

VenaTech® Convertible

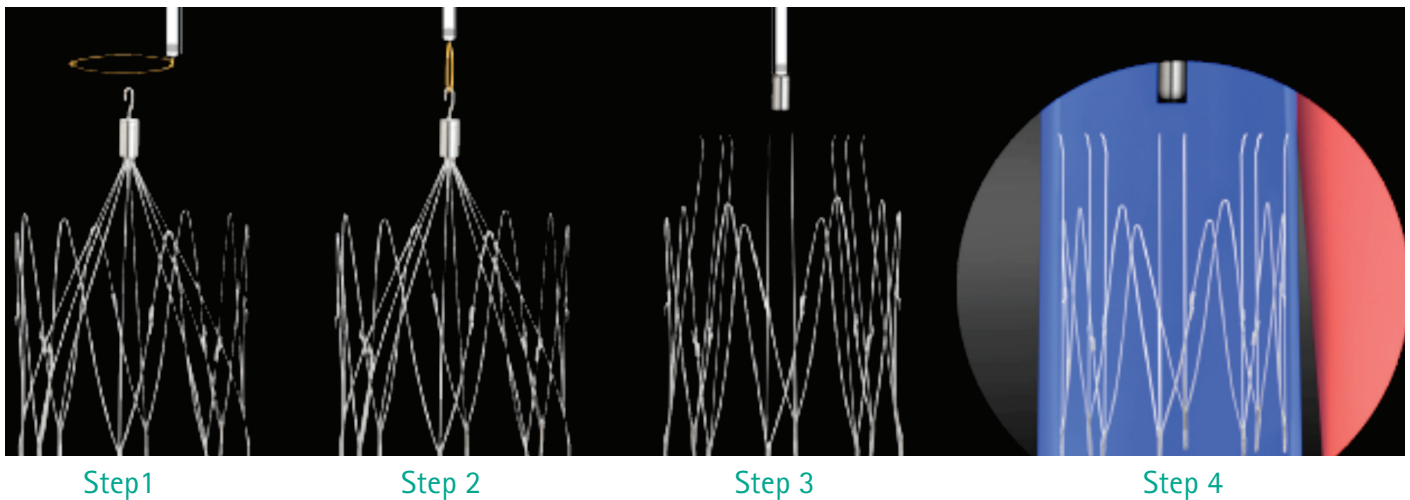
VENA CAVA FILTER



Proven VenaTech® Clot-Trapping Capability - For Temporary or Permanent Protection from Pulmonary Embolism

Extraordinary Design For Exceptional Performance

- Patented design provides safe and effective protection against pulmonary embolism where the patient's risk is temporary or permanent.
- A proven, self-expanding, conical filter design for effective clot-trapping and preservation of caval patency.
- Made from cobalt chromium, a non-ferromagnetic metal alloy with MRI Conditional testing, radiopacity, and proven performance.
- Pre-loaded cartridge for either Jugular or Femoral Introduction.
- Self-Centering stabilization legs with eight anchoring hooks to securely position the filter in the center of the Vena Cava and optimize clot trapping filtration.
- Filter head is firmly attached to the filtering legs by a secure locking mechanism and can be safely unlocked during filter conversion procedure.
- Flexible wire filter design is indicated for use in Vena Cava up to 28mm in diameter.
- By design, filter contact with the IVC wall is evenly distributed, with no single points of contact or stress points, reducing the risk of IVC perforation.
- Unique patented concept of filter deactivation: When clinically indicated, the clot-trapping features of the filter can be deactivated by percutaneously converting the filter to an open configuration



U.S. Multi-Center Clinical Study Results:

- 100% of filters were successfully placed at 11 U.S. study sites, 149/149 subjects
- 92.7% filter conversion success rate
- Mean days to filter conversion was 130.7 days (range 15 to 391 days)
- Average filter conversion procedure time was 30.7 minutes

0.0% Technical Complications Reported For:

- Deployed at unintended position
- Filter fracture
- Filter implanted upside down
- Inadequate distribution of filtering legs
- Incomplete opening of stabilizing legs during deployment
- Spontaneous conversion of filter

No reports of device or procedure-related major adverse events post-conversion, defined as:

- Symptomatic caval thrombosis or caval occlusion
- Perforation of the IVC and/or adjacent organs or vertebral bodies
- Pulmonary embolism
- Filter migration

No reports of spontaneous filter conversion or loss of the filter head during the conversion procedure

Step 1

Introduce the snare* through the snare catheter to the top of the hook on the filter cone. After filter head removal, use of an accessory to aid in filter conversion is probable due to the fibrin strands or cellular growth that may collect at the top of the filtration cone. It is recommended that the physician be prepared to utilize an accessory device such as a diagnostic catheter, guide wire, or angioplasty balloon to assist in completely opening constrained filter legs.

Step 2

Capture the hook on the cone of the filter with the snare loop. Advance the snare catheter over the snare while maintaining tension on the snare and ensuring that the snare catheter, snare, and the hook are in the same plane.

Step 3

Maintain tension on the snare and advance the snare catheter downwards until it covers the hook. Pin the snare catheter in place and pull the snare proximally until the filter head unlocks.

Step 4

Maintain traction on the snare to ensure that the hook remains in the snare catheter at all times. Remove the snare catheter, snare, and filter head as a single unit. *The VenaTech® Convertible™ Vena Cava Filter was qualified for use with the 15, 20, or 25mm GooseNeck™ Snare and 6F Catheter.