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 fr - Fabriqué pour :
 es - Fabricado para:
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REF 05010024

MODEL NUMBER 31335



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F1943 Ed.02 (10/2010) Ime M. SAUV. - Album / F.C. B.120.916.924

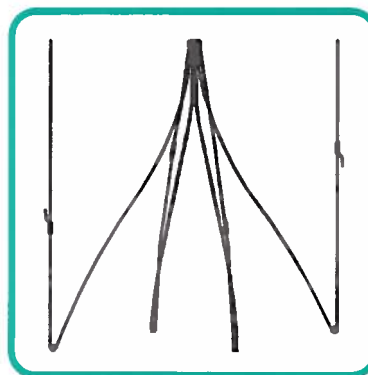
VenaTech™ LP

en : Vena Cava Filter System
 fr : Filtre de veine cave
 es : Sistema de Filtro de Vena Cava

REF 05010024

MODEL NUMBER 31335

Femoral



en : Femoral approach
 fr : Voie fémorale
 es : Vía Femoral

ENGLISH

FRANÇAIS

ESPAÑOL

Symbols Glossary Glossaire des symboles Glosario de Símbolos



en - Contents of the kit
fr - Contenu de l'ensemble
es - Contenido del equipo



en - Jugular approach
fr - Voie jugulaire
es - Vía yugular



en - Femoral approach
fr - Voie fémorale
es - Vía femoral



en - Jugular and femoral approaches
fr - Voies jugulaire et fémorale
es - Vías yugular y femoral



en - One filter loaded in one cartridge.
This filter can be implanted via
femoral or jugular approaches.
fr - Un filtre chargé dans sa cartouche.
Ce filtre peut être implanté par la
voie fémorale ou jugulaire.
es - Un filtro cargado en un cartucho.
Este filtro puede ser implantado
por la vía femoral o yugular.



en - DEHP free
fr - Sans DEHP
es - Sin DEHP



en - Latex-free
fr - Sans latex
es - Sin látex



en - Caution, consult accompanying documents
fr - Attention, consulter les documents d'accompagnement
es - Atención, consulte los documentos adjuntos



en - Catalog number
fr - Numéro de catalogue
es - Número de catálogo



en - Lot number
fr - Numéro de lot
es - Número de lote



en - Use by date
fr - A utiliser avant la date
es - Utilícese antes de



en - Do not re-use
fr - Ne pas réutiliser
es - No reutilizar



en - Do not re-sterilize
fr - Ne pas restériliser
es - No reesterilizar



en - Do not use if package is damaged
fr - Ne pas utiliser si l'emballage est endommagé
es - No utilizar si el embalaje está deteriorado

MODEL NUMBER

en - Model Number
fr - Modèle Numéro
es - Número de Modelo

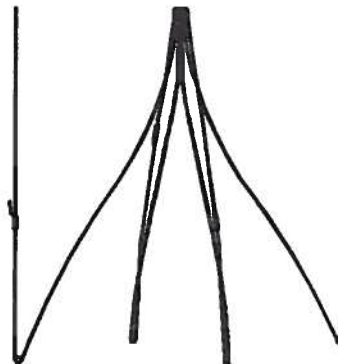
STERILE EO

en - Sterilized using ethylene oxide
fr - Stérilisé en utilisant de l'oxyde d'éthylène
es - Esterilizado por óxido de etileno

VenaTech™ LP

Vena Cava Filter System

Instructions for use for implantation using the: **femoral approach**



Use this booklet only if you have chosen to implant the filter
from the femoral approach.
Do not use this booklet for any other approach.



Device Description

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

The VenaTech™ LP vena cava filter is a flexible, symmetrical, self-expanding vena cava filter intended for deployment in the infrarenal inferior vena cava. The filter is a conical-shaped filter constructed with a radiopaque metal alloy. The filter is designed to trap large, life-threatening emboli and therefore prevent recurrent pulmonary embolism, while maintaining caval patency.

The VenaTech™ LP filter is pre-loaded in a cartridge and provided with introducer accessories and instructions to accommodate delivery and implantation either via the femoral or jugular approach. The components of the VenaTech™ LP Filter system include the following:

- "J" Guidewire
- Introducer System
 - Introducer (sheath and dilator)
 - Pushers
- Filter System
 - Filter (in cartridge)
 - Cartridge cradle

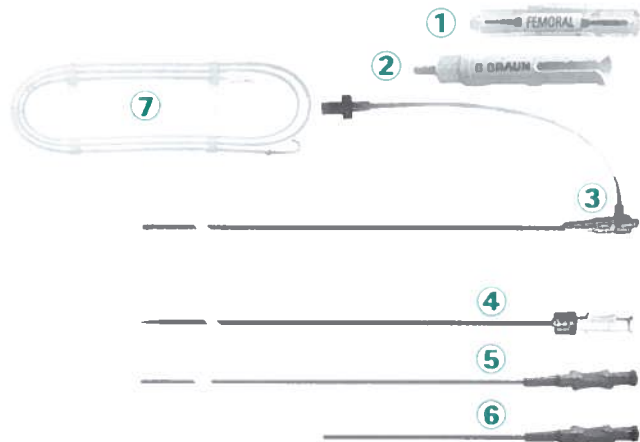
Supplies required for the pre-placement cavography which are not included in the package include the following :

- Puncture needle with "Y" connector and 5 ml syringe
- Short "J" guidewire, length = 70 cm, diameter = 0.89 mm (0.035 inch)
- Disposable number E11 scalpel
- 9F catheter introducer with hemostasis valve, "Y" connector and stopcock.

A separate accessory package is available to accommodate delivery and implantation of the VenaTech™ LP filter in an antecubital (brachial) approach.

System Contents

- (1) Filter in its cartridge
- (2) Cartridge cradle
- (3) 9F O.D. x 56 cm Introducer sheath with hemostasis valve and side port tubing
- (4) 7F x 65 cm Dilator
- (5) 7F x 62 cm Long Pusher (white)
- (6) 7F x 14.5 cm Short Pusher (blue)
- (7) PTFE coated "J" guide, length = 150cm, diameter = 0.89mm (0.035 in)



Important Information

• **Instruction manual**

This instruction manual is to be used only when implantation from the femoral approach has been selected. Set aside the manual provided for the other approaches prior to beginning the implantation procedure.

• **Implantation period**

This filter is designed to provide effective protection against permanent or long term risk of pulmonary embolism.

• **Implantation approach**

This filter is designed for insertion via:

- the right femoral vein
- the left femoral vein

when placement from below has been selected.

Warning : Avoid the use of a venous access site which was previously used for an implanted central venous catheter. Implantation of a vena cava filter using an existing access site can result in incomplete filter deployment. This could in turn result in filter migration and/or inadequate protection against pulmonary embolism.

Note: Extreme care must be exercised during approaches through tortuous anatomies which can cause sheath kinking and make filter insertion difficult or impossible. Under extreme conditions, attempting to force the filter through a kinked sheath could result in a sheath perforation. When resistance is encountered, stop advancing the filter and remove the filter and the introducer assembly.

• **Diameter of the vena cava**

The maximum diameter of the vena cava, as evaluated during cavography, must be less than or equal to **28 mm** from an AP projection when corrected for magnification.

In cases in which measurement is accomplished using Computed Tomography (CT), the section with the largest diameter should be used.

Warning: Do not attempt to increase the diameter of the filter.

• **Filter placement in pregnant women**

In pregnant patients where the fetus may be endangered by fluoroscopy, risks and benefits should be carefully assessed.

• **Compatibility with Magnetic Resonance Imaging (MRI)**

The VenaTech™ LP filter is **MRI-compatible**. The product is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

• **Secondary Catheterization**

Following filter placement, no central venous catheterization should be attempted without fluoroscopic guidance.

Potential Adverse Effects

- Air embolism
- Caval thrombosis or caval occlusion
- Damage to the inferior vena cava
- Death
- Deep vein thrombosis
- Embolization of the device possibly resulting in cardiac arrhythmia or compromise of cardiac valve function
- Extravasation of contrast material at time of vena cavogram causing tissue damage
- Access site thrombosis
- Perforation of the inferior vena cava and/or adjacent organs or vertebral bodies
- Pulmonary embolism
- Thrombosis or stenosis at implant site
- Venous insufficiency
- Wound infection at access site

Indications

The VenaTech™ LP 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.

Contraindications

- Vena cava filters should not be implanted in patients with risk of septic embolism.
- Patients with a vena cava which has a diameter greater than 28 mm (due to the risk of device migration).

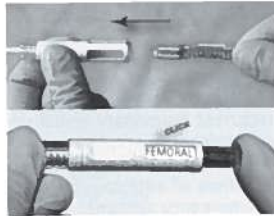
Implantation Procedure

Pre-implant cavography is required:

- To confirm the patency and visualize the anatomy of the vena cava,
- To mark the level of the renal veins,
- To locate the highest level of any thrombus which may be present,
- To determine the desired level for filter deployment and to mark the position with respect to the vertebral bodies,
- To confirm that the diameter of the vena cava (AP projection) at the site where the filter is to be deployed is less than or equal to the maximum authorized diameter.

A) Preparation of the implantation accessories

1. The filter is pre-loaded into its cartridge. Load the cartridge into the cartridge cradle as shown on the photo.



Warning 1: A "click" must be heard to guarantee complete insertion.

Warning 2: The side window of the cradle must read "FEMORAL".

2. Immerse the assembly in a container of heparinized saline.

Note: This precaution reduces the possibility of thrombus formation around the filter during its movement through the introducer sheath.

B) Puncture of the vein

1. Prepare the patient for access from the selected approach.
2. Puncture the vein using the Seldinger technique (or perform a surgical cut-down of the vein). Confirm venous reflux into the syringe.
3. Advance a guidewire (0,89 mm -- 0.035 in.) and then remove the Seldinger needle.

C) Control cavogram, marking the filter implant site

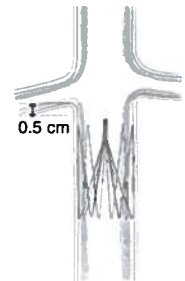
1. Create a small incision with a scalpel to facilitate the passage of the introducer. Insert a catheter introducer over the guidewire. Remove the guidewire. Perform a cavogram using the catheter introducer or a catheter of your choice.

Caution: If ilio-caval clot is present, extreme care must be exercised to avoid dislodging the clot.

2. Locate the renal veins and select the location for filter placement. Mark the planned position of the top of the filter cone by placing a metallic marker (e.g. a hemostat) horizontally across the abdomen.

Note: Choice of the site for filter deployment:

When possible, it is preferable to place the filter just below the renal veins. A security margin of 0.5 cm should be left from the level of the lowest renal vein to the top of the filter.



D) Passage of the "J" guidewire

Remove the angiographic catheter and advance the "J" guidewire (150 cm - diameter 0,89 mm / 0.035 in.). Follow its progress under fluoroscopy.

Warning: To prevent the introducer from inadvertently passing outside of the IVC (e.g. into a tributary vessel) verify that the "J" portion of the guidewire is located above the renal veins.

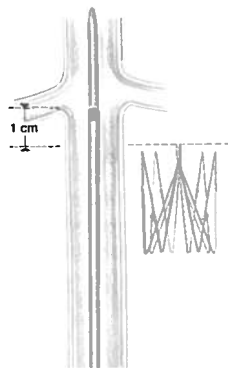
Note: In the event of difficulty advancing the guidewire because of the "J", remove the guidewire and use the other end, which is straight and supple.

E) Placement of the introducer

1. Insert the dilator into the introducer sheath. Connect the Luer-Lock connecting the sheath and dilator.

2. Remove the catheter introducer. Place the introducer assembly over the "J" guidewire. Advance it over the guidewire.

3. Continue to advance the introducer until the marker is a little bit further than one cm above the deployment site marker (hemostat) placed on the abdomen.



Note: The level of the metallic marker on the introducer corresponds to the top of the filter cone when it is collapsed within the sheath prior to deployment.

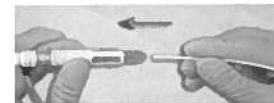
This maneuver pre-positions the filter slightly above the level chosen for deployment. Withdrawing the sheath slightly adjusts the filter position before deployment.

Note: Final adjustment of the filter position will be made just prior to deployment.

Warning: Hold the guidewire firmly as the introducer is advanced to prevent the guidewire from moving or developing a kink.

F) Placement of the filter into the sheath

1. Disconnect the luer lock connecting the sheath and dilator.
2. Remove the "J" guidewire and the dilator taking care not to move the sheath.
3. Flush through the side connection of the sheath with 10 ml of heparinized saline.
4. Screw the cartridge cradle with the filter clockwise onto the sheath. Ascertain that both are securely locked together.
5. Using the short pusher (blue), insert the filter into the sheath. The pusher must be completely inserted.



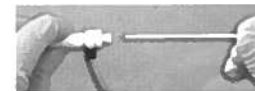
6. Unscrew the cartridge cradle and remove it with the pusher as a unit.

Note: The cartridge cradle must be removed to ensure a correct filter implantation.

7. Inject several milliliters of heparinized saline to prevent thrombus formation in the sheath, using the side port connection.

G) Advance the filter through the sheath

1. Insert the distal end of the long pusher (white) into the sheath. Hold the sheath firmly, not allowing it to move.
2. Using the long pusher (white), advance the filter through the sheath under fluoroscopy, until the short proximal mark on the pusher is aligned with the mouth of the introducer sheath.
3. The filter is now located at the distal end of the sheath. The system is ready for final positioning prior to deployment.



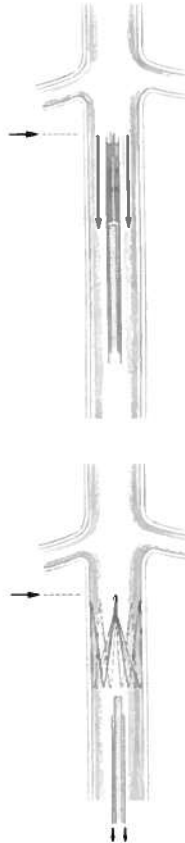
H) Deployment of the filter

1. Under fluoroscopic guidance, align the top of the filter cone with the metallic marker placed on the patient at the beginning of the procedure. (This is the final adjustment of filter position prior to deployment).
2. Once the filter has reached the proper level for deployment, be careful not to move the introduction system.
3. Confirm under fluoroscopy that the sheath has not moved and that the filter is properly positioned at the desired level for deployment.
The top of the filter should be at the level of the metallic marker previously placed on the patient.
4. Holding the pusher firmly with one hand, take the sheath in the other hand and, under fluoroscopic guidance, withdraw the sheath. This movement deploys the filter.

Reminder: To assure good filter position, it is extremely important not to move the pusher :

- during the step prior to filter deployment,
- during filter deployment

5. The filter is now implanted.



Note: To perform a cavogram at this time,

1. Remove the pusher while keeping the sheath in place.
2. Perform the cavogram by manually injecting contrast material through the side port connection.
6. Remove the assembly sheath/pusher (or sheath alone if the pusher has already been removed to perform a cavogram).

I) Final check

Take a final film Kidneys Urethra Bladder (KUB) which documents the location and deployment of the filter.

Important

The VenaTech™ LP Vena Cava Filter System is STERILE and non-pyrogenic, sterilized using Ethylene Oxide. Check that the sterile packaging is undamaged before opening. Do not use if package is damaged. **For single use only.** Dispose of system components after filter implantation. Components may not be cleaned, resterilized or reused. Store at room temperature. Avoid freezing and excessive heat.

Please review the sections of the instructions for use which describe:

- the implantation procedure
- the indications for filter placement
- the contraindications to filter placement.

Opening the sterile packaging:

Confirm the date of sterile expiration on the labelling. Never implant an IVC filter which has exceeded its sterile expiration date. To maintain sterility, all normal operating room sterile procedures should be followed.



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