BD | WavelinQ™ EndoAVF System

ENGLISH

Instructions For Use

WavelinQ™ EndoAVF System (WavelinQ™ System, WavelinQ™ or REF WQ4305) Components

- WavelinQ™ Arterial Catheter
- WavelinQ™ Venous Catheter

WavelinQ™ EndoAVF System Rated Accessory Voltage

- WavelinQ™ Venous Catheter is rated for 700Vpeak

Commercially Available Devices

- TVA or BD ESU-1 Electrosurgical Unit (ESU)
- Electrosurgical Pencil:
  - Must have a 3-prong universal connector that interfaces with the ESU-1 Electrosurgical Generator
  - Must have a minimum Rated Accessory Voltage of 700V and a Yellow activation button.
  - Ground Pad
  - Must have a universal connector that interfaces with the ESU-1 Generator
  - Must be rated to disperse a minimum of 60 W for 1 Second.
  - TZ Medical Arm Board and Fixation Straps: CZ-400-TVA (Arm Restraint) and TVA-MC-2 (Fixation Straps)

System Description

The WavelinQ™ EndoAVF System consists of two 4 Fr single-use, disposable, magnetic, hydrophilic coated catheters; a venous catheter and an arterial catheter. It is used with the ESU-1 Electrosurgical Unit and an Electrosurgical Pencil. The WavelinQ™ venous catheter is a flexible 4 Fr magnetic catheter that contains a radiofrequency (RF) electrode, a hemostasis valve crosser for interfacing with the introducer sheath on the distal end, and has a cable and plug for the delivery of radiofrequency energy. The WavelinQ™ venous catheter connects via the Electrosurgical Pencil to the ESU for delivery of radiofrequency energy with standard grounding pads. The WavelinQ™ arterial catheter is a flexible 4 Fr magnetic catheter that contains a backstop for receiving the electrode. When placed in proximity, the magnets contained in each catheter attract to each other, while aligning the electrode with the backstop. Rotational indicators are present in each catheter and used to accurately position the catheters. Radiofrequency energy can then be delivered through the electrode for cutting and/or coagulating tissue.

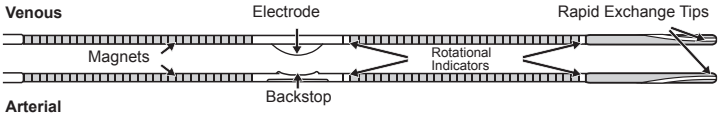

Figure 1. WavelinQ™ Venous and Arterial Catheter Cross-Section

Figure 2. WavelinQ™ Venous Catheter with Hemostasis Valve Crosser in place

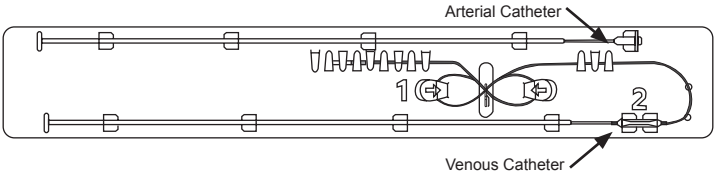

Figure 3. WavelinQ™ Packaging and Catheter Identification

Table 1. Specifications

	WavelinQ™ Venous Catheter	WavelinQ™ Arterial Catheter
Maximum guidewire size	0.014 in (0.356 mm)	0.014 in (0.356 mm)
Catheter working length, cm/in	42 cm (16.4 in)	50 cm (19.7 in)
Maximum diagonal of square section	1.55 mm (0.061 in)	1.55 mm (0.061 in)
Minimum sheath introducer inner diameter	1.78 mm (0.070 in)	1.78 mm (0.070 in)
Recommended sheath introducer size	5 Fr	5 Fr
Rated Accessory Voltage	700 Vp	-
Electrosurgical Generator Settings	Cut T, 60 W, 0.7 Sec	-

Indications

The WavelinQ™ EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications

- Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation.
- Known allergy or reaction to any drugs/fluids used in this procedure.
- Known adverse effects to moderate sedation and/or anesthesia.
- Distance between target artery and vein > 1.5 mm.
- Target vessels < 2 mm in diameter.

Warnings, Cautions, and Precautions

Warnings

1. **The WavelinQ™ EndoAVF System is only to be used with the approved commercially available devices specified above. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system.**
2. **The WavelinQ™ catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure, potentially resulting in serious injury or death.**
3. **Use caution when performing electrosurgery in the presence of pacemakers.**
4. **Improper use could damage insulation that may result in injury to the patient or operating room personnel.**
5. **Do not plug device into the electrosurgical pencil with ESU on.**
6. **Keep active accessories away from patient when not in use.**
7. **Do not permit cable to be parallel to and/or in close proximity to leads of other devices.**
8. **Do not wrap cable around handles of metallic objects such as hemostats.**
9. **Consult the ESU User's Guide on its proper operation prior to use.**
10. **Do not use closure devices not indicated to close the artery used for access.**

Cautions

1. Only physicians trained and experienced in endovascular techniques should use the device.
2. Adhere to universal precautions when utilizing the device.
3. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable.
4. Avoid sharp bends. This may cause the device to become inoperable.
5. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable.
6. Do not bend the rigid portion of the catheter near the electrode or backstop.
7. Do not touch or handle the active electrode. Electrode dislodgement may occur.
8. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crosser may damage electrode.
9. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

Precautions

1. Care should be taken to avoid the presence of fluid on the ESU.
2. Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker.
3. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed.
4. The safety and performance of this device has not been established for pediatric patients.
5. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury.
6. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

Electrical Safety

The WavelinQ™ EndoAVF System complies with the electrical safety standards 60601-1, 60601-1-2 and 60601-2-2.

Potential Adverse Events

The known potential risks related to the WavelinQ™ EndoAVF System and procedure, a standard AVF, and endovascular procedures may include, but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; aneurysm; sepsis; steal syndrome or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

How Supplied

Packaging

The WavelinQ™ EndoAVF System is supplied STERILE and intended for single use only. Catheters are considered sterile only if the pouch is undamaged and unopened. The outer surfaces of the carton and pouch are NON-STERILE and must not be placed in the sterile field. Open the pouch using aseptic techniques so that its inner contents are delivered to the sterile field. The WavelinQ™ catheters are sterilized with ethylene oxide gas.

Storage

Store the WavelinQ™ EndoAVF System in a cool, dark, dry place.

Additional Equipment

Note: While exhaustive, this equipment list is not meant to cover all possible scenarios.

Additional Equipment

- Ultrasound machine and ultrasound probe
- Two (2) 5 Fr introducer sheaths
- Two (2) 0.014" (0.356 mm) guidewires
- 4 Fr guide catheter (as needed)
- Tourniquet or blood pressure cuff
- Anticoagulant medication, as needed
- Vasodilator medication, as needed

Electrode Activation

- ESU-1 Electrosurgical unit
- Electrosurgical pencil
- Ground pad
- Arm restraint and fixation straps

Instructions For Use

Pre-Procedural Preparations

1. The procedure should be performed in an angiography room and carried out under X-ray control.
2. Patient preparation and sterile precautions should be the same as for any percutaneous transcatheter procedure. The medication is decided by the physician, including anesthesia and precautions to reduce pain, clotting, and vasospasm during the procedure according to latest scientific guidelines and with respect to the individual patient.
3. Place ESU on a flat secure surface located near operative field making sure that the ground pad and electrosurgical pencil cabling have sufficient length to be connected during subsequent procedural steps.
4. Turn on ESU. Ensure the **Cut T** mode is illuminated, the power setting LED display reads **60 W**, and the maximum activation time of **0.7 SEC** is set in the time LED display.
5. Place ground pad on patient following standard guidelines for electrosurgical patient grounding and insert ground pad plug in to ESU. Confirm indicator light changes from red to green, ensuring appropriate patient contact.
6. Turn off ESU until ready for energy delivery in order to prevent inadvertent activation.

Vascular Access

7. Administer anesthesia or conscious sedation per hospital protocol.
8. Secure the patient's procedure arm in a restraint to prevent arm movement.
9. Use tourniquet or blood pressure cuff to facilitate vessel access as required per standard protocol.
10. Gain percutaneous access to target vein with a puncture needle.
11. Introduce a guidewire into the vein through the needle and advance an adequate length to facilitate introducer sheath insertion. A microintroducer sheath may be used to first confirm intraluminal position of guidewire.
12. Insert a 5 Fr sheath into the vein over the guidewire.
13. Inject contrast media and perform a venogram to assess appropriateness of vessel anatomy for procedure. Limit the dose of contrast depending on the patient's residual renal function. Alternate contrast methods may be used at the discretion of physician.
14. Gain access to target artery with a puncture needle and introduce a guidewire into the artery.
15. Insert a 5 Fr sheath into the artery over the guidewire.
16. Using physician discretion, administer anticoagulant and vasodilator intra-arterially or intravenously.
17. Insert a 0.014" guidewire into the artery and deliver to the target AV creation site.
18. Insert a 0.014" guidewire into the vein and deliver to the target AV creation site.
19. Orient fluoroscope perpendicular to the target artery and vein using guidewires, ultrasound, or contrast as guidance.
20. Remove tourniquet or blood pressure cuff (if applied).

Preparation of the Catheters

21. Carefully inspect the WavelinQ™ EndoAVF System pouch for any evidence of damage to the sterile barrier. If there is evidence of damage, do not use the WavelinQ™ EndoAVF System.
22. After inspection of the pouch, carefully peel open the pouch and transfer the sterile WavelinQ™ EndoAVF System to sterile field using standard transfer precautions.

EndoAVF Creation Procedure

23. Remove the arterial catheter from the packing card and inspect for damage (see Figures 1-3). Evaluate the distal end of the catheter. If it is suspected that the sterility or performance of the catheter has been compromised, the catheters should not be used.
24. Advance the arterial catheter over the 0.014" wire and insert through the arterial sheath, taking care not to kink the distal magnet arrays. Under fluoroscopic guidance, advance the catheter to the target AVF location.
25. Rotate the arterial catheter until the illumination of the rotational indicators is maximized and the concave surface of the backstop is pointed at the venous wire.
26. Remove the venous catheter from the packing card:
    a) Removing the plug and cable bundle from the card tabs
    b) Unclip the venous handle and then slide the catheter out of its containment tube. See Figures 1-3.
27. Inspect the venous catheter for damage. If it is suspected that the sterility or performance of the catheter has been compromised, the catheter should not be used.
28. Catheters have a hydrophilic coating and at the physician's discretion may be hydrated prior to insertion by wiping with saline in the sterile field.
29. Advance the venous catheter over the 0.014" wire until the yellow hemostasis valve crosser encounters the hemostasis valve of the introducer sheath. Grasp and insert the yellow hemostasis valve crosser though the hemostasis valve until it stops in the sheath hub. Grasp the proximal end of the yellow valve crosser and advance the catheter simultaneously through the yellow crosser and the sheath. Fluoroscopically inspect the electrode after venous catheter insertion to confirm proper electrode form. If the electrode appears deformed, gently remove venous catheter and inspect. If upon direct visual inspection the electrode appears damaged, replace the venous catheter. If venous catheter is removed and requires reinsertion, reposition the yellow valve crosser over the electrode prior to advancing through the hemostasis valve.

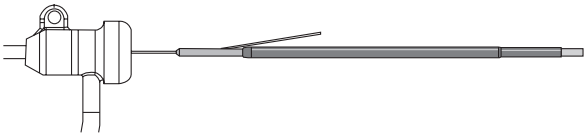

Figure 4. Venous Catheter & Valve Crosser, Pre-insertion

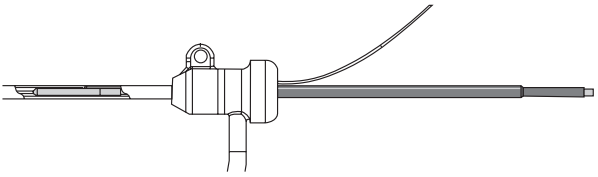

Figure 5. Venous Catheter & Valve Crosser, Post-insertion

30. Under fluoroscopic guidance, advance the venous catheter towards the target location until the distal magnets of the venous catheter begin to engage the first proximal magnets of the arterial catheter. In this location, pause to rotate the venous catheter until the illumination of the rotational indicators are maximized and the arc of the electrode is pointed at the arterial catheter. Adjust the arterial catheter as needed to confirm that catheters are aligned and prepared for venous catheter advancement.
31. Advance the venous catheter until the arc of the electrode is congruent with concave surface of the arterial backstop. Electrode should appear compressed. Confirm that the rotational indicators appear aligned and rotationally similar.
32. Rotate the fluoroscope to visualize the maximum tissue thickness distance between arterial and venous catheters. Confirm that the tissue thickness adjacent to the electrode housing is no greater than the width of the magnet array which is 1mm. If tissue thickness appears greater, adjust catheter position to a thinner tissue segment.
33. With catheters in confirmed activation position, remove cable tie, remove preassembled insert, and then connect venous catheter plug to electrosurgical pencil. Fully insert plug until there is no metallic surface exposed.
34. Pass electrosurgical pencil hand switch connector out of the sterile field and connect it to ESU's Monopolar 1 receiver.
35. Retract or remove both 0.014" guidewires from the catheter activation zone. No guidewires should be present between the proximal and distal magnet zones during activation.
36. Ensure tourniquet has been removed (if applied).
37. Do not allow catheters to move in order to minimize chance of misalignment.
38. Using fluoroscopy, verify final catheter and electrode position before energy delivery.

Figure 6. Activation Position

39. Hold patient's procedure arm at the wrist with firm pressure to minimize arm flexion and rotation during energy delivery.
40. Turn on ESU and again ensure the **Cut T** mode is illuminated, the power setting LED display reads **60 W**, and the maximum activation time of **0.7 SEC** is set in the time LED display.
41. While imaging with fluoroscopy, deliver RF energy by firmly pressing and holding the **yellow** cut switch on the electrosurgical pencil until the audible ESU activation tone stops. The electrode should visibly advance and touch the arterial backstop. If electrode does not contact backstop, an additional activation may be administered under the condition that the catheters have not been moved from their original position. Do not activate the device more than 3 times.

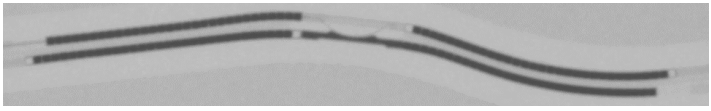

Figure 7. Electrode Advanced to Backstop

42. Remove the venous catheter. Remove the arterial catheter.
43. Perform arteriogram via the arterial sheath to confirm AVF creation. Alternate contrast methods may be used at the discretion of physician.
44. Embolize a brachial vein if patient anatomy allows.
45. Remove the arterial sheath and venous sheath and complete the puncture site closure to achieve hemostasis.

Device Disposal

WavelinQ™ EndoAVF System components that have been in contact with body fluids are a potential biohazard. Handle and dispose of the catheters and components using acceptable medical practice and all applicable local, provincial, and federal laws and regulations.

WavelinQ™ EndoAVF System has been previously referred to as the everlinQ™ endoAVF System.

Summary of Supplementary Clinical Information (WavelinQ™ EndoAVF System)

Objective

The WavelinQ™ EndoAVF System was supported by a global analysis ("4Fr Global Analysis") that was designed to aggregate and analyze safety and performance data from the EASE, EASE-2, and EU Study studies of subjects. The three studies enrolled subjects with chronic kidney disease who need hemodialysis and were candidates for percutaneous AVF creation with the WavelinQ™ EndoAVF System.

Design

Safety and performance data were collected on all study subjects during the follow-up period and the results reported here are the 6-month results of all available data. The pooled population evaluated for the aggregate study was 91 subjects.

Safety Endpoints

The safety endpoints are defined as the proportion of subjects with the following:

1. Significant Events
2. Serious Adverse Events (SAEs)
3. Device-related SAEs
4. Procedure-related SAEs
5. Closure device-related SAEs
6. Coil-related SAEs

Effectiveness Endpoints

The effectiveness endpoints are defined as the proportion of subjects with the following:

1. Procedure Success: Successful endoAVF creation is confirmed via intraprocedural angiography/fistulogram or duplex ultrasound verification performed post-procedure. This definition corresponds to the term "Technical Success" used by others.
2. Time to cannulation: The interval of time from the index procedure to the first successful 2-needle cannulation of the endoAVF.
3. Cannulation success: A successful cannulation of the endoAVF with 2-needles for dialysis. A subject may be called a 'cannulation success' with the first successful 2-needle cannulation of the endoAVF.
4. Primary patency: The interval from the time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, access abandonment, or the time of measurement of patency (SVS Reporting Standards definition).
5. Modified primary patency: Identical to Primary Patency except that loss was also triggered by reinterventions not directly related to the access circuit; namely coiling or vessel ligation of venous outflow tributaries to encourage flow into the superficial, more easily accessible veins of the upper arm.
6. Assisted primary patency: The interval from access placement to thrombosis or abandonment; not triggered by access circuit interventions performed in the absence of occlusion.
7. Secondary patency: The interval from the time of access placement until access abandonment, lost to thrombosis, or the time of patency measurement including intervening manipulations (surgical or endovascular interventions) designed to re establish functionality in thrombosed access (SVS Reporting Standards definition).
8. Functional patency: The interval of time from the first 2-needle dialysis utilizing the access until access abandonment (SVS Reporting Standards definition).
9. Functional cannulation: Successful 2-needle access of the endoAVF access circuit with performance of more than 2/3rds of dialysis sessions of at least 120 minutes in duration over a continuous 28-day period. This measure was defined to more aptly measure whether an endoAVF resulted in a working access site for a subject, and is more pertinent to a subject, as opposed to Successful Cannulation, which is limited to completing a single successful 2-needle cannulation.

Safety Results

In total, 22.0% (20/91) of the 4 Fr endoAVF subjects experienced a significant event, defined as device or procedure-related adverse events that either could be limb-threatening if not promptly identified or treated, or required additional therapy to reestablish patency of the endoAVF access circuit, irrespective of whether they met the criteria for an SAE. These significant events included stenosis, occlusion, thrombosis, and pseudoaneurysm of the access circuit and/or endoAVF, as well as one subject with abandonment of the endoAVF after a cannulation induced brachial artery injury.

SAEs were reported in 26.4% (24/91) of the Pooled Population. Of these events, 18/24 (75.0%) were unrelated to the device and unrelated to the procedure. There were 3 device-related SAEs reported in the studies (3/91, 3.3%) and included 1 thrombosis of the endoAVF, 1 stenosis of the endoAVF, and 1 access circuit false aneurysm. There were 5 procedure related SAEs reported in 5.5% (5/91) of the Pooled Population. None of the SAEs were related to the method of arterial access for the procedure. There were no reports of Unanticipated Adverse Device Effects (UADEs). There were no closure device-related SAE's or coil related SAE's reported.

Effectiveness Results

Procedural success, defined as the successful creation of an endoAVF with blood flow confirmed intraoperatively by fistulography or postoperative duplex ultrasonography, was achieved in 96.7% (88/91) of the Pooled Population. Using Kaplan-Meier (K-M) point estimates at month 6, the cannulation success rate was 84.9% ± 5.3% for subjects in the dialysis subset. The mean time to cannulation was 2.0 ± 1.6 months. Functional cannulation rate was achieved in 91.7% ± 7.8% of dialysis subjects.

Primary, Assisted Primary, and Secondary patency were determined using the K-M point estimates at month 6. Primary Patency was achieved in 72.4% ± 5.2%. at 6 months. Corresponding rates for Assisted Primary and Secondary Patency were each 77.3% ± 5.0%. Modified Primary Patency was achieved in 69.7% (±5.4%) and Functional Patency was achieved in 100% at 6 months in the Pooled Population.

Conclusion

The aggregate data presented confirm the safety and performance of the WavelinQ™ EndoAVF System for the creation of AVF for hemodialysis access.

REF

Catalogue Number
Numéro de catalogue
Katalognummer
Numero di catalogo
Número de catálogo
Catalogusnummer
Número do catálogo
Αριθμός καταλόγου
Katalognummer
Artikelnummer
Luettelonumero
Katalognummer
Numer katalogowy
Katalógusszám
Katalógové číslo
Katalog Numarası
目錄編號
카탈로그 No.
Номер по каталогу

LOT

Lot Number
Numéro de lot
Los Nummer
Numero di lotto
Número de lote
Lotnummer
Número do lote
Αριθμός παρτίδας
Lotnummer
Lot-nummer
Eränumero
Lotnummer
Numer serii
Tételszám
Číslo šarže
Parça Numarası
批號
로트 번호(Lot No.)
Номер партии

Use By Date
Date limite d'utilisation
Verwendbar bis
Utilizzare entro
Usar antes de
Te gebruiken vóór
Prazo de validade
Ημερομηνία λήξης
Anvendes før
Utgångsdag
Käytettävä ennen
Brukes innen
Termin ważności
Felhasználható
Datum použitelnosti
Son Kullanım Tarihi
有效期限
유효기한
Срок годност

Do Not Re-use
Ne pas réutiliser
Nicht wiederverwenden
Non riutilizzare
No reutilizar
Niet opnieuw gebruiken
Não reutilizar
Μην επαναχρησιμοποιείτε
Ikke til flergangsbrug
Får ej återanvändas
Ei saa käyttää uudestaan
Ikke til gjenbruk
Nie używać ponownie
Újrahasználni tilos
K jednorázovému použití
Tekrar Kullanmayınız
請勿重複使用
재사용하지 마십시오
Не подлежит повторному использованию

Do Not Resterilize
Ne pas restériliser
Nicht resterilisieren
Non risterilizzare
No reesterilizar
Niet opnieuw steriliseren
Não reesterilizar
Μην επαναποστειρώνετε
Må ikke resteriliseres
Får ej omsteriliseras
Ei saa steriloida uudestaan
Må ikke resteriliseres
Nie sterylizować ponownie
Újrasterilizálni tilos
Neprovádějte resterilizaci
Tekrar Sterilize Etmeyiniz
請勿重複消毒
재멸균하지 마십시오
Повторная стерилизация запрещается

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Obsah
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裝物
내용물
Комплектация

Consult Instructions for Use
Consulter le mode d'emploi
Gebrauchsanweisung beachten
Leggere le istruzioni per l'uso
Consulte las Instrucciones de uso
Raadpleeg de gebruiksaanwijzing
Consultar as instruções de utilização
Συμβουλευτείτε τις οδηγίες χρήσης
Se brugsanvisningen
Se bruksanvisning
Lue käyttöohjeet
Se bruksanvisning
Zapoznać się z instrukcją obsługi
Lásd a használati útmutatót
Řiďte se návodem k použití
Kullanma Talimatlarına Başvurun
請參考使用説明
사용 지침 참조
Обратитесь к инструкциям по применению

Keep Away From Sunlight
Conserver à l'abri de la lumière du soleil
Von Sonneneinstrahlung fern halten
Tenere al riparo dalla luce solare
Mantener alejado de la luz solar
Uit de buurt van zonlicht houden
Manter afastado da luz solar
Φυλάσσετε το προϊόν μακριά από το ηλιακό φως
Beskyttes mod sollys
Får ej utsättas för solljus
Suojattava auringon valolta
Beskyttes mot sollys
Chronić przed promieniowaniem słonecznym
Napfénytől védve tartandó
Nevystavujte působení slunečního záření
Güneş Işığından Uzak Tutunuz
避免日光照射
직사광선에 노출시키지 마십시오
Оберегать от воздействия солнечных лучей

Keep Dry
Conserver à l'abri de l'humidité
Trocken halten
Mantenere asciutto
Mantener seco
Droog bewaren
Manter seco
Διατηρείτε το προϊόν στεγνό
Opbevares tørt
Förvaras torrt
Suojattava kosteudelta
Oppbevares tørt
Chronić przed wilgocią
Szárazon tartandó
Uchovávejte v suchu
Kuru Tutunuz
保持乾燥
건조한 상태로 보관
Хранить в сухом месте

Not Made with Natural Rubber Latex
Fabriqué sans latex naturel
Nicht aus Naturgummilatex hergestellt.
Non prodotto con lattice di gomma naturale Este producto no se fabrica con látex de caucho natural
Niet gemaakt met latex van natuurlijk rubber
Não contém látex de borracha natural
Δεν κατασκευάζεται από φυσικό ελαστικό λάτεξ
Ikke fremstillet med naturlig gummilatex
Ej tillverkad med naturgummilatex
valmistuksessa ei ole käytetty luonnonkumilateksia
Dette produktet er ikke produsert med naturlig gummilateks
Produkt nie jest wytwarzany z lateksu kauczuku naturalnego
Nem tartalmaz természetes gumilatexet.
Není vyroben z přírodního pryžového latexu
Doğal Kauçuk Lateksten Üretilmemiştir
製造未採用天然膠乳
천연 고무 라텍스를 사용해 제조되지 않음
Не содержит натуральный каучуковый латекс

Do Not Use If Package Is Damaged
Ne pas utiliser si l'emballage est endommagé
Nicht verwenden, wenn die Verpackung beschädigt ist
Non utilizzare se la confezione è danneggiata
No usar si el envase está dañado
Niet gebruiken wanneer de verpakking beschadigd is
Não utilizar se a embalagem estiver danificada
Μη χρησιμοποιείτε το προϊόν εάν η συσκευασία του έχει υποστεί ζημιά
Må ikke bruges, hvis emballagen er beskadiget
Använd inte produkten om förpackningen skadats
Ei saa käyttää, jos pakkaus on vaurioitunut
Skal ikke brukes hvis pakningen er skadet
Nie stosować, jeśli opakowanie jest uszkodzone
Ne használja fel, ha a csomagolás sérült
Nepoužívejte, pokud je obal poškozen
Paket Hasarlıysa Kullanmayınız
如果包裝已受損，請勿使用
포장이 손상되어 있다면 사용하지 마십시오
Не использовать, если упаковка повреждена

Sterlized By Using Ethylene Oxide
Stérilisé à l'oxyde d'éthylène
Sterilisiert mit Ethylenoxid
Sterilizzato mediante ossido di etilene
Esterilizado mediante óxido de etileno
Gesteriliseerd met behulp van ethyleenoxide
Esterilizado por óxido de etileno
Αποστειρωμένο με αιθυλενοξείδιο
Steriliseret ved etylenoxid
Steriliserad med etylenoxid
Steriloitu etyleenioksidilla
Sterilisert med etylenoksid
Produkt sterylizowany tlenkiem etylenu
Etilén-oxiddal sterilizálva
Etilén-oxiddal etylenoxidem
Etilen Oksit ile Sterilize Edilmiştir
使用環氧乙烷消毒
산화에틸렌 멸균
Стерилизовано этиленоксидом

Non-Pyrogenic
Apyrogène
Pyrogenfrei
Apirogeno
Apirógeno
Niet-pyrogeen
Apirogénico
Μη πυρετογόνο
Pyrogenfri
Pyrogenfri
Pyrogeeniton
Pyrogenfri
Apirogenny
Pirogénmentes
Apyrogenní
Pirojenik değildir
無熱原
비발열성
Апирогенно

Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Fabrikant
Fabricante
Κατασκευαστής
Producent
Tillverkare
Valmistaja
Produsent
Producent
Gyártó
Výrobce
Üretici
製造商
제조사
Производитель

Date Of Manufacture
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fecha de fabricación
Productiedatum
Data de fabrico
Ημερομηνία κατασκευής
Fremstillingsdato
Tillverkningsdatum
Valmistuspäivämäärä
Produksjonsdato
Data produkcji
Gyártás dátuma
Datum výroby
Üretim Tarihi
製造日期
제조 연월일
Дата производства

Maximum Guidewire
Guide maximal
Maximalgröße Führungsdraht
Dimensione massima del filo guida
Máximo de guía
Maximale geleidedraad
Fio-guia máximo
Μέγιστο οδηγό σύρμα
Maks. guidewire
Max ledare
Ohjainvaijeri enintään
Maksimal ledevaier
Maksymalny rozmiar prowadnika
Maximális vezetődrót
Maximální vodicí drát
Maksimum Kılavuz Tel
最大導線
최대 가이드와이어
Максимальный диаметр проводника

Minimum Introducer
Introducteur minimum
Mindestgröße Einführhilfe
Introduttore minimo
Introductor mínimo
Minimale inbrenger
Introdutor mínimo
Ελάχιστος εισαγωγέας
Mindste introducer
Minsta införingsanordning
Pienin sisäänviejä
Minste innfører
Minimalny rozmiar introduktora
Minimálisan szükséges bevezető
Minimální zavaděč
Minimum İntrodüser
最小導引器
최소 유도관
Минимальный калибр интродьюсера

D

External Diameter
Diamètre externe
Außendurchmesser
Diametro esterno
Diámetro externo
Buitendiameter
Diâmetro externo
Εξωτερική διάμετρος
Udvendig diameter
Yttre diameter
Ulkoläpimitta
Utvendig diameter
Średnica zewnętrzna
Külső átmérő
Vnější průměr
Dış Çap
外徑
외경
Внешний диаметр

Type B Applied Part
Pièce de type B
Anwendungsteil vom Typ B
Componente applicato di tipo B
Parte aplicada de tipo B
Type B toegepast onderdeel
Peça aplicada de tipo B
Εξάρτημα εφαρμογής τύπου BF
Type B anvendt del
Typ B-tillämpad del
Tyypin B liityntäosa
Anvendt del av type B
Część aplikacyjna typu B
B típusú alkalmazott alkatrész
Použitá část typu B
B Tipi Uygulamalı Parça
B 型觸身部件
유형 B 적용 부품
Контактирующая часть типа B

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Co. Wexford, Ireland

Assembled in Ireland

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