BARD

CE 0344

Manufacturer

Bard Access Systems, Inc.

605 North 5600 West
Salt Lake City, Utah 84116 USA
801-595-0700

Clinical Information / Ligne directe d'informations cliniques / Hotline für klinische Informationen / Linea diretta per le informazioni cliniche / Teléfono de información clínica / Telefonische hulplijn voor klinische informatie / Linha de informações clínicas / Γραμμή βοηθείας κλινικών πληροφοριών / Hotline for klinisk information / Telefonnummer för klinisk information / Kliiniset tiedustelut numerosta / klinisk informasjon / Klinikai tájékoztató forródrót / klinické informace / Informacje kliniczne / Klinik Bilgi Acil Hattı:

800-443-3385

Ordering Information / Informations relatives aux commandes / Bestellinformationen / Per ordinare / Información para pedidos / Bestelinformatie / Informação sobre encomendas / Πληροφορίες παραγγελίας / Bestillingsinformation / Beställningsnummer / Tilaustiedot / Bestillingsinformasjon / Rendeléssel kapcsolatos információ / Informace k objednávkám / Informacje nt. zamawiania / Sipariş Bilgisi:

800-545-0890

EC REP

BARD LIMITED
Crawley, West Sussex
RH11 9BP UK

www.powerpiccsolo.com

www.bardaccess.com

0719938 0904R

PowerPICC Solo* Catheter

Power. Saline. One.*

BARD Access Systems

PowerPICC Solo* Catheter
Polyurethane Valved PICC with Microintroducer — Instructions for Use

PowerPICC Solo* Cathéter
PICC (Cathéter veineux central périphérique) à valve en polyuréthane avec micro-introducteur — Consignes d'utilisation

PowerPICC Solo*-Katheter
Polyurethan-PICC mit Ventil und Mikroeinführbesteck — Gebrauchsanleitung

PowerPICC Solo* Catetere
PICC con valvole in poliuretano con microintroduttore— Istruzioni per l'uso

Catéter PowerPICC Solo*
Catéter central de inserción periférica con válvula de poliuretano y microintroductor: instrucciones de uso

PowerPICC Solo* katheter
Polyurethaan PICC met klep en micro-introducer — Gebruiksaanwijzing

Cateter PowerPICC Solo*
PICC de Poliuretano Com Válvula e Microintrodutor — Instruções de Utilização

Καθετήρας PowerPICC Solo*
ΠΕΚΚ πολυουρεθάνης με βαλβίδα και μικροεισαγωγέα — Οδηγίες χρήσης

PowerPICC Solo* kateter
PICC med polyurethanventil med mikroindfører — Brugsanvisning

PowerPICC Solo* kateter
Polyuretanventil-PICC med mikroinföringsinstrument — bruksanvisning

PowerPICC Solo* -katetri
Polyuretaaniventtiilillinen PICC mikrosisäänvientitupella — Käyttöohjeet

PowerPICC Solo* -kateter
Polyuretan PICC med ventil og mikrointroduser — bruksanvisning

PowerPICC Solo* Catheter
Katetr PICC s polyuretanovým ventilem a mikrozavaděčem — návod k použití

PowerPICC Solo* Katéter
Poliuretán szelepes perifériásan bevezetett centrális katéter (PICC) mikrobevezetővel — Használati utasítás

Cewnik PowerPICC Solo*
Poliuretanowy cewnik PICC z zaworem i mikrointroducerem — Instrukcja użycia

PowerPICC Solo* Kateter
Poliüretan Ventilli PICC ve Mikro Yerleştirici — Kullanım Talimatları

Symbols / Symboles / Symbole / Simboli / Símbolos / Symbolen / Símbolos / Σύμβολα / Symboler / Symboler / Symbolit / Norsk / Jelzések / Symboly / Symbole / Semboller

Break This Seal / Briser ce cachet / Dieses Siegel brechen / Rompere il sigillo / Romper este sello / Verbreek deze verzegeling / Quebre este selo / Σπάστε αυτήν τη σφράγιση / Bryd denne forsegling / Bryt förseglingen / Riko tämä sinetti / Bryt denne forseglingen / Fel kell törni a pecsétet / Otevřete pečeť / Przerwać uszczelnienie / Bu Mührü Bozun

French Size / Taille French / Größe / Misura French / Tamaño French / maat: Ch. / Tamanho French / Μέγεθος σε French / French størrelse / Storlek i French / F-koko / French Str. / Fr. méret / Velikost (French) / Rozmiar [F] / French Boyut

Contents / Contenu : / Inhalt / Contenuto / Contenidos / Inhoud / Conteúdo / Περιεχόμενα / Indhold / Innehåll / Sisältö / Innhold / Tartalom / Obsah / Zawartość / İçindekiler

Sterile, Non-Pyrogenic unless package is damaged or opened. / Stérile et non pyrogène sauf si l'emballage est endommagé ou ouvert. / Dieses Produkt ist nur steril und pyrogenfrei, wenn die Verpackung nicht beschädigt oder geöffnet ist. / Sterile e apirogeno a meno che la confezione non sia danneggiata o aperta. / Estéril y no pirogénico si el embalaje no está abierto ni dañado. / Steriel en pyrogeenvrij tenzij de verpakking is beschadigd of geopend. / Esterilizado e não pirogénico, desde que a embalagem não seja danificada nem aberta. / Αποστειρωμένο, μη πυρετογενές εκτός εάν η συσκευασία είναι κατεστραμμένη ή ανοιγμένη. / Steril og pyrogenfri, medmindre emballagen er åbnet eller beskadiget. / Vid oskadad och oöppnad förpackning är produkten steril och icke pyrogen. / Steriili, ei-pyrogeeninen, ellei pakkausta ole vaurioitettu tai avattu. / Sterilt, ikke-pyrogent unntatt hvis emballasjen er skadet eller åpnet / Steril, nem pirogén, amennyiben a csomag sértetlen és zárt. / Sterilní a apyrogenní, pokud obal není poškozen nebo otevřen. / Jałowe i niepirogenne pod warunkiem, że opakowanie nie zostało uszkodzone lub otwarte. / Ambalajı açık ya da hasarlı değilse sterildir ve ateş yapmaz.

The Greendot / Le Point vert / Der Grüne Punkt / The Greendot / El punto verde / De groene stip / Ponto verde / Η Πράσινη Κουκκίδα / Den grønne prik / Grön punkt / Grønt punkt / Vihreä piste / A zöld pont / Zelený bod / Zielony Punkt / Yeşil nokta işareti

Recyclable Polyethylene Terephthalate / Polyéthylène téréphthalate recyclable / Recyclingfähiges Polyethylenterephthalat / Polietilentereftalato riciclabile / Polietilentereftalato reciclable / Recyclebaar polyethyleentereftalaat / Tereftalado de polietileno reciclável / Ανακυκλώσιμο τερεφθαλικό πολυαιθυλένιο / Polythylen-terephthalat til genbrug / Återanvändbar polyetylentereftalat / Kierrätettävä polyetyleenitereftalaatti / Resirkulerbar polyetylentereftalat / Újrahasznosítható polietilén tereftalát / Recyklovatelný polyetylentereftalát / Tereftalan polietylenu do wtórnego wykorzystania / Geri Dönüşümlü Polietilen Tereftalat

Patent Information Enclosed / Informations sur les brevets incluse / Patienteninformationen anbei / Informazioni sui brevetti incluse / Información de patente adjuntada / Patiëntinformatie ingesloten / Informações sobre patentes incluídas / Εσωκλείονται πληροφορίες διπλώματος ευρεσιτεχνίας / Oplysninger om patent vedlagt / Patentinformation medföljer / Patenttitiedot oheisena / Patentinformasjon er vedlagt / Beteginformáció csatolva / Informace o patentech přiloženy / Załączone informacje o patentach / Patent Bilgisi Eklidir

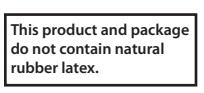
Microintroducer / Micro-introducteur / Mikroeinführungsbesteck / Microintroduttore / Microintroductor / Micro-introducer / Micro introdutor / Μικροεισαγωγέας / Mikrointroducer / Mikroinförare / Mikrosisäänviejä / Mikrointroduser / Mikrobevezető / Mikrozavaděč / Mikrointroducer / Mikro Yerleştirici

Single Lumen / Lumière unique / Einlumig / Lumen singolo / Un lumen / Enkel lumen / Lúmen simples / Μονός αυλός / Enkelt lumen / En lumen / Yksilumeninen / Enkellumen / Egyszeres lumen / Jednolumenový katetr / Jednokanałowy / Tek Lümen

Dual Lumen / Lumière double / Doppellumig / Lumen doppio / Dos lúmenes / Dubbel lumen / Lúmen duplo / Διπλός αυλός / Dobbelt lumen / Två lumen / Kaksilumeninen / Dobbellumen / Kettős lumen / Dvoulumenový katetr / Dwukanałowy / Çift Lümen

Triple Lumen / Lumière triple / Dreilumig / Lumen triplo / Tres lúmenes / drie lumina / Lúmen triplo / Τριπλός αυλός / Tredobbelt lumen / Tre lumen / Kolmelumeninen / Tredobbellumen / Háromszoros lumen / Trojlumenový katetr / Trójkanałowy / Üçlü Lümen

Length / Longueur / Länge / Lunghezza / Longitud / Lengte / Comprimento / Μήκος / Længde / Längd / Pituus / Lengde / Hossz / Délka / Długość / Uzunluk



This product and package do not contain natural rubber latex / Ce produit et son emballage ne contiennent aucune trace de latex en caoutchouc naturel / Dieses Produkt und die Verpackung enthalten kein Naturlatex / Il prodotto e la confezione non contengono lattice di gomma naturale / Este producto y su embalaje no contienen látex de goma natural / Dit product en de verpakking bevatten geen natuurlijke rubberlatex / Este produto e respectiva embalagem não contêm látex de borracha natural / Το παρόν προϊόν και η συσκευασία δεν περιέχουν λάτεξ από φυσικό καουτσούκ / Dette produkt indeholder ikke naturgummilatex / Denna produkt och förpackning innehåller inte naturligt gummilatex / Tämä tuote ja sen pakkaus eivät sisällä luonnonkumilateksia / Dette produktet og emballasjen inneholder ikke naturlig gummilateks / Ez a termék és csomagolása nem tartalmaz természetes gumilatexet / Výrobek a obal neobsahují přírodní kaučukový latex / Produkt i opakowanie nie zawierają kauczuku lateksu naturalnego / Bu ürün ve ambalaj, doğal lastik lateks içermez

Sterilized by Ethylene Oxide / Stérilisé á l'oxyde d'éthylène / Sterilisiert mit Äthyenoxid / Sterilizado con óxido de etileno / Esterilizado con óxido de etileno / Gesteriliseerd met ethyleenoxide / Esterilizado com óxido de etileno / Αποστειρωμένο με Οξείδιο τον Αιθυλενίου / Steriliseret med ætylenoxid / Steriliserad med etylenoxid / Steriloitu etyleenioksidilla / Sterilisert med etylenoksid / Etilén-oxiddal sterilizálva / Sterylizowane tlenkiem etylenu / Sterilizováno etylenoxidem / Etilen oksit ile sterilize edilmiştir

Single Use. Do Not Resterilize. / Produit à usage unique - Ne pas restériliser / Zum einmaligen Gebrauch. Nicht resterilisieren / Monouso. Non risterilizzare / De un solo uso. No reesterilizar / Eenmalig gebruik / Uso único. Não re-utilize / Μιας χρήσης. Μην το επαναποστειρώνετε / Til engangsbrug. Må ikke resteriliseres / Endast för engångsbruk. Får inte resteriliseras / Kertakäyttöinen. Ei saa steriloida uudelleen / Til engangsbruk. Ikke resterilisere / Egyszeri használatra. Ne sterilizálja újra! / Pro jedno použití. Neprovádějte opak ovanou sterilizaci / Jednorazowego użytku. Nie sterylizować ponownie / Tek Kullanımlıktır, Tekrar Sterilize Etmeyin.

PVC Tubing Does Not Contain DEHP / Tubulure en PVC ne contient pas de DEHP / PVC-Schlauch enthält kein DEHP / Tubo in PVC Non Contiene DEHP / Los tubos de PVC no contienen DEHP / PVC-slangen bevatten geen diethylhexylftalaat (DEHP) / O tubo de PVC não contém DEHP / Η σωλήνωση PVC δεν περιέχει DEHP / PVC-slange indeholder ikke DEHP / PVC-slang innehåller ej DEPH / PVC-letku ei sisällä DEHP:tä / PVC-slangen inneholder ikke DEHP / A PVC csővezeték nem tartalmaz DEHP-t (dietil-hexil-ftalátot) / Hadičky z PVC neobsahují DEHP / Rurki PCW nie zawierają DEHP / PVC Tüp DEHP İçermez

Attention. See Instructions For Use / Attention, se reporter au mode d'emploi / Achtung, Gebrauchsanweisung lesen / Attenzione, leggere le istruzioni per l'uso / Atención vea las instrucciones de uso/ Opgelet: zie gebruiksaanwijzing / Atenção, ver instrções de utilização / Ιιροσχή, Βλέπε Οδηγίες Χρήσης / Bemærk: Se Brugsanvisningen / Obs! Se bruksanvisningen / Huomio, lue käyttöohjeet / NB! Se Bruksanvisningen / Figyelem, lásd a használati utasítást / Pozor, čtěte návod k použití / Uwaga, przeczytać instrukcję przez użyciem / Dikkat, Kullanım Yönergelerini İnceleyiniz

USA Only / USA seulement / Nur USA / Solo negli Stati Uniti / EEUU solamente / VS alleen / Apenas EUA / ΗΠΑ μόνο / Kun USA / Endast USA / Vain USA / Kun USA / Csak USA / Pouze pro USA / Dotyczy tylko USA / Yalnız ABD

NEW IMPORTANT INFORMATION:

Recommended Flushing/Maintenance Procedure(s)

The catheter should be maintained in accordance with standard hospital protocols. Recommended catheter flushing/maintenance is as follows:

1. Flush the catheter after every use, or at least weekly when not in use. Use a 10 ml or larger syringe.
2. Flush the catheter with a minimum of 10 ml of 0.9% sodium chloride, using a "pulse" or "stop/start" technique. Use of heparinized saline to lock each lumen of the catheter is optional.
3. Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely. **Caution**: Always remove needles or syringes slowly while injecting the last 0.5 ml of saline.
4. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 ml saline and flush to clear TPN from the catheter.
5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.

NOTE: When injecting or infusing medications that are incompatible, you should always flush the catheter with a minimum of 10 ml saline before and after each medication.
NOTE: When maintained in accordance with these instructions, the **PowerPICC SOLO*** catheter does not require the use of heparinized saline to lock the catheter lumens. However, use of heparinized saline will not adversely effect the catheter and may be necessary based on patient status or use of alternate flushing and locking techniques.
Caution: Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
Caution: The **PowerPICC SOLO*** catheter is designed for use with needleless injection caps or "direct-to-hub" connection technique. Always apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**
Warning: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Product Description

A family of peripherally inserted central catheters made from specially formulated and processed medical grade materials. Each **PowerPICC SOLO*** catheter has a kink resistant, reverse tapered design. Catheters are packaged in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

Sterilized by ethylene oxide. Do not re-sterilize.

PowerPICC SOLO* Catheter Valve Function

The **PowerPICC SOLO*** catheter valve controls the flow of fluids to provide clamp-free infusion therapy. Positive pressure into the catheter (gravity, pump, syringe) will open the valve, allowing fluid infusion. When negative pressure (aspiration) is applied, the valve opens allowing for the withdrawal of blood into a syringe.

Indications

The **PowerPICC SOLO*** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Contraindications

The device is contraindicated whenever:
- The presence of device-related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors will prevent proper device stabilization and/or access.

ChloraPrep* Solution One-Step Applicator Contraindications:

- Do not use in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption.
- Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alchohol.
- Do not use for lumbar puncture or allow contact with meninges.
- Do not use on open skin wounds or as a general skin cleanser.

Warnings

General Warnings

- When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
- Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.
- Intended for Single Patient Use. DO NOT REUSE. The **PowerPICC SOLO*** is a single use device and should never be re-implanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Re-sterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood must not be reused or re-sterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
- CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

Placement Warnings

- If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
- Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.
- This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

Power Injection Warnings

- Exceeding the maximum flow rate of 5 ml/sec, or the maximum pressure of power injectors of 300 psi (2068 kPa), may result in catheter failure and/or catheter tip displacement.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
- Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
- **PowerPICC SOLO*** catheter indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

ChloraPrep* Solution One-Step Applicator Warnings

- Flammable, keep away from fire or flame.
- Do not use with electrocautery procedures.
- For external use only.
- When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.
- Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Precautions

General Precautions

- Sterilized by ethylene oxide. Do not re-sterilize.
- Carefully read and follow all instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, including contrast media, as specified by their manufacturer.
- Precautions are intended to help avoid catheter damage and/or patient injury.
- To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.
- Always remove needles or syringes slowly while injecting the last 0.5 ml of saline.
- Acetone and tincture of iodine should not be used.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed.
- Inspect kit for inclusion of all components.
- Flush the catheter with sterile normal saline prior to use. Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
- Accessories and components used in conjunction with this device should incorporate luer lock connections.
- DO NOT USE A SYRINGE SMALLER THAN 10 ml. Prolonged infusion pressure greater than 25 psi (172 kPa) may damage blood vessels or viscus.

Precautions Related to Device Placement Procedure

- The **PowerPICC SOLO*** catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the **PowerPICC SOLO*** catheter above antecubital fossa is recommended.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Do not place suture around the catheter. Sutures may damage the catheter or compromise catheter patency.
- Do not cut stylet.
- Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position.
- Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atraumatic clamps or forceps.
- Avoid perforating, tearing or fracturing the catheter when using a guidewire.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen.
- The **PowerPICC SOLO*** catheter is designed for use with needleless injection caps or "direct-to-hub" connection technique. Always apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**

Possible Complications

The potential exists for serious complications including the following:

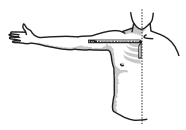
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Myocardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

Insertion Instructions

1. Identify the Vein and Insertion Site

- Apply a tourniquet above the anticipated insertion site.
- Select and mark the vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.
  Caution: The **PowerPICC SOLO*** catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the **PowerPICC SOLO*** catheter above antecubital fossa is recommended.
  Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Release tourniquet.

2. Patient Position / Catheter Measurement



- Position the arm at a 90˚ angle.
- For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava (SVC). Measure from the planned insertion site to the right clavicular head, then down to the third intercostal space.
  Note: The external measurement can never exactly duplicate the internal venous anatomy.

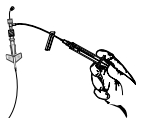
3. Skin Preparation

- Don prep gloves, head cover and mask.
- Apply underdrape.
- Prepare the site with the ChloraPrep* Solution One-Step Applicator or according to institutional policy using sterile technique.
- Pinch the wings of the ChloraPrep* Solution One-Step Applicator to break the ampule and release the antiseptic. **Do not touch the sponge.**
- Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.
- Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. **Do not blot or wipe away.**
- Maximum treatment area for one applicator is approximately 130 cm^2 (10 cm x 13 cm). Discard the applicator after a single use.
- When alcohol is used as a skin prep, it must be allowed to completely air dry before proceeding with insertion.
- Remove and discard gloves.

4. Sterile Field Preparation

- Apply the tourniquet above the intended insertion site to distend the vessel.
- Don sterile gloves and gown.
- Apply fenestrated and body drapes & complete sterile field preparation.

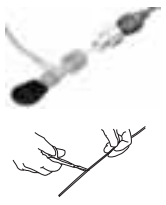
5. Preflush the Catheter



- Attach prefilled syringe to the luer attachment on the T-Lock extension set.
- Flush catheter lumen(s) until saline drips out of distal end of the catheter.
- The syringe may be left attached during procedure.

6. Modification of Catheter Length

Note: Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion according to hospital protocol. Catheter depth markings are in centimeters.



A. Measure the distance from the zero mark to the desired tip location.
B. Disconnect the T-Lock from the stylet funnel.
C. Withdraw the entire T-Lock connector/stylet assembly, as one unit.
D. Retract the stylet to well behind the point the catheter is to be cut.
E. Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy if necessary.
   Caution: Do not cut stylet.
F. Inspect cut surface to assure there is no loose material.
G. Re-advance the T-lock connector/stylet assembly locking the connector to the stylet funnel. Assure stylet tip is intact.
H. Gently retract the stylet through the locked T-lock connector until the stylet tip is contained inside the catheter.
I. Assure proper alignment of the stylet to the distal end of the trimmed catheter.

English

English

7. Perform Venipuncture

- Anesthetize with local anesthesia as required.
- Insert the safety introducer needle into the desired vein.

  Alternate Technique: The safety IV catheter may be used as an alternate to the safety introducer needle. Remove the needle from the catheter after the vein is accessed.

  Warning: If the artery is entered, withdraw the needle or safety IV catheter and apply manual pressure for several minutes.
- Release tourniquet.
- Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle or catheter and into the vein. Advance the guidewire to the desired depth.

  Caution: Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.
- Gently withdraw and remove the safety introducer needle or catheter, while holding the guidewire in position.

  Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Advance the small sheath and dilator together as a unit over the guidewire, using a slight rotational motion. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guide lines concerning the use of a safety scalpel prior to making incision.
- Withdraw the dilator and guidewire, leaving the small sheath in place.

  Warning: Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.

8. Insert and Advance the Catheter

- Insert the catheter into the introducer sheath.
- Advance the catheter slowly.
- Complete catheter advancement into the desired position.

9. Complete Catheter Insertion

- Continue to advance the catheter. For central placement, when the tip has advanced to the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible insertion into the jugular vein.

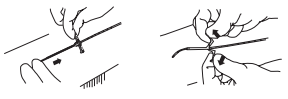
  The **PowerPICC SOLO*** catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the **PowerPICC SOLO*** catheter above antecubital fossa is recommended.

  Note: Resistance may be felt approximately 7cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter (O.D.) The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

  Note: PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or appropriate technology.

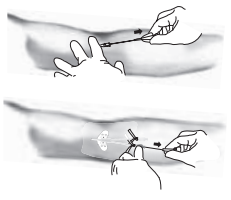
  Warning: This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

10. Retract and Remove the Introducer Sheath



- Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath.
- Withdraw the introducer sheath from the vein and away from the site.
- Split the introducer sheath and peel it away from the catheter.

11. Remove the Stylet, Stylet Funnel, and T-Lock Assembly



- Disconnect the T-Lock and stylet funnel from the catheter luer connector.
- Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
- Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through T-Lock.

  Caution: Never use force to remove the stylet. Resistance can damage the catheter.

  If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position.

12. Aspirate and Flush

- Attach primed extension set and/or saline-filled syringe.
- Aspirate for adequate blood return and flush catheter with 10ml normal saline to ensure patency.

  Caution: The **PowerPICC SOLO*** catheter is designed for use with needleless injection caps or "direct-to-hub" connection technique. Always apply a sterile end cap on the catheter hub to prevent contamination when not in use. Use of a needle longer than 1.6 cm may cause damage to the valve.

  Caution: Always remove needles or syringes slowly while injecting the last 0.5 ml of saline.
- Cap catheter.

  Warning: The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.

13. Securing the PowerPICC SOLO* Catheter

The StatLock* catheter stabilization device is included in **PowerPICC SOLO*** catheter kits. Please refer to Instructions For Use on the proper use and removal. The StatLock* catheter stabilization device should be monitored daily and replaced at least every seven days.

Caution: To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.

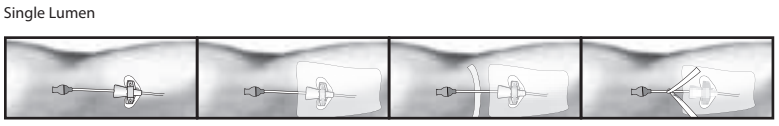
Warning: When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Warning: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Warning: Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.

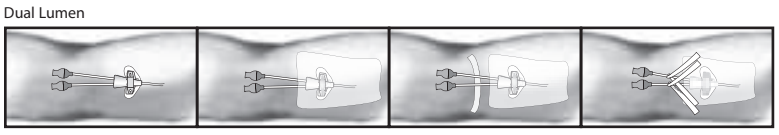
The StatLock* Stabilization Device Procedure

Single Lumen



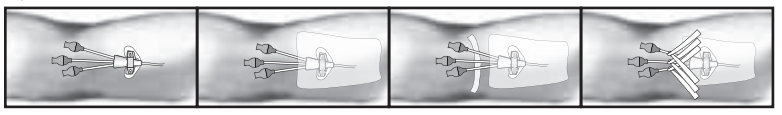
1. Secure catheter with the StatLock* stabilization device.
2. Cover site and the StatLock* stabilization device with transparent dressing.
3. Place anchor tape sticky side up, under hub. Wedge tape between hub and wings.
4. Chevron anchor tape on top of transparent dressing.

Dual Lumen



1. Secure catheter with the StatLock* stabilization device.
2. Cover site and the StatLock* stabilization device with transparent dressing.
3. Place 1st anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. Place 2nd anchor tape sticky side up under hub. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.

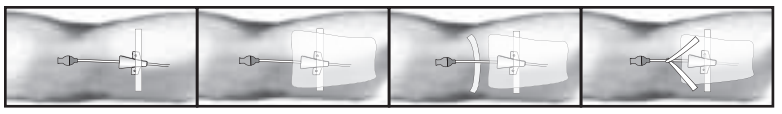
Triple Lumen



1. Secure catheter with the StatLock* stabilization device.
2. Cover site and the StatLock* stabilization device with transparent dressing.
3. Place 1st anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. Place 2nd and 3rd anchor tapes sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.

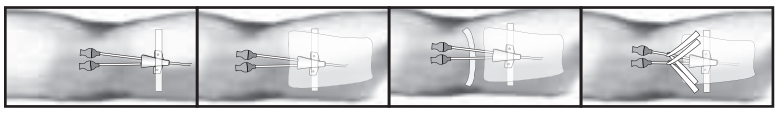
Tape Strip Stabilization Procedure

Single Lumen



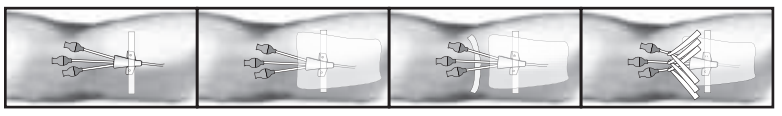
1. Place 1st anchor tape over wings or junction.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.
3. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings.
4. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub

Dual Lumen



1. Place 1st anchor tape over wings or bifurcation.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.
3. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings. Anchor only one hub of dual lumen catheter.
4. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub

Triple Lumen



1. Place 1st anchor tape over wings or trifurcation.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.
3. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings. Anchor only one hub of the triple lumen catheter. Chevron anchor tape on top of transparent dressing.
4. Place 2nd and 3rd anchor tapes sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing and place third anchor tape over hub.

14. Verify Placement

- PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or appropriate technology.

15. Power Injection Procedure

Warning: **PowerPICC SOLO*** catheter indication for power injection of contrast media implies the catheter's ability to with stand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

A. Remove the injection/needleless cap from the **PowerPICC SOLO*** catheter.
B. Attach a 10 ml or larger syringe filled with sterile normal saline.
C. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
D. Detach syringe.
E. Attach the power injection device to the **PowerPICC SOLO*** catheter per manufacturer's recommendations.
F. Contrast media should be warmed to body temperature prior to power injection.
   Warning: Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
G. Use only lumens marked "Power Injectable" for power injection of contrast media.
   Warning: Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
H. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5ml/sec.
   Warning: Exceeding the maximum flow rate of 5 ml/sec, or the maximum pressure of power injectors of 300 psi (2068 kPa), may result in catheter failure and/or catheter tip displacement.
   Warning: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
I. Disconnect the power injection device.
J. Replace the injection/needleless cap on the **PowerPICC SOLO*** catheter.
K. Flush the **PowerPICC SOLO*** catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. Use of heparinized saline to lock each lumen of the catheter is optional.

- The **PowerPICC SOLO*** catheter testing included 10 power injection cycles.

16. Suggested Catheter Maintenance

A. **Dressing Changes**
   1. Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.
   2. Maintain according to hospital protocol. Avoid using acetone based solutions, or ointment. These substances are known to degrade polyurethane.
   3. Chlorhexidine gluconate is the suggested antiseptic to use. 2% Chlorhexidine gluconate /70% isopropyl alcohol swab sticks may be used for dressing changes. Povidone-iodine may also be used as an antiseptic.
   4. Allow all cleaning agents / antiseptics to dry completely before applying dressing.

      Caution: Acetone and tincture of iodine should not be used.

      Warning: When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

B. **Flushing**
   1. Flush the catheter after every use, or at least weekly when not in use. Use a 10 ml or larger syringe.
   2. Flush the catheter with a minimum of 10 ml of 0.9% sodium chloride, using a "pulse" or "stop/start" technique. Use of heparinized saline to lock each lumen of the catheter is optional.
   3. Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.

      Caution: Always remove needles or syringes slowly while injecting the last 0.5 ml of saline.
   4. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 ml saline and flush to clear TPN from the catheter.
   5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.

      NOTE: When injecting or infusing medications that are incompatible, you should always flush the catheter with a minimum of 10 ml saline before and after the medication.

      NOTE: When maintained in accordance with these instructions, the **PowerPICC SOLO*** catheter does not require the use of heparinized saline to lock the catheter lumens. However, use of heparinized saline will not adversely effect the catheter and may be necessary based on patient status or use of alternate flushing and locking techniques.

      Caution: Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

      Caution: The **PowerPICC SOLO*** catheter is designed for use with needleless injection caps or "direct-to-hub" connection technique. Always apply a sterile end cap on the catheter hub to prevent contamination when not in use.

Use of a needle longer than 1.6 cm may cause damage to the valve.

Warning: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

C. **Occluded or Partially Occluded Catheter**

Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.

D. **When Cleaning the Exit Site**

Warning: Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.

- Maintain according to hospital protocol. Avoid using acetone based solutions, or ointment. These substances are known to degrade polyurethane.
- Use chlorhexidine gluconate or povidione iodine to clean the exit site around the catheter.
- Allow all cleaning agents/antiseptics to dry completely before applying dressing.

17. Central Venous Pressure Monitoring

- Prior to conducting central venous pressure monitoring:
- Ensure proper positioning of the catheter tip.
- Flush catheter vigorously with sterile normal saline.
- Ensure the pressure transducer is at the level of the right atrium.
- It is recommended that a continuous infusion of saline (3 ml/hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.
- Use your institution's protocols for central venous pressure monitoring procedures.

Warning: CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

18. Catheter Removal

- Remove dressing and StatLock* catheter stabilization device or tape securement strips.
- Grasp catheter near insertion site.
- Remove slowly. Do not use excessive force.
- If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
- Resume removal procedure.
- Examine catheter tip to determine that the entire catheter has been removed.

Bard Access Systems, Inc. warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard Access Systems, Inc. for repair or replacement, at Bard Access Systems, Inc. option. All returns must be authorized in advance in accordance with Bard Access Systems, Inc. Returned Goods Policy found in its then current Price List. The liability of Bard Access Systems, Inc. under this limited product warranty does not extend to any abuse or misuse of this product or its repair by anyone other than an authorized Bard Access Systems, Inc. representative.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD ACCESS SYSTEMS WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: April 2009

*Bard, PowerPICC, PowerPICC SOLO, "The Power of Purple", Power. Saline. One., "The Simplicity of Saline", "One Valve. One PICC.", StatLock, Sherlock, and the color purple are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

ChloraPrep is a trademark and/or registered trademark of Cardinel Health, Inc or an affiliate.

NOUVELLES INFORMATIONS IMPORTANTES :

Procédures de rinçage et de maintenance

Le cathéter doit être entretenu conformément au protocole hospitalier standard. Nous conseillons le rinçage et l'entretien du cathéter suivants :

1. Rincer le cathéter après chaque utilisation, ou au moins une fois par semaine tant que vous ne l'utilisez pas. Utiliser une seringue d'au moins 10 ml.
2. Rincer le cathéter avec au minimum 10 ml de chlorure de sodium à 0,9%, à l'aide d'une technique de "pulsations", ou "arrêt/départ". Verrouiller chaque lumière du cathéter avec de la solution saline héparinisée est une opération facultative.
3. Débrancher la seringue et fixer un capuchon stérile à l'embase du cathéter, fermer soigneusement. **Attention** : Toujours retirer les aiguilles ou les seringues doucement, en injectant les 0,5 derniers millilitres de solution saline.
4. Avant tout prélèvement d'un échantillon de sang lors de la perfusion d'une nutrition parentérale, suivre la procédure d'entretien de routine, mais utiliser 20 ml de solution saline et rincer le cathéter pour le nettoyer du liquide nourrissant.
5. En cas de résistance lors du rinçage, il convient de cesser toute autre tentative. Une autre tentative de rinçage pourrait entraîner la rupture du cathéter et une éventuelle embolisation. Se reporter au protocole de l'établissement concernant les cathéters obstrués.

REMARQUE : En cas d'injection ou de perfusion de médications présentant des incompatibilités, il convient de rincer le cathéter systématiquement, à l'aide d'au moins 10 ml de solution saline avant et après chaque administration de médicament.
REMARQUE : S'il est entretenu conformément à ces instructions, il n'est pas nécessaire de verrouiller les lumières du cathéter **PowerPICC SOLO*** à l'aide d'une solution saline héparinisée. Toutefois, l'utilisation d'une telle solution saline héparinisée n'abîmera pas le cathéter. Elle peut éventuellement s'avérer nécessaire selon l'état du patient, ou l'utilisation de techniques de rinçage et de verrouillage différentes.
Attention : Utiliser les techniques d'asepsie chaque fois que la lumière du cathéter est ouverte ou connectée à d'autres dispositifs.
Attention : Le cathéter **PowerPICC SOLO*** est conçu pour être utilisé avec des capuchons d'injection sans aiguille ou avec une technique de connexion directe à l'embase. Utiliser systématiquement une capsule stérile sur l'embase du cathéter pour éviter toute contamination lorsque qu'il n'est pas utilisé. **L'utilisation d'une aiguille de plus de 1,6 cm peut endommager la valve.**
Avertissement : Ne pas utiliser d'alcool pour verrouiller, imprégner ou décolmater les cathéters de polyuréthane car on sait que l'alcool dégrade les cathéters de polyuréthane en cas de contact répété et prolongé.

Description du produit

Gamme de cathéters veineux centraux périphériques fabriqués à partir de matériaux de type médical spécialement formulés et traités. Chaque cathéter **PowerPICC SOLO*** bénéficie d'une conception anti-plicature en forme de cône inversé. Les cathéters sont emballés sur un plateau avec des accessoires pour un accès vasculaire fiable de longue durée (plus de 30 jours) ou de courte durée (moins de 30 jours).

Stérilisé à l'oxyde d'éthylène. Ne pas restériliser.

Fonction de la valve du cathéter PowerPICC SOLO*

La valve du cathéter **PowerPICC SOLO*** contrôle le débit des liquides, afin d'assurer une thérapie par infusion sans clamp. Une pression positive dans le cathéter (gravité, pompe, seringue) ouvre la valve, ce qui permet la perfusion du liquide. En cas de pression négative (aspiration), la valve s'ouvre, ce qui permet le prélèvement de sang dans une seringue.

Indications

Le cathéter **PowerPICC SOLO*** est indiqué pour l'accès périphérique à court et long terme au système veineux central pour les traitements par intraveineuse et l'injection sous pression de produits de contraste ; il permet aussi la surveillance de la pression veineuse centrale. Pour le prélèvement d'échantillons de sang, la perfusion ou le traitement, utiliser un cathéter de 4F ou plus. Le débit de perfusion maximal recommandé est de 5ml/s pour l'injection sous pression d'un produit de contraste. Pour la surveillance continue de la pression veineuse centrale, il est conseillé d'utiliser une lumière de cathéter de calibre 20 ou plus.

Contre-indications

Ce dispositif est contre-indiqué dans les cas suivants :

- Présence connue ou soupçonnée d'une infection, d'une bactériémie ou d'une septicémie liée au dispositif.
- La taille corporelle du patient est insuffisante pour la taille du dispositif implanté.
- On sait ou on soupçonne que le patient est allergique aux matériaux qui composent le dispositif.
- Une irradiation antérieure du site prévu pour l'insertion.
- Des épisodes antérieurs de thrombose veineuse ou d'intervention chirurgicale vasculaire au niveau du site prévu pour le positionnement.
- Si les caractéristiques des tissus du site empêchent la stabilisation et/ou l'accès convenable au dispositif.

Contre-indications de l'applicateur ChloraPrep Solution One-Step :

- Ne pas utiliser chez les enfants de moins de 2 mois en raison du risque d'irritation cutanée excessive et d'augmentation de l'absorption médicamenteuse.
- Ne pas utiliser chez les patients présentant des allergies connues au gluconate de chlorhexidine ou à l'alcool isopropylique.
- Ne pas utiliser pour la ponction lombaire ni mettre en contact avec les méninges.
- Ne pas utiliser sur des blessures cutanées ouvertes ou comme nettoyant cutané à usage général.

Avertissements

Avertissements généraux

- En cas d'utilisation d'alcool ou d'antiseptiques contenant de l'alcool avec les cathéters de polyuréthane, éviter soigneusement tout contact prolongé ou excessif. Laisser les solutions sécher complètement avant d'appliquer un pansement occlusif. Les antiseptiques dont l'utilisation est suggérée sont le gluconate de chlorhexidine et/ou la polyvidone iodée.
- Ne pas utiliser d'alcool pour verrouiller, imprégner ou décolmater les cathéters de polyuréthane car on sait que l'alcool dégrade les cathéters de polyuréthane en cas de contact répété et prolongé.
- Ne pas utiliser le cathéter en présence de signes de détérioration mécanique ou de fuite. La détérioration du cathéter peut provoquer sa rupture, sa fragmentation, un risque d'embolie et conduire à son retrait chirurgical.
- En cas de signes d'extravasation, arrêter l'injection. Démarrer immédiatement l'intervention médicale appropriée.
- Ne frottez pas le cathéter avec des solutions à base d'acétone ou des pommades contenant du polyéthylèneglycole. Au fil du temps, ils peuvent endommager le matériau en polyuréthane.
- N'utiliser que pour un seul patient. NE PAS RÉUTILISER. Le **PowerPICC SOLO*** est un dispositif à usage unique, à ne jamais réimplanter. Leur réutilisation est à la seule responsabilité du soignant en cas d'infection croisée, quelle que soit la méthode de nettoyage ou de stérilisation. La restérilisation d'un dispositif incomplètement nettoyé peut s'avérer inefficace. Aucun dispositif ayant été contaminé par du sang ne doit être réutilisé ou restérilisé.
- Après son utilisation, ce produit peut devenir un contaminant potentiel. Le manipuler et en disposer conformément aux pratiques médicales acceptées et aux lois et réglementations applicables au niveau fédéral, de l'état et local.
- Le niveau de liquide dans le cathéter baisse si le connecteur du cathéter est positionné au-dessus du niveau du cœur du patient et ouvert à l'air libre. Pour empêcher le niveau de liquide de baisser (et l'air d'entrer) lors du changement des capuchons d'injection, placer le connecteur sous le niveau du cœur du patient avant de retirer le capuchon d'injection.
- La surveillance continue de la pression veineuse centrale doit toujours être mise en place conjointement avec les autres mesures d'évaluation du patient lors du contrôle de la fonction cardiaque.

Avertissements relatifs à la mise en place

- En cas de pénétration dans l'artère, retirer l'aiguille et appliquer une pression manuelle pendant plusieurs minutes.
- Placer un doigt sur l'orifice de la gaine pour limiter la perte sanguine et le risque d'aspiration d'air. Le risque d'embolie gazeuse est réduit lorsque le patient effectue la manœuvre de Valsalva pendant cette partie de la procédure jusqu'à ce que le cathéter soit inséré dans la gaine.
- Ce cathéter n'est pas destiné à l'oreillette droite. Éviter de positionner l'embout du cathéter dans l'oreillette droite. La mise en place ou la migration de l'embout du cathéter dans l'oreillette droite peut provoquer une arythmie cardiaque, une érosion du myocarde ou une tamponnade cardiaque. Le risque de telles complications est plus grand chez les patients nouveaux-nés.

Avertissements relatifs à l'injection sous pression

- Le dépassement du débit maximal de 5 ml/s ou de la pression maximale de 300 psi (2068 kPa) des injecteurs à haut débit peut provoquer une défaillance du cathéter et/ou le déplacement de l'embout du cathéter.
- Faute de vérifier la perméabilité du cathéter avant l'injection sous pression, le cathéter pourrait présenter une défaillance.
- Si le produit de contraste n'est pas à température du corps au moment de l'injection sous pression, le système de cathéter peut ne pas fonctionner.
- L'utilisation de lumières ne portant pas la mention « Power Injectable » (Compatible avec l'injection sous pression) pour l'injection sous pression d'un produit de contraste peut endommager le cathéter.
- La fonction de limitation de pression d'une pompe à injection peut ne pas empêcher la surpression dans un cathéter obstrué, ce qui peut endommager le cathéter.
- La prescription du cathéter **PowerPICC SOLO*** pour l'injection sous pression d'un produit de contraste implique la capacité pour le cathéter à supporter le mode opératoire, mais n'implique pas l'adaptation de la procédure à un patient donné. Un médecin hospitalier convenablement formé est responsable de l'évaluation de l'état de santé d'un patient dans le cadre de la procédure d'injection sous pression.