**CT MIDLINE CATHETER**

**INSTRUCTIONS FOR USE**

**INDICATIONS FOR USE:**
- The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

**IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:**
- Contrast media should be warmed to body temperature prior to power injection. **Warning:** Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the CT Midline catheter using a 10cc 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 catheter prior to power infusion and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. **Do not** proceed with a subsequent 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 maximum flow rate printed on the catheter. **Warning:** Power injection machine presetting flow rate may not prevent over pressurization of an occluded catheter. **Warning:** Exceeding the maximum flow rate indicated flow rate may result in catheter failure and/or catheter tip displacement.

**Warning:** CT Midline catheter indication of power injection of contrast media implies that 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.

**Description:**
- This catheter is manufactured from soft radiopaque polyurethane material that provides increased patient comfort and excellent biocompatibility.

**CONTRAINDICATIONS:**
- This catheter is not intended for any use other than that which is indicated. Do not implant catheter in atherosclerotic vessels.
- The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
- The presence of device related bacteremia or sepsis.
- History of mastectomy on insertion side.
- Previous history of venous/subclavian thrombosis or vascular procedures at insertion site.
- Fever of unknown origin.
- 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.

**POSSIBLE COMPLICATIONS:**
- Local tissue factors will prevent proper device stabilization and/or access.

**WARNINGs:**
- Therapies not appropriate for midline catheters include those therapies requiring central venous access. Refer to the latest standards of practice and institutional policies.
- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath/dilator and guidewire must be removed together.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- This catheter is for Single Use Only.
- Do not re-sterilize the catheter or accessories by any method.
- Re-use may lead to infection or injury.
- The manufacturer shall not be liable for any damage caused by re-use or re-sterilization of this catheter or accessory.
- Contests sterile and non-pyrogenic in unopened, undamaged package.
- STERILE 100% STERILIZED BY ETHYLENE OXIDE GAS

**DIRECTIONS FOR SELDINGER INSERTION:**
- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified healthcare professional under the direction of a physician.
- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

**PRIOR TO PLACEMENT:**
- Identify insertion site and vein, taking into account the following variables:
  - patient diagnosis
  - age and size of patient
  - unusual anatomical variables
  - type and purpose of IV therapy
  - anticipated dwell time of catheter
- Examine catheter lumen and extension(s) before and after each infusion for damage.
- To prevent accidents, assure the security of all caps and connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Repeatedly tightening of luer lock connections, syringes, and caps will reduce connector life and could lead to potential connector failure.

**INSERTION SITES:**
- The basilic, median cubital, or cephalic vein may be catheterized. The basilic vein is the preferred site.

**Medline / Basilic Vein Insertion:**
- Insert indwelling catheter into the skin at an oblique angle.
- Insert the Seldinger needle over the guidewire into the target vein.
- Remove syringe(s) prior to clamping extension(s).

**Caution:**
- The needleless access port should not be used with needles, blunt cannula, or other non-catheter connective, or connector with visible defects. If needle access is attempted, the needleless access port must be replaced immediately. Do not exceed 100 actuations. Follow local institutional policy.

**INSERTION:**
- Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask.

**PREPARE CATHETER**

**WARNING:**
- Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.
- Do not apply forceps, use only the in-line clamps provided.

**Note:** For insertion with a stiffening styler, see Sterile Technique section for Stiffening Styler and Slideport Adapter Section.
- Attach needleless access port(s) to female luer(s) of catheter.
- Attach a saline filled syringe to the needleless access port and completely flush catheter. For multi-lumen catheters, flush all lumens. Remove syringe(s) prior to clamping extension(s).

**Caution:**
- The needleless access port should not be used with needles, blunt cannula, or other non-catheter connective, or connector with visible defects. If needle access is attempted, the needleless access port must be replaced immediately. Do not exceed 100 actuations. Follow local institutional policy.

**CATHETER PRECAUTIONS:**
- Do not use syringes with a needle or replacement sheath/dilator is fully inserted.
- Do not proceed with the procedure until the sheath/dilator is fully inserted.
- Do not clamp the lumens portion of the catheter. Clamp only the extension(s). Do not use serrated forceps, use only the in-line clamps provided.

**Note:** Do not clamp the lumens portion of the catheter. Clamp only the extension(s). Do not use serrated forceps, use only the in-line clamps provided.

- Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If exesse rate resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain adequate flow.
- Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

**Caution:**
- Small syringes will generate excessive pressure and may damage the catheter. The use of 10cc or larger syringes are recommended.

**Appropriate IV Complications:**
- Hematoma
- Phlebitis
- Infections
- Extravasation
- Exit site infection
- Catheter occlusion
- Thrombotic occlusion
- Phlebitis
- Damage to vein including arterio-venous fistula
- Headache
- Stroke
- Inflammatory responses
- Repeated over tightening of luer lock connectors
- Repeatedly tightening of luer lock connections, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Do not re-sterilize the catheter or accessories by any method.
- Re-use may lead to infection or injury
- The manufacturer shall not be liable for any damage caused by re-use or re-sterilization of this catheter or accessory.
- Contests sterile and non-pyrogenic in unopened, undamaged package. STERILE 100% STERILIZED BY ETHYLENE OXIDE GAS

**TERMINATION SITES:**
- The basilic, median cubital, or cephalic vein may be catheterized. The basilic vein is the preferred site.

**Medline / Basilic Vein Insertion:**
- Insert the introducer needle with attached guidewire into the target vein.
- Aspirate to ensure proper placement. Release tourniquet.
- Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw the flexible end of marked 0.18" guide wire back into advance so that only the end of the guidewire is visible. Insert the advance wire's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.
- Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into target vein.

**Caution:**
- Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.
- Remove dilator from sheath.
- 11. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
- 12. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).
- Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only few centimeters at a time.
- Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only few centimeters at a time.
- Do not clamp the lumens portion of the catheter. Clamp only the extension(s). Do not use serrated forceps, use only the in-line clamps provided.
- 13. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If excessive resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain adequate flow.
- 14. Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.
- 15. Small syringes will generate excessive pressure and may damage the catheter. The use of 10cc or larger syringes are recommended.
- 16. Remove the syringe(s) and close extension(s) clamp(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and aspirating the tubing when not in use.
- 17. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

**CATHETER SECUREMENT AND WOUND DRESSING:**
- The insertion site and external portion of the catheter should always be covered with a protective dressing.
- 18. Cover the exit site with an occlusive dressing according to the facility policy.
- 19. Record catheter length, catheter lot number, and tip position on patient’s chart.
**POWER INJECTION PROCEDURE**

1. Remove the injection/needleless cap from the CT Midline catheter.

2. Using a 10cc or larger syringe(s), aspirate catheter lumen(s) to ensure patency and remove locking solution. Discard syringe(s).

3. Attach a 10cc or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 10cc 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 CT Midline catheter per manufacturer’s recommendations.

**Warning:** Always use connector tubing between power injector syringe and catheter.

Do not attempt to connect power injector syringe directly to the catheter. Damage may result.

6. Complete power injection study taking care not to exceed the flow rate limits.

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

7. Disconnect the power injection device.

8. Flush the CT Midline catheter with 10cc of sterile normal saline, and discard flush, and it has been determined that the catheter is occluded with blood, follow institutional decontamination procedure.

**Caution:** Due to risk of exposure to HIV or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

- Sterile technique should always be strictly adhered to.
- Clinically recognized infection should be treated promptly per institutional policy.

**CATHETER PERFORMANCE**

- Occluded/Partially Occluded Catheter: If resistance is encountered to aspirating or flushing, the lumen may be partially or completely occluded.

**Warning:** Do not flush against resistance.

- If the lumen will neither aspirate nor flush, and it has been determined that the catheter is occluded with blood, follow institutional decontamination procedure.

**Infection**

**Caution:** The needleless access port should not be used with needles, blunt cannula, or other non-luer connectors, or luer connectors with visible defects. If needle access is attempted, the needleless access port must be replaced immediately. Do not exceed 100 actuations.

**PREPARE CATHETER**

1. Preflush catheter, sidetip adapter, and needleless access ports.

- Attach saline filled syringe to luer of sideport adapter and flush catheter and sidetip adapter.

- Clamp sidetip extension and remove syringe. If using multi-lumen catheter, attach needleless access port to remaining extension. Attach saline filled syringe to the needleless access port and completely flush catheter lumens. Remove syringe from needleless access port prior to clamping extension. Flush remaining needleless access port and set aside.

**Caution:** Never close clamp on catheter stylet, as it may cause catheter damage.

**INSERTION**

2. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask.

3. Apply tourniquet to arm above the insertion site.

**CATHETER REMOVAL**

**Warning:** Only a clinician familiar with the appropriate techniques should attempt the following procedures.

**Caution:** Always review facility protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Wash hands, gather equipment.

2. Remove old dressing and inspect insertion site for redness, tenderness, and drainage.

3. Grasp catheter near insertion site and using slow steady motion, remove catheter from vein.

4. If resistance is felt - STOP. Retag the catheter and apply a warm compress to the extremity for 20-30 minutes.

5. Resume removal procedure. If catheter remains “stuck” follow institutional policy for further intervention.

6. Apply pressure, if necessary, until bleeding stops and drape site feels firm.

**Note:** Inspect catheter and measure length. It must be equal to baseline measurement taken when the catheter was inserted.

**STIFFENING STYLET AND SIDEPORT ADAPTER**

**Injection Caps - Injection cap(s) or needleless access port(s) should be changed per institutional policy. If using the supplied needleless access port(s), do not exceed 100 actuations.**

**Caution:** Never attempt to cut stylet.

**Occluded/Partially Occluded Catheter -**

1. Grasp catheter near insertion site and partially occluded. Insert stiffening stylet into the needleless access port. Attach saline filled syringe to luer of sideport adapter, aspirate lumen, and clamp the stylet back beyond the point where the catheter was trimmed by at least 1/2 inch (1cm).

**Caution:** Do not clamp lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps, use only the in-line clamps(s) provided.

**CAUTION:** Always remove stylet back beyond the tip of the catheter prior to insertion.

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

**INFORMATION**

1. If difficulty and/or bunching of the catheter are experienced while removing the stylet, additional flushing of the catheter may be helpful. The catheter may need to be repolished to allow for removal of the stylet.

**INFUSION**

- Before infusion begins all connections should be examined carefully.

- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.

- If a leak is found, the catheter should be clamped immediately and replaced.

**Caution:** Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the treatment.

**Note:** Excessive blood loss may lead to patient shock.

**CATHETER MAINTENANCE**

**Dressing Changes -** A dressing should cover the insertion site at all times. The dressing should be changed per institutional policy or any time the dressing becomes soaked, wet, or non-occlusive.

**Warning:** Perioperative patient should be sedated.

**Preparation of equipment -**

1. Remove the injection/needleless cap on the CT Midline catheter.

**Caution:** Necessary remedial action must be taken prior to the continuation of the treatment.

**Warning:** Only a clinician familiar with the appropriate techniques should attempt the following procedures.

**Caution:** Always review facility protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Wash hands, gather equipment.

2. Remove old dressing and inspect insertion site for redness, tenderness, and drainage.

3. Grasp catheter near insertion site and using slow steady motion, remove catheter from vein.

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5. Resume removal procedure. If catheter remains “stuck” follow institutional policy for further intervention.

6. Apply pressure, if necessary, until bleeding stops and drape site feels firm.

**Note:** Inspect catheter and measure length. It must be equal to baseline measurement taken when the catheter was inserted.

**INFORMATION**

1. If difficulty and/or bunching of the catheter are experienced while removing the stylet, additional flushing of the catheter may be helpful. The catheter may need to be repolished to allow for removal of the stylet.

**Caution:** Do not attempt to reinset stylet once it has been withdrawn.

**Caution:** Never leave stylet in place after catheter insertion; injury may occur. Remove both stylet and sidetip adapter after insertion.

13. Continue following directions at step #13 of “Insertion” Section.