COLOR

2C BLACK PANTONE 136C

No printing

SCALE : 100%

IFU

420×297mm

Terumo Maintenance Code *MC17M101C*

TERUMO

2026-01/Rev.1

SURFLO MIDELA™ Midline Catheter

Basic Kit

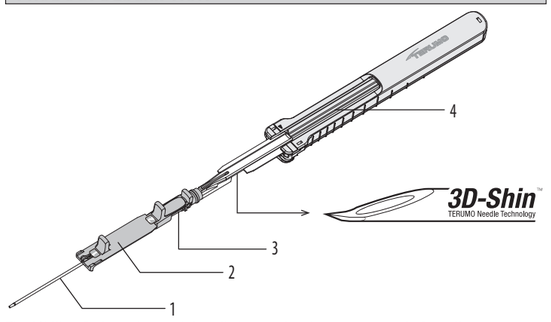
1 Each: SURFLO MIDELA™ Midline Catheter
1 Each: SURFLO MIDELA™ Securement Device

SURFLO MIDELA™ Midline Catheter

INDICATION FOR USE

The Midline Catheter is intended for insertion into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. It may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Midline Catheter is suitable for use with power injectors.

PRODUCT DESCRIPTION



The Midline Catheter is a peripherally inserted catheter composed of a radiopaque polyurethane catheter (1), a catheter slider (2), a catheter hub (3), and a 3D-Shin™ needle featuring an engineered three-dimensional geometry of the needle tip with a passive safety mechanism (4). After observing the blood return, the 3D-Shin™ needle is withdrawn, and the needle tip is fully covered by the safety mechanism, reducing the risk of accidental needlestick injury.

CONTRAINDICATIONS

The device is contraindicated for, but not limited to the following:
- Confirmed or suspected infection, bacteremia, or sepsis related to the device.
- The patient's body size is insufficient to accommodate the size of the device.
- Confirmed or suspected allergy of the patient to the materials contained in the device.
- Local tissue factors and/or past treatment will prevent proper device stabilization and/or access.
- History of radiation therapy, thrombosis, or vascular surgery at the puncture site.

WARNINGS

- **Alcohol should not be used to lock, soak, or declot Midline Catheter.**
- **Ointments containing acetone and polyethylene glycol should not be used with polyurethane catheters, as these may cause failure of the device.**
- **(Pediatrics) The puncture method and placement location are usually adjusted according to the child's body size and developmental age. The operation of placing a venous catheter in pediatric patients can only be performed by clinical medical staff who have the experience to accurately position and place the catheter in this patient population.**
- **The pressure limiting function of the power injectors may not prevent over-pressurization of the blocked catheter, which could potentially lead to catheter failure.**
- **Power injection pressure should not exceed 325 psi (2241 kPa), otherwise it may lead to catheter failure and/or displacement of the catheter distal end.**
- **If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.**
- **Some drugs used for central venous catheter therapy are not suitable for midline catheters. Refer to practice standards and institutional policies to select venous infusion drugs suitable for midline catheters.**
- **After advancing the catheter, do not reinsert the needle or pull back the catheter. If you need to reposition the catheter, you must first completely remove the needle or do it without the help of the needle to prevent the catheter from being damaged by the needle tip.**
- **Once the steel needle is completely or partially withdrawn, it is prohibited to reinsert it.**
- **In very rare cases, the catheter hub or infusion connector may fall off during use or insertion. In this case, all necessary steps and preventive measures should be taken to prevent blood loss or air embolism, including the withdrawal of the catheter.**
- **Before removing the infusion connector, the catheter must be lowered below the patient's heart.**
- **If abnormal resistance is encountered, the catheter cannot be advanced further.**
- **If the artery is accidentally entered, withdraw the needle and apply manual pressure for several minutes to prevent potential blood loss in the patient.**
- **If the infusion connector is placed above the patient's heart and exposed to air, the fluid level inside the catheter will drop. When removing the infusion connector, first place the infusion connector below the patient's heart, then remove the infusion connector to prevent the fluid level from dropping and potential air embolism.**

PRECAUTIONS

- Please read the instructions for use of this device and the devices and medicines used in conjunction with it.
- When using this device , follow universal precautions and manufacturer's guidelines for all infusates. Local factors or past treatments may affect device use.
- Only qualified healthcare practitioners should insert, manipulate, and remove these devices.
- It is a single-use sterile product. Re-sterilization and reuse are prohibited. Do not use if the packaging is damaged. Reuse and/or repackaging may pose a risk of infection to the patient or user, or compromise the integrity of the device structure, and/or the basic materials and design characteristics, which may lead to device failure, and/or cause injury, illness, or death to the patient.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems, or patient discomfort.
- Aseptic technique, proper skin preparation, and continued maintenance of the puncture site are essential. Follow universal precautions.
- Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- If there is any mechanical damage or leakage, do not use the catheter. Continued use may cause the catheter to break or shatter, potentially leading to an embolism, which in severe cases may require surgical removal.
- When using room temperature(20°C)contrast with a 26.6mPa· s viscosity, maximum flow rate not be achieved.
- Do not store at extreme temperatures.
- Drugs, fluids and scenarios that are not suitable for infusion:
  Continuous infusion of irritant drugs and foaming agents.
  Parenteral nutrition solution.
  Liquids or drugs with pH less than 5 or greater than 9.
  Liquids or drugs with an osmotic pressure greater than 900mOsm/L.
  Small size veins.

SPECIAL PATIENT POPULATION

NOTE: (Pediatric) Insertion of the Midline Catheter in pediatric patients may require the use of accessories or components not included in this configuration, based on the size and developmental age of the child and facility protocol. Follow manufacturer's recommendations regarding use of any drugs or medications.

NOTE: (Pediatric)Midline catheter: For neonates and pediatric patients, select an upper arm site using the basilic, cephalic, and brachial veins. Additional site selections include veins in the leg (e.g. saphenous, popliteal, femoral) with the tip below the inguinal crease and in the scalp with the tip in the neck, above the thorax.[4,6] (IV) [Infusion Therapy Standards of Practice, 2024]

NOTE: (Pediatric)Use both aqueous and alcohol-based chlorhexidine with caution in preterm neonates, low-birth-weight neonates, and within the first 14 days of life due to risks of chemical burns to the skin. Systemic absorption is possible due to skin immaturity; however, systemic effects are not documented. Use chlorhexidine antiseptic agents with caution in infants under 2 months of age. Studies have not established one antiseptic solution as superior for safety or efficacy in neonates. [Infusion Therapy Standards of Practice , 2024].
Consider chlorhexidine gluconate or povidone iodine as disinfectant agents for skin antisepsis. Remove povidone iodine prior to dressing application. Rationale: Removing povidone iodine minimizes the risk for tissue damage, absorption, and thyroid suppression. [Peripherally Inserted Central Catheters: Guideline for Practice, 3rd edition, 2015]

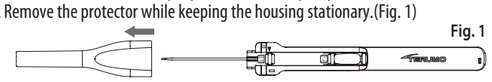
COMPLICATIONS

Possible Complications associated to catheterization include, but are not limited to, the following:
- Air Embolism
- Bleeding
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Exit Site Infection
- Exit Site Necrosis
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- Extravasation/infiltration
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration or Perforation of Vessels or Viscus
- Phlebitis
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Fibrin Sheath Formation

DIRECTIONS FOR USE

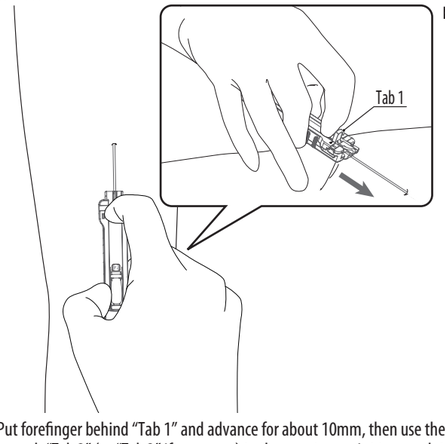
1. Check the package integrity and expiration date before use. Do not use if the packaging is compromised or the device is expired.
2. Carefully remove the product from the package.
3. Disinfect the insertion site per your institution's policy.
4. Remove the protector while keeping the housing stationary.(Fig. 1)

Fig. 1



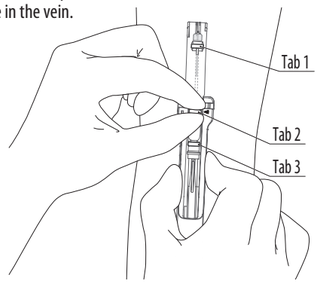
5. Hold the grip, identify the target vessel, and puncture at an appropriate angle. Ensure that the catheter slider does not move during puncture.
   Note: Ultrasound device may be used for identifying the position of the needle tip and blood vessel while puncturing.
6. Observe for blood return in the catheter, lower the insertion angle, and advance the catheter for 1-2mm.

Fig. 2



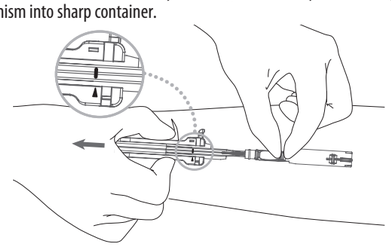
7. Put forefinger behind "Tab 1" and advance for about 10mm, then use the other hand to push "Tab 2" (or "Tab 3" if necessary) to the puncture point to complete the catheter insertion. Alternatively use one hand for complete insertion.
   Note: An ultrasound probe can also be used to make sure the catheter is in the right place in the vein.

Fig. 3



8. Stabilize "Tab 2" while keeping catheter slider stationary. Pull the grip backwards with the hand holding the device until "▬" aligns with "▲" (Fig. 4). Safety cover detaches from catheter slider (this is when needle-stick injury protection mechanism and hemostatic valve automatically activate), immediately discard the protection mechanism into sharp container.

Fig. 4



9. Remove catheter slider, connect infusion device with catheter hub immediately.
   Note: Refer to the SURFLO MIDELA™ Securement Device for instructions.

CATHETER MAINTENANCE

Dressing changes

- The dressing should always cover the puncture site. Change the dressing whenever leak or moisture is detected, or when the dressing becomes loose.
  Caution: If alcohol or disinfectant containing alcohol is used, attention should be paid to avoid excessive or prolonged exposure to prevent the catheter from degrading.
  Warning: Ointments containing acetone and polyethylene glycol should no be used with polyurethane catheters, as these may cause failure of the device.

Flushing

- Flush the catheter with 10 mL of sterile saline every 12 hours or after each use or per facility protocol.
  Caution: (Pediatric) When infusion volume is a concern in small or pediatric patients, flush with 3 mL or per facility guidelines.

Occluded or partially occluded Catheter

- Catheters that present resistance to flushing and aspiration may be partially or completely occluded.
  Warning: Do not flush against resistance. If the catheter will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a decluttering procedure per institution protocol may be appropriate.

CATHETER PRIMING VOLUME(S)

Gauge	Length	Priming volume
18 GA	8 cm	0.12 mL
	10 cm	0.14 mL
20 GA	8 cm	0.09 mL
	10 cm	0.10 mL
22 GA	8 cm	0.08 mL

POWER INJECTION PROCEDURE

- Remove the injection connector from the device. (This step is not necessary if a needle-free connector is used.)
  Warning: The fluid level in the catheter will drop if the catheter connector is held above the patient's heart and opened to air. To help prevent a drop in the fluid level and potential air embolism while removing the injection connector, hold the connector below the patient's heart before removing it.
- Attach a 10 mL or larger syringe filled with sterile saline (sterile infusion connector shall be sanitized first). Aspirate for adequate blood return and flush the catheter. Failure to ensure patency of the catheter prior to the power injection may result in catheter failure.
- Detach the syringe.
- Attach the catheter to the pressure extension tube on the power injector per manufacturer's guidelines (if a needle-free connector is present, sanitize the connector before attaching).
- To achieve maximum flow rate, contrast media is recommended to be warmed to body temperature before power injection.
- Maximum flow rate and maximum pressure are given in below table.

Gauge size	Contrast media*1 temperature	Contrast media*1 viscosity	Max flow (mL/sec)	Injector safety cut-off (psi)
18G	37℃	11.8 mPa·s	7	325 Max
20G			5	
22G			2	

*1. Visipaque 320

Caution: If the catheter is occluded, it can cause an injection pressure. The power injector machine pressure limiting feature may lead to power injection failure. Exceeding the maximum flow rate or the maximum pressure may result in catheter failure and/or catheter tip displacement.

- Detach the power injector machine.
- Attach new infusion connector to catheter hub.
- Flush the device with 10 mL of sterile saline or per the institution's protocol.

NOTE: (Pediatric) When infusion volume is a concern in small or pediatric patients, flush with 3 mL or per facility guidelines.

REMOVAL

Warning: Read IFU before removing the catheter, be aware of potential complications and possible treatment, precautions, and warnings.

- Hold the extension tube to remove the dressing and any securement device. Check if there is swelling, pain, or exudates in the puncture site.
- Grasp catheter near the insertion site, and remove the catheter slowly from the vein. If resistance is felt, stop removal. Restabilize the catheter hub apply a warm compress and wait 20-30 minutes.
- Resume removal procedure. If resistance is still felt, notify the physician.
- If necessary, press the puncture site after removal until the bleeding stops. Then dress the wound per protocol.

Note: When catheter is removed, check if the catheter is intact. If rupture or breakage is identified, notify the physician immediately.

ADDITIONAL PRECAUTIONS

- When removing the protector, be careful not to let the needle tip touch the protector. If the needle tip accidentally gets caught on the protect or, please safely dispose of the device as soon as possible.
- Once the protector is removed, do not put it back. Otherwise, needle stick injury may occur.
- Do not touch the catheter or needle with your hands throughout the procedure, as doing so may lead to needle stick or infection.
- Hold the grip and catheter slider while advancing the catheter slider. At this point, do not touch the safety mechanism to avoid increasing resistance of advancing the catheter slider.
- Once the needle-stick injury protection mechanism is activated, do not pull, rotate, bend, or squeeze the protection mechanism. Otherwise, the mechanism may detach or be damaged which may result in needle tip exposure. Immediately discard the protection mechanism safely into a sharp container.
- Once the needle is withdrawn from the vein if not fully covered by the protection mechanism, immediately dispose of it following the policies and procedures of your facility, as well as federal and local regulations for "Sharps Disposal". You should always distance yourself and your finger away from the needle.
- If a needle stick occurs, immediately report it per your established protocol. Exposure to blood contaminated needles, can cause serious diseases, such as hepatitis, or other infectious diseases.
- When removing the needle:
  (1) Hold the catheter in place with the left hand to prevent the catheter from slipping out of the vein.
  (2) Grasp the grip with the right hand to remove the needle (make sure to hold only the grip, and remove the needle swiftly and straight out. During the withdrawal, do not tilt the needle away from the catheter or rotate the needle.
  (3) Always remove the needle backward as opposed to the direction of puncturing. An angled exit would cause the catheter to be dragged out from the vein.
  (4) During the process of removing the needle, do not pause when the tip of the needle is pulled close to the catheter hub, as this may cause blood leakage.
- Use chlorhexidine gluconate and/or povidone iodine is recommended skin disinfectant. Allow all cleaning agents to dry completely before applying the dressing.
- Due to the risk of HIV or other blood disease infections, healthcare providers should follow standard precautions for preventing blood and body fluid infections when treating patients.
- The power injection of contrast media indicated in the product indications means that the catheter is capable of performing this procedure, but it does not necessarily indicate that the procedure is appropriate for a specific patient. Clinicians who have received adequate training are responsible for evaluating the health status of patients related to the power injection procedure.
- Consider alternate placement site when there has been:
  (1) Past irradiation of prospective insertion site.
  (2) Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- After use, this product may be a potential hazard. Handle and dispose of all contaminated materials according to facility protocol observing appropriate local guidelines for biohazard disposal.
- This product can only be used in conjunction with devices with Luer taper. Otherwise, there is a risk of falling off. However, it should not be excessively twisted when used with the device, otherwise, it may cause the connector to leak or break.

CAUTION

℞ ONLY Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

MR CONDITIONAL

MR Non-clinical testing demonstrated that the SURFLO MIDELA™ Midline Catheter is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 20T/m or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode) and a maximum scan time of one hour.

Artifact Information

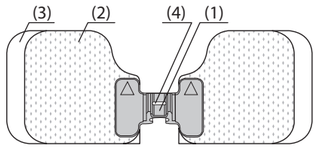
In non-clinical testing, the image artifact caused by the catheter extends approximately 10-mm from the catheter when imaged using a 3-Tesla MR system.

SURFLO MIDELA™ Securement Device

INDICATION FOR USE

This device is intended for use by healthcare professionals as an intravascular catheter securement device. It has an adhesive backing and is placed over a midline catheter to keep the catheter hub flat and securely anchored to the skin.

PRODUCT DESCRIPTION



The product consists of a retainer (1) with a slit (4), a breathable adhesive (2), and a backing (3).

CONTRAINDICATIONS

None.

WARNINGS

- **This is a sterile single-use product. Do not resterilize or reuse.**
- **Do not use this product on patients with an altered mental status who may inadvertently remove the device themselves.**

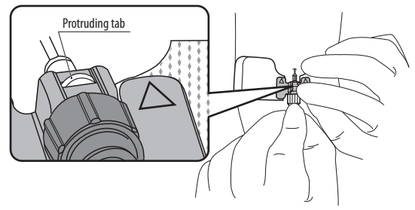
SAFETY INFORMATION

- Only trained healthcare professionals may use this product.
- Do not use the product if its integrity is compromised.

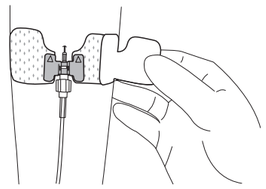
INSTRUCTIONS FOR USE

Application

1. Disinfect the midline catheter access site and the intended application site of the securement device using alcohol swabs or other disinfectants. Allow the disinfected area to dry completely. For optimal adhesive performance, perform skin preparation at the application site if necessary, and confirm the site is dry before proceeding.
2. Keep the midline catheter hub stable. With one hand, hold one side of the securement device, ensuring the arrow on the device is aligned toward the puncture site. Snap the protruding tab on the catheter hub firmly into the slit of the retainer.



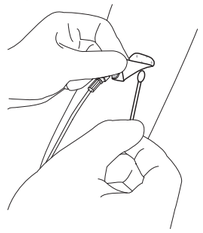
3. Gently peel off the backing. Peel one side at a time. Firmly press the breathable adhesive onto the patient's skin.



4. After applying the securement device, use a dressing to protect the puncture site. The dressing must fully cover the securement device. Document the application date of both the securement device and the dressing. Place a warning label if necessary.

Removal

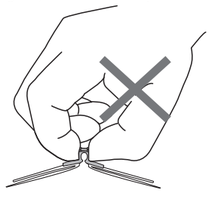
1. Carefully remove the dressing.
2. Moisten the edges of the breathable adhesive with an alcohol swab or other disinfectant while lifting the adhesive from the skin. Fold the adhesive back as you go, continuously moistening the skin-adhesive interface until the device is completely peeled off.



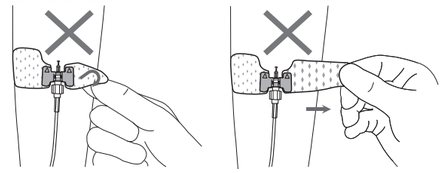
3. Carefully detach the catheter hub from the securement device's retainer.

PRECAUTIONS

- Adhesion strength will be reduced if the product is applied to areas with residual povidone-iodine, sweat or dried blood. Thoroughly remove all such substances before application.
- Prior to product use, verify that the midline catheter is correctly positioned in the patient's vein.
- When attaching the device to the catheter hub, do not exert excessive force on the retainer. Over-squeezing may deform the component and result in failed connection.



- Do not apply the product directly to the puncture site or any damaged/injured skin areas.
- Contact with alcohol or acetone may impair the adhesion strength of the breathable adhesive and loosen the bond between the adhesive and the retainer. Avoid such exposure.
- Before application, remove any grease or moisturizers from the intended application site.
- After cleaning the site with alcohol swabs, confirm the skin is fully dry before applying the device.
- Do not apply the device in the reverse direction of the arrow indicator, as this may cause catheter displacement or detachment.
- Do not peel off the backing of the breathable adhesive and attach the device to the skin before securing it to the catheter hub.
- Minimize contact with the catheter hub during both application and removal of the device.
- After application, confirm that the protruding tab on the catheter hub is fully and securely snapped into the retainer's slit. Inadequate engagement may lead to catheter shifting or dislodgement.
- Do not stretch or peel the breathable adhesive forcefully.
- When removing the dressing, avoid pulling on the catheter hub to prevent accidental displacement or removal of both the securement device and the midline catheter.
- When peeling the breathable adhesive from the skin, do not pull in a direction away from the catheter hub - retainer connection. Such action may cause the adhesive to separate from the hub.



Additional Precautions

- Conduct daily visual inspections of the securement device. Replace it immediately if any abnormalities are detected, including detachment, damage, contamination, or if clinically indicated by a healthcare professional. Routine replacement is recommended every 7 days.
- Regularly confirm the proper placement of the midline catheter.
- Discontinue use immediately if the patient develops dermatological reactions, such as rash, erythema, pruritus, or blisters, and implement appropriate clinical interventions.
- Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Do not store at extreme temperatures.

SYMBOL GLOSSARY

Consult instructions for use			
Do not use if package is damaged and consult instructions for use			
Do not re-use		Do not resterilize	
Single sterile barrier system		Sterilized using ethylene oxide	
Non-pyrogenic		Unique device identifier	
Contents		Catalogue number	
Batch code		Use-by date	
Date of manufacture		Manufacturer	
Maximum allowable injection pressure			

TERUMO MEDICAL PRODUCTS (HANGZHOU) CO., LTD.
M4-9-5 Hangzhou Economic and Technological Development Zone, 310018 Hangzhou, P.R.CHINA MADE IN CHINA

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