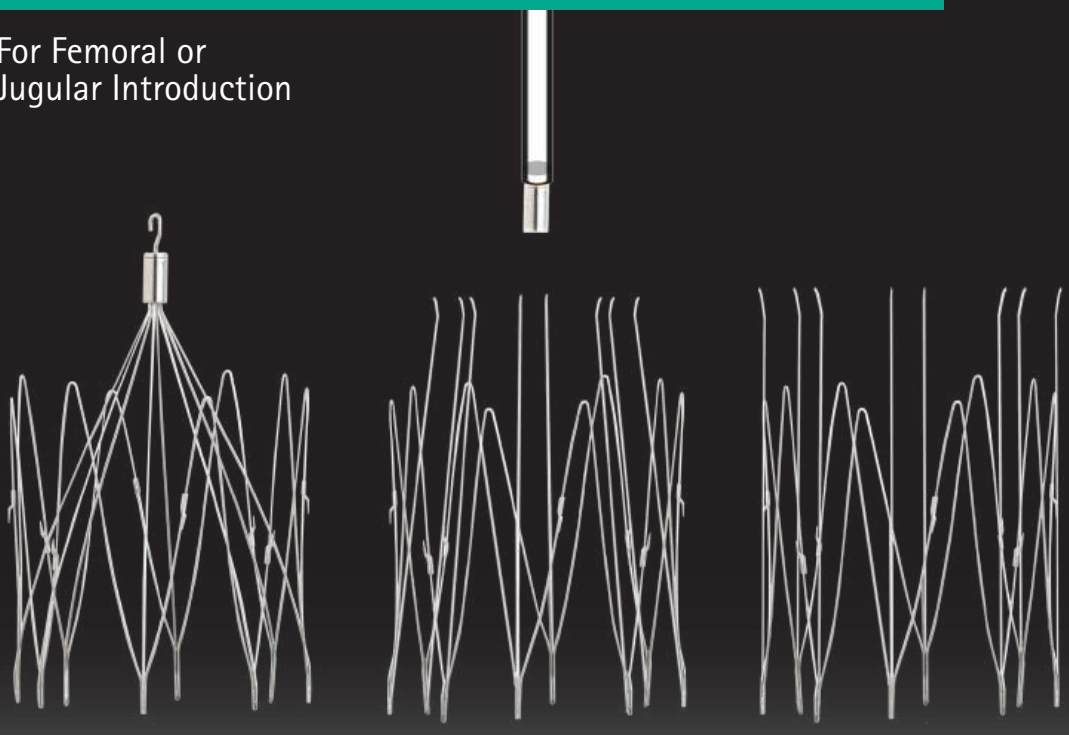
Interventional Systems
B BRAUN
SHARING EXPERTISE

UNLOCKING THE FUTURE OF IVC FILTRATION

New
VenaTech® Convertible™
Vena Cava Filter System

For Femoral or
Jugular Introduction



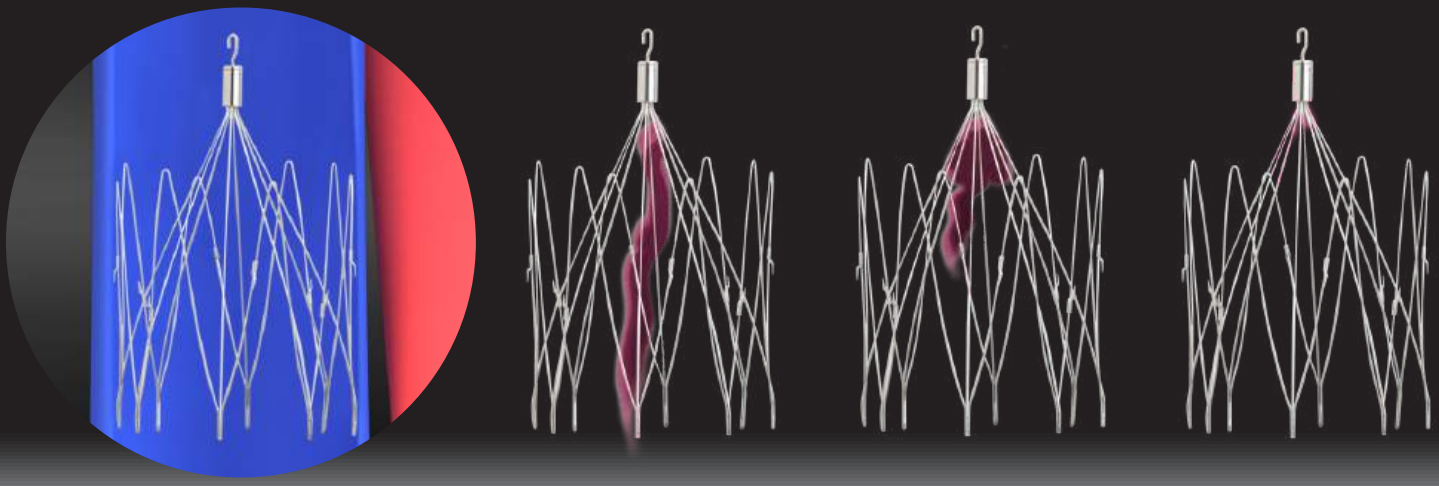
PROVEN VenaTech Performance with Added Versatility.

IT'S TIME TO CONVERT!

For Temporary or Permanent Protection
from Pulmonary Embolism

VenaTech® Convertible™ Vena Cava Filter

Proven VenaTech® Clot-Trapping Capability



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.

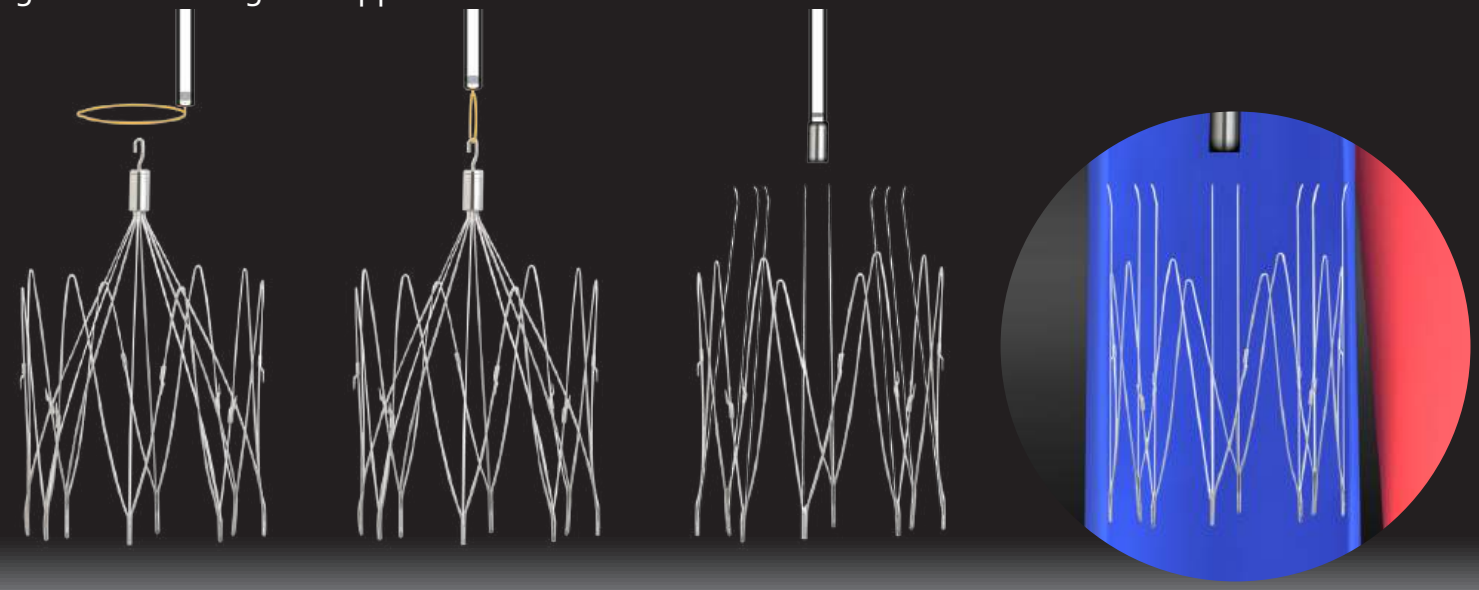
SIR, 2015 Clinical Abstract of the Year Recipient

Multi-Center Trial of the VenaTech® Convertible™ Filter: A Novel Approach to IVC Filtration

VenaTech® Convertible™ Vena Cava Filter

Converting the Filter to an Open Configuration

Right Internal Jugular Approach is Recommended



1

Introduce the snare* through the snare catheter to the top of the hook on the filter cone.

*The VenaTech® Convertible™ Vena Cava Filter was qualified for use with the 15, 20, or 25mm GooseNeck™ Snare and 6F Catheter.

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.

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.

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.

Conversion of the VenaTech Convertible Vena Cava Filter should only be performed using an Amplatz GooseNeck™ snare. Use of another snare may result in complications, including embolization of the filter head and/or snare fracture.

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, guidewire, or angioplasty balloon to assist in completely opening constrained filter legs.

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

Femoral IFU

Read the IFU, inclusive of the complete Clinical Study Summary

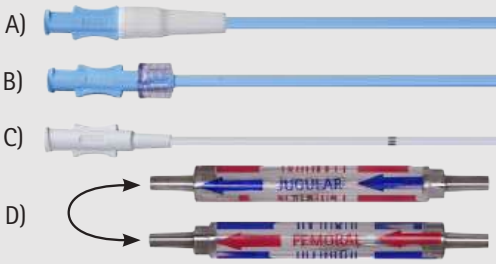
Jugular IFU

Ordering Information

VenaTech® Convertible™ Vena Cava Filter System

For Femoral or Jugular Introduction

A) Introducer sheath 12.9F O.D.
B) Dilator 10F O.D.
C) Pusher 10F O.D.
D) Filter pre-loaded in its cartridge



Order Number 05010028

MRI Safety Information

Non-clinical testing has demonstrated the VenaTech® Convertible™ Vena Cava Filter is MR Conditional.
A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3T
- Maximum spatial field gradient of 1,160 gauss/cm (11.6 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Note: The MRI information is related to the implanted filter only. The implantation accessories were not tested.

Under the scan conditions defined above, the VenaTech Convertible is expected to produce a maximum temperature rise of less than 3.3° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 11mm from the VenaTech Convertible when imaged with a gradient echo pulse sequence and a 3T MRI system.

Indications For Use:
The VenaTech® Convertible™ Vena Cava Filter System is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

When clinically indicated after implantation, the VenaTech Convertible Vena Cava Filter can be converted to an open configuration to discontinue filtration according to the 'Conversion Procedure' in the Instructions for Use.

Refer to the Instructions for Use for complete indications, relevant warnings, precautions, complications, and contraindications.

For more information or to place an order, contact your B. Braun Interventional Systems Inc. representative or call 1-877-VENA CAV (836-2228)

Rx only

CV-2034 6/17

LATEX Not made with natural rubber latex

DEHP Not made with DEHP

Watch Product Video

Link to Web Page

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B. Braun Interventional Systems Inc. | 824 Twelfth Avenue | Bethlehem, PA 18018 USA
Tel 877 836 2228 | Fax 610 849 1334 | www.bisusa.org