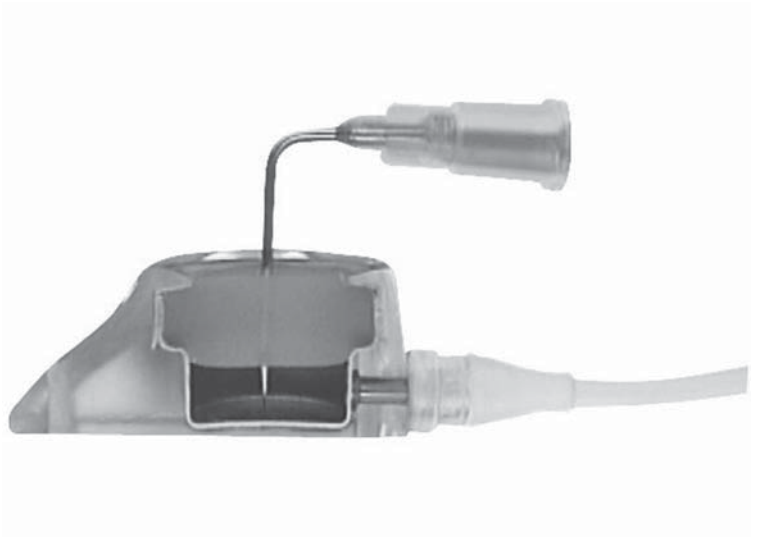
Celsite®



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CE
0459

B|BRAUN

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X1900 Ed08 (08/2013)

B|BRAUN

en: Description of the Device: Celsite® Access Ports are totally implantable access devices. The system consists of an access port, with a silicone septum, which is connected to a catheter. The catheter may be made of Silicone (Si), Polyurethane (PUR) or Polyamide (PA) depending on the reference. Access to the system is via percutaneous injection using a special non-coring needle. Both the port and the catheter are radio-opaque.

MR Information

General Information

According to IEC Standard 60601-2-33(2008), the scanner must be operated in Normal Operating Mode (defined as the mode of operation of the MR system in which none of the outputs have a value that causes physiological stress to the patient):

The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg

The head SAR must be < 3.2 W/kg

Device Information

MR Conditional

The Celsite® Access Ports was determined to be MR-Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Non-clinical testing demonstrated that the Celsite® Access Ports is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

Static magnetic field of 3-Tesla and 1.5-Tesla

Maximum spatial gradient magnetic field of 710 Gauss/cm or less

Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning

MRI-Related Heating

In non-clinical testing, the Celsite® Access Ports produced the maximum temperature rise during MRI performed for 15-min (i.e., per pulse sequence) in 3-Tesla (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as:

MRI Condition	MR System Reported, Maximum Whole Body Average SAR (W/kg)	Calorimetry Value (W/kg)	Highest Temperature Change	Time for MRI (per pulse sequence)
3-T / 128-MHz	2.9	2.7	2.2 °C	15 min

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Celsite® Access Ports. Therefore, optimization or MR imaging parameters to compensate for the presence of this device may be necessary.

fr : Description du dispositif : Les chambres implantables Celsite® sont des dispositifs totalement implantables. Ce dispositif est constitué d'une chambre avec un septum en silicone relié à un cathéter. Le cathéter peut être en silicone (Si), en polyurethane (PUR) ou en polyamide (PA) en fonction de la référence. L'accès au dispositif se fait par injection percutanée à l'aide d'une aiguille atraumatique, spécialement adaptée à la ponction des chambres implantables. La chambre et le cathéter sont radio opaques.

Informations sur IRM

Informations générales

Selon la norme 60601-2-33(2008) de la CEI, l'IRM doit être utilisé en mode de fonctionnement normal (défini comme étant le mode de fonctionnement dans lequel aucun réglage du système n'a de valeur susceptible de provoquer un stress physiologique chez le patient) :

Le taux d'absorption spécifique (TAS) moyen pour tout le corps doit être ≤ 2,0 W/kg ;

Le TAS pour la tête doit être < 3,2 W/kg

Informations sur le dispositif

Compatible sous conditions avec la RM

Les chambres implantables Celsite® ont été définies comme étant compatibles sous conditions avec la RM, selon la terminologie utilisée par la Société américaine des analyses et des matériaux [American Society for Testing and Materials, ASTM], Désignation internationale : F2503-08. Pratiques normalisées pour le marquage des dispositifs médicaux et des autres dispositifs de sécurité dans l'environnement d'un système d'imagerie par résonance magnétique.

Des tests non cliniques ont démontré que les chambres implantables Celsite® étaient compatibles sous conditions avec la RM. Un patient avec ce dispositif peut tout à fait être soumis à une imagerie par résonance magnétique, juste après sa mise en place, en respectant les conditions suivantes :

Champ magnétique statique de 3 Tesla et 1,5 Tesla ;

Gradient spatial maximal du champ magnétique de 710 Gauss/cm ou moins ;

Taux d'absorption spécifique (TAS) moyen maximum pour tout le corps de 2,9 W/kg pendant 15 minutes de procédure d'imagerie.

Production de chaleur liée à l'IRM

Dans les tests non cliniques, les chambres implantables Celsite® ont produit l'augmentation maximale de température au cours d'une IRM de 15 mn (par exemple, en séquence d'impulsions) effectuée dans un système de RM de 3 Tesla (Excite HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, Wisconsin):

Réglages de l'IRM	TAS moyen maximum pour tout le corps du système de RM (W/kg)	Valeur calorimétrique (W/kg)	Changement maximal de température	Durée de l'IRM (par fréquence d'impulsions)
3 T / 128 MHz	2,9	2,7	2,2 °C	15 min

Informations sur les artefacts

La qualité de l'image par résonnance magnétique peut être altérée si la zone étudiée se superpose ou est relativement proche du site des chambres implantables Celsite®. Par conséquent, une optimisation des paramètres de l'IRM peut être nécessaire pour compenser la présence de ce dispositif.

de: Beschreibung des Systems: Celsite® Portkatheter-Systeme sind vollständig implantierbar. Das System besteht aus einer Portkanüle mit Silikon-Septum, das mit dem Katheter verbunden ist. Der Katheter kann je nach Referenz aus Silikon (Si), Polyurethan (PUR) oder Polyamid (PA) bestehen. Der Zugang zum System erfolgt mittels einer perkutanen Injektion mit einer speziellen Nadel ohne Stanzeffekt. Der Port und der Katheter sind röntgendurchlässig.

MR Information

Allgemeine Information

Gemäß dem IEC Standard 60601-2-33(2008), muss der Scanner im Betriebsmodus Normal verwendet werden (definiert als der Betriebsmodus des MR-Systems, in dem keiner der Outputs Werte hat, die für den Patienten zu physiologischen Belastungen führen):

Die durchschnittliche spezifische Absorptionsrate (SAR) für den ganzen Körper muss ≤ 2,0 W/kg sein

Die Kopf-SAR muss < 3,2 W/kg sein

Geräteinformation

MR Conditional

Die Celsite® Access Ports sind gemäß der von der "American Society for Testing and Materials International" (ASTM) "MR-Conditional", Bezeichnung: F2503-08. Standardverfahren zur sicheren Kennzeichnung medizinischer Geräte und anderer Gegenstände für Magnetresonanzumgebungen.

Außerklinische Tests haben gezeigt, dass Celsite® Access Ports "MR Conditional" sind. Patienten mit diesem Gerät können unmittelbar nach der Platzierung sicher gescannt werden, dabei gelten die folgenden Voraussetzungen:

Statisches Magnetfeld von 3-Tesla und 1,5-Tesla

Maximales Magnetfeld mit einem räumlichen Gradienten von 710 Gauss/cm oder weniger

Durchschnittliche spezifische Absorptionsrate (SAR) für den ganzen Körper höchstens 2,9 W/kg für einen Scanvorgang von 15 Minuten

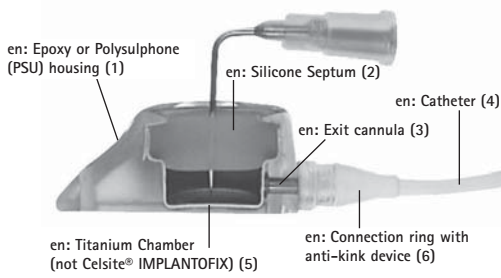
MRI-bedingte Erwärmung

In außerklinischen Tests bewirkten die Celsite® Access Ports während einer 15-minütigen MRI (d.h. pro Pulssequenz) in 3-Tesla (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR Systemen eine maximale Temperaturerhöhung von:

MRI Bedingung	MR System-Ausgabe, Maximal SAR Ganzkörperdurchschnitt (W/kg)	Kalorimetrie-Wert (W/kg)	Größte Temperaturänderung	Zeit für MRI (pro Pulssequenz)
3-T / 128-MHz	2,9	2,7	2,2 °C	15 min

Produktinformation

Die MR Bildqualität kann beeinträchtigt werden, wenn sich der betroffene Bereich genau an der oder in der Nähe der Position des Celsite® Access Ports befindet. Daher kann eine Optimierung der MR-Bildparameter erforderlich sein, um die Präsenz des Gerätes zu kompensieren.



(1)

fr : Boîtier en époxy ou en polysulphone (PSU)
de: Gehäuse aus Epoxid oder Polysulphon (PSU)
es: Cubierta de epoxy o polisulfona (PSU)
it: Guscio esterno in resina epossidica o polisulfone (PSU)
sv: Hus av epoxi eller polysulfon (PSU)
pt: Bolsa de epoxy ou polisulfona (PSU)
zh: 环氧树脂或聚砜(PSU)外部包装
ru: Наружная камера порта из эпоксидной смолы или полисульфона (PSU)
nl: Epoxy- of polysulfoon (PSU) behuizing
no: Ramme av epoksy eller polysulfon (PSU)
da: Epoxy- eller polysulfon- (PSU) hus
fi: Epoksi- tai polysulfoni-kotelo (PSU)
pl: Obudowa z żywic epoksydowych lub polisulfonu (PSU)
el: Περίβλημα εποξικής ρητίνης ή πολυσουλφόνης (PSU)
tr: Epoksi veya Polisülfon (PSU) gövde
cs: Pouzdro z epoxidu nebo polysulfonu (PSU)
th: กระเปาะอีพอกซี่หรือโพลีซัลโฟน (PSU)
ko: 에폭시 혹은 폴리설폰(PSU) 포장
vi: Vị trí Epoxy hoặc Polysulphone (PSU)
ro: Carcasă din răşină epoxi sau polisulfona (PSU)
bg: Кожух от епоксидна смола или полисулфон (PSU)
et: Epoksüvaigust või polüsulfoonist (PSU) korpus
hu: Epoxi vagy poliszulfon borítás (PSU)
lt: Epoksido arba polisulfono (PSU) korpusas
sk: Puzdro z epoxidu alebo polysulfonu (PSU)

(2)

fr : Septum en silicone
de: Silikon-Septum
es: Séptum de silicona
it: Setto in silicone
sv: Silikonmembran
pt: Septo de silicone
zh: 硅胶隔膜
ru: Силиконовая мембрана
nl: Siliconenseptum
no: Silikonseptum
da: Silikoneseptum
fi: Pistokalvo silikonia
pl: Silikonowa membrana
el: Διάφραγμα σιλικόνης
tr: Silikon Septum
cs: Silikonové septum
th: ผนังยางซิลิโคนสำหรับแทงเข็ม
ko: 실리콘 격막
vi: Vách ngăn Silicone
ro: Perete despărţitor din silicon
bg: Силиконова мембрана
et: Silikoonist membraan
hu: Szilikon szeptum
lt: Silikoninė pertvara
sk: Silikónové septum

(3)

fr : Cannule de sortie
de: Auslasskanüle
es: Cánula de salida
it: Cannula di uscita
sv: Utloppsrör
pt: Extremidade da cânula
zh: 出口套管
ru: Выводная канюля
nl: Uitgangscanule
no: Utgangs-kanyle
da: Udgangs-kanyle
fi: Ulostulokanyyli
pl: Kaniula wyjściowa
el: Σωληνισκος εξόδου
tr: Çıkış kanülü
cs: Výstupní kanyla
th: ท่อต่อระหว่างกระเปาะกับสายสวน
ko: 삽입관 출구
vi: Ống dò thoát
ro: Canulă de ieşire
bg: Изходна канюла
et: Väljaviiv kanüül
hu: Kivezető kanül
lt: Išėjimo kaniulė
sk: Výstupná kanyla

(4)

fr : Cathéter
de: Katheter
es: Catéter
it: Catetere
sv: Kateter
pt: Cateter
zh: 导管
ru: Катетер
nl: Katheter
no: Kateter
da: Kateter
fi: Katetri
pl: Cewnik
el: Καθετήρας
tr: Kateter
cs: Katétr
th: สายสวน
ko: 카테터
vi: Ống thông dò
ro: Cateter
bg: Катетър
et: Kateeter
hu: Katéter
lt: Kateteris
sk: Katéter

(5)

fr : Réservoir en titane (sauf Celsite® IMPLANTOFIX)
de: Titankammer (nicht Celsite® IMPLANTOFIX)
es: Cámara de titanio (no Celsite® IMPLANTOFIX)
it: Camera in titanio (non in Celsite® IMPLANTOFIX)
sv: Titankammare (ej Celsite® IMPLANTOFIX)
pt: Câmara de titânio (excepto para o porte Celsite® IMPLANTOFIX)
zh: 钛腔(Celsite® IMPLANTOFIX 不带钛腔)
ru: Внутренняя титановая камера (нет в Celsite® IMPLANTOFIX)
nl: Titaniumkamer (niet bij Celsite® IMPLANTOFIX)
no: Titaniumkammer (ikke Celsite® IMPLANTOFIX)
da: Titankammer (ikke Celsite® IMPLANTOFIX)
fi: Titaanikammio (paitsi Celsite® IMPLANTOFIX)
pl: Komora tytanowa (nie dotyczy portów Celsite® IMPLANTOFIX)
el: Κάψα τιτανίου (όχι Celsite® IMPLANTOFIX)
tr: Titanyum hazne (Celsite® IMPLANTOFIX de yok)
cs: Titanová komůrka (ne Celsite® IMPLANTOFIX)
th: กระเปาะไททาเนียม (ยกเว้นเซลไซต์ รุ่มอิมพลานโทฟิก)
ko: 티타늄 챔버 (셀싸이트® 임플란토픽스 제외)
vi: Khoang Titanium (không phải Celsite® IMPLANTOFIX)
ro: Rezervor din titan (cu excepţia lui Celsite® IMPLANTOFIX)
bg: Камера от титан (не при Celsite® IMPLANTOFIX)
et: Titaanist kamber (mitte Celsite® IMPLANTOFIX)
hu: Titán kamra (kivéve a Celsite® IMPLANTOFIX)
lt: Titano kamera (išskyrus Celsite® IMPLANTOFIX)
sk: Titánová komôrka (nie Celsite® IMPLANTOFIX)

(6)

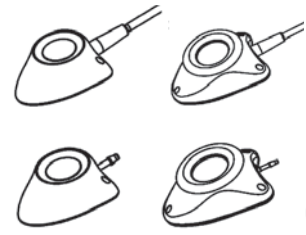
fr : Bague de connexion avec système antiplicature
de: Konnektionsring mit Knickschutz
es: Rosca de conexión con dispositivo anti-acodamiento
it: Anello di collegamento con dispositivo anti-piegamento
sv: Kopplingsring med knickskydd
pt: Anel de conexão com dispositivo antidobra
zh: 带有反纠结装置的联接环
ru: Соединительное кольцо с защитным устройством от скручивания
nl: Aansluitingsring met antikinkvoorziening
no: Koplingsring med innretning mot knekk
da: Forbindelsesring med knækbeskyttelse
fi: Kiinnitysrengas kinkkauksenestolla
pl: Pierścień łączący, wyposażony w urządzenie zapobiegające zaginaniu się przewodów
el: Συνδετικός δακτύλιος με διάταξη κατά της συστροφής
tr: Anti-kink parçacıklı bağlantı halkası
cs: Spojovací kroužek zajištěný proti zalomení
th: วงแหวนสำหรับครอบกับอุปกรณ์เพื่อป้องกันสายสวนหักงอ
ko: 비틀림 방지 장치를 가진 연결 고리
vi: Vòng kết nối với thiết bị chống xoắn
ro: Inel de conectare cu dispozitiv de anti-buclare
bg: Съединителен пръстен с устройство против прегъване
et: Ühendusrõngas keerdumisvastase seadmega
hu: Csatlakozó gyűrű csavarodásgátló eszközzel
lt: Jungiamasis žiedas su apsauginiu įtaisu nuo susisukimo
sk: Spájací krúžok zaistený proti zalomeniu

(en) Contents: Refer to unit package label for actual content list.
(fr) Contenu : Se référer à l'étiquette de l'emballage individuel pour la liste du contenu.
(de) Inhalt: Die Auflistung der Bestandteile entnehmen Sie bitte der Packungsbeilage.
(es) Contenido: Observar la etiqueta del embalaje de la unidad para consultar la lista de contenidos.
(it) Contenuto: Fare riferimento all'etichetta sulla confezione dell'unità per l'elenco del contenuto effettivo.
(sv) Innehåll: Se etikett på enhetens förpackning beträffande aktuellt innehåll.
(pt) Conteúdo: Consultar o folheto informativo para saber a lista de componentes.
(zh) 物品目录：包装内物品清单请参见产品包装上的标注.
(ru) Комплектация: для полного списка комплектации обратитесь к наклейке на упаковке устройства.
(nl) Inhoud: Zie het verpakkingslabel van de unit voor de inhoudslijst.
(no) Innhold: Se etiketten på forpakninen for aktuell innholdsliste.
(da) Indhold: Der henvises til enhedens emballageetiket for liste over det aktuelle indhold.
(fi) Sisältö: Varmista yksikköpakkauksen nimiöstä pakkauksen sisältö.
(pl) Zawartość: Faktyczna zawartość podana na opakowaniu.
(el) Περιεχόμενο: Αναφερθείτε στην επισήμανση της συσκευασίας του προϊόντος για τον ακριβή κατάλογο περιεχομένω.
(tr) İçerik: içerdiği maddeler için ambalajınvn üzerindeki etikete bakınız.
(cs) Obsah: Aktuální seznam je uveden na obalu.
(th) ส่วนประกอบใน 1 ชุด ประกอบด้วยรายการต่าง ๆ ตามรายการ ดังนี้
(ko) 내용물: 실제 내용물 목록은 각 포장 라벨을 참조
(vi) Nội dung: Tham khảo nhãn bao gói cho danh mục nội dung thực tế.
(ro) Conținut: Consultați eticheta de pe pachetul dispozitivului pentru a vedea lista conținutului actual.
(bg) Съдържание: Вижте листовката в опаковката на устройството за списък на действителното съдържание.
(et) Sisu: Pakendi täpset sisu vaadake komponendi pakendi sildilt.
(hu) Tartalom: a tényleges tartalomlistáról a csomagolási egység címkéje ad tájékoztatást
(lt) Turinys: Realaus turinio sąrašas nurodytas gaminio pakuotės etiketėje.
(sk) Obsah: Aktuálny zoznam je uvedený na obale.


Celsite® Discreet


Celsite® IMPLANTOFIX


Celsite® Concept


Celsite®

en Access port
fr Chambre implantable
de Port
es Reservorio de acceso
it Port di accesso
sv Injektionsport
pt Porte de acesso
zh 埋入式输液壶
ru Порт
nl Patiënt port
no Port
da Adgangsport
fi Implantoitava portti
pl Port dostępu
el Κάψα προσβάσεως
tr Erişim portu
cs Vstupní port
th อุปกรณ์ช่องนำเข้าถึง
ko 접근 포트
vi Cổng truy cập
ro Port de acces
bg Порт за достъп
et Ligipääsuport
hu Beültetett port
lt Prieigos portas
sk Vstupný port

1 F = 0,33 mm

en Connection rings (x2)
fr Bagues de connexion (x2)
de Konnektionsringe (x2)
es Dispositivo de seguridad del catéter (x2)
it Fermi per catetere (x2)
sv Fixeringsdon till katetern (x2)
pt Dispositivo de segurança do cateter (x2)
zh 连接套环 (x2)
ru Соединительные муфты (2)
nl Katheter-Koppelstukken (x2)
no Kateter sikringsutstyr (x2)
da Kateter-fastgørelsesanordninger (x2)
fi Kiinnitysrenkaat (x2)
pl Pierścienie łączące (x2)
el Συνδετικοί δακτύλιοι (x2)
tr Bağlantı halkaları (x2)
cs Kroužky k zajištění katétru (x2)
th วงแหวนสำหรับครอบอุปกรณ์ (x2)
ko 연결 고리 (x2)
vi Các loại vòng nối (x2)
ro Inele de conectare (2)
bg Съединителни пръстени
et Ühendusrõngad (x2)
hu Csatlakozó gyűrű (x2)
lt Jungiamieji žiedai
sk Krúžky na zaistenie katétra (x2)

en J guide wire
fr Guide J
de Seldinger-Draht mit «J» -Spitze
es Guia en J
it Guida J
sv J-ledare
pt Fio guia J
zh J头导丝
ru J-образный проволочный проводник
nl J-voerdraad
no J guide wire
da J fremføringsledning
fi J ohjainvaijeri
pl Prowadnica J
el Συρμάτινος οδηγός J
tr J kılavuz teli
cs Vodicí drát J
th เส้นลวดนำร่อง
ko J형 유도선
vi Dây dẫn J
ro Fir de ghidare J
bg J-образен гъвкъв метален водач
et J-kujuline juhtetraat
hu J vezetődrót
lt J kreipiamoji viela
sk Vodiaci drôt J

en Catheter
fr Cathéter
de Katheter
es Catéter
it Catetere
sv Kateter
pt Cateter
zh 导管
ru Катетер
nl Catheter
no Kateter
da Kateter
fi Katetri
pl Cewnik
el Καθετήρας
tr kateter
cs Katétr
th สายสวน
ko 카테터
vi Ống thông
ro Cateter
bg Катетър
et Kateeter
hu Katéter
lt Kateteris
sk Katéter

en Syringe
fr Seringue
de Spritze
es Jeringa
it Siringa
sv Spruta
pt Seringa
zh 注射器
ru Шприц
nl Spuit
no Sprøyte
da Sprøjte
fi Ruisku
pl Strzykawka
el Σύριγγα
tr Şırınga
cs Injekční stříkačka
th กระบอกฉีดยา
ko 주사기
vi Ống tiêm
ro Seringă
bg Спринцовка
et Süstal
hu Fecskendő
lt Švirkštas
sk Injekčná striekačka

en Thin wall needle 18G/20G
fr Aiguille à corps fin 18G/20G
de Dünnwandkanüle 18G/20G
es Aguja de cuerpo fino 18G/20G
it Ago a corpo fine 18G/20G
sv Tunn väggnål 18G/20G
pt Agulha de parede fina 18G/20G
zh 18 G/20G 薄壁 穿刺针
ru Тонкостенная игла 18G/20G
nl Dunne wand naald 18G/20G
no Tynnvegget nål 18G/20G
da Tyndvægsnål 18G/20G
fi Ohutseinnämäinen neula 18G/20G
pl Igła cienka 18G/20G
el Βελόνα λεπτή 18G/20G
tr İnce cidarlı iğne 18G/20G
cs Tenká žilní jehla 18G/20G
th เข็มแบบผนังบาง เบอร์ 18G/20G
ko 벽이 얇은 바늘 18G/20G
vi Kim tiêm thành mỏng 18G/20G
ro Ac subțire 18G/20G
bg Тънкостенна игла 18G/20G
et Õhukese seinaga nõel (18G/20G)
hu Vékony falú tű 18G/20G
lt Plonasienė adata 18G/20G
sk Tenká žilová ihla 18G/20G

en Vein lifter
fr Lève veine
de Venenheber
es Elevador de vena
it Dispositivo per il repertamento del vaso
sv Venelevator
pt Elevador da veia
zh 血管拔
ru Веноподъемник
nl Vene teugel
no Vene løfter
da Åreløfter
fi Suonen kohottaja
pl Podnośnik żyły
el Φλεβικός ανασπαστήρας
tr Damar kaldırıcı
cs žilní elevátor
th ตัวยกหลอดเลือดดำ
ko 정맥 올림기
vi Vật nâng tĩnh mạch
ro Ridicător de venă
bg Венозен филтър
et Veenitõstja
hu Véna kiemelő
lt Venos kėliklis
sk Žilový elevátor

en Winged Surecan®
fr Surecan® à ailettes
de Surecan® mit Fixierflügeln
es Surecan® con alas
it Surecan® con alette
sv Surecan® med vingar
pt Surecan® com asas
zh 带蝴蝶翼 SURECAN® 无损穿刺针
ru Игла Surecan® с крылышками
nl Surecan® naalden met fixatievleugels
no Surecan® med vinger
da Surecan® med vinger
fi Surecan®-neula siivillä
pl Surecan® ze skrzydełkami
el Surecan® με πτερύγια
tr Kanatlı Surecan®
cs Surecan® s křidélky
th เข็มชัวร์แคนแบบมีปีก
ko 날개 장착한 슈어캔®
vi Kim cánh Surecan®
ro Surecan® cu aripioare
bg Surecan® с крилца
et Nõel Winged Surecan®
hu Szárnyas Surecan®
lt Surecan® su sparneliais
sk Surecan® s krídelkami

en Surecan® needle 22G (x2)
fr Aiguille Surecan® 22G (x2)
de 22G Surecan®-Portkanüle (x2)
es Agujas 22G Surecan® (x2)
it Aghi Surecan® 22G (x2)
sv Surecan®-nålar 22G (x2)
pt Agulha Surecan® de 22G (x2)
zh 22G SURECAN® 无损穿刺针 (x2)
ru Игла Surecan® 22G (2)
nl 22G Surecan®-naalden (x2)
no 22G Surecan®-kanyler (x2)
da 22G Surecan® nåle (x2)
fi 22G Surecan®-neula (x2)
pl Igła Surecan® 22G (x2)
el Βελόνα Surecan® 22G (x2)
tr 22G Surecan® kanül (x2)
cs Jehla 22G Surecan® (x2)
th เข็มชัวร์แคนเบอร์ 22 (x2)
ko 슈어캔® 바늘 22G (x2)
vi Kim Surecan® 22G (x2)
ro Ac Surecan® 22 G (2)
bg Surecan® игла 22G (x2)
et Nõel Surecan® (22G) (x2)
hu Surecan® tű 22G (x2)
lt Surecan® adata 22G (x2)
sk Ihla 22G Surecan® (x2)

en Dilator 6F
fr Dilatateur 6F
de Dilatator 6F
es Dilatador 6F
it Dilatatore 6F
sv Dilatatorn 6F
pt Dilatador 6F
zh 6F 扩张器
ru Дилататор 6F
nl Dilatator 6F
no Dilatoren 6F
da Dilatatoren 6F
fi Laajennin 6F
pl Rozszerzacz 6F
el Διαστολέας 6F
tr Genişletici 6F
cs Dilatátor 6F
th ตัวขยายขนาด 6 เฟรนช์
ko 확장기 6F
vi Bánh (gân làm trương khí quản) 6F
ro Dilatator 6F
bg Дилататор 6F
et Dilataator 6F
hu Tágító eszköz 6F
lt Plėtiklis 6F
sk Dilatátor 6F

en Tunnelling rod
fr Tunnelliseur
de Tunnelingnadel
es Tunelizador
it Tunnellizzatore
sv Tunnelleringsstav
pt Vareta de tunelização
zh 隧道针
ru туннелизатор
nl Tunnel naald
no Tunneleringsstav
da Tunnelstang
fi Tunnelointineula
pl Tunelizator
el Ραβδίο διανοίξεως σήραγγας
tr Tünel iğnesi
cs Sondička
th แท่งโลหะสำหรับนำสายสวนผ่านเนื้อเยื่อ
ko 터널링 막대
vi Thanh ống dẫn
ro Tijă de tunelizare
bg Образуващ тунел ствол
et Läbistusvarras
hu Vezető pálcika
lt Tunelizatorius
sk Sondička

en Peelable introducer
fr Introducteur pelable
de Spittbare Einführhülse
es Introductor pelable
it Introduttore peel-away
sv Delbar introducer
pt Introdutor descascavel
zh 可撕裂穿刺导鞘
ru Расщепляемый интродьюсе
nl Peel-away introducer
no Splittbar introducer
da Afskrælningsindfører
fi Halkaistava sisäänviejä
pl Osłonka rozrywalna
el Εισαγωγέας με αποσπώμενο περίβλημα
tr Ayrılabilir klavuz
cs Snímatelný zavaděč
th ปลอกใส่นำตัวขยาย
ko 필러블 안내 도관
vi Vật mang có thể loại bỏ vỏ bọc
ro Dispozitiv de introducere exfoliant
bg Обелващ се интродюсер
et Mitmekihiline sisestaja
hu Széttéphető bevezető kanül
lt Nuplėšiamas įvediklis
sk Snímateľný zavádzač

en Splittocan® cannula
fr Canule Splittocan®
de Splittocan® Kanüle
es Cánula Splittocan®
it Cannula Splittocan®
sv Splittocan®-kanyl
pt Cânula Splittocan®
zh Splittocan® 套管针
ru Канюля Splittocan®
nl Splittocan®-canule
no Splittocan®-kanyle
da Splittocan® kanyle
fi Splittocan® kanyyli
pl Kaniula Splittocan®
el Κάνουλα Splittocan®
tr Kanül Splittocan®
cs Kanyla Splittocan®
th เข็มสปริทโตแคน
ko 스플리토캔® 캐뉼러
vi Ống thông dò Splittocan®
ro Canulă Splittocan®
bg Splittocan® канюла
et Kanüül Splittocan®
hu Splittocan® kanül
lt Splittocan® kaniulė
sk Kanyla Splittocan®

en ECG cable
fr Câble ECG
de EKG Kabel
es 1 cable de ECG
it 1 cavo ECG
sv EKG Kabel
pt 1 cablo ECG
zh 心电图连接导线
ru Кабель для ЭКГ
nl ECG kabel
no EKG-kabel
da EKG-kabel
fi EKG-kaapeli
pl Kabel do EKG
el Καλώδιο ΗΚΓ
tr EKG kablosu
cs 1 EKG kabel
th สายเคเบิ้ลสำหรับกระตุ้นหัวใจ (ECG)
ko 심전도 전선
vi Cáp ECG
ro Cablu EKG
bg ЕКГ кабел
et EKG-kaabel
hu EKG-kábel
lt EKG kabelis
sk EKG kábel

en Introcan® i.v. cannula 20G
fr Canule Introcan® 20G
de Introcan®-Kanüle 20G
es Cánula Introcan® 20G
it Cannula Introcan® 20G
sv Introcan®-kanyl 20G
pt Cânula Introcan® 20G
zh 20G Introcan® 静脉留置针
ru Канюля Introcan® 20G
nl Introcan®-canule 20G
no Introcan® Kanyle 20G
da Introcan® kanyle 20G
fi Introcan®-punktioneula 20G
pl Kaniula Introcan® 20G
el Σωληνίσκος Introcan® i.v. 20G
tr Introcan® damar kanülası 20G
cs Nitrožilní kanyla Introcan® 20G
th ไอวี แคทติเตอร์ เมอร์ 20G
ko 인트로캔® 정맥주사용 캐뉼러 20G
vi Ống thông dò Introcan® ví du ống thông dò loại 20G
ro Canulă IV Introcan® 20G
bg Introcan® интравенозна канюла 20G
et I.v. kanüül Introcan (20G)
hu Introcan®-kanül 20G
lt Introcan® i.v. kaniulė 20G
sk Vnútrožilová kanyla Introcan® 20G

en Catheter with mandrin and Y-connector
fr Cathéter avec mandrin et connecteur Y
de Katheter mit Mandrin und Y-Verbinder
es Catéter con mandril y conector Y
it Catetere con mandrino e connettore Y
sv Kateter med införingsanordning och Y-konnektor
pt Cateter com mandril e conector em Y
zh 带探针和Y形接头的导管
ru Катетер с мандреном и Y-коннектором
nl Katheter met mandrijn en Y-connector
no Kateter med mandreng og Y-kopling
da Kateter med dorn og Y-forbindelse
fi Katetri mandriinilla ja Y- yhdistäjä
pl Cewnik z mandrynem i złącznikiem Y
el Καθετήρας με στειλεό και συνδετήρα σχήματος Y
tr Delgili katater ve Y konnektörü
cs Katetr s mandrinem a konektorem Y
th สายสวนพร้อมด้ามจับและมีตัวเชื่อมต่อ
ko 맨드린 및 Y형 연결기 있는 카테터
vi Ống thông có lõi và đầu nối Y
ro Cateter cu mandrin şi conector în Y
bg Катетър с мандрен и Y-образен съединител
et Kateeter toestussüdamiku ja Y-liitmikuga
hu Katéter mandrinnal és Y-elágazóval
lt Kateteris su mandrinu ir Y jungtimi
sk Katéter s mandrinom a konektorom Y

en Screw connector, connection spanner
fr Vis de connection, clé
de Konnektionsring, Schraubenschlüssel
es Conectores de rosca, llave de enroscado
it Connettore a vite, chiave per collegamento
sv Skruvkopplingar, Skruvnyckel
pt Conectores roscados, Chave de conector
zh 螺旋式连接器、连接扳手
ru Соединительный винт, ключ
nl Schroefkoppelingen, Aandraaisleutel
no Skrukopling, Koplingslås
da Strueforbindelser, Tilslutningsnøgle
fi Katetrinyhdistäjä, Katetrin kiristysväline
pl lacznik zakręcany, kluczyk do dokręcania lacznika
el Κοχλιωτός συνδετήρας, κοχλιωτήρας συνδέσεως
tr Vidali Konnektörler, konneksiyon spanneri
cs Sroubovací koncktory, Spojovací klič
th สกูร, ประแจไข
ko 나사형 연결기와 연결 스패너
vi Đầu nối vít, đai ốc kết nối
ro Conector filetat, cheie de piuliţe
bg Винтов съединител, гаечен ключ
et Kruvitav liitmik, liitmiku pinguti
hu Csavaros csatlakozó, csavarkulcs
lt Jungiamasis varžtas, raktas
sk Skrutkovacie konektory, Spájací kľúč

Celsite® ST304

en Access port
fr Chambre implantable
de Port
es Reservorio de acceso
it Port di accesso
sv Injektionsport
pt Porte de acesso
zh 埋入式输液壶
ru Порт
nl Patiënt port
no Port
da Adgangsport
fi Implantoitava portti
pl Port dożylny, dootrzewnowy
el Κάψα πρόσβασης
tr Akses port
cs Přístupový port
th อุปกรณ์ฝังติดกาย
ko 접근 포트
vi Cổng truy cập
ro Port de acces
bg Порт за достъп
et Ligipääsuport
hu Beültetett kanül
lt Prieigos portas
sk Prístupový port

en Screw connector, connection spanner
fr Vis de connection, clé
de Konnektionsring, Schraubenschlüssel
es Conectores de rosca, llave de enroscado
it Connettore a vite, chiave per collegamento
sv Skruvkopplingar, Skruvnyckel
pt Conectores roscados, Chave de conector
zh 螺旋式连接器、连接扳手
ru Соединительный винт, ключ
nl Schroefkoppelingen, Aandraaisleutel
no Skrukopling, Koplingslås
da Strueforbindelser, Tilslutningsnøgle
fi Katetrinyhdistäjä, Katetrin kiristysväline
pl Łącznik zakręcany, kluczyk do dokręcania łącznika
el Κοχλιωτός συνδετήρας, κοχλιωτήρας συνδέσεως
tr Vidali Konnektörler, konneksiyon spanneri
cs Šroubovací koncktory, Spojovací klíč
th สกูร, ประแจไข
ko 나사형 연결기와 연결 스패너
vi Đầu nối vít, đai ốc kết nối
ro Conector filetat, cheie de piuliţe
bg Винтов съединител, гаечен ключ
et Kruvitav liitmik, liitmiku pinguti
hu Csavaros csatlakozó, csavarkulcs
lt Jungiamasis varžtas, raktas
sk Skrutkovacie konektory, Spájací kľúč

en Catheter PUR, anti-kink device, catheter coupling device 19/20G
fr Cathéter PUR, système anti-plicature, système de connexion 19/20G
de PUR Katheter, Knickschutz, Katheterkupplung 19/20G
es Catéter de poliuretano, Dispositivo antiacodamiento, Sistema de unión 19/20G
it Catetere in poliuretano, Dispositivo anti inginocchiamento, Sistema di connessione 19/20G
sv Kateter av polyuretan, Knickskydd, Kopplingsanordning 19/20G
pt Cateter de poliuretano, Dispositivo anti-dobra, conectores roscados 19/20G
zh PUR导管、防纽装置、19/20G 连接器
ru Полиуретановый катетер, приспособление против перекручивания катетера, Устройство для соединения с катетером 19/20G
nl Polyurethaan katheter, anti-knikmechanisme, Koppelingsysteem voor katheter 19/20G
no Polyuretan-kateter, anti-knekk-utslyr, Kateterkoplingssystem 19/20G
da Polyurethankateter, anti-knæk anordninger, Kateter forbindelsessystem 19/20G
fi Polyuretaanikatetri, kinkkauksen estäjä, katetrinyhdistäjä 19/20G
pl Cewnik poliuretanowy, przyrząd zapobiegający załamywaniu się cewnika, łącznik zakręcany 19/20G
el Καθετήρας PUR, αντιστρεβλωτική συσκευή, Σύστημα σύζευξης 19/20G
tr Poliüretan kateter, anti-kink aletleri, kateter konnektörleri 19/20G
cs Katétr z polyuretanu, systém proti zauzlení 19/20G
th สายสวน โพลียูเทน พร้อม อุปกรณ์ป้องกันสายหักงอ และ อุปกรณ์เชื่อมต่อ ขนาด 19/20
ko 폴리우레탄 카테터, 비틀림방지 장치
vi Ống thông PUR, thiết bị chống xoắn, thiết bị nối ống thông 19/20G
ro Cateter PUR, dispozitiv de anti-buclare, dispozitiv de cuplare la cateter 19/20G
bg Катетър PUR, устройство против прегъване 19/20G
et PUR-kateeter, keerdumisvastane seade 19/20G
hu PUR katéter, csavarodásgátló eszköz, katétercsatlakoztató eszköz 19/20G
lt Kateteris PUR, apsauginis įtaisas nuo susisukimo 19/20G
sk Katéter z polyuretánu, systém proti zauzleniu 19/20G

en Catheter PA, anti-kink device, catheter coupling device 19/20G
fr Cathéter PA, système anti-plicature, système de connexion 19/20G
de Polyamid Katheter, Knickschutz, Katheterkupplung 19/20G
es Catéter de poliamida, Dispositivo antiacodamiento, Sistema de unión 19/20G
it Catetere in poliammide, Dispositivo anti inginocchiamento, Sistema di connessione 19/20G
sv Kateter av polyamid, Knickskydd, Kopplingsanordning 19/20G
pt Cateter de poliamida, Dispositivo antidobra, conectores roscados 19/20G
zh PA导管、防纽装置、19/20G 连接器
ru Полиамидный катетер, приспособление против перекручивания катетера, Устройство для соединения с катетером 19/20G
nl Polyamide katheter, anti-knikmechanisme, Koppelingsysteem voor katheter 19/20G
no Polyamid-kateter, anti-knekk-utstyr, Kateterkoplingssystem 19/20G
da Polyamidkateter, anti-knæk anordninger, Kateter forbindelsessystem 19/20G
fi Polyamidikatetri, kinkkauksen estäjä, katetrinyhdistäjä 19/20G
pl Cewnik poliamidowy, przyrząd zapobiegający załamywaniu się cewnika, łącznik zakręcany 19/20G
el Καθετήρας PA, αντιστρεβλωτική συσκευή, Σύστημα σύζευξης 19/20G
tr Poliamid kateter, anti-kink aletleri, kateter konnektörleri 19/20G
cs Katétr z polyamidu, systém proti zauzlení 19/20G
th สายสวนโพลีเอไมด์ พร้อม อุปกรณ์ป้องกันสายสวนหักงอ และ อุปกรณ์เชื่อมต่อ ขนาด 19/20
ko 폴리아미드 카테터, 비틀림방지 장치
vi Ống thông PA, thiết bị chống xoắn, thiết bị nối ống thông 19/20G
ro Cateter PA,dispozitiv de anti-buclare, dispozitiv de cuplare la cateter 19/20G
bg Катетър PA, устройство против прегъване 19/20G
et PA-kateeter, keerdumisvastane seade 19/20G
hu PA katéter, csavarodásgátló eszköz, katétercsatlakoztató eszköz 19/20G
lt Kateteris PA, apsauginis įtaisas nuo susisukimo 19/20G
sk Katéter z polyamidu, systém proti zauzleniu 19/20G

en Syringe
fr Seringue
de Spritze
es Jeringa
it Siringa
sv Spruta
pt Seringa
zh 注射器
ru Шприц
nl Spuit
no Sprøyte
da Sprøjte
fi Ruisku
pl Strzykawka
el Σύριγγα·
tr Enjektör
cs Stříkačka
th กระบอกฉีดยา
ko 주사기
vi Ống tiêm
ro Seringă
bg Спринцовка
et Süstal
hu Fecskendő
lt Švirkštas
sk Striekačka

en Syringe LOR
fr Seringue LOR
de Spritze LOR
es Jeringa LOR
it Siringa LOR
sv Spruta LOR
pt Seringa LOR
zh LOR 注射器
ru Шприц LOR
nl LOR-Spuit
no LOR-Sprøyte
da Sprøjte LOR
fi Ruisku LOR
pl Strzykawka LOR
el Σύριγγα απώλειας αντιστάσεως
tr Enjektör LOR
cs Stříkačka LOR
th กระบอกฉีดยา แอลโออาร์
ko 긴 개방형 눈금을 가진(LOR) 주사기
vi Ống tiêm LOR
ro Seringă LOR
bg Спринцовка LOR
et LOR-süstal
hu LOR fecskendő
lt Švirkštas LOR
sk Striekačka LOR

en STERICAN® needle 20G 70 mm
fr Aiguille STERICAN® 20G 70 mm
de STERICAN® Portkanüle 20G 70 mm
es Aguja STERICAN® 20G 70 mm
it Ago STERICAN® 20G 70 mm
sv STERICAN®-nål 20G 70 mm
pt Agulha STERICAN® 20G 70 mm
zh 20G 70 mm STERICAN® 无损穿刺针 (x2)
ru Игла STERICAN® 20G 70 мм
nl STERICAN®-naald 20G 70 mm
no STERICAN®-kanyle 20G 70 mm
da STERICAN® nål 20G 70 mm
fi STERICAN®-neula 20G 70 mm
pl Igła STERICAN® 20G 70 mm
el Βελόνα STERICAN® 20G 70 mm
tr STERICAN® kanül 20G 70 mm
cs STERICAN® jehla 20G 70 mm
th เข็ม สเตอร์ริแคน เบอร์ 20 G 70 มม
ko 스테리칸® 바늘 20G 70mm
vi Kim STERICAN® 22G 70mm
ro Ac STERICAN® 20G 70 mm
bg Sterican® игла 20G 70mm
et Nõel STERICAN® (20G, 70 mm)
hu STERICAN® tű 20G 70 mm
lt STERICAN® adata 20G 70 mm
sk STERICAN® ihla 20G 70 mm

en Surecan® needle 22G (x2)
fr Aiguille Surecan® 22G (x2)
de 22G Surecan®-Portkanüle (x2)
es Agujas 22G Surecan® (x2)
it Aghi Surecan® 22G (x2)
sv Surecan®-nålar 22G (x2)
pt Agulha Surecan® de 22G (x2)
zh 22G SURECAN® 无损穿刺针 (x2)
ru Игла Surecan® 22G (2)
nl 22G Surecan®-naalden (x2)
no 22G Surecan®-kanyler (x2)
da 22G Surecan® nåle (x2)
fi 22G Surecan®-neula (x2)
pl Igła Surecan® 22G (x2)
el Βελόνα Surecan® 22G (x2)
tr 22G Surecan® kanül (x2)
cs 22G Surecan® jehly (x2)
th เข็มซัวร์แคน เบอร์ 22G (x2)
ko 슈어캔® 바늘 22G (x2)
vi Kim Surecan® 22G (x2)
ro Ac Surecan® 22G (2)
bg Surecan® игла 22G (x2)
et Nõel Surecan® (22G) (x2)
hu Surecan® tű 22G (x2)
lt Surecan® adata 22G (x2)
sk 22G Surecan® ihly (×2)

en Filter 0,2 µ
fr Filtre 0,2 µ
de Flachfilter 0,2 µ
es Filtro de 0,2 µ
it Filtro da 0,2 µ
sv Bakteriefilter 0,2 µ
pt Filtro de 0,2 µ
zh 0.2µ过滤器
ru 0,2 µ Фильтр
nl 0,2 µ filter
no 0,2 µ filter
da 0,2 µ filter
fi 0,2 µ suodatin
pl Filtr 0,2 µ
el Φίλτρο 0,2 µ
tr 0,2 µ filtre
cs 0,2 µ filtr
th ตัวกรองขนาด 0"2 ไมครอน
ko 여과기 0.2µ
vi Bộ lọc kích thước 0,2 µ
ro Filtru 0,2 µ
bg Филтър 0,2µ
et Filter 0,2 µ
hu 0,2 µ szűrő
lt Filtras 0,2 µ
sk 0,2 µ filter

en Tunnelling rod
fr Tunnelliseur
de Tunnelingnadel
es Tunelizador
it Tunnellizzatore
sv Tunnelleringsstav
pt Vareta de tunelização
zh 隧道针
ru туннелизатор
nl Tunnel naald
no Tunneleringsstav
da Tunnelstang
fi Tunneloiintineula
pl Tunelizator
el Ραβδίο διανοίξεως σήραγγας
tr Tünel iğnesi
cs Tunelizátor
th แท่งโลหะสำหรับนำสายสวนผ่านลอด
ko 터널링 막대
vi Thanh ống dẫn
ro Tijă de tunelizare
bg Образуващ тунел ствол
et Läbistusvarras
hu Vezető pálcika
lt Tunelizatorius
sk Sondička

en Tuohy needle 16/18G
fr Aiguille de Tuohy 16/18G
de Tuohy-Kanüle 16/18G
es Aguja Tuohy 16/18G
it Ago Tuohy 16/18G
sv Tuohy-nål 16/18G
pt Agulha Tuohy 16/18G
zh 16/18 G Tuohv 穿刺针
ru Игла Tuohy 16/18G
nl Tuohy-naald 16/18G
no Tuohy-kanyle 16/18G
da Tuohy nål 16/18G
fi Tuohy-neula 16/18G
pl Igła Tuohy 16/18G
el Βελόνα Tuohy 16/18G
tr Tuohy kanül 16/18G
cs Tuohy jehly 16/18G
th เข็มเตาไฮเบอร์ 16/18 G
ko 투오히(Tuohy) 바늘 16/18G
vi Kim Tuohy 16/18G
ro Ac Tuohy 16/18G
bg Tuohy игла 16 /18G
et Nõel Tuohy (16/18G)
hu Tuohy-tű 16/18G
lt Tuohy adata 16/18G
sk Tuohy ihly 16/18G

en Scalpel E10, E11
fr Scalpel E10, E11
de Einmalskalpell E10, E11
es Bisturí E10, E11
it Bisturi per dissezione E10, E11
sv Skalpell E10, E11
pt Bisturi E10, E11
zh E10、E11号手术刀
ru Скальпель E10, E11
nl Scalpel E10, E11
no Skalpell E10, E11
da Skalpel E10, E11
fi Veitsi E10, E11
pl Skalpel E10, E11
el Χειρουργικά μαχαιρίδια μεγέθους E10 και E11
tr Skalpel E10, E11
cs Skalpel E10, E11
th ด้ามมีดเบอร์ 10, 11
ko 외과용 메스 E10, E11
vi Dao mổ E10, E11
ro Scalpel E10, E11
bg Скалпел E10, Ell
et Skalpell E10, E11
hu E10, E11 szike
lt Skalpelis E10, E11
sk Skalpel E10, E11

en Winged Surecan®
fr Surecan® à ailettes
de Surecan® mit Fixierflügeln
es Surecan® con alas
it Surecan® con alette
sv Surecan® med vingar
pt Surecan® com asas
zh 带蝴蝶翼SURECAN®无损穿刺针
ru Игла Surecan® с крылышками
nl Surecan® naalden met fixatievleugels
no Surecan® med vinger
da Surecan® med vinger
fi Surecan®-neula siivillä
pl Surecan® ze skrzydełkami
el Surecan® με πτερύγια
tr Kanatlı Surecan®
cs Surecan® s křídélky
th เข็มซัวร์แคนแบบมีปีก
ko 날개를 장착한 슈어캔®
vi Kim cánh Surecan®
ro Surecan® cu aripioare
bg Surecan® с крилца
et Nõel Winged Surecan®
hu Szárnyas Surecan®
lt Surecan® su sparneliais
sk Surecan® s krídelkami

INSTRUCTIONS FOR USE
Celsite® ACCESS PORTS

PLEASE READ CAREFULLY

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I – INDICATIONS

- Venous Access Ports are intended to be used for repeated intra-venous administration of, for example, chemotherapy, antibiotic and anti-viral drugs, parenteral nutrition, blood sampling or transfusion. Certain Celsite® Access Ports may be used for Contrast Enhanced Computerised Tomography (CECT) using high pressure injection (see "X - High pressure injection"). For full list of validated references please refer to the tables on pages 109 and 110.
- Arterial Access Ports are intended to be used for intra-arterial administration of chemotherapy.
- Epidural or intra-thecal ports are intended to be used for spinal administration of pain relieving drugs.
- Peritoneal ports are intended to be used for intra-peritoneal administration of chemotherapy.
- Peritoneal/Pleural ports are intended to be used for intra-peritoneal administration of chemotherapy, hydration, drainage of malignant ascites, or drainage of malignant pleural effusion.

II – CONTRAINDICATIONS

The following are contraindications to port placement:

- Known infection, bacteraemia or septicaemia.
- Known allergy to any of the materials contained in the access port or catheter.
- If the medications to be used in the access port are incompatible with any of the materials contained in the access port or catheter.
- If the patient's anatomy does not allow the insertion of the catheter into the chosen access site or if the patient has had previous radiotherapy in the chosen area.
- Previous venous thrombosis.
- Heparin induced thrombocytopaenia (Celsite® Interventional with Anthron® catheter only).

III – POTENTIAL COMPLICATIONS (Immediate and delayed)

Air embolism	Cerebral infarction or thrombosis (arterial)	Liver failure (arterial)
Angiospasm (arterial)	Embolism	Pericarditis (arterial)
Angitis (arterial)	Explantation of the port secondary to inflammatory reaction	Pneumothorax
Aneurysm/false aneurysm (arterial)	Fibrin sheath formation	Port/Catheter migration
Brachial plexus injury	Haematoma	Thromboembolism/Thrombophlebitis
Cardiac arrhythmia, tamponade, perforation	Haemothorax	Thrombosis
Catheter disconnection, rupture or fragmentation	Heparin Induced Thrombocytopaenia (HIT)	Ulcer related to cytotoxic drugs (arterial)
Catheter occlusion	Infection/Sepsis	

Before implantation of the access port system these, and other, well documented potential complications should be considered.

IV – WARNINGS

During storage avoid freezing or excessively high temperatures, storage at room temperature is recommended. Anthron® catheters should be protected from light.
Celsite® Access Ports are for single use only, do not re-sterilise the product, or any of the components, and destroy after use. 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.
The product is sterilised using Ethylene Oxide and is sterile and non-pyrogenic in unopened, undamaged, individual packages.
Refer to unit package label for actual content list.
Check the expiry date before use and never implant a device past the expiry date.
Do not remove from the unit carton until ready for use and ensure that all handling and use is under strict aseptic conditions.
This product should not be implanted or accessed except by personnel experienced in the technical and clinical aspects of access ports.

Special Warning for Anthron® catheter:

- The Anthron® catheter is made of PUR with a heparin coating.
- The Anthron® catheter should not be used for blood sampling for coagulation studies as the results may be affected by the release, however small, of heparin.
- As for all heparin, regular supervision of platelet levels is required during the use of the catheter due to the risk of heparin induced thrombocytopenia (HIT).

V – SPECIAL ATTENTION

V-1 PATIENT

Ensure that use of the access port is indicated taking into consideration the patients' anatomy, needs and proposed use of the port.
Check the condition of the skin over the proposed implantation and puncture sites.
For venous catheter placement, place the patient slightly inclined head down.

V-2 CATHETER POSITION

To ensure that the system works correctly, there should be no kinking of the catheter.
It is recommended that the catheter is tunnelled sub-cutaneously to the port.
The position of the tip of the catheter may change when the patient moves.

V-2-1 Venous catheters

a) The catheter tip should always be positioned in the Superior Vena Cava at the entrance to the right atrium taking into account possible catheter tip movement (see Fig. 1, page 115). A radiograph should be taken to verify catheter position and exclude haemothorax or pneumothorax.

b) Particular attention should be paid when the catheter is to be implanted via the sub-clavian route. It is recommended that the catheter be inserted outside the costo-clavicular space (see Fig. 2, page 115). Catheter ruptures have been observed with the sub-clavian route, the associated risk of extravasation of the infused drugs and embolisation of the distal extremity may have serious consequences. This is due to rupture of the catheter secondary to the catheter being pinched in the costo-clavicular space (Pinch-Off syndrome). It is necessary to pay particular attention to catheters used for long periods or for ambulatory patients rather than short term catheters. Catheter rupture can occur with silicone and polyurethane catheters.

The following clinical signs may suggest catheter pinching:

- The patient needs to lift the arm to permit infusion.
- Intermittent malfunction of the catheter, such as difficulty with aspiration or infusion.
- Sub-clavicular pain or swelling during infusion.
- Palpitations or chest discomfort may indicate catheter fracture.

Remove any sub-clavian catheter which presents any of the signs of Pinch-Off.
A radiograph with contrast injection may be useful to detect catheter abnormalities at the costoclavicular level.

V-2-2 Percutaneously placed Arterial catheters (Celsite® InterVentional with Anthron® catheter)

a) It is recommended that the catheter be placed via the femoral artery (see Fig. A, page 114). The entry point into the artery should be below the inguinal ligament. The access port should be positioned on the patient's thigh, medial to the iliac crest, to avoid kinking of the catheter (see Fig. B, page 114). The catheter should not traverse the inguinal ligament sub-cutaneously.

b) If needed, access may be via the axillary (see Fig. B, 2, page 114), acromiothoracic (see Fig. B, 3, page 114) or brachial artery (see Fig. B, 4, page 114). Care should be taken with these routes in patients with diabetes, hyperlipaemia and hyper-tension. The risk of cerebral embolism is higher in these patients.

c) Placement in the sub-clavian artery is not recommended as this may lead to catheter displacement and subsequent fracture, and carries an increased risk of cerebral thrombosis or infarct in case of catheter thrombosis.

V-3 DRUG INCOMPATIBILITIES

Never use incompatible drugs together or in sequence: the port should be rinsed of all residues with 10 mL sodium chloride (NaCl) 0.9% between each medication.

V-4 NEEDLES

V-4-1 Puncture of the Celsite® Access Port

Always use special bevelled needles, such as Surecan®, Winged Surecan® or Cytocan, which are adapted for use with implantable access port systems.
Normal hypodermic needles will damage the septum and may cause leakage of the system or blockage due to small silicone particles.

V-4-2 Puncture of the Vein

Certain references contain a Safety Seldinger needle. The Safety Seldinger needle is designed to reduce the risk of accidental needle stick injury. Care must be taken to avoid needle sticks in accordance with local Infection Control standards (and avoid the risk of exposure to contaminated blood).

Access the vein with the needle in the normal manner. After withdrawal of the Safety Seldinger needle activate the safety clip. To do this grasp the clear clip housing, which houses the metal safety clip, with your free hand. Advance the clear clip housing forward along the Safety Seldinger needle towards the needle bevel in one continuous motion. Advance the clip housing over the needle bevel activating the safety mechanism. The clip will remain on the needle bevel. The clip housing will separate from the clip and needle. Dispose of the needle and the clear clip housing immediately into sharps container.

Do not attempt to re-insert the needle into the patient or to re-cap the needle with the protective guard.

V-5 OCCLUSION

Always use a syringe equal to or greater than 10 mL volume when rinsing the port to avoid generating excessive pressures in case of occlusion of the system.

In case of obstruction of the system never try to clear the blockage using a fluid under high pressure which carries the risk of catheter fracture and migration. According to validated protocols, and under medical supervision, 2 mL of 70% alcohol may be used to aid the unblocking of silicone catheters when the blockage is due to lipid deposits. The use of alcohol with PUR catheters is not recommended.
According to validated protocols, and under medical supervision, 2 mL of Hydrochloric acid (HCl) 0.1 mol/L may be used to aid the unblocking of both silicone and PUR catheters when the blockage is due to mineral deposits.

V-6 INFECTION

In case of infection, if appropriate treat with antibiotic drugs. If this fails, or is not appropriate, the catheter and port should be removed.

VI – IMPLANTATION TECHNIQUES

General considerations :

- To prevent shearing of the guide-wire never withdraw the J guide-wire through the Seldinger needle.
- Remove the guide-wire and the dilator together. Do not remove the guide-wire through the dilator as this may result in the guide-wire unravelling.
- To prevent shearing of the catheter, never withdraw the epidural/spinal catheters through the Tuohy needle.
- It is recommended that NaCl 0.9% (with or without heparin according to local protocols) be used to flush, and lock the port and catheter during implantation (see Fig. 3, page 115).
- During implantation ensure that the catheter is not damaged by unguarded forceps, suture needle or other sharp instruments.
- If using the Celsite® Concept ports (with silicone inserts) it is recommended that the suture be placed within the square indicated on the silicone.
- The catheter should be mounted on the exit cannula along its axis (see Fig. 11 a-b-c, page 115) and not across the axis and should be completely mounted on the exit cannula before the connection ring is slid over the catheter.

VI-1 CENTRAL VENOUS IMPLANTATION TECHNIQUES

VI-1-1 Percutaneous Technique

a) Insert the Seldinger needle into the chosen vein; verify the position by observing blood reflux (see Fig. 4, page 115).
b) Insert the J guide-wire into the vein, when the correct position is reached, withdraw the needle (see Fig. 5, page 115).
c) Thread the assembled dilator and peelable sheath over the guide-wire using a twisting motion to pass through the skin planes (see Fig. 6, page 115).
d) Remove the dilator and guide-wire from the vein and insert the catheter through the peelable sheath (see Fig. 7, page 115) to the desired position at the junction of the Superior Vena Cava and the right atrium (see Fig. 1, page 115). Check catheter tip position using fluoroscopy.
e) Remove the peelable sheath from the vessel by pushing down on the 2 handles of the sheath, then peel the sheath from the catheter ensuring that the catheter is not dislodged from the vessel (see Fig. 8, page 115).
f) Prepare the port pocket at the chosen site, the port should lie approximately 1/2 - 1 cm below the skin surface away from the injection site. Cut the luer connector from the catheter and attach to the tunnelling rod (see Fig. 9, page 115).
g) Tunnel the catheter from the puncture point to the port pocket (see Fig. 10, page 115); ensure there is no kinking of the catheter. Cut the excess catheter (at right-angles) prior to connecting to the port.
h) Catheter port/connection:

- Celsite®, Celsite® Concept, Celsite® Discreet:
Slide the connection ring over the catheter, firmly push the catheter onto the exit cannula ensuring the catheter covers the length of the exit cannula, slide the connection ring over the catheter and exit cannula. The connection ring should be in contact with the port (see Fig. 11c, page 115).

- Celsite® IMPLANTOFIX:
Slide the screw connector over the catheter, firmly push the catheter onto the exit cannula ensuring the catheter covers the length of the exit cannula, slide the screw connector over the catheter and exit cannula. The screw connector should be tightened by hand and the spanner used to give the final tightening to the securement device, until an audible click is heard, to ensure correct attachment between the port and catheter.

- Celsite® Interventional with Anthron® catheter:
If necessary, cut the anti-kink portion of the connection ring to the desired length (a minimum of 1.5 cm should remain), then slide the connection ring over the catheter, firmly push the catheter onto the exit cannula ensuring the catheter covers the length of the exit cannula, slide the connection ring over the catheter and exit cannula. The connection ring should touch the port.

i) Confirm catheter connection by gently pulling on the catheter.
j) Insert the port into the port pocket, paying attention not to kink the catheter.
k) Confirm catheter patency (by ensuring that both aspiration and injection are possible), ensure that the skin incision is 1 cm from the injection site.
l) It is possible to fix the access port to the fascia with sutures.

- Celsite® DRAINAPORT:
Both the connection ring and the catheter must be threaded together on the exit cannula to facilitate connection.

VI-1-2 Surgical Cut-down Technique

a) The skin is incised and the tissue dissected (see Fig. 12, page 115).
b) The selected vessel is identified and tapes passed under it. The vessel is incised with a scalpel or with scissors (see Fig. 13, page 115).
c) The previously flushed catheter is inserted into the vessel, using either a small vessel dilator or vein lifter (see Fig. 14, page 115).
d) Follow from point e) - l) of the preceding paragraph: "Percutaneous Technique".

VI-1-3 References requiring modifications to the above techniques

VI-1-3-1 Over-the Wire Technique

This technique can only be used with the references ST301OTW and Celsite® IMPLANTOFIX references 04438604, 04438647.
Follow steps a) and b) above: "Percutaneous Technique".
c) Thread the dilator over the guide-wire using a twisting motion to pass through the skin planes. Remove the dilator (see Fig. 15, page 115).
d) Flush the catheter with sodium chloride (NaCl) 0.9 %, and pass the catheter over the guide wire to the desired position at the junction of the Superior Vena Cava and the right atrium (see Fig. 1, page 115).
e) Follow from point e) - l) above: "Percutaneous Technique".

VI–1–3–2 Brachial Implantation Technique

Brachial ports and catheters can be placed using either the OTW (Over-the Wire), Percutaneous or Surgical Cut-down Technique, (see Fig. E, page 114).
Select the appropriate vein on the anterior aspect of the elbow, normally the Basilic or Cephalic vein.
Ensure that the access port is not placed over the mid-line of the selected vein. The port and catheter should be positioned above the elbow on the internal surface of the arm.

VI–1–3–3 ECG Technique

This technique can only be used with the ECG references which have specially adapted accessories.

Percutaneous Technique: (see Fig. E, page 114)

a) Place ECG pads on the patient's chest.
b) Follow steps a) to c) above: "Percutaneous Technique".
Note: A separate J-guide wire (0.035") is needed for access to the vein.
c) Prepare the catheter by inserting the specially marked J-guide wire, which is contained in the kit, into the catheter.
d) Remove the J-guide wire and dilator from the sheath and insert the catheter and guide-wire into the peelable sheath. The guide-wire should be pulled back into the catheter during placement into the vein.
e) When approximately 10-13 cm of the catheter has been placed into the vein the guide-wire should be advanced into the catheter until the mark on the guide wire reaches the level of the luer connector on the catheter.
f) When the mark on the guide-wire is at the level of the luer connector the tip of the guide-wire is in the desired position at the tip of the catheter.
g) The sterile ECG cable is attached to the guide-wire, connected to the monitor via a universal adapter and switched to internal monitoring mode. The catheter and guide-wire are advanced using the ECG image to monitor progress.
h) As the catheter approaches the right atrium the P wave starts to elevate ❶. Maximal P wave height is reached and maintained when the catheter enters into the right atrium. Note that the amplitude of the P wave will decrease if the catheter is advanced down into the inferior vena cava. After identifying the area where the P wave begins to develops its maximal amplitude (which corresponds anatomically to the junction between superior vena cava and the right atrium) advance the catheter a further 2 cm ❷. This is the final position of the catheter tip. As the procedure is performed with the patient in the supine position this catheter position allows for the 2-3 cm cranial movement of the catheter which occurs when the patient is upright..
i) Remove the guide-wire while maintaining the catheter in place, flush and clamp the catheter.

Follow from point e) - l) above: "Percutaneous Technique".

A post-operative radiograph should be taken to confirm catheter position and exclude haemothorax or pneumothorax.

Surgical Cut-down Technique: (see Fig. F, page 114)

This technique combines the Surgical Cut-down Technique with the ECG technique described above.
If no ECG change is noted catheter tip position has to be confirmed with fluoroscopy as catheter tip malposition is to be suspected.

The Celsite® Access Port with ECG technique should not be placed if any of the following is applicable to the patient:
- The presence of a cardiac pacemaker.
- Known cardiac abnormalities, or heart rhythm disturbances.
- Access through the Inferior Vena Cava.

With regard to the ECG lead:

Safety regulations according to IEC 601-1 and NF EN 60601-2-25.

Protection against the risks of current leakage:
Only use Class 1 ECG monitor CE marked, with floating input (Type CF).
Connect additional potential equalisation (earth) on the monitor.

Protection against the risks of electrostatic discharge:
- Use only in rooms protected from electrostatic discharge (conductive flooring).
- Theatre shoes should be made of a recommended polymer material.
- Do not allow the J guide-wire to come into contact with external conductive parts.
- Before use, check that all connections are secure.
- Do not autoclave.
- Do not immerse in liquid.
- Repairs must be carried out only by the manufacturer.

VI–1–3–4 Braunule Technique

a) Puncture the vein with the Splittocan® needle percutaneously or through a skin incision.
b) Flush the catheter with sodium chloride (NaCl) 0.9 %. Remove the stilette from the cannula, and insert the catheter through the cannula to the desired position at the junction of the Superior Vena Cava and the right atrium.
c) Gently withdraw the cannula over the catheter.
d) Follow from point e) - l) above: "Percutaneous Technique".
For the ST301M and ST305M, remove the mandrin from the catheter prior to cutting the Y connector off the catheter.

VI–1–3–5 Valved catheter

Do not place the catheter over the guide-wire, as this may cause damage to the valve.
The catheter must be tunnelled from the puncture point to the port pocket; the tunnelling rod must not be placed through the valve.

VI–1–3–6 Pre-connected catheter and port

The catheter should be measured and trimmed to the correct length before insertion in the vein.
The catheter must be tunnelled from the port pocket to the puncture point.

VI–2 ARTERIAL IMPLANTATION TECHNIQUES (FOR H.A.I.T.)

H.A.I.T. = Hepatic Arterial Infusion Therapy

VI–2–1 Surgical Implantation Technique

a) Perform a pre-operative arteriogram.
b) Any accessory arteries to adjacent organs must be embolised.
c) The catheter is sutured to the chosen artery using the suture beads at the tip of the catheter.
d) Perfusion of the organ should be verified after placement of the catheter.
e) Tunnel the catheter to the port pocket, the port should lie approximately 1/2 - 1 cm below the skin surface. Flush the port with sodium chloride (NaCl) 0.9 %.

VI–2–2 Percutaneous implantation Technique

Percutaneous placement of an arterial catheter is generally via the femoral artery. Access may also be via the axillary, acromiothoracic or brachial artery, and can be made either percutaneously or by surgical cut-down, depending on physician's choice.

An introducer should not be used during arterial procedures.
System implantation and catheter placement may be accomplished through a variety of techniques and the physician must choose the appropriate method for the patient and the intended result. Wider application, addition or alteration will be based on the experience of the physician. In the following chapter we present two of the most commonly used techniques for hepatic artery infusion.

VI–2–2–1 Catheter tip in gastro-duodenal artery (see Fig. C, page 114)

Note: The port/catheter reference R305-A5ST has a side hole in the catheter 19 cm from the catheter tip. As the tip of the catheter will be embolised in place no flow occurs from the catheter tip. The taper of the catheter should be trimmed to the correct length (distal to the side hole) before placement in the gastro-duodenal artery so that the flow of medication is not obstructed and the side hole is in the proper hepatic artery.

A rigid 0.018" angiography guide-wire is required for placement of the tapered Anthron® catheter.

As the catheter is embolised in place, removal of the catheter percutaneously may not be possible.

a) An arteriogram should be performed to confirm the location of the tumour, the anatomy of the blood vessels and blood supply to adjacent organs.
b) Any accessory arteries to adjacent organs which arise distally to the proposed location of the side hole should be embolised.
c) Place an exchange guide-wire (minimum length 2 m, diameter 0.018") through the angiography catheter to the desired position in the gastro-duodenal artery.
d) Remove the angiography catheter and place the Anthron® catheter over the guide-wire (do not use an introducer).
e) Remove the guide-wire.
f) A check arteriogram should be performed to confirm catheter position.
g) The tip of the catheter should be fixed in place using embolisation coils, a gluing agent or other means of immobilising the catheter tip, and of embolising the gastro-duodenal artery. Access should be via a contra-lateral approach or through a micro-catheter which permits embolisation. Flow of medication is via the catheter side-hole.
h) In order to prevent displacement of the catheter tip during movement of the patient allow the catheter to sag or loop in the aorta.
Follow from point e) – l): "Percutaneous Technique".

The access port should be placed in the pelvic area ensuring that there is a solid base behind the port.
The port should not be placed over the abdominal cavity.

VI–2–2–2 Catheter tip in hepatic artery (see Fig. D, page 114)

a) An arteriogram should be performed to confirm the location of the tumour, the anatomy of the blood vessels and blood supply to adjacent organs.
b) Any accessory arteries to adjacent organs which arise distally to the proposed location of the catheter tip should be embolised.
c) Place a guide-wire through the angiography catheter to the desired position in the hepatic artery.
d) Remove the angiography catheter and place the Anthron® catheter over the guide-wire (do not use an introducer).
e) Remove the guide-wire.
f) A check arteriogram should be performed to confirm catheter position, function and adequate perfusion of the liver.
g) Ensure that a sufficient length of catheter is left in the aorta to prevent catheter tip displacement during patient movement.
Follow from point e) - l): "Percutaneous Technique".

The access port should be placed in the pelvic area ensuring that there is a solid base behind the port.
The port should not be placed over the abdominal cavity.

VI–3 PERITONEAL AND PLEURAL IMPLANTATION TECHNIQUES

The catheter and port may be implanted either surgically or percutaneously, and may be used for locoregional chemotherapy or for drainage of symptomatic malignant ascites.

VI–3–1 Peritoneal – Surgical implantation Technique

a) During laparotomy the tip of the catheter is placed in the area of interest depending on the indication.
b) The catheter may be sutured to the fascia if the cuffed catheter (Drainaport) is used, and then tunnelled to the port pocket at the base of the ribs.
c) Catheter function and position should be confirmed by flushing the port.
d) The catheter is cut to the desired length and attached to the access port, taking care that the skin incision does not lie over the septum and that the catheter is not kinked anywhere along its length.
e) Confirm catheter and port function before closing the skin.
f) It is possible to fix the access port to the fascia with sutures.

VI–3–2 Peritoneal – Percutaneous implantation Technique

(Implantation accessories are available separately).

a) Identify the desired final position of the catheter tip using ultra-sound guidance.
b) With the 18G needle access the peritoneal cavity sub-cutaneously, taking care not to puncture the intestine. A curved needle may be used to aid entry into the peritoneal space.
c) Pass the 0.035" (0.89mm) guide-wire through the needle into the peritoneal cavity, remove the needle.
d) Pass the 12F dilator over the guide-wire to dilate the catheter route, followed by the 16F peelable sheath. Place the catheter into the desired position in the peritoneal space.
The use of a rigid catheter placed telescopically inside the peritoneal catheter and a super-stiff guidewire may facilitate its placement. Drain any fluid into a sterile bowl.
e) Create a pocket for the access port at the base of the ribs or over the iliac crest. If necessary further tunnel the catheter to the port pocket. It is advisable to have the cuff, if used, in the sub-cutaneous tissue so that tissue in-growth helps maintain catheter position.
f) Trim the catheter to the desired length and attach to the access port, take care that the skin incision does not lie over the septum and that the catheter is not kinked anywhere along its length.
g) Confirm catheter and port function before closing the skin.
h) It is possible to fix the access port to the fascia with sutures.

VI–3–3 Pleural – Percutaneous implantation technique

(Implantation accessories are available separately).

a) Identify the desired puncture point using ultra-sound (US) guidance. If the procedure is performed without US guidance, the puncture point will be marked by aspiration of pleural fluid through the needle used for injecting local anaesthetic.
b) With the 18G needle access the pleural space, taking care not to puncture the lung or liver.
c) Pass the 0.035" (0.89mm) guide-wire through the needle into the pleural cavity, remove the needle.
d) Pass the 12F dilator over the guide-wire to dilate the catheter route, followed by the 16F peelable sheath. Remove the guide-wire and dilator. Place the catheter into the desired position in the pleural space. Drain any fluid into a sterile bowl.
e) Create a subcutaneous pocket for the access port at the base of the ribs. Tunnel the catheter to the port pocket. Place the cuff in the sub-cutaneous tissue so that tissue in-growth helps maintain catheter position.
f) Trim the catheter to the desired length and attach to the access port. Take care that the skin incision does not lie over the septum and that the catheter is not kinked anywhere along its length.
g) Confirm catheter and port function before closing the skin.
h) It is possible to fix the access port to the fascia with sutures.

VI–4 SPINAL IMPLANTATION TECHNIQUES

a) Select the level for introduction of the catheter (L2-L3 or lower), and infiltrate the chosen area with local anaesthetic.
b) Select the position for the port pocket, this should be over a bony structure (the base of the ribs is usually chosen), and infiltrate local anaesthetic.
c) Make a small incision at the chosen entry site and enter the epidural or intra-thecal space using the Tuohy needle.
d) Introduce the catheter into the Tuohy needle using the insertion aid on the catheter, and advance into the chosen position, the catheter is marked at 5 cm intervals to aid placement. It is suggested that a minimum of 5 cm should be placed in the epidural space. The PU catheter should be advanced until the mandrin reaches the end of the needle, the mandrin should then be withdrawn while advancing the catheter into the intra-thecal or epidural space.
e) Remove the Tuohy needle from the puncture site while holding the catheter in a fixed position.
f) To verify the patency of the catheter attach the catheter to the catheter coupling device* (see Fig. 17, page 115). Attempt aspiration and inject 3-5 mL of dilute local anaesthetic for epidural placement. For spinal placement confirm the catheter position by ensuring aspiration of CSF (Cerebro-spinal-fluid) is possible.
g) Prepare the port pocket at the chosen site, the port should lie approximately 1/2 - 1 cm below the skin surface.
h) Thread the anti-kink device onto the catheter and attach the anti-kink device to the fascia with a suture.

i) Attach the catheter to the tunnelling rod, the route of the tunnelling rod may be anaesthetised with local anaesthetic prior to tunnelling. The catheter is then tunnelled to the port pocket. It may be necessary to do this in two or more steps.
j) Cut the catheter, at right-angles, to the desired length allowing sufficient length for patient movement.
k) Slide the connection ring over the catheter; push the catheter onto the exit cannula of the chamber.
The connection ring should be tightened by hand and the spanner used to give the final tightening to the securement device.
l) The assembled port and catheter should again be checked for patency.
m) The chamber may then be sutured into the port pocket, taking care that the skin incision is not at the injection site.

* Attention: confirm that the catheter is pushed to the end of the catheter coupling device before closing to ensure correct function (see Fig. 17, page 115).

VII - USE OF THE PORT AND CATHETER

VII–1 VENOUS PORTS

Always verify that the port and catheter are functional by aspirating 2 mL of blood into a syringe and injecting 5 mL of sodium chloride (NaCl) 0.9% before attempting to start an infusion.
If aspiration of blood is not possible, attempt to slowly inject 2 mL of sodium chloride (NaCl) 0.9% into the port. If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected. In this case, device integrity should be verified using X-ray and contrast media studies.
During treatment, the infusion should be stopped immediately if any pain or swelling is noted or if blood return is absent.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VII–2 ARTERIAL PORTS

Before attempting to start an infusion, verify that the port and catheter are functional. Using a syringe containing sodium chloride (NaCl) 0.9 %, attempt to inject into the port. Current practice is not to verify function by aspiration of blood into the syringe.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VIII - MAINTENANCE OF THE PORT AND CATHETER

General recommendations:

- If heparinised sodium chloride (NaCl) 0.9% is used the system should be rinsed first with sodium chloride (NaCl) 0.9% alone, as some drugs may react with heparin and result in blockage of the port/catheter due to the formation of precipitates.
- Always rinse the system between administration of different drugs. Special care should be taken with drugs which have a higher risk of precipitation, with anti-coagulation agents, after blood sampling or after transfusion to reduce the risk of catheter occlusion.
- Failure to maintain the system may result in occlusion of the catheter.

VIII–1 RINSING AND HEPARINISATION

VIII–1–1 Venous ports

Rinsing of the access port is essential.
Rinse the port with 10 mL of sodium chloride (NaCl) 0.9% after each use and every 4 weeks when no treatment is being given.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VIII–1–2 Arterial ports

Arterial ports and catheters should be rinsed with 10 mL of sodium chloride (NaCl) 0.9% followed by heparinised sodium chloride (NaCl) 0.9% after each treatment and regularly, according to clinical needs (eg every 4 weeks) when no treatment is being given.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VIII–1–3 Epidural or Intra-thecal ports

Sodium chloride (NaCl) 0.9%, 0,5 mL may be used to flush the system after use. Heparin should not be used in an epidural or spinal port.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VIII–1–4 Peritoneal ports

Peritoneal ports may be rinsed with 20 mL sodium chloride (NaCl) 0.9% after each treatment.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

VIII–1–5 Pleural ports

Pleural ports should be rinsed with 20 mL of heparinised sodium chloride (NaCl) 0.9%, initially this should occur weekly. The interval between rinsing may be extended according to clinical needs.

If resistance to injection is noted, or if swelling occurs around the port or along the catheter, device malfunction should be suspected.

IX – DURATION OF IMPLANTATION AND REMOVAL OF THE PORT

IX–1 DURATION OF IMPLANTATION OF THE SYSTEM

The port and catheter system should be removed at the end of treatment.
The duration of the system is mostly dependant on the catheter. Fracture is the most common complication of ageing. Risk of fracture may increase over time depending on the material of the catheter, the pathway, and the entry point of the catheter into the vessel.

IX–2 REMOVAL OF THE SYSTEM

When removing the system, care must be taken not to fracture the catheter. If the catheter is sutured into the vessel, the sutures should first be removed. Control the catheter while removing the system from the port pocket. Be vigilant if there is excessive resistance to the removal of the catheter. Catheters may become encapsulated and attached to the vein wall. Should this occur and it is not possible to remove the catheter without risking catheter fracture, or if the catheter is fractured, the advice of an Interventional Radiologist, Surgeon or other Physician with endo-luminal experience should be sought.
Arterial catheters - If the catheter has been immobilised in an artery, using either coils or gluing techniques, removal of the catheter may not be possible. Attempts at removal may result in fracture of the catheter within the artery and/or vessel injury.

IX–3 SPECIAL ATTENTION: BABYPORT®, BABYPORT® S, BABYPORT® PC AND SMALL PORTS

Following implantation of a port in a child particular attention should be given to the position of the catheter tip. Over time, as the child grows, the position of the catheter tip will change and move higher in the Superior Vena Cava. As for any catheter, a high tip position in the SVC predisposes the catheter to fibrin sheath formation and other mechanical difficulties.
The position of the catheter tip should be checked radiographically a minimum of every 12 months or more frequently if the child is growing quickly. The system should be changed when the tip reaches the level of T4.

X - HIGH PRESSURE INJECTION

SPECIAL ATTENTION

- Always verify that the Celsite® reference implanted is included in the table on page 109 and 110, only these references may be used for high flow rate/high pressure injection.
- Always verify that the port and catheter are functional by aspirating 2 mL of blood into a syringe and injecting 5 mL of sodium chloride (NaCl) 0.9% into the port/catheter before attempting to start an infusion of medication.
- Do not exceed the recommended pressure (325 psi- 22.4 bars) and flow rate as Access Port system failure may occur.
- Contrast media should be warmed to 37°C (98.6°F) before use. According to drug manufacturers recommendations. Failure to follow this recommendation will result in up to 50% lower flow rates and/or Access Port or injection system failure.
- Use only Winged Surecan® (without Y-site) or Angled Surecan® needles.
  Do not use needles which may not withstand high pressure.
- Use only 20G or 22G needles for Babyport® and Brachial ports. Use of 19G needles may lead to leakage of contrast media.
- Ensure that the needle is correctly placed in the port, securely taped to the skin and covered with an adhesive dressing before commencing high pressure injection.
- Catheter lengths more than 20 cm will result in reduction in flow rates.
- Depending on the technical characteristics of the injector system, the target flow rate might not be attained.
- The Access Port system should be flushed with 10 mL of sodium chloride (NaCl) 0.9% before, and after, using the port for CECT, followed by usual rinsing procedures.

		en: Recommended maximum flow rates (mL/s)*[1]						
		Contrast media at 37°C (98,6°F) [3]						
		Viscosity 5,8 mPa.s (cP)** [4]			Viscosity 11,4 mPa.s (cP)** [5]			Recommended maximum pressure setting (CT function) [8]
		Winged / Angled Surecan® needle [7]			Winged / Angled Surecan® needle [7]			
		22G	20G	19G	22G	20G	19G	
	Babyport® - Babyport® PC (1,5 x 0,8 mm)	2	4		1	3		
	Brachial (1,6 x 1,1 mm)	2	4		1	3		
	Brachial L - Brachial R (1,6 x 1,1 mm)	2	4		1	3		
	Babyport® S (2,0 x 1,2 mm)	2	4		2	4		
Double port [9]	ST405L (3,2 x 1,2 mm)	2	5	6	2	4	6	
Small Size Port[10]	STL205P - STR205P (2,1 x 1,4 mm)	2	4	6	2	3	5	
	ST305P (2,1 x 1,4 mm)	2	4	6	2	3	4	
	ST305C - CR305-A5 (1,7 x 1,1 mm)	2	4	5	1	3	4	
	CR305-A6 (2,0 x 1,2 mm)	2	4	7	2	3	4	
	T/ST305 - T/ST205 - ST505 ST315 - ST215 - ST205F ECG (2,2 x 1 mm)	2	4	5	2	3	4	
	STL205F - STR205 F (2,2 x 1 mm)	2	4	5	2	3	4	
	ST305L - ST505L - ST205ECG - ST315L (2,8 x 1,1 mm)	2	4	5	2	3	5	
	ST305M (2,0 x 1,2 mm)	2	4	6	2	3	4	325 psi
	ST305H - ST505H (2,8 x 1,6 mm)	2	5	7	2	4	6	
Double port [9]	ST401L (3,2 x 1,2 mm)	2	5	7	2	4	6	
Standard Size Port[11]	ST301M (2,0 x 1,2 mm)	2	5	8	2	4	5	
	ST301C - ST501C - ST201C - ST301OTW CR301-A5 (1,7 x 1,1 mm)	2	5	6	2	4	5	
	CR301-A6 (2,0 x 1,2 mm)	2	5	6	2	4	6	
	T/ST301F - ST311F T/ST201F - T/ST501F - ST201F ECG (2,2 x 1 mm)	2	5	6	2	4	6	
	T/ST301P - ST201P (2,1 x 1,4 mm)	2	5	6	2	4	6	
	T/ST301 - ST311 T/ST201 - T/ST501 - ST201ECG (2,8 x 1,1 mm)	2	5	6	2	4	6	
	STL201L - STR201L (2,8 x 1,1 mm)	2	5	6	2	4	6	
	ST201H - T/ST301H - ST311H - ST501H (2,8 x 1,6 mm)	2	5	7	2	5	7	
	STL201H - STR201H (2,8 x 1,6 mm)	2	5	7	2	5	7	
	ST301G - ST201G - ST501G (3,2 x 1,6 mm)	2	5	8	2	5	7	

* With a catheter of 20 cm [2]

** Or any contrast media with a similar viscosity at 37°C [6]

en: FOR COUNTRY UNDER CE MARK ONLY / fr: POUR LES PAYS SOUS MARQUAGE CE UNIQUEMENT / de: NUR FÜR LÄNDER MIT GÜLTIGKEIT DES CE ZEICHENS / es: SÓLO APLICABLE A LOS PAÍSES BAJO LA MARCA CE / it: SOLO PER PAESI IN CUI E' NECESSARIO IL MARCHIO CE / sv: ENDAST FÖR LÄNDER MED CE-MÄRKNING / pt: APENAS PARA PAÍSES SUJEITOS A MARCA CE / zh: 仅限CE标志适用国家 / ru: ТОЛЬКО ДЛЯ СТРАН ПОД МАРКОЙ CE / nl: VOOR LANDEN MET CE-MARKERING / no: KUN FOR LAND MED CE MERKING / da: KUN FOR CE MÆRKEDE LANDE / fi: MAAT JOILLA ON CE-MERKINTÄ / pl: WYŁĄCZNIE DLA KRAJÓW UŻYWAJĄCYCH OZNACZNIE CE / el: ΜΟΝΟ ΓΙΑ ΧΩΡΕΣ ΟΠΟΥ ΑΠΑΙΤΕΙΤΑΙ ΠΙΣΤΟΠΟΙΗΣΗ CE / tr: SADECE CE BELGESİNİN GEÇERLİ OLDUĞU ÜLKELER İÇİN / cs: POUZE PRO ZEMI S OZNAČENÍM CE / ko: 유럽연합 통합규격마크 인증 받은 나라만 해당 / vi: CHỈ ÁP DỤNG CHO NHỮNG NƯỚC ĐẠT CHỨNG NHẬN EC / ro: DOAR PENTRU ŢĂRILE CU MARCAJ CE / bg: ЗА ДЪРЖАВИ, ПРИЛАГАЩИ CE МАРКИРОВКА / et: CE MÄRGISTUS / hu: ORSZÁG SZERINTI CE ENGEDÉLY / lt: CE ŠALIMS / sk: IBA PRE KRAJINU S OZNAČENÍM CE

		Recommended maximum flow rates (mL/s)*[1]						
		Contrast media at 37°C (98,6°F) [3]						
		Viscosity 5.8 mPa.s (cP)** [4]			Viscosity 11.4 mPa.s (cP)** [5]			
		Surecan® Safety II			Surecan® Safety II			Recommended maximum pressure setting (CT function) [8]
		22G	20G	19G	22G	20G	19G	
	Babyport® - Babyport®PC (1,5 x 0,8mm)	2	4	-	1	3	-	325 psi
	Brachial (1,6 x 1,1mm)	2	5	-	1	4	-	
	Brachial L - Brachial R (1,6 x 1,1mm)	2	5	-	1	4	-	
	Babyport® S (2,0 x 1,2mm)	2	5	-	1	4	-	
Double port [9]	**ST405L** (3,2 x 1,2mm)	2	5	8	1	4	6	
Small Size port [10]	**STL205P - STR205P** (2,1 x 1,4mm)	2	5	8	1	4	5	
	ST305P (2,1 x 1,4mm)	2	5	8	1	4	5	
	ST305C - CR305-A5 (1,7 x 1,1mm)	2	5	7	1	3	5	
	CR305-A6 (2,0 x 1,2 mm)	2	5	7	1	3	5	
	T/ST305 - T/ST205 - ST505 ST315 - ST215 - ST205F ECG (2,2 x 1mm)	2	5	8	1	4	6	
	STL205F - STR205F (2,2 x 1mm)	2	5	8	1	4	6	
	ST305L - ST505L - ST205ECG - ST315L (2,8 x 1,1mm)	2	5	8	1	3	6	
	ST305M (2,0x 1,2mm)	2	5	8	1	3	6	
	ST305H - ST505H (2,8 x 1,6mm)	2	6	9	1	4	6	
Double port (9)	**ST401L** (3,2 x 1,2mm)	2	5	8	1	4	6	
Standard Size port [11]	**ST301M** (2,0 x 1,2mm)	2	6	7	1	4	6	
	ST301C - ST501C - ST201C - ST301OTW CR301-A5 (1,7 x 1,1mm)	2	5	6	1	3	5	
	CR301-A6 (2,0 x 1,2 mm)	2	5	6	1	3	5	
	T/ST301F - ST311F T/ST201F - T/ST501F - ST201F ECG (2,2 x 1mm)	2	6	7	1	4	5	
	T/ST301P - ST201P (2,1 x 1,4mm)	2	5	7	1	4	6	
	T/ST301 - ST311 T/ST201 - T/ST501 - ST201ECG (2,8 x 1,1mm)	2	6	7	1	4	6	
	STL201L - STR201L (2,8 x 1,1mm)	2	6	7	1	4	6	
	ST201H - T/ST301H - ST311H - ST501H (2,8 x 1,6mm)	2	6	8	1	4	7	
	STL201H - STR201H (2,8 x 1,6mm)	2	6	8	1	4	7	
	ST301G - ST201G - ST501G (3,2 x 1,6mm)	2	6	9	1	4	6	

*With a catheter of 20 cm [2]

**Or any contrast media with a similar viscosity at 37°C [6]

en: Translations : see page 111 / fr: Traductions : Voir page 111 / de: siehe Seite 111 / es: Traducción: ver página 111 / it: Traduzioni: vedere a pagina 111 / sv: Översättningar: Se sidan 111 / pt: Traduções: consulte a página 111 / zh: 翻译 : 请参阅第111页 / ru: Перевод: см. на стр.111 / nl: Vertalingen: zie pagina 111 / no: Oversettelser: se side 111 / da: Oversættelse: se side 111 / fi: Käännös : katso sivu 111 / pl: Tłumaczenia: patrz strona 111 / el: Μεταφράσεις: Βλέπε σελίδα 111 / tr: Çeviriler : Sayfa 111'e bakınız / cs: Překlady: viz str. 111 / ko: 번역: 111쪽 / vi: Phần dịch: xem trang 111 / ro: Pentru traducere consultaţi pagina 111 / bg: Превод: моля виж стр. 111 / et: Tõlked : vt. Lk. 111 / hu: fordítás: lásd a 111. oldalon / lt: vertimą žiūrėkite psl. Nr.111 / sk: Preklady: vid' str. 111.

NEW

Celsite® ST205L / ST205P / ST205H
CT Marking of Epoxy Access Ports

Special Attention: FOR COUNTRY UNDER CE MARK ONLY

The following venous Access Ports are marked with "CT" to indicate compatibility with power injection. This marking is visible on X-ray.
All characteristics of these devices are summarized below :

Reference	Port/catheter material	Dead volume of port	Dead volume of catheter/cm	Implantation route	Possible implantation techniques
ST205L	Epoxy Resin / Silicone	0.25 ml	0.02 ml	Venous	Surgical, Seldinger
ST205P	Epoxy Resin / PUR	0.25 ml	0.015 ml	Venous	Surgical, Seldinger
ST205H	Epoxy Resin / PUR	0.25 ml	0.02 ml	Venous	Surgical, Seldinger

		Recommended maximum flow rates (mL/s)*											
		Contrast media at 37°C (98,6°F)											
		Viscosity 5.8 mPa.s (cP)**			Viscosity 11.4 mPa.s (cP)**			Viscosity 5.8 mPa.s (cP)**			Viscosity 11.4 mPa.s (cP)**		
		Surecan® Safety II			Surecan® Safety II			Winged/Angled Surecan			Winged/Angled Surecan		
		22G	20G	19G	22G	20G	19G	22G	20G	19G	22G	20G	19G
Small Size port (10)	ST205P (2,1 x 1,4mm)	2	5	8	1	4	5	2	4	6	2	3	4
	ST205L (2,8 x 1,1mm)	2	5	8	1	3	6	2	4	5	2	3	5
	ST205H (2,8 x 1,6mm)	2	6	9	1	4	6	2	5	7	2	4	6
*With a catheter of 20 cm (2)													
**Or any contrast media with a similar viscosity at 37°C (8)													

en: Translations: see page 111-112-113. NEW. All characteristics of these devices are summarized below.
fr: Traductions : voir page 111-112-113. NOUVEAU. Toutes les caractéristiques de ces dispositifs sont résumées ci-dessous.
de: siehe : seite 111-112-113. NEU. Alle Eigenschaften dieser Produkte sind untenstehend zusammengefasst.
es: Traducción: ver página 111-112-113. NUEVO. Todas las características de este dispositivo están resumidas a continuación.
it: Traduzioni: vedere a pagina 111-112-113. NUOVO. Tutte le caratteristiche di questi dispositivi sono riassunte di seguito.
sv: Översättningar: Se sidan 111-112-113. Ny. Alla egenskaper hos dessa produkter sammanfattas nedan.
pt: Traduções: consulte a página 111-112-113. NOVO. Todas as características dos dispositivos são sumarizadas nos quadros seguintes.
nl: Vertalingen: zie pagina 111-112-113. NIEUW. Alle eigenschappen van deze producten zijn hieronder opgesomd.
no: Oversettelser: se side 111-112-113. NYTT. Alle egenskaper til disse produktene er listet nedenfor.
da: Oversættelse: se side 111-112-113. NYHED. Alle egenskaber for disse produkter er opsummeret hereunder.
fi: Käännös : katso sivu 111-112-113. UUTUUS. Yhteenveto näiden laitteiden ominaisuuksista löytyy alla.
pl: Tłumaczenia: patrz strona 111-112-113. NOWOŚĆ. Pełna charakterystyka tych urządzeń w podsumowaniu poniżej.
el: Μεταφράσεις: Βλέπε σελίδα 111-112-113. ΝΕΟ. Όλα τα χαρακτηριστικά των συσκευών αυτών συνοψίζονται παρακάτω.
tr: Çeviriler : Sayfa 111-112-113'e bakınız. YENİ. Bu ürün ile ilgili tüm özellikler aşağıda özetlenmiştir.
cs: Překlady: viz str. 111-112-113. NOVÉ. Všechny vlastnosti těchto zdravotnických prostředků jsou uvedeny níže.
ro: Pentru traducere: consultați pagina 111-112-113. NOU. Toate caracteristicile acestui dispozitiv sunt descrise mai jos.
bg: Превод: моля виж стр. 111-112-113. НОВО. Всички характеристики на тези изделия са обобщени по-долу
et: Tõlked : vt. Lk. 111-112-113. UUS. Seadmete kõik omadused kokkuvõtvalt allpool.
hu: fordítás: lásd a 111-112-113 oldalon. Új. A termékek jellemzőinek összefoglalása.
lt: vertimą žiūrėkite psl. Nr. 111-112-113. Naujiena. Žemiau yra apibendrinami visų šių prietaisų požymiai.
sk: Preklady: viď str. 111-112-113. NOVÉ. Všetky vlastnosti týchto zdravotníckych prostriedkov sú uvedené dole.

A0554 Ed01 (01/2013)

NEW

Celsite® BT301P / BT305P

en: Special Attention: FOR COUNTRY UNDER CE MARK ONLY / fr : Attention spéciale : POUR LES PAYS SOUS MARQUAGE CE UNIQUEMENT / de: Besondere Aufmerksamkeit: NUR FÜR LÄNDER MIT GÜLTIGKEIT DES CE ZEICHENS / es: Atención especial: SOLO APLICABLE A LOS PAISES BAJO LA MARCA CE / it: Prestare particolare attenzione: SOLO PER PAESI IN CUI E' NECESSARIO IL MARCHIO CE / sv: OBSERVERA! ENDAST FÖR LÄNDER MED CE-MÄRKNING / pt: Nota especial: APENAS PARA PAISES SUJEITOS A MARCA CE / zh: 特殊申明：仅限CE标志适用国家 / ru: Особое внимание. Только для стран под маркой CE / nl: Let op! VOOR LANDEN MET CE-MARKERING / no: OBS: KUN FOR LAND MED CE MERKING / da: Vær opmærksom på: KUN FOR CE MÆRKEDE LANDE / fi: Erityistä huomioitavaa: MAAT JOILLA ON CE-MERKINTÄ / pl: Ważna uwaga: WYŁĄCZNIE DLA KRAJÓW UŻYWAJĄCYCH OZNACZNIE CE / el: Ειδική Προσοχή: ΜΟΝΟ ΓΙΑ ΧΩΡΕΣ ΟΠΟΥ ΑΠΑΙΤΕΙΤΑΙ ΠΙΣΤΟΠΟΙΗΣΗ CE / tr: Özel Dikkat: SADECE CE BELGESİNİN GEÇERLİ OLDUĞU ÜLKELER İÇİN / cs: Zvláštní upozornění: POUZE PRO ZEMI S OZNAČENÍM CE / ko: 유의사항: 유럽연합 통합규격마크 인증 받은 나라만 해당 / vi: Lưu ý đặc biệt: CHỈ ÁP DỤNG CHO NHỮNG NƯỚC ĐẠT CHỨNG NHẬN EC / ro: Atenţionare specială: DOAR PENTRU ŢĂRILE CU MARCAJ CE / bg: Моля обърнете внимание: ЗА ДЪРЖАВИ, ПРИЛАГАЩИ CE МАРКИРОВКА / et: Tähelepanu: CE MÄRGISTUS / hu: Speciális figyelmeztető: ORSZÁG SZERINTI CE ENGEDÉLY / lt: Ypatingas dėmesys: CE ŠALIMS / sk: Zvláštne upozornenie: IBA PRE KRAJINU S OZNAČENÍM CE

en: All characteristics of these devices are summarized below :

Reference	Port/catheter material	Dead volume of port	Dead volume of catheter/cm	Implantation route	Possible implantation techniques
BT301P	Polysulphone / PUR	0.50 ml	0.015 ml	Venous	Surgical
BT305P	Polysulphone / PUR	0.25 ml	0.015 ml	Venous	Surgical

	Recommended maximum flow rates (mL/s)* (1)											
	Contrast media at 37°C (98,6°F) (3)											
	Viscosity 5.8 mPa.s (cP)** (4)			Viscosity 11.4 mPa.s (cP)** (5)			Viscosity 5.8 mPa.s (cP)** (4)			Viscosity 11.4 mPa.s (cP)** (5)		
	Surecan® Safety II			Surecan® Safety II			Winged/Angled Surecan (7)			Winged/Angled Surecan (7)		
	22G	20G	19G	22G	20G	19G	22G	20G	19G	22G	20G	19G
BT301P (2,1 x 1,4 mm)	2	5	7	1	4	6	2	5	6	2	4	6
BT305P (2,1 x 1,4 mm)	2	5	8	1	4	5	2	4	6	2	3	4
*With a catheter of 20 cm (2)												
**Or any contrast media with a similar viscosity at 37°C (6)												

en: Translations: see page 111-112-113. NEW. All characteristics of these devices are summarized below.
fr: Traductions : voir page 111-112-113. NOUVEAU. Toutes les caractéristiques de ces dispositifs sont résumées ci-dessous.
de: siehe : seite 111-112-113. NEU. Alle Eigenschaften dieser Produkte sind untenstehend zusammengefasst.
es: Traducción: ver página 111-112-113. NUEVO. Todas las características de este dispositivo están resumidas a continuación.
it: Traduzioni: vedere a pagina 111-112-113. NUOVO. Tutte le caratteristiche di questi dispositivi sono riassunte di seguito.
sv: Översättningar: Se sidan 111-112-113. Ny. Alla egenskaper hos dessa produkter sammanfattas nedan.
pt: Traduções: consulte a página 111-112-113. NOVO. Todas as características dos dispositivos são sumarizadas nos quadros seguintes.
nl: Vertalingen: zie pagina 111-112-113. NIEUW. Alle eigenschappen van deze producten zijn hieronder opgesomd.
no: Oversettelser: se side 111-112-113. NYTT. Alle egenskaper til disse produktene er listet nedenfor.
da: Oversættelse: se side 111-112-113. NYHED. Alle egenskaber for disse produkter er opsummeret hereunder.
fi: Käännös: katso sivu 111-112-113. UUTUUS. Yhteenveto näiden laitteiden ominaisuuksista löytyy alla.
pl: Tłumaczenia: patrz strona 111-112-113. NOWOŚĆ. Pełna charakterystyka tych urządzeń w podsumowaniu poniżej.
el: Μεταφράσεις: Βλέπε σελίδα 111-112-113. ΝΕΟ. Όλα τα χαρακτηριστικά των συσκευών αυτών συνοψίζονται παρακάτω.
tr: Çeviriler : Sayfa 111-112-113'e bakınız. YENİ. Bu ürün ile ilgili tüm özellikler aşağıda özetlenmiştir.
cs: Překlady: viz str. 111-112-113. NOVÉ. Všechny vlastnosti těchto zdravotnických prostředků jsou uvedeny níže.
ro: Pentru traducere consultaţi pagina 111-112-113. NOU. Toate caracteristicile acestui dispozitiv sunt descrise mai jos.
bg: Превод: моля виж стр. 111-112-113. НОВО. Всички характеристики на тези изделия са обобщени по-долу.
et: Tõlked : vt. Lk. 111-112-113. UUS. Seadmete kõik omadused kokkuvõtvalt allpool.
hu: fordítás: lásd a 111-112-113 oldalon. Új. A termékek jellemzőinek összefoglalása.
lt: vertimą žiūrėkite psl. Nr.111-112-113. Naujiena. Žemiau yra apibendrinami visų šių prietaisų požymiai.
sk: Preklady: vid' str. 111-112-113. NOVÉ. Všetky vlastnosti týchto zdravotníckych prostriedkov sú uvedené dole.

A0555 Ed01 (10/2013)

en: Special Attention

CT Marking of Epoxy Access Ports

Contrast Enhanced Computerized Tomography (CECT) – refer to I – Indications

The following venous access ports are marked with “CT” to indicate compatibility with power injection. This marking is visible on X-ray. Please refer to page 109 for recommended maximum flow rates (mL/sec).

Paediatric	Small / Double	Standard / Double
Babyport®	STL205P, STR205P	ST201C
Babyport® PC	T/ST205, STL205F, STR205F	T/ST201F
Brachial	ST215	ST201F ECG
Brachial L, Brachial R	ST205F ECG	T/ST201, STL201L, STR201L
Babyport® S	ST205ECG	ST201ECG
	ST405L	ST201H, STL201H, STR201H
		ST201G
		ST201P
		ST401L

fr: Attention spéciale : **Marquage CT pour les chambres implantables en époxy** — Tomographie par ordinateur avec injection de contraste – Merci de vous référer à la partie I – Indications. Les chambres implantables suivantes ont un marquage “CT” pour indiquer la compatibilité avec la haute pression. Ce marquage est visible aux rayons X (radiographie). Merci de vous référer à la page 109 pour les débits maximum recommandés (ml/sec). Pédiatrique – Petite / Double – Standard / Double.

de: Besondere Aufmerksamkeit: **CT Markierung der Epoxy Access Ports** — Kontrastmittel unterstützte Computertomographie (CECT) – siehe I – Anwendungsgebiete. Die folgenden venösen Portkatheter-Systeme sind mit “CT” markiert um die Kompatibilität mit Hochdruckinjektionen anzuzeigen. Diese Markierung ist im Röntgenbild sichtbar. Bitte beachten Sie Seite 109 für die empfohlenen maximalen Flussraten (ml/s). Paediatrisch – Klein / Doppelport – Standard / Doppelport.

es: Atención especial: **Marca CT en los Reservorios de Acceso Epoxy.** — Tomografía Computerizada con Realce de Contraste (CECT) – consulte I- Indicaciones. Los siguientes reservorios de acceso venoso están marcados con las letras “CT” indicando la compatibilidad de los mismos con la inyección a alta presión / alta velocidad de flujo. Esta marca es visible a través de rayos X. Por favor, consulte la tabla de la página 109 para verificar los flujos máximos recomendados. Pediátrico – Bajo perfil / Doble – Estándar / Doble.

it: Prestare particolare attenzione: **Marchio CT sui Port in Resina Epossidica** — Tomografia Computerizzata con mezzo di contrasto (TAC con mezzo di contrasto) – fare riferimento al paragrafo “I – Indicazioni”. I seguenti codici di port venosi sono stati contrassegnati con il marchio “CT” per indicarne la compatibilità con iniezioni ad alta pressione. Tale marchio è visibile ai Raggi X. Prego fare riferimento alla pagina 109 per indicazioni sui tassi di flusso massimi raccomandati (mL/sec). Versione pediatrica – Basso profilo / Doppio – Standard / Doppio.

sv: OBSERVERA! **CT Märkning av Celsite® injektionsportar (Epoxy Portar)** — KONTRASTFÖRSTÄRKT DATORTOMOGRAFI – se I - Indikationer. Följande venösa injektionsportar är markerade med «CT» för att indikera kompatibilitet med högtrycksinjektioner. Denna märkning syns på röntgen. Se sid 109 för rekommenderade maximala flödeshastigheter (ml / sek). Paediatric – Liten / Dubbel – Standard / Dubbel.

pt: Nota especial: **Marca CT nos Access Ports em epóxido** — Tomografia de Contraste Computorizada – refere a I - Indicações. Os seguintes catéteres totalmente implantáveis contêm a marca CT para indicar a sua compatibidade com injecção a alta pressão. Esta marca é visível com RX. Por favor consulte a página 109 para taxas de fluxo máximas recomendadas (mL/seg). Pediátrico – Pequeno/Duplo – Standard/ Duplo.

zh: 特殊申明: **环氧树脂植入式给药装置的CT标志** — 增强计算机层析成像 (CECT) – 参考 I – 适应症. 以下静脉型植入式给药装置都标有“CT”标志来表示可进行高压注射的兼容性。此标志在X-射线下可见。请参阅第109页上的推荐的最大流速 (毫升/秒). 儿童型 – 小药盒 / 双腔药盒 – 标准药盒 / 双腔药盒.

ru: Особое внимание. **Обозначение CT на эпоксидных имплантируемых портах** — Компьютерная томография(КТ-исследование) с контрастированием см. I- Показания. Следующие порты для венозного доступа имеют обозначение «CT» и совместимы для введения контрастного вещества под давлением. Это обозначение видно при рентген-визуализации. Пожалуйста, обратитесь к стр.109 для уточнения рекомендуемой скорости введения контраста (мл/сек). Детский – Малый / Двойной – Стандартный / Двойной.

nl: Let op! **Epoxy port systemen met ‘CT’-markering** — Contrast Enhanced Computerized Tomography (CECT) – zie I – Indicaties. De volgende veneuze Celsite Port systemen zijn gemarkeerd met ´CT´ om aan te geven dat deze geschikt zijn voor hogedrukinjecties. Deze markering is zichtbaar op röntgen. Op pagina 109 treft u het overzicht met de aanbevolen maximale injectiesnelheden (ml/s) aan. Kinderen – Klein/Dubbel – Standaard/ Dubbel.

no: OBS: **CT merking av Epoxy Veneport** — Kontrastforsterkende, datastyrt tomografi– med referanse til I- Indikasjoner. Følgende veneporter er merket med “CT” for å betegne kompatibilitet med høyttrykksinjeksjon. Denne merkingen er synlig på røntgen. Vennligst se side 109 for anbefalt, maksimal strømningshastighet (ml/sek.). Pediatrisk – Liten/Dobbel – Standard/Dobbel.

da: Vær opmærksom på: **CT mærkning af Access Ports** — Contrast Enhanced Computerized Tomography (CECT) – refererer til I – Indikationer. Nedenstående vene port er mærket med “CT” for at indikere kompabilitet med power injektion. Denne markering er synlig på røntgen. Se venligst på side 109 for anbefalede maximum flow rates (mL/sec). Pædiatrisk – Lille / Dobbelt – Standard / Dobbelt.

fi: Erityistä huomioitavaa: **CT merkintä Epoxy -laskimoporteissa** — CECT. Alla luetelluissa laskimoporteissa on merkintä "CT", joka viittaa siihen, että portit soveltuvat korkeapaineinjektiointiin. Tämä merkintä näkyy röntgenissä. Katso sivun 109 suositukset maksimivirtausnopeuksista (ml/s). Pediatrinen – Pieni/Tupla – Standard/Tupla.

pl: Ważna uwaga: **Oznakowanie CT portów dostępu Epoxy** — Podanie kontrastu pod wysokim ciśnieniem w tomografii komputerowej (CECT) - dotyczy I - Wskazania. Następujące porty dostępu żylnego są oznaczone znakiem «ct» w celu potwierdzenia, iż można je użyć do podania kontrastu pod wysokim ciśnieniem. Znak ten jest widoczny w promieniowaniu RTG. Na stronie 109 znajdują się zalecane maksymalne prędkości przepływu (ml / s). Pediatryczny – Mały/Podwójny – Standardowy/Podwójny.

el: Ειδική Προσοχή: **Σήμανση Αξονικής Τομογραφίας για τα συστήματα τυμπάνου – καθετήρα από εποξική ρητίνη** — Αξονική τομογραφία με έγχυση σκιαγραφικού (CECT) – αναφορά σε Ε – ενδείξεις. Τα ακόλουθα συστήματα έγχυσης καθετήρα – τυμπάνου φέρουν την ένδειξη “CT” προκειμένου να υποδειχθεί η συμβατότητά τους με τη δυναμική έγχυση σκιαγραφικού. Η σήμανση αυτή είναι ακτινοσκιερή. Παρακαλώ ανατρέξατε στη σελίδα 109 για τις προτεινόμενους μέγιστους ρυθμούς ροής (mL/sec). Παιδιατρικά – Χαμηλού προφιλ / Διπλά – Κανονικού προφίλ / Διπλά.

tr: Özel Dikkat: **CT işaretli Epoxy Akses Portlar** — Contrast Enhanced Computerized Tomography (CECT) – Kontras Geliştirilmiş Bilgisayarlı Tomografi – “I-Endikasyonlar”a bakınız. Aşağıdaki tabloda yer alan venöz akses portlar, basınçlı enjeksiyona uygun olduklarını belirlemek için “CT” ile işaretlenmiştir. Bu işaret x-ray de görünür. Önerilen maksimum akış hızları (ml/sn) için lütfen sayfa 109’a bakınız. Pediatrik – Küçük / Double – Standart / Double.

cs: Zvláštní upozornění: **Označení epoxidových implantabilních portů pro CT** — Kontrastní počítačová tomografie (CECT) – viz I – Indikace. Níže uvedené žilní implantabilní porty jsou označeny písmeny „CT”, což znamená kompatibilitu s vysokotlakou injekcí. Toto označení je viditelné při RTG. Doporučené maximální průtoky (ml/s) viz strana 109. Pediatrické – Malé / Dvojité – Standardní / Dvojité.

ko: 유의사항: **에폭시 액세스 포트의 컴퓨터 단층촬영 마킹** — 대비색이 강화된 컴퓨터 단층촬영 – 보험 적용 관련. 다음 정맥 액세스 포트는 고압주입에 적절함을 알리기 위해 “CT” 라고 표기되어 있습니다. 이 표기는 엑스선에서도 식별이 가능합니다. 109쪽에 나와있는 최대 권장 유율 (mL/sec)을 참고하세요. 소아과 – 스몰/더블 – 스탠다드/더블.

vi: Lưu ý đặc biệt: **Đánh dấu chụp CT của Epoxy Access Ports —** Chụp CT có cản quang (CECT) – tham khảo I – những chỉ định. Access ports sau đây được đánh dấu “CT” cho biết liều lượng tiêm phù hợp. Việc đánh dấu này nhìn thấy trên X-quang. Vui lòng tham khảo trang 109 để xem tốc độ dòng chảy (mL/giây). Trẻ em – Loại nhỏ / 02 buồng – Loại chuẩn/ 02 buồng.

ro: Atenţionare specială: **Marcaj CT pentru Epoxy Access Ports** — Computer tomograf cu substanţă de contrast – consultaţi Cap. I – Indicaţii. Următorele catetere pentru acces venos sunt marcate “CT” pentru a indica compatibilitatea cu injectarea sub presiune înaltă. Acest marcaj poate fi vizualizat sub raze X. Consultaţi pagina 109 pentru ratele de debit maxim recomandate (ml/ sec). Pediatrice – Dimensiune mică/ Dublu port – Standard/ Dublu port.

bg: Моля обърнете внимание: **СТ маркиране на портове за достъп от епоксидна смола —** Контрастна подсилена компютърна томография (CECT) – вижте I – Показания. Следните портове за венозен достъп са маркирани с „CT” за означаване съвместимост с приложение на инжектор за контрастно вещество. Тази маркировка се вижда на рентген. Моля, вижте страница 109 за препоръчвани максимални скорости на вливане (mL/sec). Педиатрични – Малки / Двойни – Стандартни / Двойни.

et: Tähelepanu: **Epoksiidportide CT märgistus** — Kontrastainega Kompuutertomograafia (CECT) – vt I- Näidustused. Alljärgnevad venoossed pordid on märgistatud “CT” tähisega, et viidata sobivusele suure rõhu all süstimiseks. Märgistus on röntgenkiirgusega nähtav. Soovituslikud maksimaalsed voolukiirused (ml/sek) vt lk. 109. Pediaatriline – Väike / kaheosaline – Standard / kaheosaline.

hu: Speciális figyelmeztető: **CT jelölés az Epoxy Access Porton —** Kontrasztanyag adagolás Computer Tomográfiához (CECT) – ajánlás – Indikáció. Az alábbi vénás portok “CT” felírattal jelölve, amely azt jelenti, hogy a port alkalmas az anyag nagynyomású befecskendezésére. Ezen jelzés Rtg. árnyékot ad. Kérjük olvassa el a 109. oldalon található maximális áramlási sebességről szóló ajánlást (mL/sec). Gyermek – Kicsi / Dupla – Normál / Dupla.

lt: Ypatingas dėmesys: **Epoksidinių „port“ tipo kateterių ženklinimas KT žymekliu —** Kompiuterinė tomografija naudojant kontrastinę medžiagą (KT)-prašome žiūrėti skyrių Nr.1 – Indikacijos. Žemiau išvardinti veniniai “port” tipo kateteriai turi “CT” žymeklį, kuris nurodo jų tinkamumą atlikti aukšto spaudimo injekcijas. Šis žymeklis yra rentgenokontrastinis. Prašome žiūrėkite psl. Nr.109, kuriame yra nurodytos maksimalios leidžiamos srovės tėkmės (mL/s). Pediatriniai – Maži/Dvigubi – Standartiniai/Dvigubi.

sk: Zvláštne upozornenie: **Označenie epoxidových implantabilných portov pre CT —** Kontrastná počítačová tomografia (CECT) – viď I – Indikácie. Žilné implantabilné porty, ktoré sú uvedené nižšie, sú označené písmenami „CT”, ktoré znamenajú kompatibilitu s vysokotlakou injekciou. Toto označenie je viditeľné pri RTG. Odporučané maximálne prietoky (ml/s) viď stranu 109. Pediatrické – Malé / Dvojité – Štandardné / Dvojité.

en : Reference (A)	Port/catheter material (B)	Dead volume of port (C)	Dead volume of catheter/cm (D) *	Implantation routes (E)	Possible implantation techniques (F)
Celsite®					
ST301V ST305V	Polysulphone (5)/Silicone (6)	0,50 mL 0,25 mL	0,018 mL	Venous (11)	Seldinger (12)
ST401L (double lumen) (1) ST405L (double lumen) (1)	Epoxy Resin (7)/Silicone (6)	0,50 mL x 2 0,25 mL x 2	0,013 mL	Venous (11)	Seldinger (12)
T201F, ST201F, ST201F ECG T301F ST301F, ST311F T305, ST305, ST315 T205, ST205, ST215 ST205F ECG	Epoxy Resin (7)/Silicone (6) Polysulphone (5)/Silicone (6) Polysulphone (5)/Silicone (6) Polysulphone (5)/Silicone (6) Epoxy Resin (7)/Silicone (6) Epoxy Resin (7)/Silicone (6)	0,50 mL 0,50 mL 0,50 mL 0,25 mL 0,25 mL 0,25 mL	0,008 mL	Venous (11)	Surgical (13), Seldinger (12) Surgical (13) Seldinger (12) Surgical (13), Seldinger (12) Surgical (13), Seldinger (12) ECG (14)
T202F (arterial) (2) T302 (arterial) (2)	Epoxy Resin (7)/Silicone (6) Polysulphone (5)/Silicone (6)	0,50 mL	0,008 mL	Arterial (2)	Surgical (13)
ST201G ST301G	Epoxy Resin (7)/Silicone (6) Polysulphone (5)/Silicone (6)	0,50 mL	0,02 mL	Venous (11)	Seldinger (12)
T301H, ST301H, ST311H ST305H ST201H	Polysulphone (5)/PUR (8) Polysulphone (5)/PUR (8) Epoxy Resin (7)/PUR (8)	0,50 mL 0,25 mL 0,50 mL	0,02 mL	Venous (11)	Surgical (13), Seldinger (12)
T201, ST201 T301, ST301, ST311 ST201ECG ST205ECG T305XL, ST305L, ST315L	Epoxy Resin (7)/Silicone (6) Polysulphone (5)/Silicone (6) Epoxy Resin (7)/Silicone (6) Epoxy Resin (7)/Silicone (6) Polysulphone(5)/Silicone (6)	0,50 mL 0,50 mL 0,50 mL 0,25 mL 0,25 mL	0,01 mL	Venous (11)	Surgical (13), Seldinger (12) Surgical (13), Seldinger (12) ECG (14) ECG (14) Surgical (13), Seldinger (12)
ST201C ST301C ST301OTW	Epoxy Resin (7)/PUR (8) Polysulphone (5)/PUR (8) Polysulphone (5)/PUR (8)	0,50 mL	0,01 mL	Venous (11)	Seldinger (12), Braunule (18) Over-the-Wire (15)
ST301M, ST305M	Polysulphone(5)/Silicone (6)	0,50 mL	0,01 mL	Venous (11)	Braunule (18)
ST305C Brachial	Polysulphone (5)/PUR (8) Epoxy Resin (7)/PUR (8)	0,25 mL 0,15 mL	0,01 mL	Venous (11)	Seldinger (12), Braunule (18) Seldinger (12), Over-the-Wire (15)
T301P, ST301P ST201P ST305P	Polysulphone (5)/PUR (8) Epoxy Resin (7)/PUR (8) Polysulphone (5)/PUR (8)	0,50 mL 0,50 mL 0,25 mL	0,015 mL	Venous (11)	Surgical (13), Seldinger (12) Seldinger (12) Seldinger (12)
T203J (peritoneal) (3) DRAINAPORT T203J-1 (pleural/peritoneal) (4)	Epoxy Resin (7)/Silicone (6)	0,50 mL	0,053 mL	Peritoneal (3) Pleural/Peritoneal (4)	Seldinger (12), Surgical (13)
Babyport®/Babyport® PC Babyport® S	Epoxy Resin (7)/PUR (8) Epoxy Resin (7)/Silicone (6)	0,15 mL	0,005 mL 0,011 mL	Venous (11)	Seldinger (12)
ST304-19G	Polysulphone (5) PUR (7)/Polyamide (9)	0,33 mL	PUR 0,003 mL PA 0,003 mL	Intrathecal (16) Epidural (17)	Intrathecal (16) Epidural (17)
ST304-20G	Polysulphone (5) PUR (7)/Polyamide (9)	0,33 mL	PUR 0,002 mL PA 0,002 mL	Intrathecal (16) Epidural (17)	Intrathecal (16) Epidural (17)
Celsite® Discreet					
STL201L, STR201L	Epoxy Resin (7)/Silicone (6)	0,50 mL	0,01 mL	Venous (11)	Seldinger (12)
STL205F, STR205F	Epoxy Resin (7)/Silicone (6)	0,25 mL	0,008 mL	Venous (11)	Seldinger (12)
STL201H, STR201H	Epoxy Resin (7)/PUR (8)	0,50 mL	0,02 mL	Venous (11)	Seldinger (12)
STL205P, STR205P	Epoxy Resin (7)/PUR (8)	0,25 mL	0,015 mL	Venous (11)	Seldinger (12)
Brachial L, Brachial R	Epoxy Resin (7)/PUR (8)	0,15 mL	0,01 mL	Venous (11)	Seldinger (12) Over-the-Wire (15)
Celsite® Concept					
T501F, ST501F ST505	Polysulphone (5)+ silicone (6)/Silicone (6)	0,50 mL 0,25 mL	0,008 mL	Venous (11)	Surgical (13), Seldinger (12) Seldinger (12)
ST501G	Polysulphone (5)+ silicone (6)/Silicone (6)	0,50 mL	0,02 mL	Venous (11)	Seldinger (12)
ST501H ST505H	Polysulphone (5) + silicone (6)/PUR (8)	0,50 mL 0,25 mL	0,02 mL	Venous (11)	Seldinger (12)
T501, ST501 ST505L	Polysulphone (5) + silicone (6)/Silicone (6)	0,50 mL 0,25 mL	0,01 mL	Venous (11)	Surgical (13), Seldinger (12) Seldinger (12)
ST501C	Polysulphone (5) + silicone (6)/PUR (8)	0,50 mL	0,01 mL	Venous (11)	Seldinger (12), Braunule (18)
Celsite® IMPLANTOFIX					
04438604, 04438620, 04430263	Polysulphone (5)/PUR (8)	0,33 mL	0,01 mL	Venous (11)	Seldinger (12), Over-the-Wire (15) Braunule (18) Surgical (13)
04438817	Polysulphone (5)/PUR arterial, open tip with two suture beads (10)	0,33 mL	0,01 mL	Arterial (2)	Surgical (13)
04438647, 04438663, 04433521	Polysulphone (5)/PUR (8)	0,08 mL	0,01 mL	Venous (11)	Seldinger (12), Over-the-Wire (15) Braunule (18) Surgical (13)
04438704 04438747	Polysulphone (5)/Silicone (6)	0,33 mL 0,08 mL	0,011 mL	Venous (11)	Seldinger (12)
Celsite® InterVentional with Anthron® catheter					
CR301-A5 CR301-A6	Polysulphone (5)/PUR (8)	0,50 mL	0,01 mL	Venous (11)	Seldinger (12)
R305-A5NT, R305-A5ST CR305-A5 CR305-A6	Polysulphone (5)/PUR (8)	0,25 mL	0,01 mL	Arterial (2) Venous (11) Venous (11)	Percutaneous (19) Seldinger (12) Seldinger (12)

***en:** to determine the priming volume of the port / catheter, multiply the catheter length by the dead volume of the catheter and add the dead volume of the port.
fr: pour déterminer le volume d'amorçage de la chambre / du cathéter, multiplier la longueur du cathéter par le volume mort du cathéter et ajouter le volume mort de la chambre.
de: Um das 'Priming Volume' von Acces Port / Katheter zu bestimmen, multiplizieren Sie die Katheterlänge mit dem Totvolumen des Katheters und rechnen Sie das Totvolumen des Acces Ports hinzu.
es: determinar el volumen de carga del reservorio/catéter, multiplicar la longitud del catéter por el volumen muerto del catéter y añadir el volumen muerto del reservorio.
it: per determinare il volume di riempimento del port /catetere, moltiplicare la lunghezza del catetere per lo spazio morto del catetere stesso ed aggiungere lo spazio morto del port.
sv: Bestäm portens/kateterns flödesvolym genom att multiplicera kateterns längd med kateterns dödvolym och lägga till portens dödvolym.
pt: para determinar o volume de preenchimento do porte/cateter, multiplique o comprimento do cateter pelo volume morto do cateter e acrescente o volume morto do porte.
zh: 插管长度乘插管死腔再加输液壶死腔、可确定输液壶/插管的吸入容量。
ru: Для определения заливочного объема порта/ катетера следует умножить длину катетера на остаточное пространство катетера и прибавить остаточный объем порта.
nl: om het volume van de port/katheter te bepalen vermenigvuldigd de lengte vna het dode volume van de katheter en voeg het dode volume van de port toe.
no: for å bestemme portens/kateterets primevolum, multipliser kateterets lengde med kateterets dødvolum og tilføy portens dødvolum.
da: for at bestemme portens/katetrets spæde-volumen skal man gange katetrets længde med katetrets dødvolumen og tilføje portens dødvolumen.
fi: Portin/katetrin alkutäytön määrittämiseksi on katetrin pituus kerrottava katetrin tyhjällä tilavuudella ja tähän on lisättävä portin tyhjä tilavuus.
pl: dla określenia podstawowej objętości portu / cewnika, należy pomnożyć długość cewnika przez objętość martwą cewnika i dodać objętość martwą portu.
el: για να καθορίσετε τον όγκο πλήρωσης του καθετήρα/κώδωνα, πολλαπλασιάστε το μήκος του καθετήρα επί του νεκρού όγκου του καθετήρα και προσθέστε τον νεκρό όγκο του κώδωνα.
tr: Port / kateterin dolum hacmini belirlemek için, kateter uzunluğunu kateterin ölü hacmi ile çarpın ve portun ölü hacmini ilave edin.
cs: k určení plnícího objemu portu / katétru vynásobte délku katétru mrtvým prostorem katétru a přičtěte mrtvý prostor portu.
th: เพื่อกำหนด priming volume ของช่องทางเข้าถึง/สายสวน ให้คูณความยาวสายสวนด้วย dead volume ของสายสวนและบวกด้วย dead volume ของช่องทางเข้าถึง
ko: 포트/카테터의 충전량을 구하려면, 카테터 길이에 카테터 사장용적을 곱하고 여기에 포트 사장용적을 더한다.
vi: để xác định dung lượng mồi của cổng/ ống thông, nhân chiều dài của ống thông với dung lượng chết của ống thông và cộng thêm khối lượng chết của cổng.
ro: Pentru a determina volumul de primare a portului/cateterului, multiplicați lungimea cateterului cu volumul mort al cateterului și adăugați volumul mort al portului.
bg: За да определите първоначалния обем на порта /катетъра, умножете дължината на катетъра по мъртвия обем на катетъра и добавете мъртвия обем на порта.
et: Pordi/kateetri praimimismahu arvutamiseks korrutage kateetri pikkus kateetri tühimahuga ja liitke pordi tühimaht.
hu: a katéter/port behelyezési méretének meghatározásához többszörözze meg a katéter hosszúságát a katéter holt térfogatával és adja hozzá a port holt térfogatát
lt: kad apskaičiuotumėte porto/kateterio užpildymo tūrį, padauginkite kateterio ilgį iš kateterio nenaudingojo tūrio ir pridėkite porto nenaudingąjį tūrį.
sk: k určeniu plniaceho objemu portu / katétru vynásobte dĺžku katétru mŕtvym priestorom katétru a pripočítajte mŕtvy priestor portu.

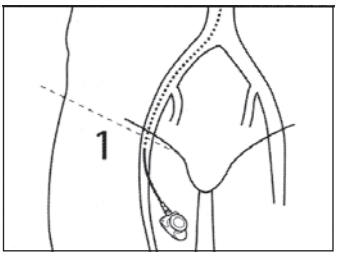

Fig. A

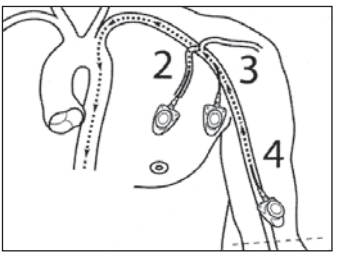

Fig. B

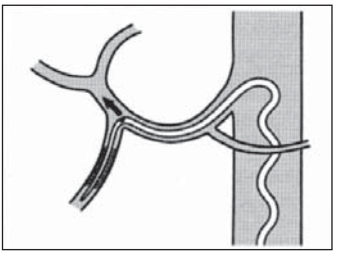

Fig. C

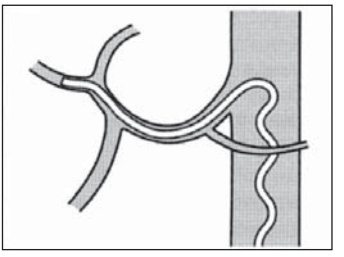

Fig. D

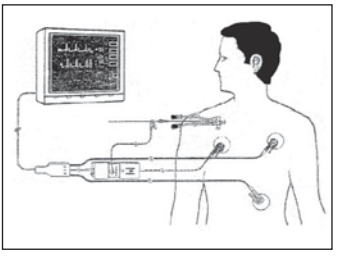

Fig. E

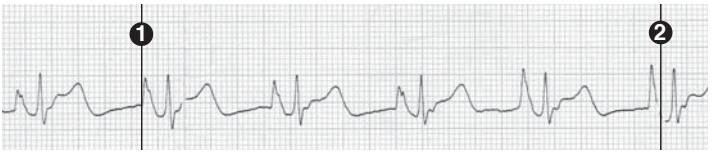

Fig. F

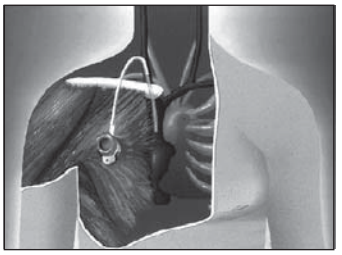

Fig. 1

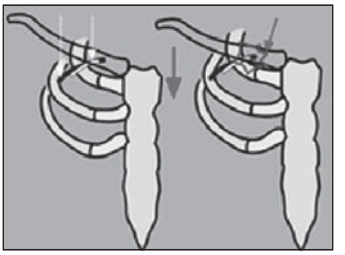

Fig. 2

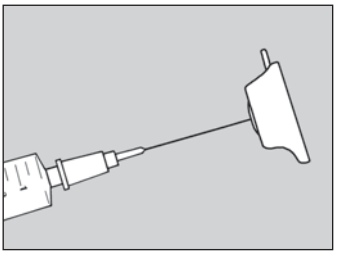

Fig. 3

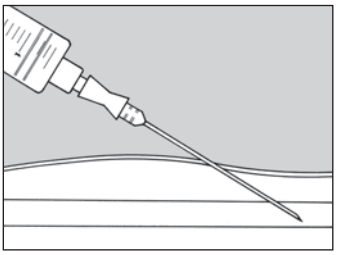

Fig. 4

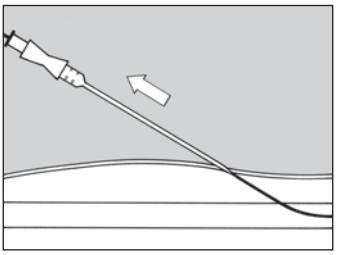

Fig. 5

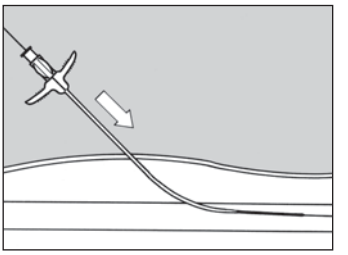

Fig. 6

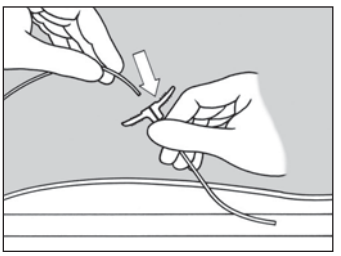

Fig. 7

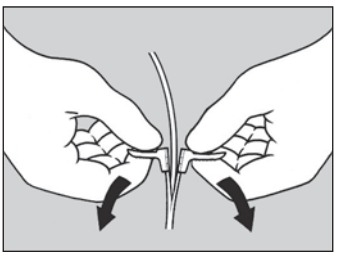

Fig. 8

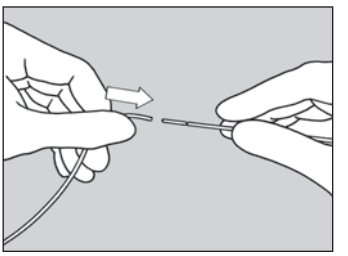

Fig. 9

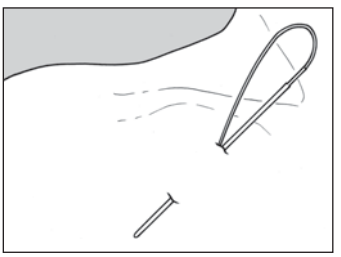

Fig. 10

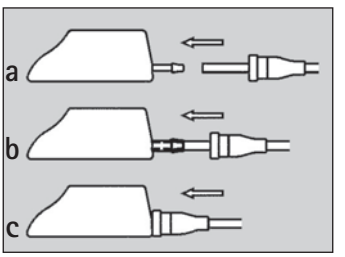

Fig. 11

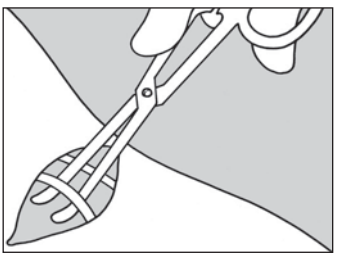

Fig. 12

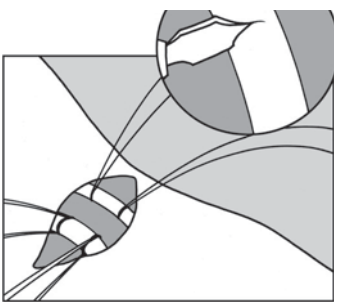

Fig. 13

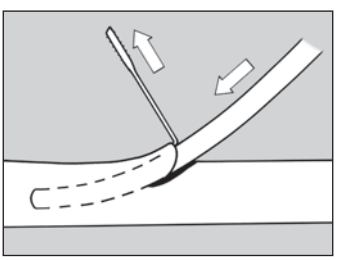

Fig. 14

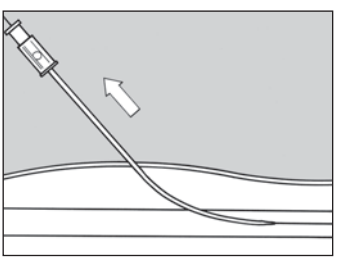

Fig. 15

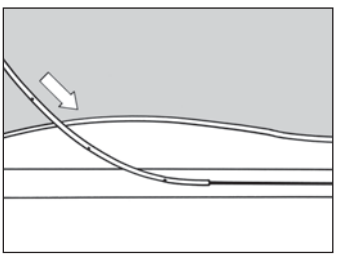

Fig. 16

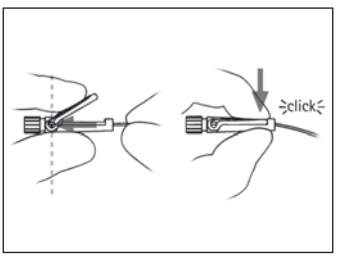

Fig. 17

en: Fig.
fr: Illustration
de: Abb.
es: Fig.
it: Fig.
sv: Fig.
pt: Fig.
zh: 图
ru: Рис.
nl: Fig.
no: Fig.
da: Fig.
fi: kuva
pl: Rys.
el: Εικ.
tr: Şek.
cs: Obr.
th: รูปที่
ko: 그림
vi: Hình
ro: Fig.
bg: Фиг.
et: Joon.
hu: ábra
lt: Pav.
sk: Obr.

en - Do not re-use
fr - Ne pas réutiliser
de - Nicht wiederverwenden
es - Un solo uso
it - Non riutilizzare
sv - För engångsbruk
pt - Não reutilizar
zh - 不要重复使用
ru - Не использовать повторно
nl - Niet hergebruiken
no - Skal ikke gjenbrukes
da - Engangs
fi - Kertakäyttöinen
pl - Jednorazowego użytku
el - Μην επαναχρησιμοποιείτε
tr - Tekrar kullanmayınız
cs - K jednorázovému použití
th - ห้ามนำกลับมาใช้ซ้ำ
ko - 단일사용(일회용)
vi - Không sử dụng lại
ro - A nu se refolosi
bg - Да не се използва повторно
et - Ühekordselt kasutatav seade
hu - Egyszerhasználatos
lt - Vienkartinio naudojimo
sk - K jednorazovému použitiu

en - Do not resterilize
fr - Ne pas restériliser
de - Nicht erneut sterilisieren
es - No re-esterilizar
it - Non risterilizzare
sv - Får ej omsteriliseras
pt - Não re-esterilizar
zh - 不要重新消毒
ru - Не стерилизовать повторно
nl - Niet hersteriliseren
no - Skal ikke re-steriliseres
da - Må ikke resteriliseres
fi - Älä sterilοi uudelleen
pl - Nie resterylizować
el - Μην επαναποστειρώνετε
tr - Tekrar sterilize etmeyiniz
cs - Nesterilizujte
th - ห้ามนำกลับมา ทำให้ปราศจาก เชื้อซ้ำ
ko - 재멸균금지
vi - Không tiệt trùng lại
ro - A nu se resteriliza
bg - Да не се стерилизира повторно
et - Mitte resteriliseerida
hu - Nem sterilezhetõ újra
lt - Negalima sterilizuoti kartotinai
sk - Nesterilizujte

en - Keep away from rain
fr - Craint l'humidité
de - Trocken aufbewahren
es - Mantener alejado de la lluvia
it - Tenere all'asciutto
sv - Får ej utsättas för regn
pt - Manter em local seco
zh - 避免雨淋
ru - Защищать от дождя
nl - Droog en vochtvrij bewaren
no - Holdes unna regn
da - Opbevares tørt
fi - Suojaa kosteudelta
pl - Chronić przed deszczem
el - Κρατείστε το μακρία από τη βροχή
tr - Yağmurdan uzak tutunuz
cs - Chraňte před deštěm
th - การเก็บรักษา ไม่ควรให้เปียกน้ำ
ko - 건조유지
vi - Tránh mưa
ro - Pastrati in locuri uscate/fara umezeala
bg - Да се пази от дъжд
et - Hoia kuivas
hu - Száraz helyen tárolandó
lt - Saugoti nuo lietaus
sk - Chráňte pred dažďom

en - MR Conditional
fr - Compatible sous conditions avec la RM
de - Bedingt MR sicher
es - RM-condicional
it - Compatibilità condizionale con RM
sv - MR-säkert under vissa förutsättningar
pt - Compatibilidade condicional com RM
zh - MR有条件
ru - Условно совместимо с МР
nl - MR voorwaardelijk
no - MR betinget
da - MR betinget
fi - Ehdollinen MRI yhteensopivuus
pl - Warunkowy dla MR
el - Κατάλληλο για μαγνητική ταυτογραφία υπό κατάλληλες συνθήκες
tr - MR Koşullu
cs - Lze používat při magnetické rezonanci podmíněně
th - เป็นไปตามเงื่อนไขการใช้ใน MR
ko - MR 환경에 따라 사용가능
vi - Chỉ an toàn trong một số môi trường Công hưởng từ
ro - A se folosi cu precautie in RMN
bg - Повлиява се при магнитен резонанс
et - MR Conditional
hu - MR-el használható
lt - Dėmesio, atsargiai naudoti MR aplinkoje
sk - Možno používať pri magnetickes rezonancii s podmienkou

en - Keep away from sunlight
fr - Conserver à l'abri de la lumière du soleil
de - Von Sonnenlicht fernhalten
es - Evitar el contacto directo con la luz solar
it - Tenere al riparo dalla luce
sv - Får ej utsättas för solljus
pt - Manter afastado da luz solar
zh - 避免阳光照射
ru - Защищать от солнечного света
nl - Niet in zonlicht plaatsen
no - Holdes unna sollys
da - Tåler ikke sollys
fi - Suojaa auringonvalolta
pl - Chronić przed słońcem
el - Κρατείστε το μακριά από το ηλιακό φως
tr - Güneş ışığından uzak tutunuz
cs - Nevystavujte slunečnímu záření
th - การเก็บรักษา ควรหลีกเลี่ยงจาก การถูกแสงแดด
ko - 햇빛을 피하세요
vi - Tránh ánh nắng
ro - Pastrati departe de razele solare
bg - Да се пази от пряка слънчева светлина
et - Hoida otsese valguse eest
hu - Napfénytől távol tatandó
lt - Saugoti nuo saulės spindulių
sk - Nevystavujte slnečnému žiareniu

en - Do not use if package is damaged
fr - Ne pas utiliser si l'emballage est endommagé
de - Nicht verwenden, falls Verpackung beschädigt
es - No utilizar si el envase está dañado
it - Non utilizzare se la confezione è danneggiata
sv - Använd ej om förpackningen är skadad
pt - Não utilizar se a embalagem estiver danificada
zh - 如果包装损坏则不要使用
ru - Не использовать при повреждении упаковки
nl - Bij beschadigde verpakking het product niet gebruiken
no - Skal ikke brukes hvis emballasjen er skadet
da - Anvendes kun hvis emballagen er ubeskadiget
fi - Älä käytä jos pakkaus on vahingoittunut
pl - Nie używać jeśli opakowanie jest uszkodzone
el - Μη το χρησιμοποιείτε σε περίπτωση κατεστραμμένης συσκευασίας
tr - Hasarlı ambalajları kullanmayınız
cs - Nepoužívejte, je-li obal poškozen
th - ไม่นำมาใช้งาน หากกล่องบรรจุภัณฑ์เกิดความเสียหาย
ko - 포장이 손상되면 사용금지
vi - Không sử dụng nếu bao bì bị hư hỏng
ro - Nu folositi daca ambalajul este deteriorat
bg - Да не се използва ако опаковката е повредена
et - Mitte kasutada, kui pakend on kahjustatud
hu - Sérülés mentes csomagolás használható
lt - Nenaudoti esant pažeistai pakuotei
sk - Nepoužívajte ak je obal poškodený

en - DEHP-free
fr - Sans DEHP
de - DEHP frei
es - Libre de DEHP
it - Privo di DEHP
sv - DEHP-fri
pt - Isento de DEHP
zh - 不含DEHP
ru - Не содержит ДЭГФ
nl - DEHP-vrij
no - Fri for DEHP
da - DEHP- fri
fi - Ei sisällä dehp
pl - Wolny od DEHP
el - Ελεύθερο DEHP
tr - DEHP içermez
cs - Neobsahuje DEHP
th - ไม่มีส่วนประกอบของ ดีอีเอชพี
ko - DEHP 무함유
vi - Không có DEHP
ro - Nu contine DEHP
bg - Не съдържа ди (2-етил-хексил)фталат
et - DEHP-vaba
hu - DEHP-mentes
lt - Be DEHP
sk - Neobsahuje DEHP

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
zh - 当心，查询所附文件
ru - Внимание! См. сопроводительные документы
nl - Let op, lees voor gebruik de bijsluiter
no - OBS! Slå opp i ledsagende dokumenter
da - Forsigtighed, se vedlagte dokumenter
fi - Lue käyttöohje
pl - Ostrzeżenie, sprawdzić towarzyszące dokumenty
el - Προσοχή, διαβάστε τα συνοδευτικά εγχειρίδια
tr - Dikkat, ürün ile birlikte verilen dökümanlara bakınız
cs - Pozor, viz přiložená dokumentace
th - ข้อควรระวัง ศึกษาวิธีการใช้เพิ่มเติมจากเอกสาร
ko - 주의, 사용 설명서를 보시오
vi - Thận trọng, xin tham khảo tài liệu kèm theo
ro - Atentie, cosultati documentele insotitoare
bg - Внимание, прочетете съпътстващите документи
et - Ettevaatust! Lugege kasutusjuhendit
hu - Figyelmesen olvassa el a mellékelt tájékoztatót
lt - Dėmesio, skaitykite pridedamus dokumentus
sk - Pozor, viď priložená dokumentácia

en - Latex-free
fr - Sans latex
de - Latex frei
es - Libre de látex
it - Privo di lattice
sv - Latexfri
pt - Isento de látex
zh - 不含乳胶
ru - Не содержит латекса
nl - Latexvrij
no - Uten latex
da - Latex-fri
fi - El sisällä lateksia
pl - Wolny od Latexu
el - Ελεύθερο Latex
tr - Lateks içermez
cs - Neobsahuje latex
th - ไม่มีลาเทกซ์ เป็นส่วนประกอบ
ko - 라텍스 무함유
vi - Không có Latex
ro - Nu contine Latex
bg - Не съдържа латекс
et - Lateksivaba
hu - Latex-mentes
lt - Be latekso
sk - Neobsahuje latex

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
zh - 采用环氧乙烷消毒
ru - Стерилизация при помощи оксида этилена
nl - Gesteriliseerd d.m.v ethyleenoxide
no - Sterilisert med etylen oksyd
da - Ethylenoxid steriliseret
fi - Sterilointimenetelmänä etyleenioksidi
pl - Sterylizowany przy użyciu tlenku etylenu
el - Αποστείρωση με αιθυλενοξείδιο
tr - Etilen oksit ile sterilize edilmiştir
cs - Sterilizováno ethylenoxidem
th - การทำให้ปราศจากเชื้อ โดย เอธิลีนอ็อกไซด์
ko - 산화에틸렌을 사용하여 멸균
vi - Tiệt trùng bằng ethylene oxide
ro - Sterilizat cu oxid de etilena
bg - Стерилизирано с етиленов оксид
et - Steriliine.Steriliseeritud etüleenoksiidiga
hu - Ethylen oxid-al sterilizált
lt - Sterilizuotas etileno oksidu
sk - Sterilizované ethylénoxidom

en - Batch code
fr - Numéro de lot
de - Chargencode
es - Número de lote
it - Numero di lotto
sv - Batchnummer
pt - Código de lote
zh - 批号
ru - Номер партии
nl - Batch
no - Batch (produksjonsserie) kode
da - Batch kode
fi - Eränumero
pl - Numer serii
el - Κωδικός παρτίδας
tr - Lot no
cs - Číslo šarže
th - หมายเลขของชุดที่ผลิต
ko - 제품번호
vi - Số lô
ro - Lot numarul
bg - Партиден номер
et - Partii
hu - LOT szám
lt - Serijos Nr.
sk - Číslo šarže

en - Date of manufacture
fr - Date de fabrication
de - Herstellungsdatum
es - Fecha de fabricación
it - Data di fabbricazione
sv - Tillverkningsdatum
pt - Data de fabrico
zh - 制造日期
ru - Дата изготовления
nl - Fabricagedatum
no - Produksjonsdato
da - Produktionsdato
fi - Valmistuspäivä
pl - Data produkcji
el - Ημερομηνία κατασκευής
tr - Üretim tarihi
cs - Datum výroby
th - วันที่ผลิต
ko - 제조일자
vi - Ngày sản xuất
ro - Data fabricarii
bg - Дата на производство
et - Tootmise kuupäev
hu - Gyártási idő
lt - Pagaminimo data
sk - Dátum výroby

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
zh - 有效期至
ru - Использовать до
nl - Exp. datum
no - Brukes innen
da - Anvendes inden
fi - Käytettävää ennen
pl - Data ważności
el - Ημερομηνία λήξης
tr - Son kullanma tarihi
cs - Použitelné do
th - วันหมดอายุ
ko - 유통기한
vi - Ngày đến hạn
ro - A se folosi inainte de
bg - Да се използва преди
et - Kasutada kuni
hu - Lejárati idő
lt - Sunaudoti ik
sk - Použiteľné do

en - Catalogue number
fr - Numéro de catalogue
de - Katalognummer
es - Referencia
it - Codice catalogo
sv - Katalognummer
pt - Número de catálogo
zh - 目录编号
ru - Номер по каталогу
nl - Artikelnr.
no - Varenummer
da - Reference nr.
fi - Tuotenumero
pl - Numer katalogowy
el - Αριθμός κωδικού
tr - Katalog numarası
cs - Katalogové číslo
th - เลขที่ผลิตภัณฑ์
ko - 목록번호
vi - Mã hàng
ro - Numar de catalog
bg - Каталожен номер
et - Kataloonumber
hu - Katalógus szám
lt - Katalogo Nr.
sk - Katalógové číslo

en - Manufacturer
fr - Fabricant
de - Hersteller
es - Fabricante
it - Fabbricante
sv - Tillverkare
pt - Fabricante
zh - 制造商
ru - Производитель
nl - Fabrikant
no - Fabrikant
da - Producent
fi - Valmistaja
pl - Producent
el - Οίκος κατασκευής
tr - Üretici
cs - Výrobce
th - ผู้ผลิต
ko - 제조사
vi - Nhà sản xuất
ro - Producator
bg - Производител
et - Tootja
hu - Gyártó
lt - Gamintojas
sk - Výrobca

en - Standard size low profile port
fr - **Chambre profilée de taille standard**
de - **Access-Port Flachprofil Standardgröße**
es - Reservorio de bajo perfil tamaño estándar
it - Port a basso profilo di dimensioni standard
sv - **Port i standardstorlek med låg profil**
pt - Porte padrão de baixo perfil
zh - 标准薄形药盒
ru - Низкопрофильный порт стандартного размера
nl - Standaard maat laag profil port
no - **Standard størrelse lavprofilport**
da - **Standard str. for lavprofil-port**
fi - **Standardikokoinen matala portti**
pl - rozmiar standardowy port niskoprofilowy
el - Τύμπανο κανονικού μεγέθους χαμηλού προφίλ
tr - Standart ebatlı düşük profilli port
cs - Port standardní velikosti s nízkým profilem
th - **ช่องทางเข้าขนาดมาตรฐาน**
ko - 표준 크기 낮은 포트
vi - **Cổng nghiêng thấp kích thước tiêu chuẩn**
ro - Port standard cu profil jos
bg - Стандартен размер на порт с нисък профил
et - **Standardsuuruses madala profiiliga port**
hu - Standard méretű, alacsony profilú port
lt - Standartinio dydžio žemo profilio portas
sk - Port štandartnej veľkosti s nízkym profilom

en - Small size low profile port
fr - **Chambre profilée de petite taille**
de - **Access-Port Flachprofil klein**
es - Reservorio de bajo perfil tamaño pequeño
it - Port a basso profilo di piccole dimensioni
sv - **Liten port med låg profil**
pt - Porte pequeno de baixo perfil
zh - 小号薄形药盒
ru - Низкопрофильный порт малого размера
nl - Kleine maat port laag profiel port
no - **Liten størrelse lavprofilport**
da - **Lille str. for lavprofil-port**
fi - **Pienikokoinen matala portti**
pl - rozmiar mały port niskoprofilowy
el - Τύμπανο μικρού μεγέθους χαμηλού προφίλ
tr - Küçük ebatlı düşük profilli port
cs - Port malé velikosti s nízkým profilem
th - **ช่องทางเข้าขนาดเล็ก**
ko - 작은 크기 낮은 포트
vi - **Cổng nghiêng thấp kích thước nhỏ**
ro - Port mic cu profil jos
bg - Малък размер на порт с нисък профил
et - Väike madala profiiliga port
hu - Kisméretű, alacsony profilú port
lt - Mažo dydžio žemo profilio portas
sk - Port malej veľkosti s nízkym profilom

en - Mini size low profile port
fr - **Mini chambre profilée**
de - **Access-Port Flachprofil mini**
es - Reservorio de bajo perfil tamaño mini
it - Port a basso profilo di dimensioni mini
sv - **Miniport med låg profil**
pt - Mini porte de baixo perfil
zh - 微型薄形药盒
ru - Низкопрофильный порт сверхмалого размера
nl - Mini maat laag profil port
no - **Mini størrelse lavprofilport**
da - **Mini str. for lavprofil-port**
fi - **Minikokoinen matala portti**
pl - rozmiar mini port niskoprofilowy
el - Τύμπανο μίνι μεγέθους χαμηλού προφίλ
tr - Küçük - Mini ebatlı düşük profilli port
cs - Port velikosti mini s nízkým profilem
th - **ช่องทางเข้าขนาดเล็กมินิ**
ko - 미니 크기 낮은 포트
vi - **Cổng nghiêng thấp kích thước rất nhỏ**
ro - Miniport cu profil jos
bg - Мини размер на порт с нисък профил
et - Üliväike madala profiiliga port
hu - Mini méretű, alacsony profilú port
lt - Mini dydžio žemo profilio portas
sk - Port veľkosti mini s nízkym profilom

en - Standard size low profile double lumen port
fr - **Chambre double lumière profilée de taille standard**
de - **Doppel-Lumen Access-Port Flachprofil Standardgröße**
es - Reservorio de doble lumen de tamaño estandar y bajo perfil
it - Port con doppio lume a basso profilo di dimensioni standard
sv - **Dubbellumenport i standardstorlek med låg profil**
pt - Porte padrão de baixo perfil com duplo lúmen
zh - 标准薄形双腔药盒
ru - Низкопрофильный двухпросветный порт стандартного размера
nl - Standaard maat laag profile dubbel lumen port
no - **Standard størrelse lavprofil dobbellumenport**
da - **Standard str. for lavprofil-port med dobbelt lumen**
fi - **Standardikokoinen matala kaksoislumenportti**
pl - rozmiar standard port podwójny niskoprofilowy
el - Τύμπανο κανονικού μεγέθους χαμηλού προφίλ με διπλό αυλό
tr - Standart ebatlı düşük profilli çift lümenli port
cs - Port standardní velikosti s nízkým profilem a s dvojitým lumen
th - **ช่องทางเข้าขนาดมาตรฐานชนิดมีสองทาง**
ko - 표준 크기 낮은 이중 내강 포트
vi - **Cổng lumen đôi nghiêng thấp kích thước tiêu chuẩn**
ro - Port standard cu profil jos şi lumen dublu
bg - Стандартен размер на порт с нисък профил и двоен отвор
et - Standardsuuruses madala profiiliga kahekordse valendikuga port
hu - Standard méretű, alacsony profilú, dupla lumenes port
lt - Standartinio dydžio žemo profilio portas, dvigubo spindžio
sk - Port štandartnej veľkosti s nízkym profilom a dvojitým lumenom

en - Small size low profile double lumen port
fr - **Chambre double lumière profilée de petite taille**
de - **Doppel-Lumen Access-Port Flachprofil klein**
es - Reservorio de doble lumen de tamaño pequeño y bajo perfil
it - Port con doppio lume a basso profilo di piccole dimensioni
sv - **Liten dubbellumenport med låg profil**
pt - Porte pequeno de baixo perfil com duplo lúmen
zh - 小号薄形双腔药盒
ru - Низкопрофильный двухпросветный порт малого размера
nl - Kleine maat laag profiel dubbel lumen port
no - **Liten størrelse lavprofil dobbellumenport**
da - **Lille str. for lavprofil-port med dobbelt lumen**
fi - **Pienikokoinen matala kaksoislumenportti**
pl - rozmiar mały port podwójny niskoprofilowy
el - Τύμπανο μικρού μεγέθους χαμηλού προφίλ με διπλό αυλό
tr - Küçük ebatlı düşük profilli çift lümenli port
cs - Port malé velikosti s nízkým profilem a s dvojitým lumen
th - **ช่องทางเข้าขนาดเล็กชนิดมีสองทาง**
ko - 작은 크기 낮은 이중 내강 포트
vi - **Cổng lumen đôi nghiêng thấp kích thước nhỏ**
ro - Port mic cu profil jos şi lumen dublu
bg - Малък размер на порт с нисък профил и двоен отвор
et - Väike madala profiiliga kahekordse valendikuga port
hu - Kisméretű, alacsony profilú, dupla lumenes port
lt - Mažo dydžio žemo profilio portas, dvigubo spindžio
sk - Port malej veľkosti s nízkym profilom a s dvojitým lumenom

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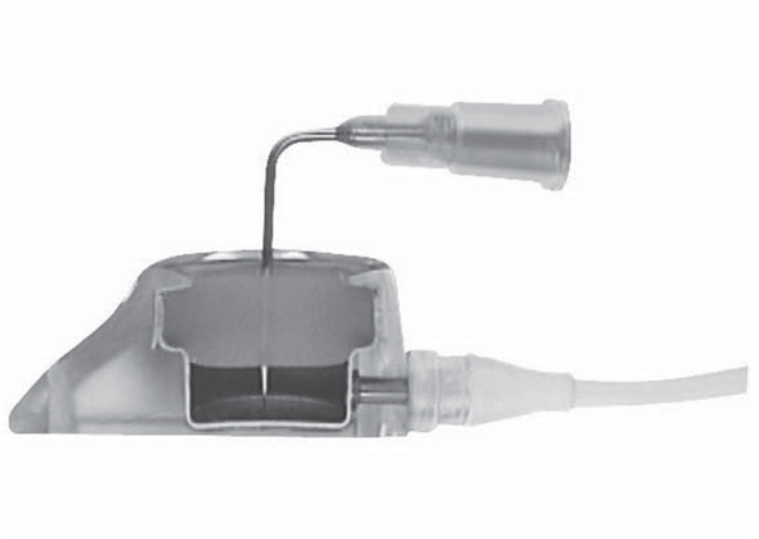

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