

# Versatility and proven safety.

## Standard or over-the-wire delivery

The only conical retrievable IVC filter cleared by the FDA for over-the-wire delivery.

- The unique filter design allows for delivery over a wire  $\leq .035$ " using the standard kit components
- The wire acts as a guide to deploy the filter straight and in the center of the IVC positioning it for easier retrieval
- Over-the-wire delivery provides stability to the apex during deployment for precise and predictable positioning in IVC

## More access for delivery

The only IVC filter cleared by the FDA for delivery via Jugular, Femoral, Antecubital and Popliteal access.

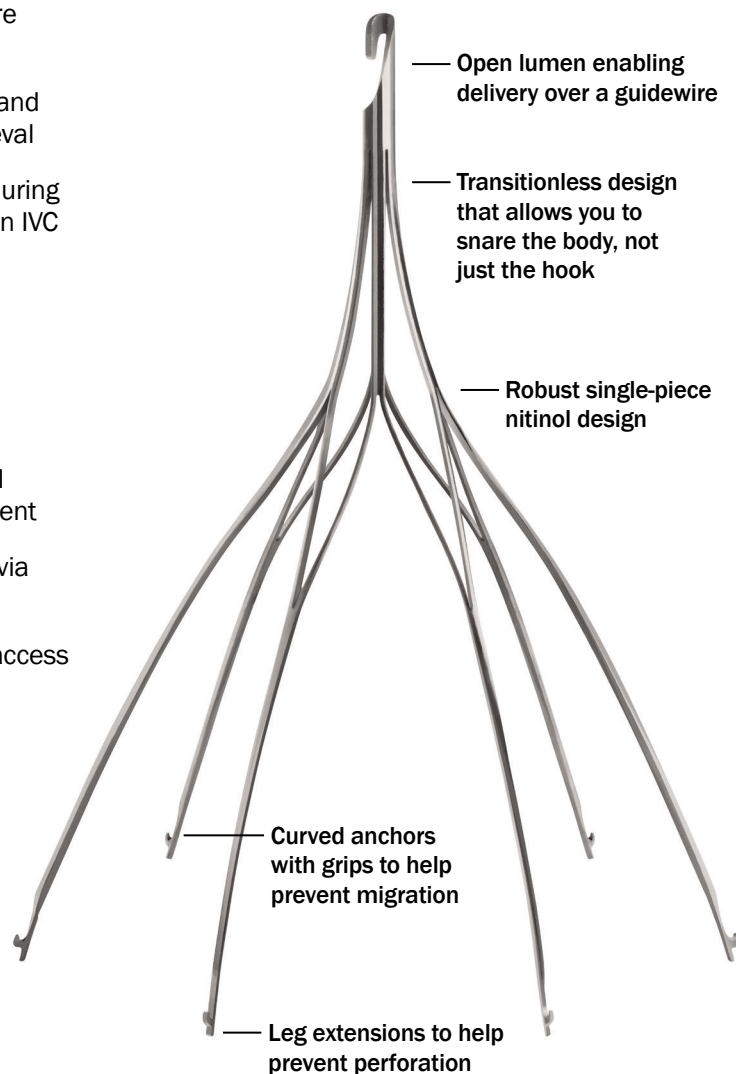
- Save time while providing PE protection during DVT treatment by delivering the OptionELITE via Popliteal access to avoid repositioning and redraping the patient
- 5 Fr ID (6.5 Fr OD) delivery system enables delivery via access in small vessels
- A single kit allows delivery from Jugular or Femoral access

## For temporary or permanent placement

- Unique anchor and apex design makes retrieval easy when the need for PE protection subsides
- Indicated for cavas up to 30mm in diameter

## Option<sup>™</sup> ELITE

Retrievable Vena Cava Filter



Initial Clinical Trial Results (2010) for the Option IVC Filter <sup>1</sup> (100 patients)	IVC Filter Performance Data (2012) from Mass General <sup>2</sup> (165 patients)
2.0% Migration	0.0% Migration
0.0% Fractures	0.0% Fractures
1.0% Perforations	1.2% Perforations
3.0% Occlusion	0.6% Occlusion

1. Johnson MS, Nemcek AA, Benenati JF, et al. The Safety and Effectiveness of the Retrievable Option Inferior Vena Cava Filter: A United States Perspective Multicenter Clinical Study. J Vasc Interv Radiol 2010; 21:1173-1184.

2. Iqbal SI, Elmi A, Hedgire S, et al. Preliminary Experience With Option Inferior Vena Cava Filter. Vasc and Endo Surg 2012; 47(1) 24-29.

# Delivering the OptionELITE IVC Filter

## Initial Delivery Steps

1. **Flush** the dilator and introducer sheath, then insert the dilator into the sheath until an audible and tactile “snap” is experienced
2. **Access** the jugular or femoral veins and insert a  $\leq .038$ " guidewire through the IVC ( $\leq .035$ " guidewire is recommended for an over-the-wire delivery)
3. **Introduce** the introducer sheath and dilator over the guidewire and advance it until the tip of the dilator is at the bifurcation of the iliac veins
4. **Remove** the guidewire
5. **Power-inject** contrast through the luer connector on the hub of the dilator ( $\leq 800$  psi),  
OR  
**Hand-inject** contrast through the side-port of the introducer sheath. Be sure to remove the dilator prior to injection
6. **Reintroduce** the guidewire
7. **Relocate** the introducer sheath to the desired location in the IVC.

NOTE: The filter is unsheathed in the IVC (not pushed out of the sheath). Therefore, distal 5-6cm of the introducer sheath should be positioned in the section of the IVC where you want the filter to deploy.

### Standard Delivery Steps

8. **Remove** the guidewire
9. **Insert** and snap the cartridge into the hub of the introducer sheath
  1. “Jugular” should be face up with the blue arrow pointing to the hub for placement via jugular access
  2. “Femoral” should be face up with the green arrow pointing to the hub for placement via femoral access
10. **Feed** the pusher wire through the filter in the cartridge and advance the pusher until the black mark aligns with the cartridge

NOTE: The pusher should be aligned and inserted such that the curve assists in positioning the introducer sheath in the center of the IVC

11. **Reconfirm** that the filter in the end of the sheath is at the desired location in the IVC using fluoroscopy
12. **Pin** the pusher in position
13. **Pull** the introducer sheath back to unsheath the filter
14. **Retract** the pusher from the filter
15. **Conduct** a post-placement cavagram
16. **Remove** the introducer sheath and follow protocol for access site closure

### Over-the-Wire Delivery Steps

8. **Backload** the cartridge over the guidewire, insert, and snap it into the hub of the introducer sheath
  1. “Jugular” should be face up with the blue arrow pointing to the hub for placement via jugular access
  2. “Femoral” should be face up with the green arrow pointing to the hub for placement via femoral access
9. **Backload** the dilator over the guidewire and advance it through the cartridge until the black mark aligns with the cartridge
10. **Reconfirm** that the filter in the end of the sheath is at the desired location in the IVC using fluoroscopy
11. **Pin** the dilator in position
12. **Pull** the introducer sheath back to unsheath the filter
13. **Retract** the guidewire from the filter
14. **Conduct** a post-placement cavagram
15. **Remove** the introducer sheath and follow protocol for access site closure

For complete and detailed instructions, please consult the instructions for use packaged with the OptionELITE IVC Filter.