FLEXICATH LTD

M/29®

Pressure Injectable Midterm® Peripherally Inserted Catheter Device

Instructions For Use

This leaflet contains instructions for both standard needle-introducer and protection contained M/29® models, i.e., with and without Safety Needle Mechanism (Hereinafter: SNM)

www.flexicath.com

US Patent No. 8,162,890 and Worldwide Pending

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1 Product Description, Indications & Contraindications

Product Description
The M/29® Peripherally Inserted Midterm® Catheter Device is a single lumen peripherally placed midline catheter which provides reliable peripheral vascular access for **up to 29 days, with a build-in 360° Maximum Barrier®**
The product is provided Sterile (EtO) and Non-Pyrogenic.

Indications
The Pressure Injectable M/29® is a Peripherally Inserted Catheter Device which is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling and pressure injection applications such as contrast media injection.
The maximum flow rate for Flexicath Pressure Injectable midline catheter may not exceed 5ml/sec.

Contraindications
The 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 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.
- Do not insert into veins currently symptomatic of phlebitis, infiltration, extravasation, or hematoma.
- Do not insert through non-intact skin.
- Use with caution in patients with known or suspected bacteremia, septicemia, or sepsis.
- Local tissue factors will prevent proper device stabilization and/or access.
- A midline catheter placement is contraindicated for patients requiring any of the following:
  - Solutions with final glucose concentrations above 10 percent;
  - Solutions with protein concentrations above 5 percent;
  - Continuous infusion of vesicants.
  - Routine administration of infusates with a pH of <5 or >9 irritant medications.

2 Cautions & Warnings

Cautions
Carefully read and follow all instructions prior to use.

- This device is to be used for **up to 29 days.**
- **This device is to be used by or on the instruction of a physician or a licensed practitioner.**
- **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician or licensed practitioner.
- Do not use if package is opened or damaged.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Do not use force to remove the stiffening wire. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop wire withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and wire together approximately 2 cm and reattempt wire removal. Repeat this procedure until the wire is easily removed. Once the wire is out, advance the catheter into the desired position, taking care to avoid catheter segment exposure. Caution must be used to avoid contamination of any exposed catheter. Do not re-advance any catheter segments suspected or known to be contaminated to avoid the risk of infection.
- To minimize the risk of catheter breakage and embolization, the catheter must be secured in place per institutional policy.
- Verify removal of remaining air from the catheter tubing, according to instructions in paragraph 5.10.

If you are using the SNM Model, PLEASE NOTE:
- The device is needle shielded.
- **Keep fingers away from activation button during insertion.**

Warnings

- Use of ointments with polyurethane M/29® catheters can cause failure of the device.
- Alcohol, tincture of iodine or acetone based solutions **should not be used** to clean the polyurethane M/29® catheter. Do not allow alcohol-based or skin preparation solutions to pool at the insertion site as the catheter may be adversely affected.
- Use CHG (Chlorohexedine Gluconate) as skin prep.
- When alcohol is used as skin prep, it must be allowed to fully air dry prior to application of the dressing.
- Intended for Single Patient - Single Use. DO NOT REUSE. Flexicath Systems products are single use devices and should never be reinserted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Re-sterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood should not be reused or resterilized.
- 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.
- For applications require high pressure injection (such as; rapid infusion of contrast medium injection), DO NOT exceed **maximum pressure of 300psi, 5ml/sec flow rate, up to 12cP drugs at room temperature and up to five high pressure injections during the catheter use.**
- Before connecting the catheter to high pressure source, verify that the catheter is not occluded with accordance to institutional procedure.
- Excessive pressure may damage the catheter.

3 Precautions

- Follow universal precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by their manufacturers.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
- 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 (and thus air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged or opened, or the expiration date has passed.
- The product was sterilized by Ethylene Oxide. **Do not resterilize.**
- Inspect kit for inclusion of all components.
- Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material.
- Avoid perforating, tearing, or fracturing the catheter if using a stylet.
- Avoid sharp or acute angles during insertion which could compromise the patency of the catheter lumen.
- Do not place suture around the catheter as sutures may damage the catheter or compromise catheter patency.

- Do not use the device if there is any evidence of mechanical damage or leakage. Damage to the catheter may lead to rupture, fragmentation and possible embolism and surgical removal.
- Accessories and components used in conjunction with this device should incorporate Luer lock connections.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Infusion pressure greater than 25 PSI (172 kPa) may damage blood vessels and viscus and is not recommended. DO NOT USE A SYRINGE SMALLER THAN 10 ml! until catheter patency has been confirmed!

4 Potential Complications

The potential exists for serious complications, including the following:

- Air Embolism
- Exit Site Infection
- Phlebitis
- Bleeding
- Exit Site Necrosis
- Spontaneous Catheter
- Brachial Plexus Injury
- Extravasation
- Tip Malposition or Retraction
- Cardiac Arrhythmia
- Fibrin Sheath Formation
- Thromboembolism
- Hematoma
- Venous Thrombosis
- Catheter Erosion through the Skin
- Intolerance Reaction to inserted Catheter
- Ventricular Thrombosis
- Vessel Erosion
- Catheter Embolism
- Laceration of Vessels or Viscus
- Risks Normally Associated with Local or General Anesthesia, Surgery and Post Operative Recovery
- Catheter Occlusion
- Catheter-related Sepsis
- Perforation of Vessels or Viscus

5.1 Identify the Vein and Insertion Site

- Apply a tourniquet above the anticipated insertion site.
- Select a vein based on patient assessment. Superficial veins near the antecubital fossa are recommended (basilic, cephalic or median cubital veins) with the basilic vein is preferred.
- Release the tourniquet.

5.2 Position Patient

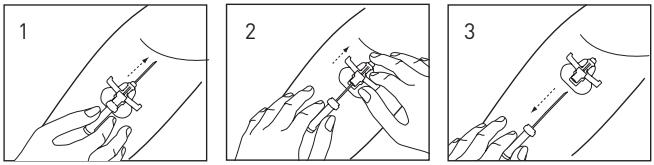
- Position the arm at a 45° - 90° angle abducted from the patient's body.

5.3 Prepare for Insertion

- Prepare the site according to institution policy, using aseptic technique.
- When alcohol-based solutions are used for skin preparation, they must be allowed to completely air dry.
- M/29® protective sleeve may reduce the amount of sterile gloves and perform hand hygiene with alcohol-based hand rub.
- M/29® protective sleeve may replace the sterile sheet drape normally used to isolate the patient body from the device if allowed by institution policy.
- Create a sterile field next to the patient's arm where you can place your catheter and supplies.
- Remove the white cap from the end of the M/29® protective sleeve and be sure that the catheter is resting just outside the tip of the protective sleeve.

5.4 Apply Tourniquet and Drape

- Reapply the tourniquet above the intended insertion site to distend the vessel.
- Reapply sterile gloves if required by institution protocol.
- Drape the patient by placing the fenestrated drape over the anticipated puncture site if contact between the glove and body is required.



5.5 Perform Venipuncture

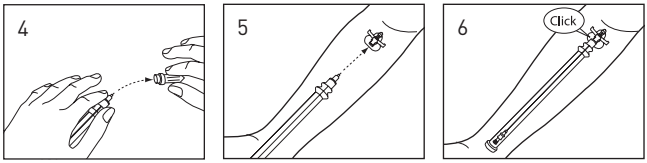
- Select the appropriate needle length per patient assessment.
- Remove the needle guard and make sure that the needle tip is fully visible.
- Grip only the needle hub during insertion. Do not apply excessive pressure to the wings. (1)
- Perform venipuncture and observe for blood flashback.
- Holding the needle stationary, advance the M/29® introducer sheath (with PeelGuard® adapter) into the vessel by pushing forward towards the insertion site. (2)

5.6 Withdraw the Introducer Needle

- Release the tourniquet.
- Support the Introducer sheath to avoid displacement.
- Apply slight pressure on the vessel proximal to the introducer's tip to minimize blood backflow.
- Withdraw the needle from the Introducer sheath.

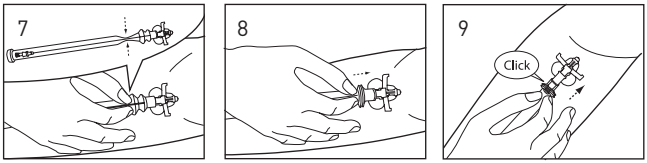
5.6.1 If you are using SNM M/29® Model with needle protection, act as follows:

- Perform the **first three (3)** stages in section **5.6**
- Withdraw the needle from the introducer sheath just until the needle tip lies in the PeelGuard luer port and then activate the safety mechanism by pressing its button to the end. The needle will then be retracted. Observe that the tip is fully covered.
- Once the needle is retracted, dispose according to applicable laws and institutional procedure.



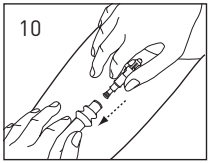
5.7 Insert and Advance the Catheter

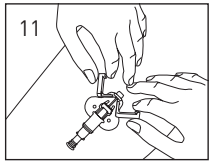
- Remove the cap of the M/29® protective sleeve (4) and firmly attach the tip to the luer connector on the PeelGuard® adaptor. (5,6)
- Advance the catheter slowly by grasping the catheter through the handgrip portion of the M/29® protective sleeve and pushing it forward. (7,8)
- Release pressure and allow the accordion-like motion of the protective

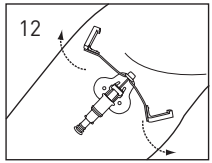


sleeve to return the handgrip portion to its original position. Repeat grasping and advance another segment of the catheter.

- Continue advancing the catheter as described above until the catheter is completely in place.
- Push the catheter hub until it is firmly seated in the protective sleeve's tip (a tactile feedback is expected). (9)
- Hold the Introducer and PeelGuard® in place and pull the protective sleeve, slowly, off the M/29® away from the insertion point and off the catheter hub. (10)







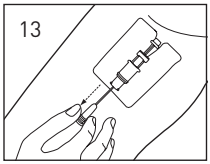
- Gently remove the protective sleeve completely. Some blood residues may remain in the protective sleeve. During the sleeve removal avoid splashing of this residue.

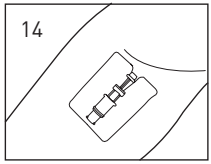
5.8 Retract and Remove the Needle Introducer Sheath

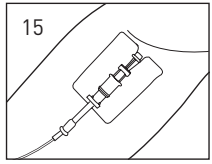
- Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath's tip.
- Split the introducer sheath and peel it away from the catheter. (11,12)

5.9 Remove the Stiffening Wire

- Release the wire's grip from the catheter hub. (13,14)
- Stabilize the catheter position by holding the catheter hub. (15)
- Slowly remove the wire.







Caution: Never use force to remove the wire. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop wire withdrawal and allow the catheter to return to normal shape. Withdraw the PeelGuard®, the catheter and the

wire together approximately 2 cm and reattempt wire removal. Repeat this procedure until the wire is easily removed. Any catheter that has been removed during the wire removal process can be replaced provided it has not been contaminated.

5.10 Aspirate and Flush for blood return

- After catheter insertion and wire removal, allow a drop of patient blood back-flow, either spontaneously or by slowly performing blood withdrawal from the catheter hub, using a syringe.
- Flush catheter per institutional policy and prescribe order to prevent clotting.

5.11 Verify Placement (as applicable)

- Verify catheter tip location according to institution protocol. Catheter is not intended for central venous placement.

5.12 Secure the Catheter

- **Caution:** To minimize the risk of catheter breakage, embolization or dislodgement the catheter must be secured in place per institutional policy.
- **Warning:** Use of ointments with the polyurethane catheter can cause failure of the device.
- **Warning:** Alcohol or acetone-based solutions should not be used to clean exposedexternal segments of polyurethane catheters or allowed to pool on.

- Care should be used when using alcohol-based prepping solutions to clean the skin at the insertion sites as the catheter may be adversely affected if allowed to pool at the site. Failure to allow skin preparation solutions to dry fully before applying dressing may result in damage to the catheter.

- **Warning:** The M/29® device is a non-repairable catheter.

6 Suggested Catheter Maintenance & Catheter Removal

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

- **Dressing Changes**
  Assess the dressing at least 24 hours after insertion for accumulation of blood, fluid or moisture beneath the dressing. It is suggested that the first dressing change occur in 24 hours and at least weekly thereafter. Follow institutional protocols for midline catheter dressing changes, including catheter securement devices. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. NOTE: Never attempt to reinsert the catheter if it has migrated out. Periodically confirm catheter placement, tip location, patency and security of dressing.

- **Flushing during use**
  FollowFor intermittent use, flush the catheter per institutional policy and follow needleless system valve manufacturer directions for catheter flushing. Usually, one mL is adequate use. Catheter fill volume is <1.0mL.

- **Occluded or Partially Occluded Catheter**
  If resistance is experienced on flushing and/or aspiration from the catheter, it may be partially or completely occluded. Do not flush against resistance. Follow institutional protocols for catheter clearance procedures.

Catheter Removal

- Remove dressing.
- Grasp catheter near insertion site.
- Remove slowly. Do not use excessive force.
- If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
- Resume removal procedure.
- Discard catheter according local laws and regulations.

An issued or revision date for these instructions is included for the user's information. In case two years have elapsed between this date and product use, the user should contact Flexicath Ltd. to check if additional product information is available (see contact details below).

This product is patented:

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