

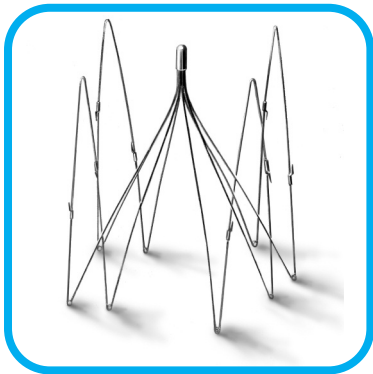
VenaTech® LP

Brachial Introducer System (Antecubital)

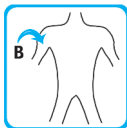
[For US market only: Vena Cava Filter
Brachial Introducer System (Antecubital)]⁽¹⁾

REF. 04439985

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CE
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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

CESKY 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 προσπέλαση
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 incluídos
no: OBS! Slå opp i vedlagte dokumenter
da: Forsigtighed, se vedlagte dokumenter
fi: Lue käyttöohje
pl: Ostrzeżenie, sprawdź 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 EO

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: Sterilointimenetelmänä etyleenioksidillä
pl: Sterylizowany przy użyciu tlenku etylenu
el: Αποστείρωση με αιθυλενοξειδίο
tr: Etilen oksit ile sterilize edilmiştir.
cs: Sterilizováno ethylenoxidem
hu: Etylen oxid-al sterilizált



en: Use by date
fr: À 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

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 **96 cm 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)
- PTFE coated "J" guide, length = 180cm, diameter = 0.89mm (0.035 in)

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, resterilized 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.



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B. Braun Medical

204, avenue du Maréchal Juin
BP 331
92107 Boulogne Cedex
FRANCE

Information :

Fax : 33 5 49 52 88 77

- (1) fr: Pour le marché américain uniquement : Système d'introducteur Brachial (Antécubital) 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 Brachial introducerings system, (Antecubital)
 fi: Vain USA:n markkinoille : 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 κοιλής φλέβας
 tr: Sadece Amerika Birleşik Devletleri pazarı 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 rendszerről (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 markkinoille
 pl: Wyłącznie dla rynku Stanów Zjednoczonych
 el: Μόνο για την αγορά των ΗΠΑ
 tr: Sadece Amerika Birleşik Devletleri pazarı 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: Produsert for
 da: Produceret for
 fi: Valmistettu
 pl: Wyprodukowano dla
 el: Κατασκευάζεται για την
 tr: Aşajıdaki için üretilmiştir
 cs: Vyrobeno pro
 hu: Gyártott.
- (4) fr: Service clients, commande
 de: Kundendienst, Bestellung
 es: Gestión de Clientes, pedidos
 it: Servizio Clienti, ordini
 sv: Kundservice, 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:⁽²⁾

Manufactured for:⁽³⁾
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www.bisusa.org

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Fax: (610) 849-1334

Technical support:⁽⁵⁾
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