The manufacturer shall not be liable for Subcutaneous hematoma
The presence of device related bacteremia
The Peripherally Inserted Central Vein
This catheter is for Single Use Only.
The patient’s body size is insufficient to
Exit site infection
Sepsis
Continuous infusion of vesicants.
Cardiac Tamponade
Re-Use may lead to infection or illness/
This catheter is manufactured from soft
Past irradiation of prospective insertion
Solutions with final glucose
Hematoma
Perforation of the vessel
• phlebitis, scars, etc.)
• The manufacturer shall not be liable for any damage caused by reuse or re-sterilization of this catheter or its accessories.
• Contents sterile and non-pyrogenic in unopened, undamaged package
• STERILIZED BY ETHYLENE OXIDE
• The basilic, median cubital, or cephalic vein.
• The patient’s body 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.

COMMON COMPLICATIONS:
• Air Embolism
• Shrink/Fracture/Friction
• Extravasation
• Hematoma
• Rash/Infusion site
• Vascular Thrombosis

POTENTIAL COMPLICATIONS:
• Site infection
• Hematoma
• Cardiac tamponade
• Vascular perforation

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

WARRANTS:
• Therapies not appropriate for midline catheters include those 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 (U.S.A) restricts this device to sale by or on the order of a physician.
• This catheter is for Single Use Only.
• This catheter is manufactured from soft radiopaque polyurethane material that provides increased patient comfort and excellent biocompatibility.
• This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessel.
• The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
• The presence of device related bacteremia commonly occurs when catheters are used in patients with venous access issues.
• 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 device stability and/or access.

A midline catheter placement is contraindicated for patients requiring any of the following:
• Solutions with final glucose concentrations above 5 percent;
• Contents sterile and non-pyrogenic in unopened, undamaged package

STERILE EO

STERILE EO

STEREILE TIP

The manufacturer shall not be liable for any damage caused by reuse or re-sterilization of this catheter or its accessories.

Contrary to popular belief, the insertion site is not sterile. Consider the patient an “open wound” in the process of healing. Therefore, there is a need to prevent any contamination of the catheter during insertion to carry it to the final target. The importance of using sterile gloves, unopened, undamaged package.

The Peripherally Inserted Central Vein
This catheter is for Single Use Only.

Common Complications:
• Air Embolism
• Shrink/Fracture/Friction
• Extravasation
• Hematoma
• Rash/Infusion site
• Vascular Thrombosis

Potential Complications:
• Site infection
• Hematoma
• Cardiac tamponade
• Vascular perforation

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

Warrants:
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• 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.
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• 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 (U.S.A) restricts this device to sale by or on the order of a physician.
• This catheter is for Single Use Only.
• This catheter is manufactured from soft radiopaque polyurethane material that provides increased patient comfort and excellent biocompatibility.
• This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessel.
• The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
• The presence of device related bacteremia commonly occurs when catheters are used in patients with venous access issues.
• 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 device stability and/or access.

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Contrary to popular belief, the insertion site is not sterile. Consider the patient an “open wound” in the process of healing. Therefore, there is a need to prevent any contamination of the catheter during insertion to carry it to the final target. The importance of using sterile gloves, unopened, undamaged package.
CATHETER PERFORMANCE

- Occluded/Partially Occluded Catheter- If resistance is encountered to aspirating or flushing, the lumens 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 decongestion procedure.

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 on any time the dressing becomes soaked, wet, or non-occlusive.

Note:
- During all dressing changes the external length of the catheter should be measured to determine if catheter migration has occurred. Periodically confirm catheter placement and tip location.

- 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 location solution.

- After drug administration each 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 needless access port(s), do not exceed 100 actuations.

CATHETER REMOVAL

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

Caution:
- Always review facility protocol, performance specifications, and their treatment, warnings, and precautions prior to catheter removal.

- Wash hands, gather equipment.
- 2. Remove old dressing and inspect site for redness, tenderness, and drainage.
- 3. Grasp catheter near insertion site and using a steady slow motion, remove catheter from vein.
- 4. If resistance is felt - STOP. Fitgape 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 according to following institutional policy.

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

ALTERNATE INSERTION TECHNIQUE USING STIFFENING STYLET AND SIDEPORT ADAPTER

PREPARE CATHETER

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

2. Attach saline filled syringe to luer of sideport adapter and flush adapter and catheter. Clamp adapter, measure depth of the growth by reading the markings on the wire. Remove the guidewire leaving the sheath and dilator in the vein.

3. 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 the hub) when initially inserting through skin, subcutaneous tissue, and the skin surface. To progress the sheath/dilator towards the vein, grasp 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.

4. Never leave sheath in place as an occluding sheath. Damage to the catheter may result.

5. After drug administration each lumen should be flushed with normal saline to prevent clotting.

6. Apply pressure, if necessary, until bleeding stops and dress site according to your institutional policy.

7. Leave locking collar of sideport and withdraw styptic stylet back past the proximal guide. The catheter is to be trimmed by at least ½ inch (1cm). Cut catheter to length determined by the facility.

Note:
- Always attempt to cut stylet.

- Once proper catheter length and stylet position has been achieved, tighten locking collar to keep styte in place.

- Remove dilator from sheath.

- Insert distal tip of catheter into and through the skin until catheter tip is correctly positioned in the target vein.

- 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 vascular damage, pull back the sheath as far as possible and tear the sheath only few centimeters at a time.

- Make any adjustments to catheter under direct vision.

- For PICC catheter insertion, the distal tip should be positioned at the level of the atrial junction.

- Do not clamp the lumen portion of the catheter. Clamp only the extender from the unit to avoid the aerated saccus, for only the in-line clamp(s) provided.

- Loosen locking collar of sideport. Remove the stylet by applying gentle pressure with one hand above the insertion site while grasping the stylet with the other hand and slowly pulling back with a constant motion. Remove sideport adapter and replace with needleless access port. Attach saline filled syringe to needleless access port, aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

Caution:
- If difficulty and/or bunching of the catheter lumen are experienced while removing the stylet, additional flushing of the catheter may be necessary. The catheter may need to be repositioned to allow for removal of the stylet.

- Do not attempt to reinsert stylet once it has been withdrawn.

- Never leave stylet in place after catheter insertion; injury may occur. Remove both stylet and sideport adapter after insertion.

- Continue following directions at step 14a of “Insertion” Section.

SYMBOL TABLE

- Manufacturer *
- Sterile *
- Upper and Lower Temperature Limits *
- Non-pyrogenic *
- Non Hazmat *
- Non-Use if Package in Date *
- Non-Bacteriostatic*
- Use-by Date *
- Non-Recommended *
- Catalog Number *
- Ref. Only *

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT MEETS THE APPLICABLE STANDARDS AND SPECIFICATIONS, FITS imperialism CLINICAL TREATMENT, AND PRODUCT MAINTENANCE 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.

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