**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 media 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 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 injection machine process may regulate the flow rate. Do not exceed the maximum flow rate. In the rare event that a hub or connector separations 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.

**CONTRAINDICATIONS:**

- 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 sites.

- Local tissue factors will prevent proper device stabilization and/or access.

**COMMON COMPLICATIONS:**

- Septicaemia
- Thrombosis
- Catheter blockage
- Malposition/Migration
- Damage/ Fracture of catheter
- Foreign body reaction
- Mechanical failure
- Drainage from insertion site
- Backflow of syringe
- Cellulitis

**POTENTIAL COMPLICATIONS:**

- Air Embolism
- Intravenous Hemorrhage
- Cardiac Arrythymia
- Cardiac Tachycardia
- Ectopic Palpitations
- Extravasation
- Infection
- Perforation of the vessel
- Thrombophlebitis
- Vascular thrombosis

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

**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 sepsis.

- History of mastectomy on insertion side.

- Previous history of venous/subclavian thrombosis or vascular surgical procedures at insertion site.

- Fever of unknown origin.

- Do not re-sterilize the catheter or accessories by any method.

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

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

- Contests sterile and non-pyrogenic in unopened, unopened package.

**STERILE EQ:**

**DIRECTIONS FOR SOLDERING INSERTION SITE:**

- 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.

**CATHETER PRECAUTIONS:**

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

- 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 hub of the lumen.

- 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.

**Midline / Baseline Vein Insertion:**

- Identify insertion site and vein, taking into account the following variables:
  - Type and purpose of IV therapy
  - Patient diagnosis
  - Age and size of patient
  - Unusual anatomical variables
  - Type and purpose of IV therapy
  - Anticipated dwell time of catheter

- Insert the introducer needle with aseptic technique 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 0.018" guidewire back into advance so that only the end of the guidewire is visible. Insert the 90-degree bend 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:** 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, repass the sheath/dilator a few centimeters (approximately 3cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

**Catheter Securement and Wound Dressing:**

- The insertion site and external portion of the catheter should always be covered with a protective dressing.

- Cover the exit site with an occlusive dressing according to the facility policy.

- Record catheter length, catheter lot number, and tip position on patient’s chart.

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

- Remove dilator from sheath.

- Insert distal tip of catheter into and through the sheath 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 grabbing the tabs and pulling the tabs in opposite directions (a slight twisting motion may be helpful).

- Do not clamp the lumen portion of the sheath catheter. To avoid vessel damage, pull back the sheath as far as possible and turn the sheath only few centimeters at a time.

- Do not clamp the lumen portion of the sheath catheter. Clamp only the extension(s). Do not use external forceps, use only the in-line clamp(s) provided.

- 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.

- Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

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

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

- 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 sites.

- Local tissue factors will prevent proper device stabilization and/or access.

- 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.

**WRITERS:**

- Therapies are not appropriate for midline catheters include those therapies requiring central venous access. Refer to standards of practice and institutional policies.

- The same location will weaken tubing. Avoid clamping near the hub of the lumen.

- 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.

**PREPARE CATHETER:**

- Preflush catheter.

**Note:** For insertion with a stiffening stylet, see reference insert image. To use the Stiffening Stylet and Suture Adapter system.

- 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-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.

**INSERTION:**

- Insert the introducer needle with aseptic technique 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 0.018" guidewire back into advance so that only the end of the guidewire is visible. Insert the 90-degree bend 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:** 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, repass the sheath/dilator a few centimeters (approximately 3cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.
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 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 CT Midline catheter per manufacturer’s recommendations.

6. Disconnect the power injection device. 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 then with a 10cc or larger syringe. For multi-lumen catheter, use a larger syringe. For multi-lumen catheter, use a larger syringe. For multi-lumen catheter, use a larger syringe. For multi-lumen catheter, use a larger syringe.

9. Replace the injection/needleless cap on the CT Midline catheter.

CATHETER PERFORMANCE

• Occluded/Partially Occluded Catheter - If occlusion 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 declogging procedure.

Warning: Only clamp catheter with in-line clamp. Do not attempt to connect power injector syringe directly to the catheter. Damage may occur to the 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 REMOVAL

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. 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 dress site follows 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 port(s).

2. Attach saline filled syringe to luer of sideport adapter and flush adapter and catheter. Clamp sideport 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 flush catheter lumen. 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; stylet and catheter damage may result.

Caution: Never clamp on catheter stylet, using and catheter damage may result.

CATHETER INSERTION

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.

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. Insert the introducer needle with attached syringe into the target vein. Gently aspirate to assure proper placement. Release tourniquet.

5. 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 0.018” guidewire back into advance so that only the end of the guidewire is visible. Insert the introducer’s distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

6. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into the target vein.

Caution: Do NOT bend the sheath/dilator during insertion as bending will cause the sheath/dilator to leak at the hub/compartment close to the tip approximately 3cm from tip when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, engage 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.

7. Loosen locking collar of sideport and withdraw stylet back beyond the point where the catheter is to be trimmed by at least 1/8 inch (1cm).

Caution: Never attempt to cut stylet.

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

9. Remove dilator from sheath.

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

11. Remove the tear-away sheaths 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 sheaths 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 the serrated forces, use only the in-line clamps) provided.

12. Loosen locking collar of sideport. Remove the stylet by applying gentle pressure with one hand above the insertion site while grasping the catheter 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 before syringe prior to clamping extension.

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

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

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

SYMBOL TABLE

Manufacturer
Keep Dry
Keep Away from Sunlight
Upper Limit of Temperature
Sterilized Using Ethylene Oxide
Use By Date
Do Not Reresterilize
Lot Number
Catalogue Number
Authorized Representative in the European Community

EU Representative:
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunsfeld
Germany

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Warranty

PN 40529
Rev. 4/15D