

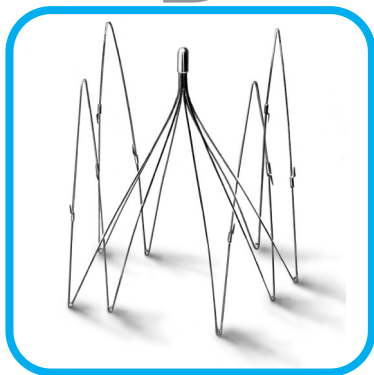
VenaTech® LP

Brachial Introducer System (Antecubital)

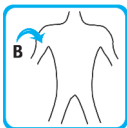
[For US market only: Vena Cava Filter
Brachial Introducer System (Antecubital)]⁽¹⁾

REF. 04439985

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- ENGLISH en
- FRANÇAIS fr
- DEUTSCH de
- ESPAÑOL es
- ITALIANO it
- SVENSKA sv
- PORTUGUÊS pt
- NORSK no
- DANSK da
- SUOMI fi
- POLSKI pl
- ΕΛΛΗΝΙΚΑ el
- TÜRKÇE tr
- ČESKÝ JAZYK cs
- MAGYAR hu

SYMBOLS GLOSSARY



en: Brachial approach
 fr: Voie brachiale
 de: Brachialer Zugang
 es: Abordaje Braquial
 it: Approccio Brachiale
 sv: Brakial metod
 pt: via braquial
 no: Brakial implantasjon
 da: Brachial adgang
 fi: Laittaminen brachialisesti
 pl: Dostęp ramienny
 el: Βραχιόνια προσέλαση
 tr: Brakial giriş
 cs: Brachiální přístup
 hu: Brachialis megközelítésből



en: Caution, consult accompanying documents
 fr: Attention, consulter les documents d'accompagnement
 de: Achtung! Siehe beiliegende Dokumente.
 es: Atención, consultar documentación adjunta
 it: Attenzione, consultare le istruzioni per l'uso
 sv: Varning, konsultera medföljande dokument
 pt: Atenção, consultar documentos inclusos
 no: OBS! Slå opp i vedlagte dokumenter
 da: Forsigtighed, se vedlagte dokumenter
 fi: Lue käyttöohje
 pl: Ostrzeżenie, sprawdźć towarzyszące dokumenty
 el: Προσοχή, διαβάστε τα συνοδευτικά εγχειρίδια
 tr: Dikkat, ürün ile birlikte verilen dokümanlara bakınız.
 cs: Pozor, viz příložená dokumentace
 hu: Figyelmesen olvassa el a mellékelt tájékoztatót



en: Manufacturer
 fr: Fabricant
 de: Hersteller
 es: Fabricante
 it: Fabbricante
 sv: Tillverkare
 pt: Fabricante
 no: Fabrikant
 da: Producent
 fi: Valmistaja
 pl: Producent
 el: Οίκος κατασκευής
 tr: Üretici
 cs: Výrobce
 hu: Gyártó

LOT

en: Batch code
 fr: Numéro de lot
 de: Chargencode
 es: Número de lote
 it: Numero di lotto
 sv: Batchnummer
 pt: Código de lote
 no: Batch (produksjonsserie) kode
 da: Batch kode
 fi: Eränumero
 pl: Numer serii
 el: Κωδικός παρτίδας
 tr: Lot no
 cs: Číslo šarže
 hu: LOT szám

STERILE/O

en: Sterilized using ethylene oxide
 fr: Stérilisé en utilisant de l'oxyde d'éthylène
 de: Sterilisation mit Ethylenoxid
 es: Esterilización mediante Óxido de Etileno
 it: Sterilizzato con Ossido di Etilene
 sv: Steriliserad med ethylenoxid
 pt: Esterilizado por óxido de etileno
 no: Sterilisert med etylen oksyd
 da: Ethylenoxid steriliseret
 fi: Steriloitimetenelmänä etyleeniksidi
 pl: Sterylizowany przy użyciu tlenku etylenu
 el: Αποστείρωση με αιθυλενοξείδιο
 tr: Etilen oksit ile sterilize edilmiştir.
 cs: Sterilizováno ethylenoxidem
 hu: Etylen oxid-al sterilizált



en: Use by date
 fr: A utiliser avant la date
 de: Verwendbar bis
 es: Fecha de caducidad
 it: Data di scadenza
 sv: Används före
 pt: Utilizar até
 no: Brukes innen
 da: Anvendes inden
 fi: Käytettävää ennen
 pl: Data ważności
 el: Ημερομηνία λήξης
 tr: Son kullanma tarihi
 cs: Použitelné do
 hu: Lejárati idő

REF

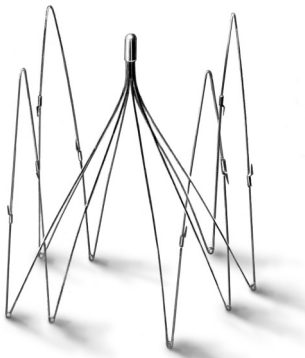
en: Catalogue number
 fr: Numéro de catalogue
 de: Katalognummer
 es: Referencia
 it: Codice catalogo
 sv: Katalognummer
 pt: Número de catálogo
 no: Varenummer
 da: Reference nr.
 fi: Tuotenumero
 pl: Numer katalogowy
 el: Αριθμός κωδικού
 tr: Katalog numarası
 cs: Katalogové číslo
 hu: Katalógus szám

VenaTech[®] LP

Brachial Introducer System (Antecubital)
[For US market only: Vena Cava Filter
Brachial Introducer System (Antecubital)]⁽¹⁾

REF. 04439985

Instructions for use for implantation
via the **brachial** approach



Use this document only if you have chosen to implant
the VenaTech[®] LP filter from the Brachial approach (Antecubital).
Do not use these instructions for use for any other approach
or for the implantation of any other vena cava filter.

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INTRODUCTION

The VenaTech® LP Brachial Introducer System (Antecubital) must be used with a VenaTech® LP vena cava filter only.

The VenaTech® LP Brachial Introducer System (Antecubital) includes a **960 mm long (37.8 in.)** sheath, designed to be used during the implantation of a VenaTech® LP vena cava filter via the Brachial approach (Antecubital).

Please refer to the VenaTech® LP instructions for use booklet (JUGULAR, or SUBCLAVIAN for OUS only, approaches) for information about the use of a VenaTech® LP vena cava filter.

SYSTEM CONTENTS

- 7F I.D. Introducer sheath with hemostasis valve and side connection
- 7F Dilator
- 7F Long Pusher (white)
- 7F Short Pusher (blue)

	Introducer Sheath	Dilator	Short Pusher	Long Pusher
Total Length (mm)	1010	1087	≥181	≥1053
Usable length (mm)	960	1048	≥140	≥1014
Internal diameter (mm)	2.4	≥1.0	NA	NA
External diameter (mm)	3.1	2.3	2.3	2.3

Supplies required for the filter implantation procedure, but not provided:

- Coated "J" Guidewire, length = 180 cm, diameter = 0.89 mm (0.035 inch)

For an implantation of a VenaTech® LP vena cava filter from the Brachial approach (Antecubital), it is mandatory to use the above-mentioned accessories, instead of the accessories available into the VenaTech® LP vena cava filter kit. The only items that must be used from the VenaTech® LP vena cava filter kit are the following:

- Filter in its cartridge
- Cartridge cradle
- Instructions for use (JUGULAR, or SUBCLAVIAN for OUS only, approaches)

INDICATIONS

The VenaTech® LP Brachial Introducer system (Antecubital) is intended for use with the VenaTech® LP Vena Cava Filter.

IMPLANTATION PROCEDURE

Please refer to the VenaTech® LP instructions for use booklet (JUGULAR, or SUBCLAVIAN for OUS only, approaches) for important warnings / indications / contraindications / implantation procedure of the VenaTech® LP Brachial Introducer System (Antecubital). [For US market only: Vena Cava Filter Brachial Introducer System (Antecubital)]⁽¹⁾

Note for the implantation from the Brachial approach:

- **Implantation approach:**
This Introducer System is designed for insertion via the **Brachial approach (Antecubital)**. If needed, this Introducer System can be used to insert the filter via the right internal jugular vein or the left or right subclavian veins. In this case, due to the length of the introducer, it is important to rigorously follow aseptic technique.
Other approaches (particularly the left internal jugular vein, the right or left external jugular veins) should not be attempted.
- **Preparation of the patient:**
Stretch the arm of the patient 90 degrees from the long axis of the spinal column. This will allow you to place the introducer in the axis of the subclavian vein.

PRECAUTIONS

During the implantation via the Brachial approach (Antecubital) the filter cartridge must be inserted in the JUGULAR position into the cartridge cradle.

Introducer system for use with VenaTech® LP vena cava filter for permanent interruption of the Inferior Vena Cava. STERILE and non-pyrogenic, sterilized using Ethylene Oxide. Contents of unopened, undamaged package are sterile and non-pyrogenic. **For single use only.** The device and its accessories are not re-usable nor designed to be re-used. Any re-use would definitely compromise the performance and safety of the device. Destroy system components after filter implantation. Components may not be cleaned, re-sterilized or reused. Store at room temperature. Avoid freezing and excessive heat. Do not remove from unit carton until ready for use.

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

Opening the sterile packaging:

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

VenaTech® LP
Brachial Introducer System (Antecubital)

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- (1) fr: Pour le marché américain uniquement : Système d'introducteur Brachial (Antecubital) de filtre de veine cave
 de: Nur für den US Markt: Vena Cava Filter Brachiales Einführbesteck (Ellenbeuge)
 es: Solo para el mercado de EUA: Sistema introductor Braquial del Filtro de Vena Cava (Antecubital)
 it: Solo per il mercato USA: Sistema per introduzione Brachiale (Antecubitale) del Filtro per Vena Cava
 sv: Endast för amerikanska marknaden: Vena Cava filter brakialt introducer system (antekubitalt)
 pt: Exclusivamente para o mercado EUA: Sistema de introdução para filtro de veia cava braquial (antecubital)
 no: Kun for US markedet: Vena Cava Filter Brakial Introducer System (antecubital)
 da: Kun til brug i USA: Vena Cava Filter Branchial introducerings system, (Antecubital)
 fi: Vain USA:n markkinolle : Vena Cava suodatin brachial sisäänvientiväline (Antecubital)
 pl: Wyłącznie dla rynku Stanów Zjednoczonych: system do wprowadzania filtra z dostępu ramiennego (zgięcie łokciowe)
 el: Μόνο για την αγορά των ΗΠΑ: Σύστημα Βραχιόνιας Εισαγωγής (Αντιβράχιο) φίλτρου κοίλης φλέβας
 tr: Sadece Amerika Birleşik Devletleri pazar için: Vena Cava Filtre Brakial Girişim Sistemi (Antekubital)
 cs: Určeno pouze pro prodej v USA: zaváděcí systém Vena Cava Filter (antekubitální)
 hu: Kizárólag az amerikai piacra: Vena Cava Filter Brachial bevezető rendszerrel (Antecubital)
- (2) fr: Pour le marché américain uniquement
 de: Nur für den US Markt
 es: Solo para el mercado de EUA
 it: Solo per il mercato USA
 sv: Endast för amerikanska marknaden
 pt: Exclusivamente para o mercado EUA
 no: Kun for US markedet
 da: Kun til brug i USA
 fi: Vain USA:n markkinolle
 pl: Wyłącznie dla rynku Stanów Zjednoczonych
 el: Μόνο για την αγορά των ΗΠΑ
 tr: Sadece Amerika Birleşik Devletleri pazar için
 cs: pouze pro prodej v USA
 hu: Kizárólag az amerikai piacra.
- (3) fr: Fabriqué pour
 de: Hergestellt von
 es: Fabricado por
 it: Prodotto da
 sv: Tillverkad för
 pt: Fabricado para
 no: Produisert for
 da: Produceret for
 fi: Valmistettu
 pl: Wyprodukowano dla
 el: Κατασκευάζεται για την
 tr: Aşğıdaki için üretildiştir
 cs: Vyrobeno pro
 hu: Gyártott.
- (4) fr: Service clients, commande
 de: Kundendienst, Bestellung
 es: Gestión de Clientes, pedidos
 it: Servizio Clienti, ordini
 sv: Kundenservice, beställning
 pt: Serviço de clientes, encomendas
 no: Kundeservice, bestilling
 da: Kundeservice, bestilling
 fi: Asiakaspalvelu, tilauksia
 pl: Obsługa klienta, zamówienia
 el: Εξυπηρέτηση πελατών, παραγγελίες
 tr: Müşteri Servisi, sipariş
 cs: Zákaznický servis, objednávky
 hu: Vevőszolgálat, megrendelés
- (5) fr: Support technique
 de: Technische Beratung
 es: Soporte Técnico
 it: Supporto tecnico
 sv: Teknisk support
 pt: Apoio Técnico
 no: Teknisk support
 da: Teknisk support
 fi: Tekninen tuki
 pl: Wsparcie techniczne
 el: Τεχνική Υποστήριξη
 tr: Teknik destek
 cs: Technická podpora
 hu: Technikai támogatás.

VenaTech® LP
Brachial Introducer System (Antecubital)

REF: 04439985



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For US market only:²³⁾

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