medCOMP®

Arch-Flo™ CT MIDLINE CATHETER

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

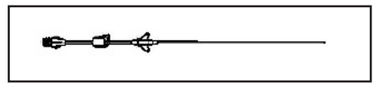
- The Arch-Flo™ CT Midline Catheter is indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. This catheter may be inserted via the basilic, cephalic, or median cubital vein.

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 Arch-Flo™ 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 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 maximum flow rate printed on the catheter. **Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter. **Warning:** Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.
- **Warning:** Arch-Flo™ CT Midline catheter indication of 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.

DESCRIPTION:

- The Arch-Flo™ Catheter is available in a 4F Single Lumen configuration. The catheter lumen terminates through an extension to a female luer-lock connector. The extension has an in-line clamp to control fluid flow and is marked POWER INJECTABLE MIDLINE along with the lumen gauge size. The transition between lumen and extension is housed within a molded hub. The hub is marked MIDLINE to identify that the catheter is not centrally placed. The tip of the lumen is notched to increase the exposed area of the lumen. The outside diameter of the lumen increases gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen is marked with depth marks every centimeter.



CONTRAINDICATIONS:

- This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.
- The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
- The presence of device related bacteremia or septicemia.
- History of mastectomy on insertion side.
- Previous history of venous/subclavian thrombosis or vascular surgical 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.
- Local tissue factors will prevent proper device stabilization and/or access.
- Refer to standards of practice and institutional policies for therapies contraindicated for midlines.

POTENTIAL COMPLICATIONS:

- Air Embolism
- Aseptic mechanical phlebitis
- Brachial Plexus Injury
- Catheter occlusion
- Cellulitis
- Damage/Fracture of catheter
- Drainage from insertion site
- Exit site infection
- Extravasation
- Hematoma
- Malposition/Migration
- Perforation of the vessel
- Sepsis
- Subcutaneous hematoma
- Thromboembolism
- Thrombosis
- Before attempting the insertion, ensure that you are familiar with the common and potential complications and their emergency treatment should any of them occur.

WARNINGS:

- Therapies not appropriate for midline catheters include those therapies requiring central venous access. Refer to 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 resterilize the catheter or accessories by any method.
- Re-use may lead to infection or illness/ injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

STERILE | EO

- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

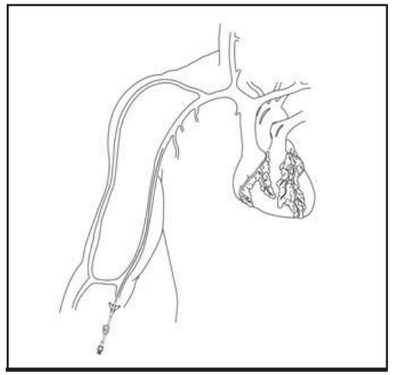
CATHETER PRECAUTIONS:

- Small syringes will generate excessive pressure and may damage the catheter. The use of 10cc or larger syringes are recommended.
- Do not trim catheter.
- Do not use sharp instruments near the extension lines or catheter lumen.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location will weaken tubing. Avoid clamping near the luer(s) and hub of the 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.
- Repeated overtightening 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.

Midline / Basilic Vein Insertion



DIRECTIONS FOR MODIFIED 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 health care 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

1. May apply tourniquet to arm above anticipated insertion site.
2. Select vein based on assessment.
3. Release tourniquet.

PREPARE CATHETER:

4. Preflush catheter.
   - 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. Remove syringe(s) prior to clamping extension(s).

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.

INSERTION:

5. Follow local institutional policy and guidelines set foth in the current standards of practice for aseptic techniques during catheter insertion, maintenance and removal.
6. May apply tourniquet to arm above anticipated insertion site to distend the vein.
7. Insert the introducer needle into the target vein. Assess for blood return to insure proper placement. Release tourniquet.
8. 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 .018" guidewire back into advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.
9. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into target vein.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/ dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

10. 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).

Caution: 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.

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

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

15. Remove the syringe(s) and close extension clamp(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. 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.

16. Cover the exit site with an occlusive dressing according to the facility policy.
17. Record catheter length and catheter lot number on patient's chart.

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the Arch-Flo™ CT Midline catheter.
2. Using a 10cc or larger syringe(s), aspirate catheter lumen(s) to assure 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 Arch-Flo™ 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 Arch-Flo™ CT Midline catheter with 10cc of sterile normal saline, using a 10cc or larger syringe after power injection.

9. Replace the injection/needleless cap on the Arch-Flo™ CT Midline catheter.

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 soiled, wet, or non-occlusive.

Note: During all dressing changes, the external length of the catheter should be assessed to determine if catheter migration has occurred.

- **Flushing and Locking** - Flush and lock catheter according to your institutional policy.
- The catheter should be flushed with normal saline prior to drug administration to remove locking solution.
- After drug administration, lumen should be flushed again with normal saline and then locked to maintain patency.

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.

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 declotting procedure.

Infection:

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 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 a slow steady motion, remove catheter from vein.
4. If resistance is felt - STOP. Retape 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 dress site following institutional policy.

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

Midline Power		
Catheter Size	**Gravity Flow**	**Full Length Priming Volume**
4F X 10CM SINGLE CT MIDLINE	56 ml/min	0.36cc

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT 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 in accordance with all relevant regulatory requirements.

SYMBOL TABLE

5.1.1	Manufacturer *
5.3.4	Keep Dry *
5.4.2	Do Not Re-use *
5.6.3	Non-pyrogenic *
5.3.2	Keep Away from Sunlight *
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *
5.2.8	Do Not Use if Package is Damaged *
5.1.4	Use By Date *
5.2.6	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
Rx Only	Prescription Use Only ***

***This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

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