

SIDE BY SIDE DOUBLE LUMEN CATHETER

雙腔血液透析導管使用說明

Side By Side双腔血液透析导管使用说明

TABLE OF CONTENTS

ENGLISH	1
CHINESE (Traditional)	5
CHINESE (Simplified)	9

SIDE BY SIDE DOUBLE LUMEN CATHETER

INDICATIONS FOR USE

The Medcomp® Side by Side Double Lumen Catheter is designed for acute hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the jugular vein. Although this catheter may be inserted into the subclavian or femoral, the internal jugular is the preferred site. This catheter is indicated for a duration less than (30) days.

CONTRAINDICATIONS

This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

POTENTIAL COMPLICATIONS

AIR EMBOLISM
BACTEREMIA
BRACHIAL PLEXUS INJURY
CARDIAC ARRHYTHMIA
CARDIAC TAMPONADE
CENTRAL VENOUS THROMBOSIS
ENDOCARDITIS
EXIT SITE INFECTION
EXSANGUINATION
FEMORAL ARTERY BLEED
FEMORAL NERVE DAMAGE
HEMATOMA
HEMORRHAGE
HEMOTHORAX
INFERIOR VENA CAVA PUNCTURE

LACERATION OF THE VESSEL
LUMINAL THROMBOSIS
MEDIASTINAL INJURY
PERFORATION OF THE VESSEL
PLEURAL INJURY
PNEUMOTHORAX
RETROPERITONEAL BLEED
RIGHT ATRIAL PUNCTURE
SEPTICEMIA
SUBCLAVIAN ARTERY PUNCTURE
SUBCLAVIAN ARTERY PUNCTURE
SUBCUTANEOUS HEMATOMA
SUPERIOR VENA CAWA PUNCTURE
THORACIC DUCT LACERATION
VASCULAR THROMBOSIS

Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter immediately.

Do not advance the stainless steel guidewire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.

WARNINGS

Federal law (USA) restricts the device to sale by or on the order of a physician.

Single use only. Do not resterilize the catheter or accessories by any method. The manufacturer will not be liable for any damages caused by re-use or resterilization of the catheter or accessories.

Re-Use may lead to infection or illness/injury.

Contents sterile and non-pyrogenic in unopened or undamaged package.

USE ONLY

Sterilized by Ethylene Oxide. STERILE | EO

Do not use catheter if package is damaged or has been opened. Do not use if catheter or components show signs of damage (crimped, crushed, cut, etc.)

CATHETER PRECAUTIONS

Do not use sharp instruments near the extension lines or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.

Use only smooth jawed forceps for clamping when not using the clamp supplied with the catheter. We recommend using only line extension clamps which have been provided for clamping. Clamping the catheter repeatedly in the same spot could weaken the tubing. Change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub of the catheter. Do not clamp the lumen portion of the catheter. Clamp only the extensions. Examine tubing for damage at the end of each treatment.

To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

It is recommended that only luer lock (threaded) connections be used with this catheter (including syringes, bloodlines, IV tubing, and injection caps). Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.

INSERTION SITES

JUGULAR

Have the patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

FEMORAL

The patient should lie completely on his/her back. Both femoral veins should be palpated for site selection and consequence assessment. The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery.

NOTE: For femoral placement, monitor patient closely for thrombosis, infection, and bleeding.

SUBCLAVIAN

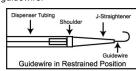
The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite that of the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area. Note the position of the subclavian vein which is posterior to the clavicle, superior to the fist rib and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib).

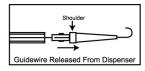
NOTE: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation. Long time use of the subclavian vein may be associated with subclavian vein stenosis.

DIRECTIONS FOR SELDINGER INSERTION:

Read instructions carefully before using this device. The catheter should be inserted, manipulated and removed only by a qualified, licensed physician or other health care practitioner, authorized by and under the direction of such physician. The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient. Use standard hospital protocols.

- Strict aseptic technique must be used during the insertion, maintenance and catheter removal procedures. Provide a sterile operative field. The operating room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.
- The selection of the appropriate cannula length is at the sole discretion of the physician. To concurrently achieve proper tip positioning, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
- 3. Administer sufficient local anesthetic to completely anesthetize the insertion site.
- Insert the introducer needle with attached syringe into the selected site. Aspirate
 to insure proper placement.
- Remove guidewire from Captive J-Straightener by grasping the shoulder of the straightener and gently pulling it from the dispenser tubing. DO NOT pull the guidewire prior to releasing the Captive J-Straightener as this may damage the guidewire.





 Remove the syringe, placing thumb over the end to prevent blood loss or air embolism. Insert the flexible end of the guidewire through the needle and into the vein.

Caution: The length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Caution: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

- Remove needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel.
- Thread dilator over guidewire into the vessel (a slight twisting motion may be used). Remove dilator when vessel is sufficiently dilated, leaving guidewire in place.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

Caution: Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

- 9. The catheter is irrigated with saline-filled syringes. The syringes are removed and the arterial extension is clamped. With the venous extension unclamped, thread the distal tip of the catheter over the guidewire. The catheter may be rotated gently during insertion until the tip is correctly positioned. The guidewire is removed, and the venous clamp is closed.
- 10. Attach syringes on both extensions and open clamps. Blood should aspirate easily from both venous and arterial sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flow. Once adequate blood flow has been established, both lumens are irrigated again with saline-filled syringes. It is necessary to open the extension clamps during the irrigation procedure. Clamp the extensions, remove the syringes and place an injection cap on each luer lock connector. Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by filling the catheter with saline prior to use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
- 11. Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamp(s) provided.
- 12. Immediately after insertion, confirm proper placement of the tip of the catheter with x-ray. The catheter tip should lie at the junction of the superior vena cava and the right atrium. Observe the patient carefully for signs and symptoms of cardiac arrhythmia caused by passage of the catheter into the right atrium. If symptoms appear, pull back the tip until they are eliminated. Femoral tip placement to be determined by physician.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

 Suture the catheter to the skin using the rotating wing. Do not suture the catheter tubing. Cover the exit site with occlusive dressing.

Record indwelling catheter length and lot number on patient's chart and check position routinely.

Before dialysis begins, all connections to the extracorporeal circuit should be checked carefully. During all dialysis procedures, frequent visual inspection should be conducted to detect leaks and prevent blood loss or entry of air into the the extracorporeal circuit. In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure. Excess blood leakage may lead to patient shock.

HEPARINIZATION

If the catheter is not used immediately for treatment, follow the suggested catheter patency guidelines:

- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- INJECT A HEPARIN SOLUTION INTO EACH LUMEN OF THE CATHETER. WHEN
 INJECTING THE HEPARIN, INJECT QUICKLY TO ENSURE THAT THE HEPARIN
 COMPLETELY FILLS THE LUMEN OF THE CATHETER. THE TOTAL VOLUME OF
 EACH HEPARIN SOLUTION SHOULD BE EQUAL TO THE INTERNAL VOLUME OF
 EACH LUMEN. EACH LUMEN MUST BE COMPLETELY FILLED WITH A HEPARIN
 SOLUTION.
- Clamp the arterial and venous extension pieces, remove syringe, and attach a sterile injection cap to each luer lock connector. Once the lumina have been heparinized, keep both extensions clamped when not attached to bloodlines or a syringe. If either clamp is opened, blood may enter the distal portion of the catheters, ultimately causing a thrombus.
- In most instances, no further heparin is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.
- The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

To maintain catheter patency, ensure that a sufficient heparin concentration is used. Since this concentration may vary from institution to institution, please consult your hospital protocol.

Before infusing fresh heparin, aspirate indwelling heparin and flush each lumen with sterile normal saline.

Never forcibly flush a clotted lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may attempt using a thrombolytic agent.

SITE CARE

Clean the skin around the catheter. Cover exit site with an occlusive dressing. Leave the extensions, clamps, adapters and caps exposed for access by the staff.

Wound dressings must be kept dry. Patient must not swim, shower, or soak dressing while bathing. If adhesion of dressing is compromised by profuse perspiration or accidental wetting, the dressing must be changed by the medical or nursing staff under sterile conditions.

INSUFFICIENT FLOWS

Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If manipulation of the catheter through rotation (except single lumen catheters) or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent. Physician discretion is advised.

MANAGEMENT OF ONE-WAY OBSTRUCTION

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition. One of the following adjustments may resolve the obstruction:

- -Reposition the patient.
- -Have the patient cough.
- -Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

WARNING: ONLY A PHYSICIAN SHOULD ATTEMPT THE FOLLOWING PROCEDURES

-Rotate the catheter to reorient the tip position with respect to vascular anatomy. In subclavian and jugular insertion, tip malposition usually can be avoided if the venous adapter is oriented toward the midline on insertion. This positions the arterial inlet away form the wall of the superior vena cava, allowing free blood flow into the arterial lumen.

-Withdraw the catheter slightly to reposition the tip. Caution: Do not insert the catheter further into the vein.

-Reverse the bloodlines. If the previous methods fail to resolve a one-way obstruction, the patient may be dialyzed by connecting the arterial bloodline to the venous adaptor and the venous bloodline to the arterial adapter. A significant increase in recirculation may occur.

-Never forcibly flush an obstructed lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using a thrombolytic agent to dissolve the clot.

INFECTION

Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use **universal blood and body-fluid precautions** in the care of all patients. Sterile technique must be strictly adhered to during the entire procedure

Clinically recognized infection at the catheter site should be treated with an appropriate antibiotic. If a fever occurs in a patient with a catheter in place, take at least two blood cultures from a site distant from the catheter site. If a blood culture is positive, the catheter should be removed and appropriate antibiotic therapy initiated. Wait 48 hours before inserting another catheter. Insertion should be made only on the side opposite the site which became infected.

CATHETER REMOVAL

<u>Warning:</u> Only a physician familiar with the appropriate techniques should attempt the following procedures.

<u>Caution</u>: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

- 1. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
- 2. Withdraw catheter through the exit site.
- 3. Apply pressure to exit site for approximately 10-15 minutes or until bleeding stops.
- 4. Apply dressing in a manner to promote optimal healing.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

Captive® J-Straightener is a registered trademark of Lake Region Manufacturing, Inc.

Medcomp® is a registered trademark of Medical Components, Inc.

Item Number:

XTP126MT-C : XTP128MT-C : XTP129MT-C : XTP125JJS-C : XTP126JJS-C : XTP128JJS-C : XTP145MTA-C : XTP146MTA-C : XTP148MTA-C : XTP149MTA-C : XTP14

XTP128IJS-C; XTP145MTA-C; XTP146MTA-C; XTP148MTA-C; XTP14 XTP145IJSA-C; XTP146IJSA-C; XTP148IJSA-C; XTP149IJSA-C;

雙腔血液透析導管使用說明

滴應症:

Medcomp Side By Side雙腔血液透析導管適用于建立短期血管通路進行血液透析和血液 淨化。導管採用經皮穿刺方式置入,最好置入頸內靜脈。雖然也可置入鎖骨下靜脈或股 靜脈,但頸內靜脈是最佳部位。導管的使用時間不能超過30天。

禁忌症:

本產品不可用於適應症以外之用途。不可用於有血栓形成之血管。

可能的併發症:

可能の切け致化・
 空氣栓塞・ 管腔栓塞・
 対血症・ 縦漏損傷・ 血管穿破・ 心律不整・ 胸肋膜損傷・ 心包填塞・ 氣胸

中央靜脈血栓
 心内膜炎
 插管處感染
 大量出血
 ・ 鎖骨下動脈穿刺

 股動脈出血
 皮下血腫

 股神經損傷
 上腔靜脈穿刺血腫

 出血
 胸管裂傷血管栓塞

 血胸
 靜脈狹窄

・ 下腔靜脈穿刺

• 血管破裂

- 導管連接埠或連接頭若於插管或使用時鬆脫,請採必要之預防性步驟以防失血或空氣栓塞,並移除導管。
- 如遇阻力請勿強行插入導引線或導管。
- 插入或移除導引線時勿過度施力,以免斷裂或線圈鬆脫。若導引線損壞請一併 移除導管及導引線。
- 警告事項:
- 本產品僅遵醫囑販售。
- 本產品僅限單次使用。
- 請勿將導管及配件重複滅菌。
- 本產品若經重複使用或滅菌而引發任何損害,製造商將不負擔任何責任。
- 若包裝完好未經開封,則為無菌且無致熱原產品。
- 本產品經EO滅菌
- 請勿使用包裝已開封或損壞之產品。若產品有任何損壞跡象則請勿使用。
- 導管注意事項:
- 不要在導管及其延長管周圍使用尖銳的器具。不要使用剪刀去除敷料,否則有可能剪斷或損壞導管。導管任何部分不能縫線。導管管身如過力擠壓或碰到粗 糙邊沿可能會損壞。
- 如果不使用包裝內的管夾,只能使用平滑的鉗子夾閉導管。 推薦只能使用延長管上自帶的管夾。在導管同一部位反復夾閉可能會使導管強度變弱。夾閉位置應經常更換,以延長導管壽命。避免在導管厄式接頭和導管座處夾閉,只能在延長管處夾閉。每次治療結束後應檢查導管管身有無損壞。
- 為防止出現意外,在治療前或治療的間隔期,必須確認所有的注射帽和血液管路的連接牢固可靠。
- 建議該導管只能與帶厄式接頭連接(如針筒、血路、靜脈輸液管和肝素帽)。
 反復過度旋緊靜脈輸液導管、針筒或肝素帽會減少接頭壽命,並可能導致接頭損壞。應經常檢視導管是否出現會影響導管性能的裂口、擦痕、割痕等。

插管部位:

頸內靜脈

使患者在床上抬頭以找出胸鎖乳突肌,插管處位於兩條肌肉形成的三角頂處,此 頂點約位於距鎖骨三指寬處。應觸診確定頸動脈位於插管處中間。

胸部X線確認導管的最終位置。初步放置導管後必須進行常規X線檢查,以便在 使用之前確認導管尖端位置。

股靜脈

病人應採取完全仰臥位。在選擇穿刺位置及隨後的評估之前,必須觸摸兩側股動脈。穿刺點同側的膝關節屈曲,大腿外展。同側足交叉放置在對側小腿上。此時 股靜脈應該在股動脈的後、內側。

注意:股靜脈置管時,請密切監測患者是否出現血栓、感染和出血。

鎖骨下靜脈

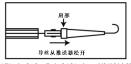
患者須呈垂頭仰臥姿,上胸敞開且頭部些微往插管處反方向轉,肩胛骨中間可墊 毛巾使胸部伸展開。注意鎖骨下靜脈的位置,在鎖骨之後、第一肋骨之上、鎖骨 下動脈之前。(正好位於鎖骨和第一肋骨交角的外側點)。

注意:使用呼吸機支持通氣的病人在行鎖骨下靜脈穿刺時氣胸風險增加,並 可能導致相應的併發症。長期使用鎖骨下靜脈會導致鎖骨下靜脈狹窄。

Seldinger穿刺技術說明

- 使用本產品前請詳閱使用說明。植人、使用與移除導管之步驟皆須由合格 醫師或其監督下由合格的醫療照護人員進行。
- 本說明書所載之醫療技術與程序無法代表所有醫學認可的方法,亦無法替代醫師個別的治療經驗與判斷。
- 請使用醫院標準程序。
- 插管、例行維護與移除導管時均應嚴格採無菌技術。準備無菌操作區域, 最好於手術室進行插管,使用無菌手術巾、器材與配件,為插管處周圍皮 膚除毛,進行外科刷手消毒,穿戴手術衣、帽、手套及面罩,並為患者戴 上口罩。
- 應由醫師判斷選用之導管長度,導管長度將決定導管尖端位置是否適當。 每次使用前應例行以X光檢查導管位置。
- 3. 插管處應注射足量的麻醉劑。
- 4. 將接上空針筒的導引針插入血管後。回抽以確認穿刺位置是否正確。
- 5. 握緊J-拉直器的肩部,將導引線從J-拉直器退回並輕輕拉回至推送管。J-拉直器鬆開之前,不可回拉導引線,否則可能會導致導引線損壞。





 移去針筒,用拇指堵住導引針尾端以防止出血或空氣栓塞。導引線彎曲端 通過導引針進入目標靜脈。

注意:導引線置人的長度根據病人的體型決定。在此過程中應監測病人是否出現心律失常的跡象。此過程中病人應處於心臟監護之下。導引線進入右心房可能導致心律失常。在此過程中應牢固把握導引線。

注意:如果使用導引針,不要對著針尖斜面拔回導引線,以免導引線被切斷。

- 7. 移除導引針,導引線留置血管內,並以刀片擴張皮膚穿刺點。
- 擴張器沿導引線插入至血管(稍微轉動有助於插入)。血管充分擴張後,移 去擴張器,導引線留在原位。

注意:擴張器不可作為留置導管留在體內,否則可能會導致血管壁穿孔。

注意:如果未充分擴張組織,會導致導管腔與導引線之間接觸過緊,造成導管 置入困難或導引線從導管內拔出時困難。這可能導致導引線彎折。

- 9. 用充滿生理鹽水的針筒灌洗導管,然後移走針筒,夾閉動脈延長管。靜脈延長管管夾開放,導管遠端沿導引線插入。在插管過程中可以輕輕旋轉導管直至導管尖端位置放置準確。移走導引線,並關閉靜脈管夾。
- 10. 在動靜脈兩處延長管尾端連接針筒並打開導管夾。應該能夠很容易從動靜脈延長管中抽出血液。如果任意一側抽血過程中發現有較大阻力,需要旋轉導管或重新調整導管位置以獲得足夠的血流。一旦能夠抽出足夠血流,兩側管腔都應該使用充滿生理鹽水的針筒進行沖洗。冲洗過程中需要打開延長管上的夾子。關閉延長管上的夾子,移去針筒,在每個厄式接頭上安放一個肝素帽。為了避免空氣栓塞,在不使用導管時請保持延長管一直處於夾閉狀態,並且在每次使用導管之前都要用生理鹽水沖洗與管。每次變更導管連接時,都要把空氣從導管或所有連接管和封帽中排出。
- 11. 不要夾閉導管的兩側管腔部分。只能夾閉延長管部分。不要使用帶齒的鉗子,只能使用包裝內提供的導管夾。
- 12. 插管完成後,立即進行X線確認導管尖端位置是否正確。導管尖端應正好位於上腔靜脈與右心房的連接處上方。密切監測患者是否出現因導管進入右心房而導致的心律不齊症狀。如出現此類症狀,回拉導管尖端,直至症狀消失。對於股靜脈置管,導管尖端位置由醫生決定。

注意:未確認導管位置可能會導致嚴重創傷或致命併發症。

13. 利用旋轉翼把導管縫在皮膚上。請勿縫在導管管身上。用封閉敷料覆蓋穿 刺點。

請在病人病例上記錄導管長度和導管批號,並進行導管位置常規檢查。透析治療之前, 應仔細檢查接到體外管路的所有接頭。血液透析所有程式過程中,應經常檢視有無洩 漏,並防止出血或空氣進入體外管路。萬一發現洩漏,應立即夾閉導管。在繼續進行透 析治療之前必須採取必要的補救措施。大量失血會導致病人休克。

肝麦生理食鹽水封管

如果導管不會被立即用於治療,請遵循下列維持導管暢通的指導建議:

- 要在兩次治療之間維持導管暢通,導管的每一個管腔內必須充滿肝素("肝素鎖")。
- 每個導管腔都應注入肝素溶液。注射時應快速,以確保肝素充滿整個導管腔。 每個管腔的肝素溶液量應等於該管腔的內部容積。每個導管腔必須完全充滿肝 素溶液。

- 關閉動靜脈延長管上的夾子,移走針筒,在每個厄式接頭上連接一個無菌肝素帽。所有導管腔肝素化後,除非需要接至血路或針筒,否則動靜脈延長管夾子 應保持關閉狀態。如果任何一個夾子打開,血液就可能會進入導管遠端,最終 導致血栓
- 在大部分情况下,如果不需要回抽或沖洗導管,48-72小時內不再需要更多的 肝素溶液
- 治療之前應把肝素溶液從管腔中去除,以免造成病人的全身肝素化。回抽肝素 溶液應該依據醫院的血液透析標準流程。

為維持導管暢通,確保使用足夠的肝素濃度。由於不同機構的該肝素濃度不同, 因此請遵循醫院的規定。

輸注新鮮肝素之前,請先抽除留置肝素並用無菌生理鹽水沖洗氛個管腔。

千萬不要強行用力沖洗血栓管腔。任何一個管腔內出現血栓,首先應嘗試用針筒 將血塊回抽出來。如果回抽沒用,醫生可以嘗試使用溶栓劑。

串部護理

清潔導管周圍皮膚,以封閉性敷料覆蓋穿刺點,保持延長管、管夾與注射帽外 露以方便操作

傷口敷料須保持乾燥清潔。患者不可游泳、淋浴或使敷料泡水。若大量出汗或 意外弄濕敷料導致影響黏貼,醫護人員須於無菌狀態下更換敷料。

導管問題

注意:若導管有問題而需要進行任何形式之機械性或化學性介入處置前,請先熟悉醫院科室規 範、潛在併發症及其處置方式、警告與注意事項。

警告:以下步驟僅可由技巧純熟的醫師進行。

流量禍小:

不得太過用力沖洗堵塞管腔。血流不夠可能是由於動脈孔被血栓堵塞或是由於側孔與靜脈壁接 觸。如果旋轉導管(單腔導管除外)或將動脈管和靜脈管互換也沒有用,醫生可以嘗試使用溶 栓劑。建議由醫生自行決定。

導管單向堵塞:

單向阴寒即為導管腔可進行灌沖,但無法順利回抽血液,通常因導管尖端位置不正確引起。 可藉由以下調整方式解決:

- 重新調整導管位置。
- 重新調整患者姿勢。 .
- 使患者試著咳嗽。
- 若灌沖時完全無阻力,可用無菌生理食鹽水大量灌沖導管使導管尖端與血管壁 分開

警告:只有醫生才能執行下列操作。

- 旋轉導管,使導管尖端在血管內的位置改變。對於鎖骨下靜脈和頸內靜脈插管,如果穿刺時 靜脈管接頭朝向中位,通常可以避免導管尖端異位。這樣可以使得動脈管口遠離上腔靜脈壁, 允許血液自由流向動脈管
- 稍微退回導管,重新放置導管尖端。注意:不要將導管繼續插入至靜脈
- -互換血路。如果前一種方法無法解決單向堵塞問題,患者血透時可以將動脈血路接到靜脈接
- 頭上,而靜脈血路接到動脈接頭上。 血流迴圈量可能會顯著提高。 一千萬不要強行用力沖洗血栓管腔。任何一個管腔內出現血栓,首先應嘗試用針筒將血塊回抽出來。如果回抽沒用,醫生可以嘗試使用溶栓劑。

感染:

因為有暴露在HIV(人類免疫缺陷病毒)或其它血媒性病原體下的風險,醫務人員在護理病人時 必須一直遵守常規血液和體液預防措施。必須一直嚴格遵守無菌技術。 在導管穿刺點發現的臨床感染必須迅速用合適的抗菌素進行治療。帶有導管的病人如果出現發

品等是不利益以交配可能不能不能不是不是不是一个。 素,應該在遊廳準管等刺點的地方採取血條,至少進行兩個血經費。如果血經營結果呈陽性, 必須立即拔除導管並使用合適的抗菌素進行治療。在重新放置導管之前要等待48小時。如果可 能,應該在原來導管受感染穿刺點的對側進行插管

導管移除

警告:以下步驟僅可由技巧純熟的醫師進行。

注意:移除導管前請先熟悉醫院科室規範、潛在併發症及其處置方式、警告與注意事項。

- 剪斷固定翼上的縫線,依照醫院規範將之移除。
- 2. 自插管處取出導管
- 按壓插管處10-15分鐘或止血即可。 3.
- 4. 蓋上敷料幫助患部癒合。

產品保證

Medcomp®保證本產品遵循正常標準與規格製造。患者狀態、臨床治療及產品維護皆會影響本產 品的使用效能。請按照使用說明及處方醫師的指示使用本產品。

為求產品持續進步,產品價格、規格與銷售型號如有更動恕不另行通知。

Captive® J-拉直器是Lake Region Manufacturing, Inc.公司的注冊商標。 Medcomp® 是Medical Components Inc.公司的注册商標。

產品型號:

XTP126MT-C: XTP128MT-C: XTP129MT-C: XTP125IJS-C: XTP126IJS-C: XTP128IJS-C: XTP145MTA-C: XTP146MTA-C: XTP148MTA-C: XTP149MTA-C: XTP145IJSA-C: XTP146IJSA-C: XTP148IJSA-C: XTP149IJSA-C: XTP149IJSA-C: XTP149IJSA-C: XTP148IJSA-C: X

製造廠名稱: 藥商名稱: Medical Components, Inc. DBA - MedComp, Inc. 景年國際有限公司

製造廠地址: 1499 Delp Drive, Harleysville, PA 19438, USA

藥商地址: 臺北市中山區建國北路二段85號3樓之1

Side By Side双腔血液透析导管使用说明

适应症:

Medcomp® Side By Side双腔血液透析导管适用于建立短期血管通路进行血液透析和血液净化。导管采用经皮穿刺方式置入,最好置入颈内静脉。虽然也可置入锁骨下静脉或股静脉,但颈内静脉是最佳部位。导管的使用时间不能超过30天。

禁忌症

此导管不适用于除本说明书规定适应症以外的其它任何用途。禁止置入血栓血管。

可能的并发症:

皮下血肿 上腔静脉损伤 胸导管损伤 静脉狭窄

下腔静脉损伤 血管损伤

血肿

出血

血胸

- 在穿刺之前,操作者应充分了解上述并发症,并能够在上述并发症发生时进行紧急处理。
- 在穿刺或使用过程中,如果发生接头或连接处断离这种偶发事件,应采取必要的步骤和 预防措施阻止出血或空气栓塞,并移除导管。
- 当遇到异常阻力时,不要继续推送导丝或导管。任何时候都不要使用暴力插入或拔除导 丝,否则导丝可能会折断或散开。如果发现导丝受损,导管必须和导丝一起拔出。

警告

- 美国联邦法律严格限定此产品必须由医生或凭医嘱销售。
- 此导管仅限一次性使用。不要使用任何方法对导管或配件进行重新灭菌。因重复使用或 重新灭菌导管及配件造成的损害,生产商不负任何责任。
- 重复使用可能会导致感染或疾病/损伤。
- 包装未打开、未破损时内容物处于无菌、无致热源状态。
- · 产品由环氧乙烷灭菌。 STERILE | EO
- 如果包装已被打开或破损,请不要使用其中的导管。如果发现导管或配件有损坏迹象(有 皱褶、压痕、裂口等),请不要使用。

导管注意事项:

- 不要在导管及其延长管周围使用尖锐的器具。不要使用剪刀去除敷料,否则有可能剪断 或损坏导管。导管任何部分不能缝线。导管管身如过力挤压或碰到粗糙边沿可能会损坏。
- 如果不使用包装内的管夹,只能使用平滑的钳子夹闭导管。 推荐只能使用延长管上自带的管夹。在导管同一部位反复夹闭可能会使导管强度变弱。夹闭位置应经常更换,以延长导管寿命。避免在导管鲁尔接头和导管座处夹闭,只能在延长管处夹闭。每次治疗结束后应检查导管管身有无损坏。
- 为防止出现意外,在治疗前或治疗的间隔期,必须确认所有的封盖和血液管路的连接牢固可靠。
- 建议该导管只能与带鲁尔旋锁(带螺纹)的接头连接(如注射器、血路、静脉输液管和 肝素帽)。反复过度旋紧静脉输液导管、注射器或肝素帽会减少接头寿命,并可能导致 接头损坏。应经常检视导管是否出现会影响导管性能的裂口、擦痕、割痕等。

穿刺部位:

颈内静脉

让病人从床上抬起头以显示胸锁乳突肌。导管应从胸锁乳突肌两头构成的三角形顶点进 入。该顶点应该在锁骨上方三指宽的地方。导管穿刺点内侧应该可以摸到颈动脉的搏动。

胸部X线确认导管的最终位置。初步放置导管后必须进行常规X线检查,以便在使用 之前确认导管尖端位置。

股静脉

病人应采取完全仰卧位。在选择穿刺位置及随后的评估之前,必须触摸两侧股动脉。穿 刺点同侧的膝关节屈曲,大腿外展。同侧足交叉放置在对侧小腿上。此时股静脉应该在 股动脉的后、内侧。

注: 股静脉置管时,请密切监测患者是否出现血栓、感染和出血。

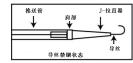
锁骨下静脉

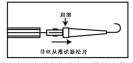
使病人处于改进的Trendelenburg体位,显露上胸部,头略微偏向穿刺点的对侧。在两肩胛之间放入一个卷成卷的毛巾,以使胸部区域更好地伸展。注意锁骨下静脉的位置,在锁骨之后、第一肋骨之上、锁骨下动脉之前。(正好位于锁骨和第一肋骨交角的外侧点)。

注意:使用呼吸机支持通气的病人在行锁骨下静脉穿刺时气胸风险增加,并可能导致相应的并发症。长期使用锁骨下静脉会导致锁骨下静脉狭窄。

Seldinger穿刺技术说明:

- 使用本产品前请仔细阅读使用说明。导管的穿刺、操作及拔除只能由合格的注册 医生执行,或在医生指导下由合格的保健专家执行。
- 本说明中所描述的医疗技术和过程并未包含所有临床可接受的规则,也不能替代医 生对治疗特殊病人时的经验和判断。
- 如果医院有标准操作流程,请以医院规定为准。
- 1. 在导管置入、护理及拔除过程中必须严格执行无菌技术。建立一个无菌手术区。手术室是放置导管最理想的地方。使用无菌辅巾、设备及配件。穿刺点上方和下方刮除毛发。执行外科清洗流程。穿戴手术衣、手术帽、手套及口罩。让病人戴上口罩。
- 2. 导管长度的选择由医生决定。为使导管尖端位于最佳位置,正确选择导管的长度非常重要。在导管放置完成之后,必须执行常规X线检查,以便在使用前确认导管位于正确的位置。
- 在穿刺点部位给予足够的局部麻醉。
- 4. 连穿刺针带注射器一起穿刺所选部位。抽吸以确认穿刺位置正确。
- 握紧J-拉直器的肩部,将导丝从J-拉直器退回并轻轻拉回至推送管。J-拉直器松开 之前,不可回拉导丝,否则可能会导致导丝损坏。





6. 移去注射器,用拇指堵住穿刺针尾端以防止出血或空气栓塞。导丝弯曲端通过穿刺 针进入目标静脉。

注意:导丝置入的长度根据病人的体型决定。在此过程中应监测病人是否出现心律失常的迹象。此过程中病人应处于心脏监护之下。导丝进入右心房可能导致心律失常。在此过程中应牢固把握导丝。

注意: 如果使用穿刺针,不要对着针尖斜面拔回导丝,以免导丝被切断。

- 7. 移去穿刺针,导丝留在血管内。用手术刀片扩大皮肤穿刺部位切口。
- 扩张器沿导丝插入至血管(稍微转动有助于插入)。血管充分扩张后,移去扩张器,导丝留在原位。

注意: 扩张器不可作为留置导管留在体内, 否则可能会导致血管壁穿孔。

注意:如果未充分扩张组织,会导致导管腔与导丝之间接触过紧,造成导管置入困难或 导丝从导管内拔出时困难。这可能导致导丝弯折。

- 9. 用充满生理盐水的注射器灌洗导管,然后移走注射器,夹闭动脉延长管。静脉延长管管夹开放,导管远端沿导丝插入。在插管过程中可以轻轻旋转导管直至导管尖端位置放置准确。移走导丝,并关闭静脉管夹。
- 10. 在动静脉两处延长管尾端连接注射器并打开导管夹。应该能够很容易从动静脉延长管中抽出血液。如果任意一侧抽血过程中发现有较大阻力,需要旋转导管或重新调整导管位置以获得足够的血流。一旦能够抽出足够血流,两侧管腔都应该使用充满生理盐水的注射器进行冲洗。冲洗过程中需要打开延长管上的夹子。关闭延长管上的夹子,移去注射器,在每个鲁尔旋锁接头上安放一个肝素帽。为了避免空气栓塞,在不使用导管时请保持延长管一直处于夹闭状态,并且在每次使用导管之前都要用生理盐水冲洗导管。每次变更导管连接时,都要把空气从导管或所有连接管和封帽中排出。
- 11. 不要夹闭导管的两侧管腔部分。只能夹闭延长管部分。不要使用带齿的钳子,只能 使用包装内提供的导管夹。
- 12. 插管完成后,立即进行X线确认导管尖端位置是否正确。导管尖端应正好位于上腔静脉与右心房的连接处上方。密切监测患者是否出现因导管进入右心房而导致的心律不齐症状。如出现此类症状,回拉导管尖端,直至症状消失。对于股静脉置管,导管尖端位置由医生决定。

注意:未确认导管位置可能会导致严重创伤或致命并发症。

13. 利用旋转翼把导管缝在皮肤上。请勿缝在导管管身上。用封闭敷料覆盖出皮部位。

请在病人病例上记录导管长度和导管批号,并进行导管位置常规检查。透析治疗之前,应仔细检查接到体外管路的所有接头。血液透析所有程序过程中,应经常检视有无泄漏,并防止 出血或空气进入体外管路。万一发艰泄漏,应立即夹闭导管。在继续进行透析治疗之前必须 采取必要的补救措施。大量失血会导致病人休克。

肝素化

如果导管不会被立即用于治疗,请遵循下列维持导管畅通的指导建议:

- 要在两次治疗之间维持导管畅通,导管的每一个管腔内必须充满肝素("肝素锁")。
- 每个导管腔都应注入肝素溶液。注射时应快速,以确保肝素充满整个导管腔。每个管腔的肝素溶液量应等于该管腔的内部容积。每个导管腔必须完全充满肝素溶液。
- 关闭动静脉延长管上的夹子,移走注射器,在每个鲁尔接头上连接一个无菌肝素帽。所有导管腔肝素化后,除非需要接至血路或注射器,否则动静脉延长管夹子应保持关闭状态。如果任何一个夹子打开,血液就可能会进入导管远端,最终导致血栓。
- 在大部分情况下,如果不需要抽吸或冲洗导管,48-72小时内不再需要更多的肝素溶液。
- 治疗之前应把肝素溶液从管腔中去除,以免造成病人的全身肝素化。抽吸肝素溶液应该 依据医院的血液透析标准流程。

为维持导管畅通,确保使用足够的肝素浓度。由于不同机构的该肝素浓度不同,因此请遵循 医院的规定。

输注新鲜肝素之前,请先抽除留置肝素并用无菌生理盐水冲洗每个管腔。

千万不要强行用力冲洗血栓管腔。任何一个管腔内出现血栓,首先应尝试用注射器将血块抽 吸出来。如果抽吸没用, 医生可以尝试使用溶栓剂。

出皮部位护理

- 清洁导管周围的皮肤。使用密封敷料覆盖出皮部位,延长管、夹子、接头及肝素帽暴露 在外以方便医护人员操作。
- 敷料必须保持清洁与干燥。病人禁止游泳、淋浴,洗澡时不要浸湿敷料。如果出汗过多 或偶然弄湿导致敷料粘性下降,医生或护理人员必须在无菌条件下及时更换敷料。

导管使用

注意:在执行任何类型的物理或化学干预治疗之前,必须回顾医院或科室的相关规定、可能的并发症及其治疗方案、警告及注意事项,以便应对导管使用过程中出现的问题。

警告: 只有熟知相关技术的医生可以执行下列操作过程。

流量不够

不得太过用力冲洗堵塞管腔。血流不够可能是由于动脉孔被血栓堵塞或是由于侧孔与静脉壁 接触。如果旋转导管(单腔导管除外)或将动脉管和静脉管互换也没有用,医生可以尝试使 用溶栓剂。建议由医生自行决定。

单向堵塞的现象,即冲洗管腔时非常顺畅,但不能抽到回血。这经常是由于尖端异位造成的。

下列方法可能会解决这种堵塞问题:

- 调整病人体位。
- 让病人咳嗽。
- 如果没有阻力,用无菌生理盐水快速冲洗导管,以使导管尖端从血管壁上移开。

警告: 只有医生才能执行下列操作。

- --旋转导管,使导管尖端在血管内的位置改变。对于锁骨下静脉和颈内静脉插管,如果穿刺 时静脉管接头朝向中位,通常可以避免导管尖端异位。这样可以使得动脉管口远离上腔静脉 壁, 允许血液自由流向动脉管。
- 稍微退回导管,重新放置导管尖端。注意:不要将导管继续插入至静脉。
- 如果前一种方法无法解决单向堵塞问题,患者血透时可以将动脉血路接到静脉 接头上,而静脉血路接到动脉接头上。血流循环量可能会显著提高。
- 任何一个管腔内出现血栓, 首先应尝试用注射器将血块 万不要强行用力冲洗血栓管腔。 抽吸出来。如果抽吸没用,医生可以尝试使用溶栓剂。

感染:

因为有暴露在HIV(人类免疫缺陷病毒)或其它血媒性病原体下的风险,医务人员在护理病 人时必须一直遵守常规血液和体液预防措施。必须一直严格遵守无菌技术。

在导管出皮部位发现的临床感染必须迅速用合适的抗菌素进行治疗。带有导管的病人如果出 现发热,应该在远离导管出皮部位的地方采取血样。至少进行两个血培养。如果血培养结果 呈阳性,必须立即拔除导管并使用合适的抗菌素进行治疗。在重新放置导管之前要等待48 小时。如果可能,应该在原来导管受感染出皮部位的对侧进行插管。

导管移除

警告: 只有熟知相关技术的医生可以执行下列操作。

注意: 在导管移除之前,必须回顾医院或科室的相关规定、可能的并发症及其治疗方案、警 告及注意事项。

- 切断固定翼上的缝线。根据医院相关规定去除皮肤上的缝线。
- 2. 从出皮部位拔出导管。
- 在出皮部位加压大约10-15分钟,或直到不再出血为止。
- 加盖敷料以促使伤口尽早愈合。

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⚠ 注意, 见使用说明书

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XTP96CT-C	XTP116MT-C	DFXL146CT-C	DSP136PC-C	XTP128MT-C	MFFS1220IJ-2-C
XTP98CT-C	XTP118MT-C	DFXL148CT-C	DSP138PC-C	XTP129MT-C	MFFS1515S-C
XTP94IJC-C	XTP119MT-C	DFXL149CT-C	DSP139PC-C	XTP125IJS-C	MFFS1520S-C
XTP96IJC-C	XTP114IJS-C	DFXL144IJC-C	DSP134IJC-C	XTP126IJS-C	MFFS1524S-C
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XTP94MT-C	XTP118IJS-C	DFXL148IJC-C	DSP138IJC-C	XTP145MTA-C	MFFS1515IJ-C
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XTP94IJS-C	MCF55-C	DFXL146MT-C	DSP136S-C	XTP149MTA-C	MFFS1515IJ-2-C
XTP96IJS-C	MCF64-C	DFXL148MT-C	DSP138S-C	XTP145IJSA-C	MFFS1520IJ-2-C
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XTP114CT-C	MCFK64-C	DFXL144IJS-C	DSP130S-C	XTP148IJSA-C	MCY308PS-C
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XTP118CT-C	MCFK100-C	DFXL148IJS-C	DSP136PS-C	MFFS1215S-C	MCYK308PS-C
XTP119CT-C	MC35-C	DFXL149IJS-C	DSP138PS-C	MFFS1220S-C	MFFS1215IJ-C
XTP114IJC-C	MC38-C	DSP134C-C	DSP139PS-C	MFFS1224S-C	MFFS1220IJ-C
XTP116IJC-C	MC35-J-C	DSP136C-C	DSP134IJS-C	MFFS1212IJ-C	MFFS1212IJ-2-C
XTP118IJC-C	MC38-J-C	DSP138C-C	DSP136IJS-C	DSP130C-C	
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SYMBOL CHART

STERILE EO	STERILIZED WITH ETHYLENE OXIDE
②0000-00	DATE OF EXPIRATION YR-MO
\triangle	SEE INSTRUCTIONS FOR USE
2	SINGLE USE
REF	PRODUCT NUMBER
LOT 000000-0000/00	LOT NUMBER - YR/MO OF MANUFACTURE
LOT 000000-00/00	LOT NUMBER - MO/YR OF MANUFACTURE

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