commercial interests within the last 12 months.

**Parker Truong, DO**



I have no relevant financial relationships or affiliations with commercial interests to disclose.



# ***My Mission Statement***



*“It takes five minutes to place a filter but it takes a lifetime to retrieve it.”*

*Parker Truong, DO*



# ***Discussion Outline***

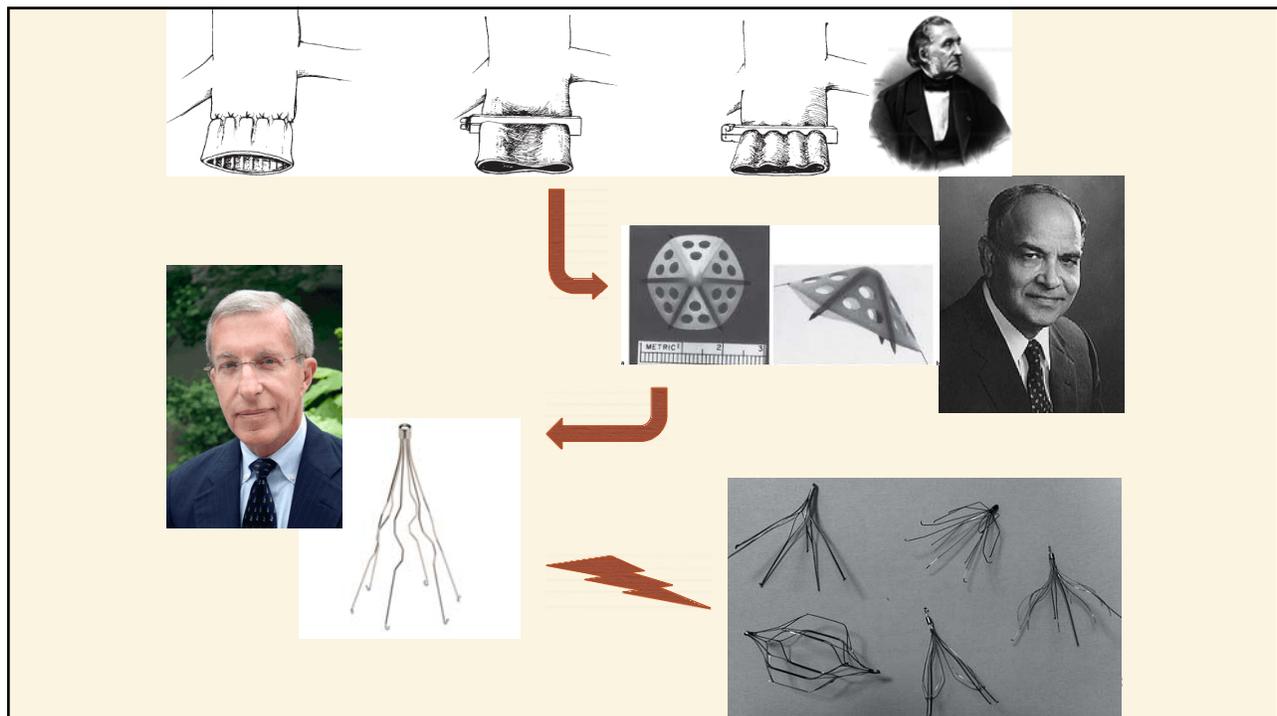


- ✦ Introduction
- ✦ The Good – How it works.
- ✦ Indications
- ✦ The Bad – What can go wrong.
- ✦ Complications
- ✦ The Avoidable – The reason I give this talk.
- ✦ Conclusion

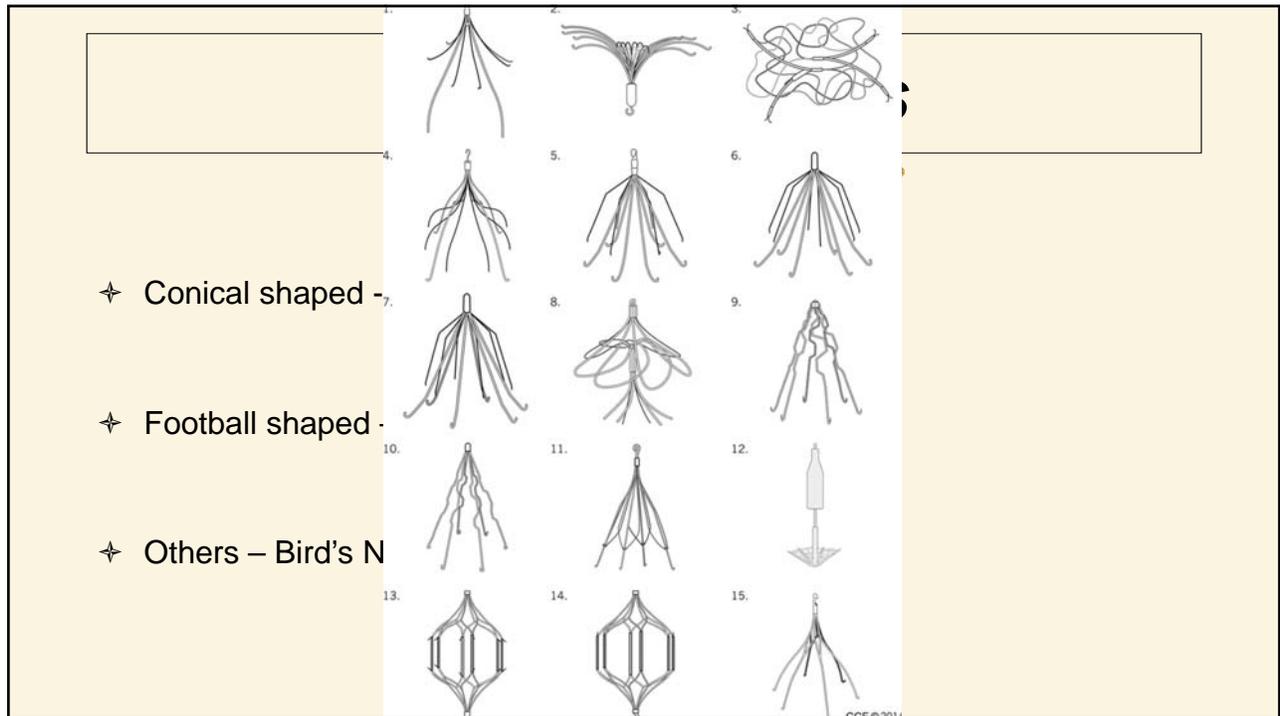
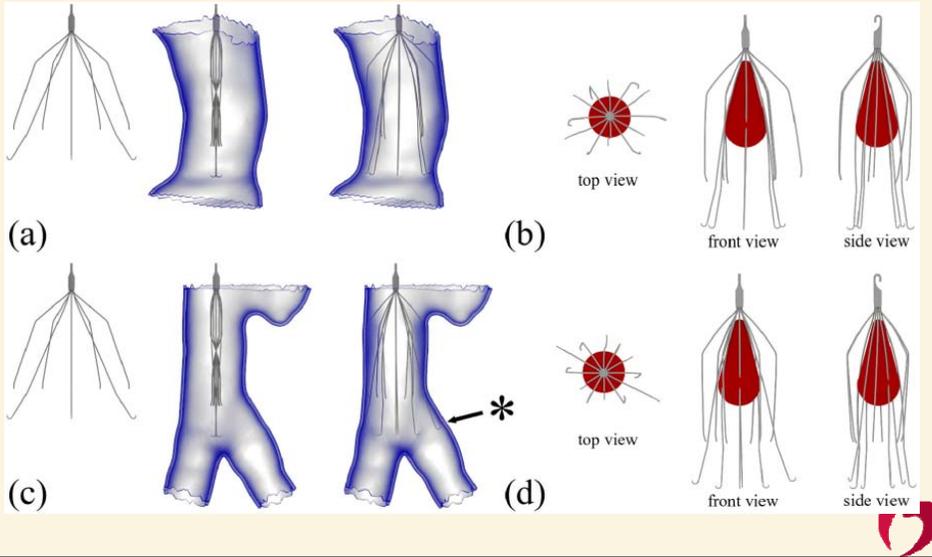


# Introduction

- ✦ First IVC filter was created by Dr. Kazi Mobin-Uddin
  - ✦ Newsweek 10/20/1969 – “*Umbrella of Life*”
- ✦ Later replaced Greenfield filter by Dr. Lazar Greenfield in 1969 which had lower rate of related complications.
- ✦ Over 50,000 IVC filters placed in the US each year.
- ✦ Defined as a “*Conical device designed to capture embolized thrombus to prevent large pulmonary embolism.*”



# The Good – How it works



## ***Indications for IVC Filters***

- ✦ Venous thromboembolism and contraindication for anticoagulation or active bleeding.
- ✦ Unstable pulmonary embolism or low cardiopulmonary reserve.
- ✦ Massive pulmonary embolism with free floating large proximal DVT.
- ✦ Trauma patients – no supported studies.
- ✦ Not indicated – prophylaxis, calf or upper extremity DVT.



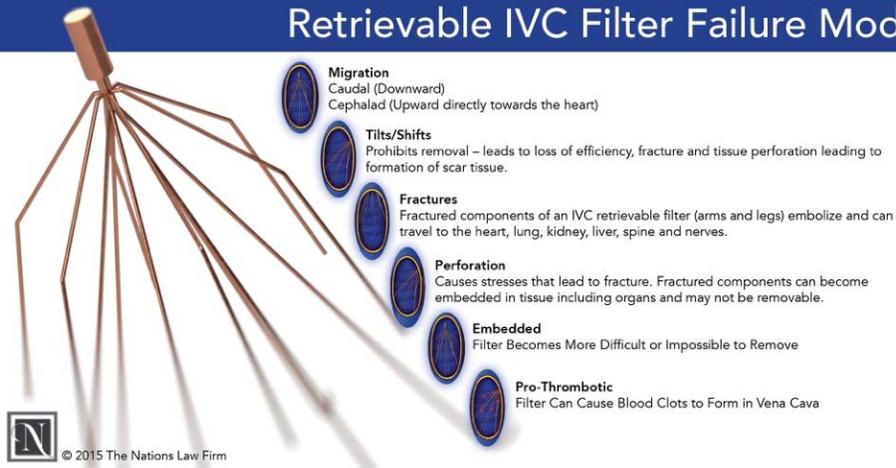
## ***The Bad – What can go wrong***

- ✦ IVC filters do not replace anticoagulation.
- ✦ Patients with IVC filters should be anticoagulated unless they are actively bleeding.
- ✦ IVC filters should be removed when no longer indicated.
- ✦ When abandoned with no anticoagulation IVC filters will thrombose leading to extensive DVT of IVC down to both legs.
- ✦ IVC filter malfunction.



# Reported Complications

## Retrieval IVC Filter Failure Modes



✦ Retrieval complications:

- ✦ Caval tear



# Statistics

- ✦ Filter penetration out of caval wall – 3 mm
  - ✦ Incidence - 70-85%
- ✦ Filter thrombosis
  - ✦ Reported incidents 2-30%
  - ✦ Asymptomatic in approximately 50% of cases
- ✦ Filter migration – 1-2 cm in either directions
  - ✦ Incidence - 2-13%
- ✦ Filter fracture
  - ✦ Incidence 1-10%



# Statistics

Filter Type	Patients	Follow up (months)	PE (Fatal)	DVT	IVC Thrombosis	Post-Phlebotic syndrome
Stainless GFF	3,184	18 (1-60)	2.6% (0.9)	5.9	3.6	19
Titanium GFF	511	5.8	3.1 (1.7)	22.7	6.5	14.4
Birds Nest	1,426	14.2	2.9 (0.9)	6	3.9	14
Simon Nitinol	319	16.9	3.8 (1.9)	8.9	7.7	12.9
Vena Tech	1,050	12	3.4 (0.3)	32	11.2	41

## The Avoidable Why they are no longer useful

- ✦ Data supporting any and all indications of IVCF are limited.
- ✦ Only 2 RCT conducted on use of IVCF.
  - ✦ PREPIC and PREPIC2 (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group)
  - ✦ IVCF prevented PE but not death (mortality benefits)
  - ✦ More DVT occurred in patients with IVCF.
- ✦ Prophylactic IVCF use is the most contentious application
  - ✦ Bariatric surgery, trauma, and spinal cord injury
  - ✦ Growing evidence of actual harms and no benefits.

Clinical research study

From the American Venous Forum

## Cost-effectiveness of guidelines for insertion of inferior vena cava filters in high-risk trauma patients

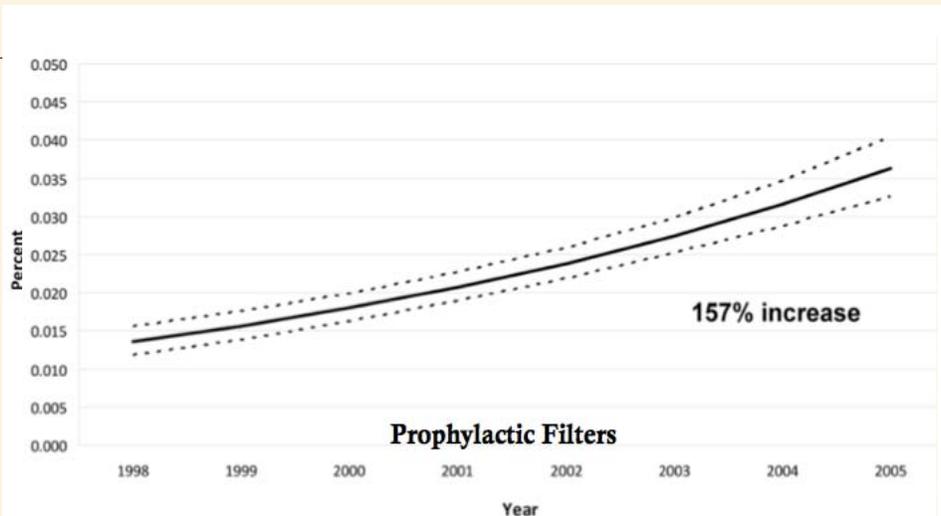
Oral presentation at the American Venous Forum, Amelia Island, Fla, Feb 13, 2010.

Emily L. Spangler MD <sup>a</sup>, Ellen D. Dillavou MD <sup>b</sup>, Kenneth J. Smith MD <sup>c</sup>

- ✦ Analysis suggests the prophylaxis IVCF are not cost effective in high risk trauma patients.
- ✦ The magnitude of this result is due to long term sequelae (venous thromboembolism and bleeding complications)
- ✦ Prophylactic IVC filter costs for the additional quality-adjusted life years gained did not justify use.



## Trends in IVC filters implantation and



injury ( $P = .03$ ) rose significantly over time.

**Conclusions:** From 1998 to 2005, the estimated rates of prophylactic VCF placement increased at a significantly higher rate than VCF placement in the setting of DVT or PE. Significant increases in the use of prophylactic VCFs were seen in the setting of morbid obesity and head injury. (J Vasc Surg 2010;52:118-26.)

## National trends in utilization of inferior vena cava filters in the United States, 2000-2009

Presented at the 2013 Vascular Annual Meeting of the Society for Vascular Surgery, San Francisco, Calif, May 30-June 1, 2013.

SreyRam Kuy MD, MHS <sup>a, 2, 3</sup>, Anahita Dua MD <sup>a</sup>, Cheong J. Lee MD <sup>a</sup>, Bhavin Patel BS <sup>b</sup>, Sapan S. Desai MD, PhD, MBA <sup>c, d</sup>, Arshish Dua BS <sup>e</sup>, Aniko Szabo PhD <sup>f</sup>, Parag J. Patel MD <sup>b</sup>

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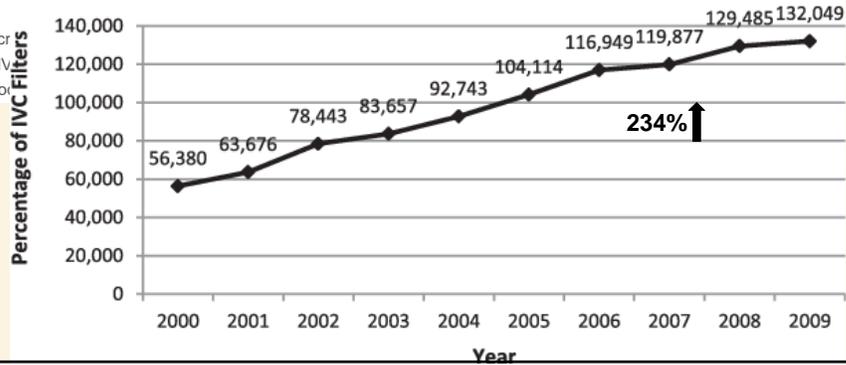
### Objective

To characterize IVC filter utilization in the U.S. by year

### Methods

Retrospective chart review from 2000 to 2009. IVC filter utilization was defined as the number of IVC filters implanted per 100,000 population per year. Data were obtained from the Ninth Edition of the National Inpatient Sample.

## National Trends in IVC Filter Utilization in the United States, 2000-2009



## FDA Warns of Adverse Events With Inferior Vena Cava Filters

Michael O'Riordan

DISCLOSURES | August 11, 2010

August 11, 2010 (Rockville, Maryland and York, Pennsylvania) — The **Food and Drug Administration** (FDA) has received more than 900 reports of adverse events with inferior vena cava (IVC) filters, leading the agency to remind clinicians that the devices should be removed as soon as it is safely possible [1]. The FDA's MedWatch warning comes as a new report on adverse events at a single center was published online August 9, 2010 in the *Archives of Internal Medicine* [2].



## FDA Updates Safety Communication on IVC Filter Retrieval

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May 7, 2014—The US Food and Drug Administration (FDA) has issued a [Safety Communication](#) regarding removal of retrievable inferior vena cava (IVC) filters. The document, which contains no new safety concerns, updates a previously issued [Initial Communication](#) from August 2010 to include information on recently published research and postmarket surveillance studies for these devices.

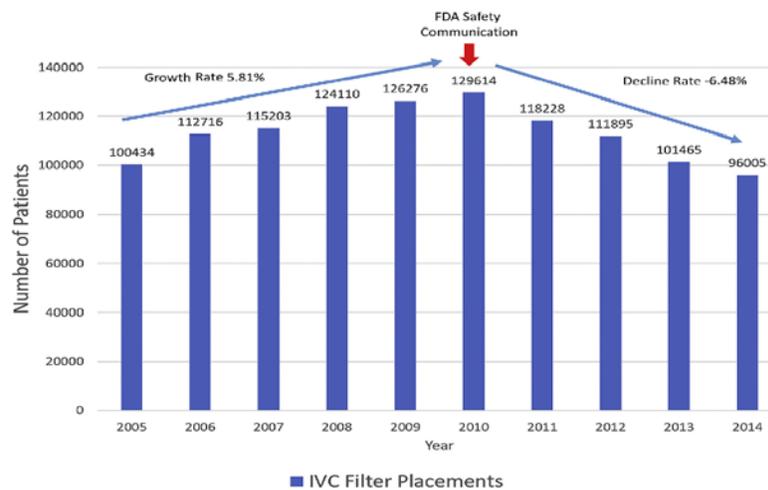
The updated communication advises that the agency has received reports of adverse events and problems associated with IVC filter devices. The reports include device migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart or lungs), perforation of the IVC, and difficulty removing the device. Some of these events led to adverse clinical outcomes. These types of events may be related to how long the filter has been implanted.

The agency noted that other known long-term risks associated with IVC filters include lower limb deep vein thrombosis and IVC occlusion.



## Decreasing Utilization of Inferior Vena Cava Filters in Post-FDA Warning Era: Insights From 2005 to 2014 Nationwide Inpatient Sample

[Vibhor Wadhwa, MD](#), [Premal S. Trivedi, MD](#), [Kshitij Chatterjee, MD](#), [Anobel Tamrazi, MD](#), [Kelvin Hong, MD](#), [Mark L. Lessne, MD](#), [Robert K. Ryu, MD](#)



## When do these filters need to be removed?

The safety communication recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed. All physicians involved in the treatment and follow-up of patients receiving IVC filters are encouraged to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.

The FDA developed a quantitative decision analysis using publicly available data from the medical literature to assess whether there is a time period during which the risk of having an IVC filter is expected to outweigh the benefits. In October 2013, Jose Pablo Morales, MD,

The mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

From the Western Vascular Society

## Factors impacting follow-up care after placement of temporary inferior vena cava filters



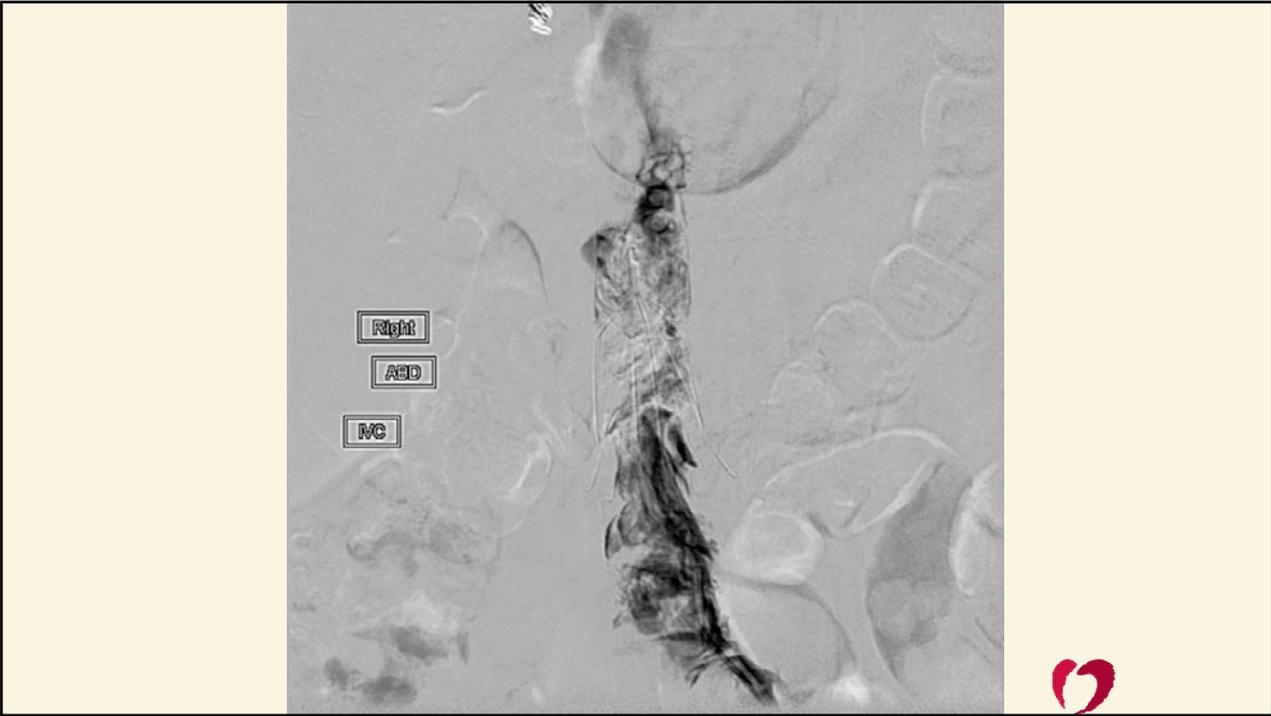
✦ R Elsie Gyang, MD, MSc, Mohamed Zayed, MD, PhD, E. John Harris, MD, Jason T. Lee, MD,  
✦ T (Ronald L. Dalman, MD, and Matthew W. Mell, MD, MS, *Stanford, Calif*

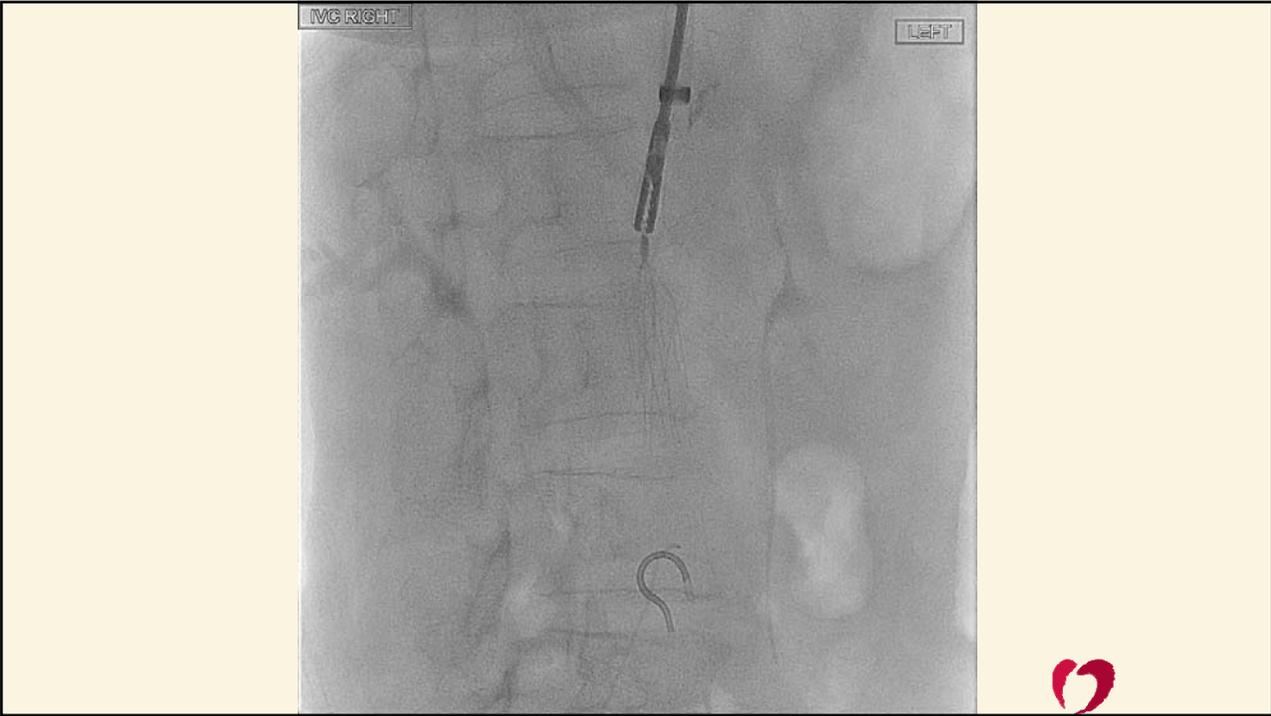
✦ *Objective:* Rates of inferior vena cava (IVC) filter retrieval have remained suboptimal, in part because of poor follow-up. The goal of our study was to determine demographic and clinical factors predictive of IVC filter follow-up care in a university hospital setting.

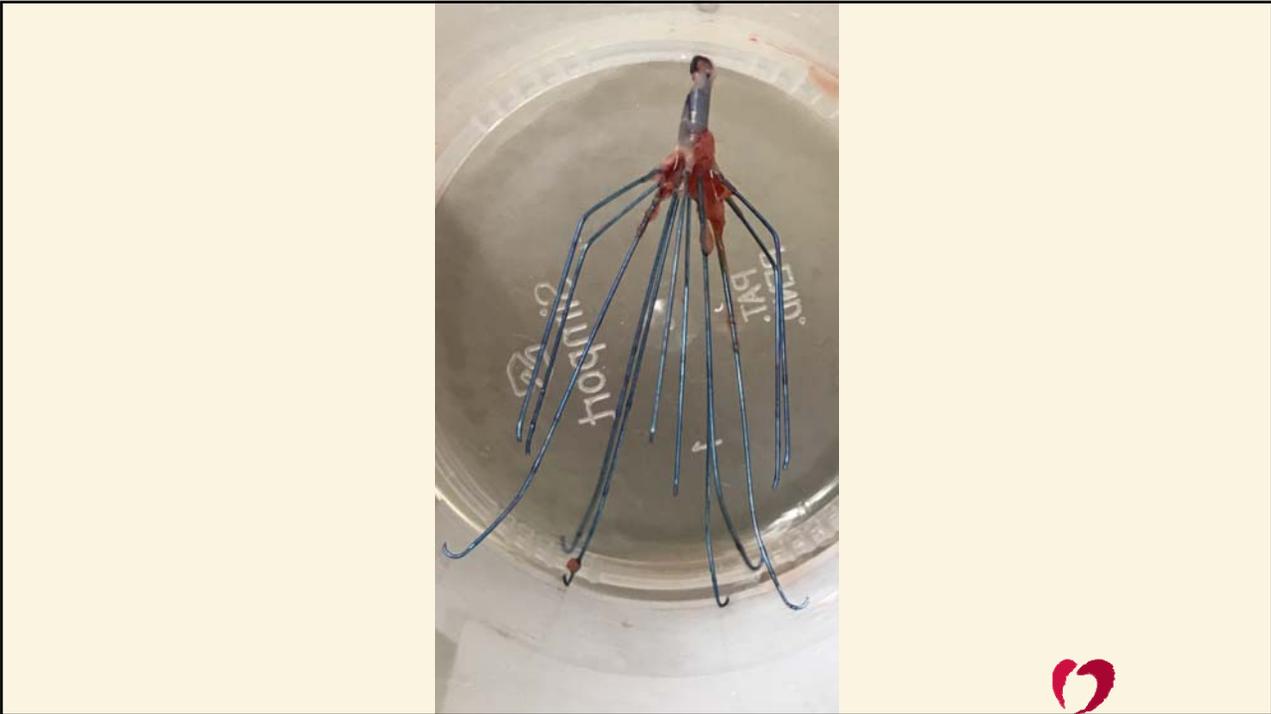
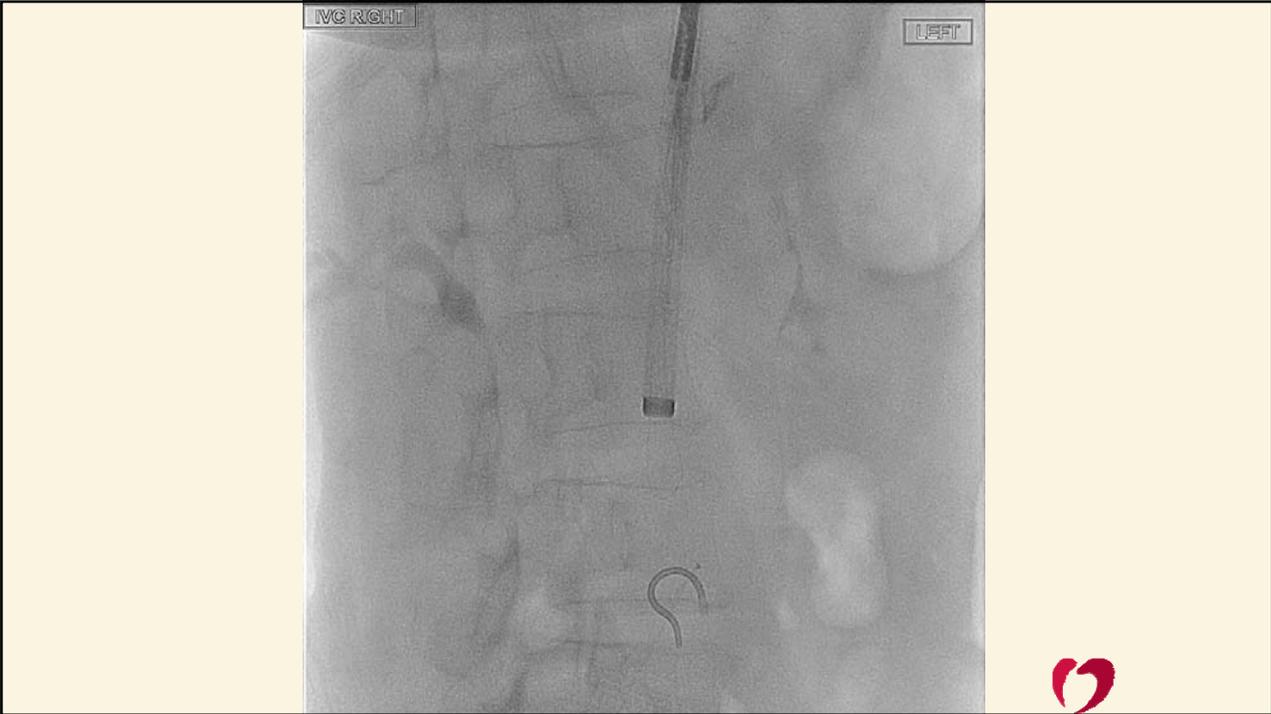
✦ R *Methods:* We reviewed 250 consecutive patients who received an IVC filter placement with the intention of subsequent retrieval between March 2009 and October 2010. Patient demographics, clinical factors, and physician specialty were evaluated. Multivariate logistic regression analysis was performed to identify variables predicting follow-up care.

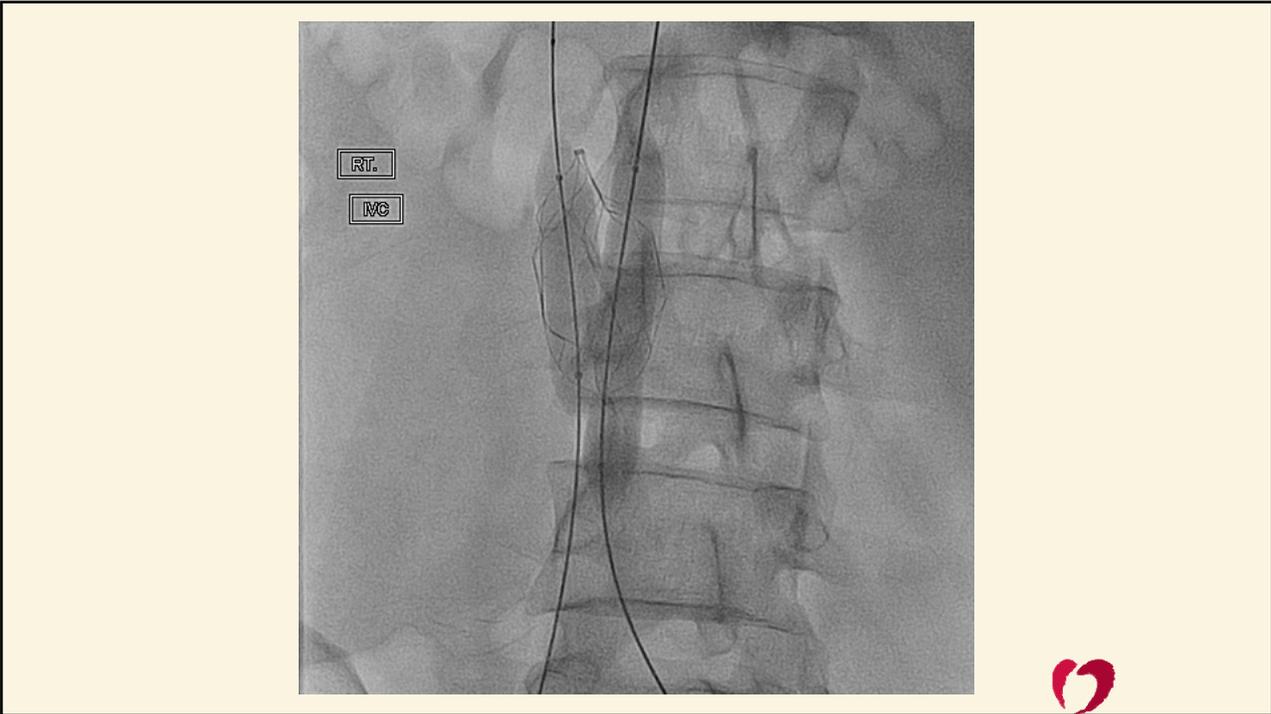
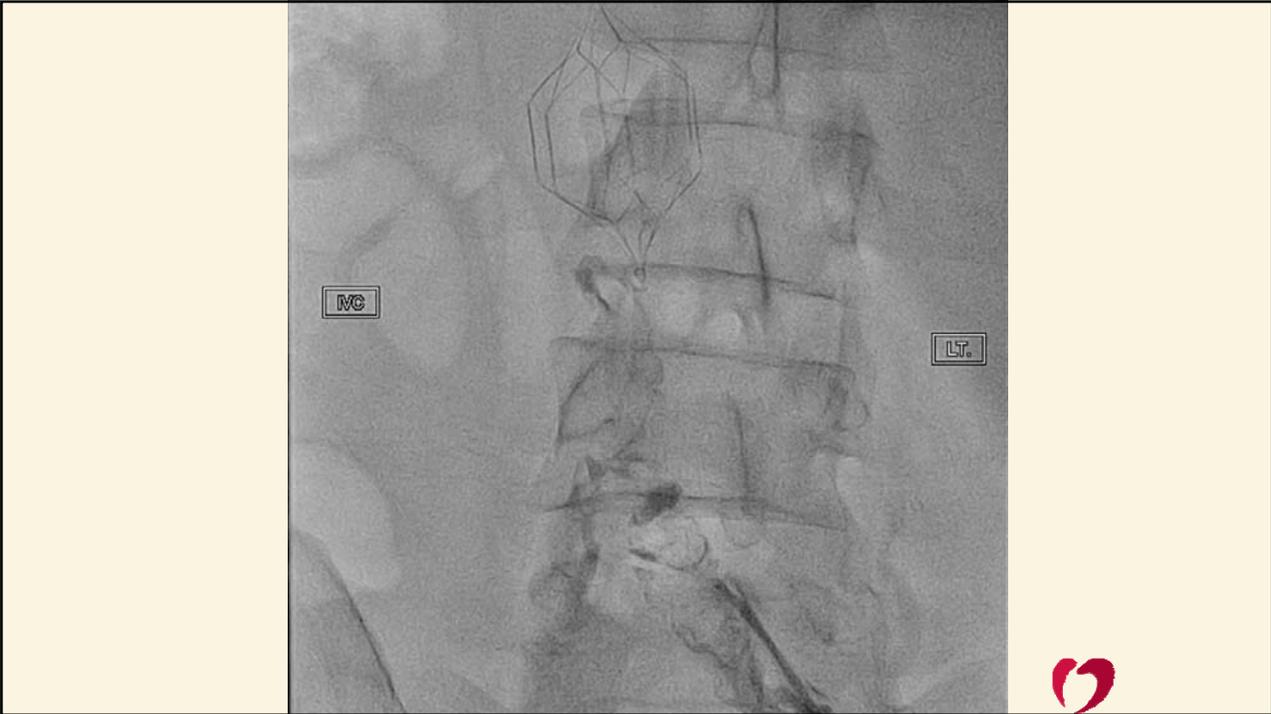
✦ L *Results:* In our cohort, 60.7% of patients received follow-up care; of those, 93% had IVC filter retrieval. Major indications for IVC filter placement were prophylaxis for high risk surgery (53%) and venous thromboembolic event with contraindication and/or failure of anticoagulation (39%). Follow-up care was less likely for patients discharged to acute rehabilitation or skilled nursing facilities ( $P < .0001$ ), those with central nervous system pathology (eg, cerebral hemorrhage or spinal fracture;  $P < .0001$ ), and for those who did not receive an IVC filter placement by a vascular surgeon ( $P < .0001$ ). In a multivariate analysis, discharge home (odds ratio [OR], 4.0; 95% confidence interval [CI], 1.99-8.2;  $P < .0001$ ), central nervous system pathology (OR, 0.46; 95% CI, 0.22-0.95;  $P = .04$ ), and IVC filter placement by the vascular surgery service (OR, 4.7; 95% CI, 2.3-9.6;  $P < .0001$ ) remained independent predictors of follow-up care. Trauma status and distance of residence did not significantly impact likelihood of patient follow-up.

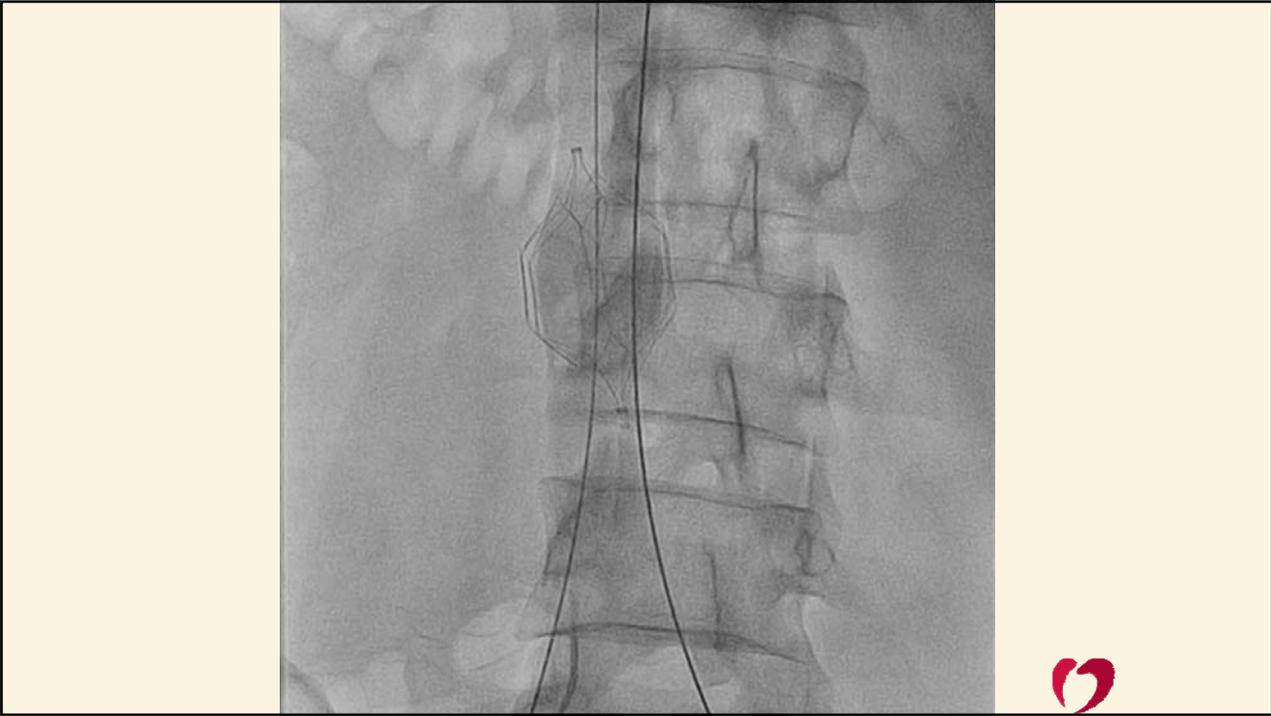
✦ P 1.99-8.2;  $P < .0001$ ), central nervous system pathology (OR, 0.46; 95% CI, 0.22-0.95;  $P = .04$ ), and IVC filter placement by the vascular surgery service (OR, 4.7; 95% CI, 2.3-9.6;  $P < .0001$ ) remained independent predictors of follow-up care. Trauma status and distance of residence did not significantly impact likelihood of patient follow-up.

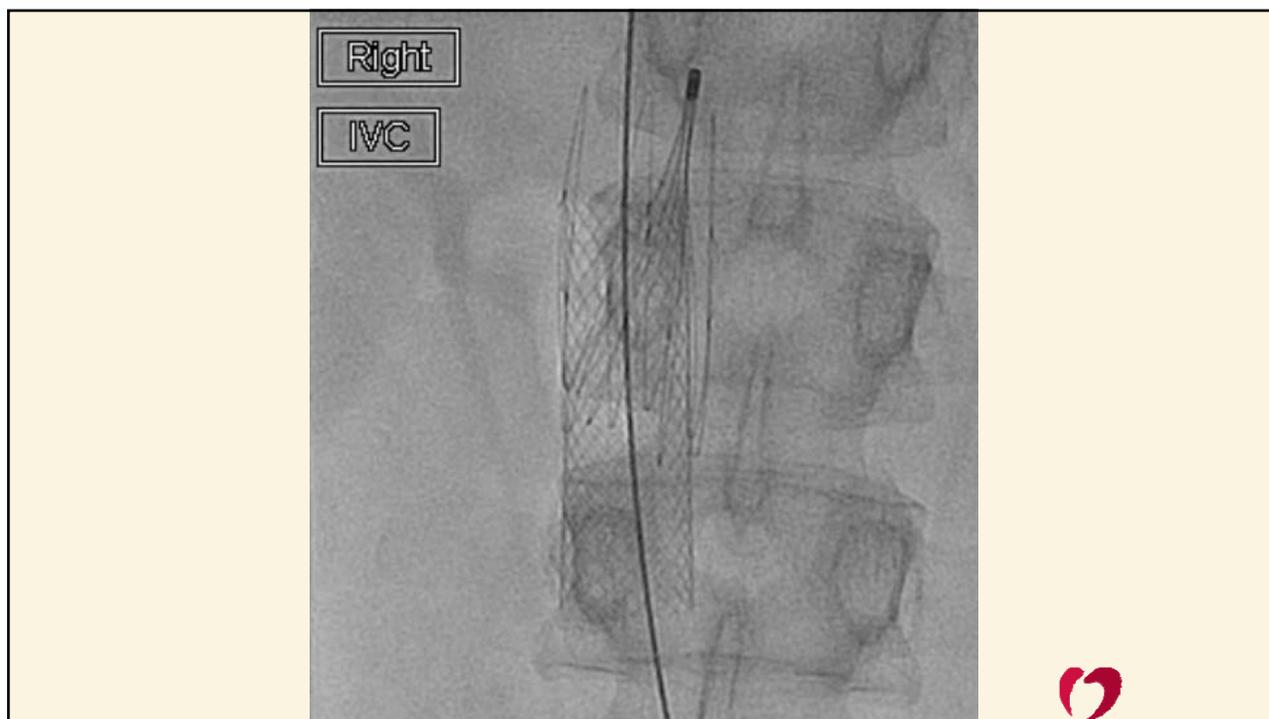












## ***At last, some good news!!!***

J Am Coll Radiol. 2018 Mar 30. pii: S1546-1440(18)30161-3. doi: 10.1016/j.jacr.2018.01.037. [Epub ahead of print]

### **Rising Retrieval Rates of Inferior Vena Cava Filters in the United States: Insights From the 2012 to 2016 Summary Medicare Claims Data.**

Ahmed O<sup>1</sup>, Wadhwa V<sup>2</sup>, Patel K<sup>3</sup>, Patel MV<sup>4</sup>, Turba UC<sup>3</sup>, Arslan B<sup>3</sup>.

**6.9% to 22.1%**

Arch Intern Med. 2011 Nov 28;171(21):1953-5. doi: 10.1001/archinternmed.2011.526.

### **Retrieval of inferior vena cava filters after prolonged indwelling time.**

Garcia-Godoy F<sup>1</sup>, Collins T, Sacks D, Vasas S, Sarani B.

J Vasc Surg. 2011 Dec;54(6 Suppl):34S-8S.e1. doi: 10.1016/j.jvs.2011.05.094. Epub 2011 Aug 6.

### **Improving retrieval rates of temporary inferior vena cava filters.**

Gasparis AP<sup>1</sup>, Spentzouris G, Meisner RJ, Ellitharp D, Labropoulos N, Tassiopoulos A.

Am Surg. 2012 Jan;78(1):94-7.

### **Improved removal rates for retrievable inferior vena cava filters with the use of a 'filter registry'.**

Kalina M<sup>1</sup>, Bartley M, Cipolle M, Tinkoff G, Stevenson S, Fulda G.

Am Surg. 2011 Jan;77(1):103-8.

### **A policy of dedicated follow-up improves the rate of removal of retrievable inferior Vena Cava Filters in trauma patients.**

O'Keefe T<sup>1</sup>, Thekkumel JJ, Friese S, Shafi S, Josephs SC.



# ***PRESERVE Study***

- ✦ **PRE**dicting the **S**afety and **E**ffectiveness of Inferio**R** **VE**na Cava Filters
- ✦ SVS/SIR/FDA Filter Task Force
- ✦ Alternative to an FDA-mandated 522 Post Market Surveillance study
- ✦ Goal:
  - ✦ Development of National IVC Filter Registry Project
  - ✦ FDA incentives to Industry
  - ✦ Funding
- ✦ Current status – Begin enrollment 2014
- ✦ Anticipated enrollment completion May 2018



# ***ACC Guidelines 2016***

- ✦ Other than appropriate patient selection
- ✦ Appropriate surveillance and retrieval equally important
- ✦ Rate of retrieval in the US as low as 30%
- ✦ The FDA issued a statement mandating practitioners to be responsible for IVCF retrieval and prompting timely retrieval.
- ✦ Centers should institute computerized surveillance system to follow IVCF insertion and retrieval.



# ***CHEST Guidelines 2017***

## **Role of Inferior Vena Cava Filter in Addition to Anticoagulation for Acute DVT or PE**

**17. In patients with acute DVT or PE who are treated with anticoagulants, we recommend against the use of an inferior vena cava (IVC) filter (Grade 1B).**



## ***Conclusion***

- ✦ IVC filters do work but are being over-utilized.
- ✦ There are very few actual indications for them.
- ✦ There are no mortality benefits for IVCF use.
- ✦ There are serious complications with their use.
- ✦ Retrieval rates are low and information regarding appropriate use and surveillance are lacking.
- ✦ Implementation of system wide mechanisms to ensure appropriate use, surveillance and retrieval is crucial to prevent clinical complications.



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- ✦ Decousus H, et al. "A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis." NEJM. 1998. 338(7):409-416.
- ✦ Mismetti P, et al. "Effect of a retrievable inferior vena cava filter plus anticoagulation vs. anticoagulation alone on risk of recurrent pulmonary embolism: a randomized clinical trial." J Am Med Assoc. 2015.313(16):1627-35.
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# Thank You!

