

Morpheus[®] SMART PICC CT Insertion Kit

Peripherally Inserted Central Catheter

INSTRUCTIONS FOR USE

ANGIODYNAMICS[®], INC.
603 QUEENSBURY AVE.
QUEENSBURY, NY 12804 U.S.A.
TOLL FREE: 800-772-6446
PHONE: 518-798-1215
FAX: 518-798-3625

AngioDynamics[®], Durathane[®] and Morpheus[®] are registered trademarks of AngioDynamics Inc. STATLOCK[®] is a registered trademark of C.R. Bard, Inc. or an affiliate. MaxPlus[®] is a registered trademark of Medegen, Inc.

ANGIODYNAMICS[®]

© AngioDynamics, Inc. 2008 all rights reserved

IC 042 Rev. B

**CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS
DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
THIS DEVICE IS STERILE AND INTENDED FOR SINGLE
PATIENT USE. DO NOT REUSE OR RE-STERILIZE.
THIS DEVICE IS STERILIZED BY ETHYLENE OXIDE.**

ANGIODYNAMICS[®]

IC 042 Rev. B

Product Description:

The AngioDynamics *Morpheus*[®] *SMART PICC CT* is a product line of peripherally placed central catheters made from specially formulated and processed medical grade materials. The AngioDynamics *Morpheus*[®] *SMART PICC CT* is packaged in a tray with accessories necessary for a percutaneous introduction (Modified Seldinger technique).

Indications for Use:

The AngioDynamics *Morpheus*[®] *SMART PICC CT* is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

CONTRAINDICATIONS:

This 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.

WARNINGS:

- Do not place catheter into or allow it to remain in right atrium or right ventricle. Central vein catheters should be positioned so that distal tip of catheter is in the superior vena cava (SVC) above the junction of the SVC and right atrium and lies parallel to the vessel wall.
- Do not apply excessive force in placing or removing catheter. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
- The practitioner must be aware of clinical conditions that may limit the use of PICCs such as: dermatitis, cellulitis and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy, contractures, mastectomy, lymph node dissection and potential use for permanent hemodialysis access.

Other Valve Flushing:

1. Flush the catheter per facility protocol; or with heparinized saline every 12 hours or after each use. Usually one ml per lumen is adequate.

NOTE: When using any positive displacement valve the PICC leg should be unclamped prior to flushing and only clamped again after removal of the syringe.

• 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, refer to institution protocol.

• When Cleaning the Exit Site:

WARNING: Do not wipe the catheter with acetone based solutions or ointments. These can damage the material if used over time.

- DO:**
- Maintain according to hospital protocol.
 - Use chlorhexidine gluconate and / or povidone iodine to clean the exit site around the catheter.
 - Allow all cleaning agents / antiseptics to dry completely before applying dressing.

Power Injections:

The *Morpheus*[®] *SMART PICC CT* testing included 10 power injection cycles of CT lumen(s). Testing was completed with fluid having a viscosity of 11.8cP.

Catheter Size	Average Dynamic Burst Pressure	Average Static Burst Pressure
6F Triple	464 PSI	279 PSI

Central Venous Pressure Monitoring Procedure:

1. Flush the catheter with normal saline per facility protocol prior to monitoring central venous pressure.
2. Follow your facility's protocols for monitoring central venous pressure.

Catheter Removal Procedure:

1. Remove dressing and sutures (if applicable). **Precaution: To minimize the risk of cutting the catheter, do not use scissors to remove dressing.**
2. Open StatLock[®] retainer wings and remove catheter from StatLock[®] posts (if applicable).
3. Remove catheter by slowly pulling it parallel to skin. **Precaution: To minimize the risk of catheter breakage, do not exert excessive force if difficulty is encountered upon removal.** If resistance is met, apply warm compress to area and wait 20-30 minutes. Gently begin pulling catheter parallel to skin. If further difficulty is encountered, obtain an x-ray and consult physician.
4. Upon removal of catheter, measure and inspect to ensure that entire catheter length has been removed.
5. Apply alcohol swab to StatLock[®] adhesive and gently lift pad off of skin (if applicable).
6. Dress insertion site.

*If you have any questions or would like additional reference information, please contact AngioDynamics, Inc.

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

WARNING: Chlorhexidine gluconate and/or povidone iodine is the antiseptic suggested for use with Durathane® catheters and components. Do not wipe the catheter with acetone based solutions or ointments. These can damage the material if used over time.

WARNING: When using alcohol or alcohol containing antiseptics with Durathane® PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing.

WARNING: Alcohol should not be used to soak or de clot Durathane® PICCs because alcohol is known to degrade Durathane® catheters over time with repeated and prolonged exposure.

WARNING: Use of ointments with the *Morpheus*® SMART PICC CT can cause failure of the device.

P. Verify Placement

1. Verify catheter tip location radiographically.

Suggested Catheter Maintenance:

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

- Dressing Changes:

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.

- Positive Displacement Valve Instructions:

NOTE: Change valves according to hospital or institution protocol.

MaxPlus® Positive Displacement Valve – Directions for Use

1. Invert MaxPlus® valve to prime.
2. Attach to catheter.
3. To access MaxPlus®, always swab top of connector with desired disinfectant according to institution protocol for 15 seconds.
4. Flush the MaxPlus® after each use with 10 mL of normal saline, or in accordance to hospital protocol. NOTE: If MaxPlus® Clear, make sure device is visually clear.
5. Disconnect from the MaxPlus® before clamping the catheter leg to facilitate positive displacement.

Flat and smooth
top for optimum
swabability



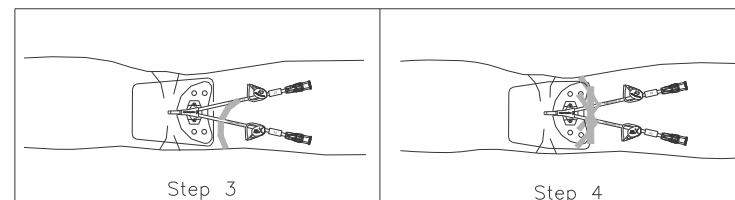
- Use of acetone based solutions or ointments with the *Morpheus*® SMART PICC CT can cause failure of the device over time. Chlorhexidine gluconate and / or Povidone iodine are the antiseptics suggested for use with Durathane® catheters and components.
- When using alcohol or alcohol containing antiseptics with Durathane® PICCs, care should be taken to avoid prolonged or excessive contact.
- When alcohol or solutions are used as a skin prep, they must be allowed to completely air dry before catheter insertion or before applying an occlusive dressing.
- Alcohol should not be used to soak or de clot Durathane® PICCs because alcohol is known to degrade Durathane® catheters over time with repeated or prolonged exposure.
- Indwelling catheters should be routinely assessed for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if catheter position has changed.
- 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.
- When the dilator and guidewire are withdrawn from the sheath, place a finger over the sheath opening 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 or by attaching a syringe or injection cap to the dilator to reduce blood flow while trimming the catheter.
- 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 medical intervention.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Do not use a syringe smaller than 10 mL.
- 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.
- Place a finger over the needle to minimize blood loss and risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient holding their breath until the guidewire is inserted into the needle.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate, and the maximum pressure of power injectors of 300 PSI, may result in catheter failure and/or catheter tip displacement.
- Morpheus® SMART PICC CT 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.

Cautions:

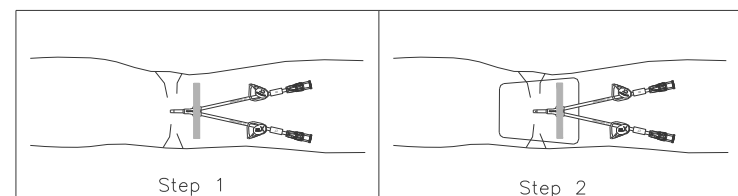
- Carefully read and follow all instructions prior to use.
- The Morpheus® SMART PICC CT line includes a reverse tapered option. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis or thrombosis. Placement of PICC above antecubital fossa is recommended.
- Only qualified healthcare practitioners should insert, manipulate and remove this catheter.
- Never use force to remove the guidewire or stylet from the catheter. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and guidewire (or stylet) together approximately 2 cm and reattempt removal. Repeat this procedure until the guidewire (or stylet) can be easily removed. Note: Flushing the stylet assembly through the sidearm while withdrawing can aid in removal. Once the guidewire or stylet is out, advance the catheter into the desired position (zero mark).
- DO NOT advance the guidewire past the axilla without fluoroscopic guidance.
- DO NOT withdraw the guidewire through the needle as transection of the guidewire may occur.
- The catheter must be secured in place to minimize the risk of catheter breakage and embolization.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Only medical practitioners licensed by law, trained and experienced in proper positioning of catheters in the central venous system using percutaneous entry (Seldinger technique) should place this catheter.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by its manufacturer.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

3. Place an anchor tape sticky side up, under one extension leg. Chevron anchor tape on top of transparent dressing.
4. Place 2nd anchor tape (if appropriate) sticky side up under other extension leg. Chevron anchor tape on top of transparent dressing. Place 3rd anchor tape over chevroned tapes across the top of transparent dressing.

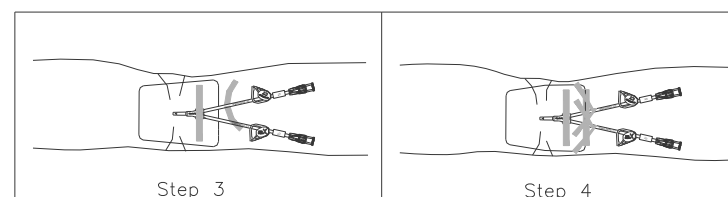


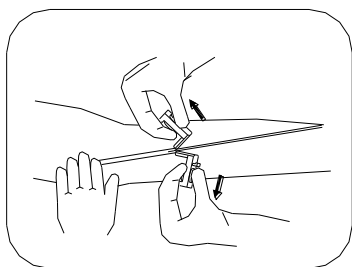
Tape Strip Stabilization Procedure

1. Place an anchor tape over wings or bifurcation.
2. Cover site including the bifurcation and anchor tape with transparent dressing.



3. Place 2nd anchor tape sticky side up under one extension leg. Chevron anchor tape on top of transparent dressing.
4. Place 3rd anchor tape (if appropriate) sticky side up under other extension leg. Chevron anchor tape on top of transparent dressing. Place 4th anchor tape over chevroned tapes across the top of transparent dressing.





M. Complete Catheter Insertion

1. 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 cannulation into the jugular vein.
2. Remove the guidewire or stylet assembly from the catheter. To remove the stylet, disconnect the y-site from the luer before withdrawing.

Caution: Never use force to remove the guidewire or stylet from the catheter. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and guidewire (or stylet) together approximately 2 cm and reattempt removal. Repeat this procedure until the guidewire (or stylet) can be easily removed. Note: Flushing the stylet assembly through the sidearm while withdrawing can aid in removal. Once the guidewire or stylet is out, advance the catheter into the desired position (zero mark).

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.

3. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
4. Place a finger over the catheter opening to minimize blood loss.

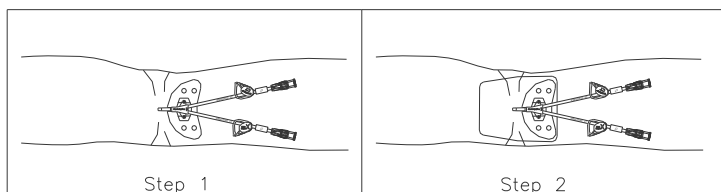
N. Aspirate and Flush

1. Attach a primed saline-filled syringe.
2. Aspirate for adequate blood return and flush each lumen of the catheter to ensure patency.

O. Stabilization and Dressing of Catheter

STATLOCK® Stabilization Device Procedure

1. Secure catheter with StatLock® stabilization device.
2. Cover site and StatLock® stabilization device with transparent dressing.



Important Information Regarding Morpheus® SMART PICC CT

- 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.
- Vigorously flush the Morpheus® SMART PICC CT using a 10 mL or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the Morpheus® SMART PICC CT and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.
WARNING: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Do not exceed the specified maximum flow rate.
- **WARNING:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
WARNING: Exceeding the maximum flow rate may result in catheter failure and/or catheter tip displacement.
WARNING: Morpheus® SMART PICC CT 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.

Power Injection Instructions:

NOTE: A chest x-ray or other means of verification of tip placement prior to each CT Injection is recommended.

1. Remove the injection/needleless cap from the Morpheus® SMART PICC CT.
2. Attach a 10 mL or larger syringe filled with sterile normal saline.
3. 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.
4. Detach syringe.
5. Attach the power injection device to the Morpheus® SMART PICC CT per manufacturer's recommendations.
6. Complete power injection study taking care not to exceed the flow rate limits.
WARNING: Exceeding the maximum flow rate may result in catheter failure and/or catheter tip displacement.
7. Disconnect the power injection device.
8. Flush the Morpheus® SMART PICC CT with 10 mL of sterile normal saline, using a 10 mL or larger syringe.
9. Replace the injection/needleless cap on the Morpheus® SMART PICC CT.

Prior to Placement:

- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The catheter is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. DO NOT RESTERILIZE.
- Inspect kit for presence of all components.

During Placement:

- Do not allow device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Do not bend the catheter at sharp angles during implantation as this can compromise patency of the catheter.
- Do not place suture around the catheter. Sutures may damage the catheter or compromise catheter patency.
- Do not advance the guidewire into superior vena cava except under x-ray or fluoroscopy. Assure proper tip position in order to prevent erosion or perforation of central venous system.

After Placement:

WARNING: Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.

- Accessories and components with Luer Lock connections should be used with this device.
- Tip position should be verified by x-ray and monitored on a routine basis.

WARNING: If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.

WARNING: Exceeding the maximum flow rate may result in catheter failure and/or catheter tip displacement.

- DO NOT USE A SYRINGE SMALLER THAN 10 mL!

4. Inspect cut surface to assure there is no loose material.

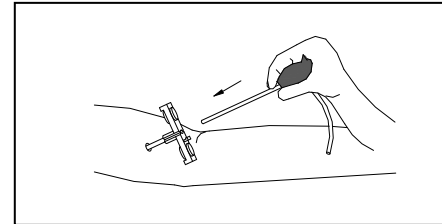
Following steps applicable to Stylet Only:

5. Advance the Y-site/stylet assembly and press fit the y-site to catheter luer.
Note: Care should be taken to not kink the stylet during advancement.
6. While holding the y-site, pull back on the stylet wire to adjust the stylet tip location.

NOTE: Stylet tip should be flush with the catheter tip or recessed within the catheter tip. DO NOT place catheter with the stylet protruding from the distal end.
NOTE: Stylet adjustments must only be made by pulling the stylet wire through the y-site. Do not push the stylet into the y-site.

K. Insert and Advance the Catheter

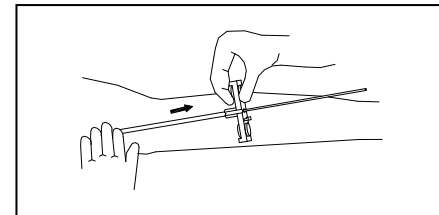
1. If using a guidewire as a stiffening tool, load into catheter at this time. Adjust position so that the flexible end of the wire is contained within the distal catheter tip and not protruding.
2. Insert the catheter into the introducer sheath.



3. Advance the catheter slowly.

L. Retract and Remove Sheath

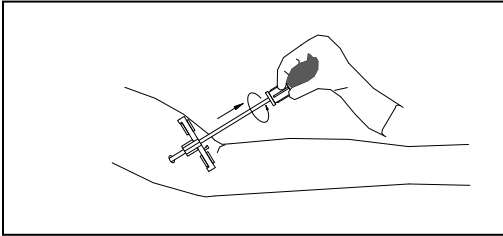
1. Stabilize the catheter position by applying pressure to the vein distal to the sheath.
2. Withdraw the sheath from the vein and away from the site.



3. Split the introducer sheath and peel it away from the catheter.

I. Remove Dilator

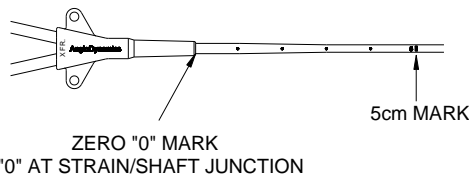
1. Rotate locking collar of dilator and remove dilator from sheath.
2. Withdraw the dilator and access wire.



Warning: Place a finger over the sheath to minimize blood loss and risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient holding their breath.

J. Modification of Catheter Length

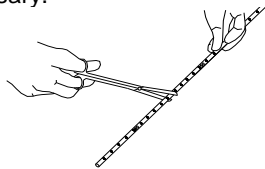
REVERSE TAPER CATHETER



NOTE: Catheters can be cut to the desired length. Catheter depth markings are in centimeters.

NOTE: If catheter contains a pre-loaded stylet, the stylet assembly must be pulled back prior to trimming the catheter length. DO NOT cut the stylet.

1. Refer to diagrams above for catheter "0" location.
2. If catheter contains a pre-loaded stylet assembly, remove y-site from catheter luer and withdraw by pulling the y-site until the stylet is well beyond the cut length. Note: If stylet becomes kinked in a location that interfaces with the catheter at any time, discontinue use of the stylet.
3. Measure the distance from the zero mark to the desired tip location, cut catheter carefully using a sterile scalpel or scissors according to institutional policy when necessary.



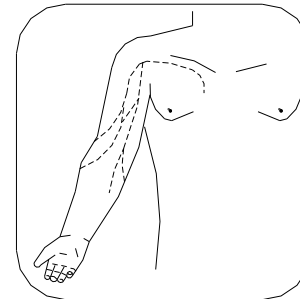
Possible Complications: The potential exists for serious complications including the following:

- 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 of Implanted Device
- Laceration of Vessels or Viscus
- Myocardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery and Post Operative Recovery

Insertion Instructions:

A. Identify the Vein and Insertion Site

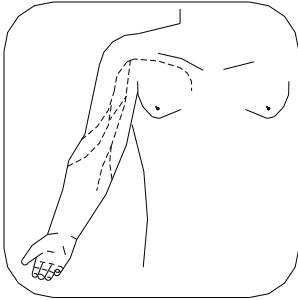
1. Apply a tourniquet above the anticipated insertion site.
2. Select a vein by assessing patient anatomy and condition. Recommended veins are with the basilic, cephalic or brachial. The *Morpheus*[®] SMART PICC CT line includes a reverse tapered option. **Caution:** Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis or thrombosis. Placement of PICC above antecubital fossa is recommended.
3. Release tourniquet.



B. Measure Distance to Tip Location

NOTE: The Method described below is only one possible method.

1. Measure the distance from the insertion site to the right clavicular head and then down to the third intercostal space with the provided tape measure. The recommended tip position is in the lower 1/3 of the Superior Vena Cava.
NOTE: This external measurement technique can not exactly duplicate the internal venous anatomy.



2. Set up the sterile field.

C. Preflush the Catheter

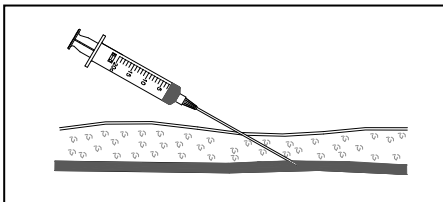
1. Flush the catheter with normal saline solution.
2. The *Morpheus*[®] SMART PICC CT Insertion Kit offering includes a catheter with pre-loaded stylet. The stylet hydrophilic coating requires activation, flush through the sidearm of the stylet assembly when present.

NOTE: The catheter may be trimmed if a shorter length is required. Refer to section J instructions.

D. Apply Tourniquet and Drape

1. Position arm at a 90° angle.
2. Re-apply the tourniquet above the intended insertion site to distend the vessel.
3. Prepare the site according to institution policy using sterile technique.
4. Drape the patient by placing a fenestrated drape over the anticipated puncture site.
5. When alcohol is used as a skin prep, it must be allowed to completely air dry.

E. Perform Venipuncture



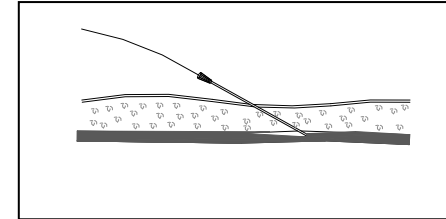
1. Remove the needle guard and attach a syringe.
2. Introduce the needle into the vessel and observe for flashback of blood.
3. When the vein has been entered, remove the syringe leaving the needle in place.

Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

Warning: Place a finger over the needle to minimize blood loss and risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient holding their breath until the guidewire is inserted into the needle.

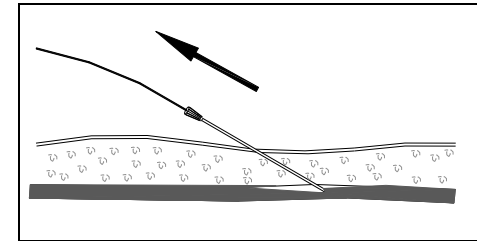
F. Advance Guidewire

1. Introduce the access guidewire through the needle; advance the guidewire 15 to 20 cm into the vessel.
Caution: Do not advance the wire past the axilla without fluoroscopic guidance.



G. Remove Needle

1. Release tourniquet. Apply slight pressure on the vessel above the insertion site, to minimize blood flow.
2. If necessary, enlarge the puncture site with a #11 scalpel blade.
3. Leaving the guidewire in place, withdraw the needle.



H. Advance Introducer

1. Advance the peelable introducer assembly (sheath and dilator) over the guidewire. Using a twisting motion, advance the assembly into the vessel.

