FRONTLINE MEDICAL PRODUCTS℠

SafetyNET™ ®

Guidewire Introducer

THINLINE® Power PICC Kit

Directions for Use

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Directions for Use
Peripherally Inserted Central Venous Catheter
THINLINE® PICC Kit

Product Description

A family of peripherally inserted central catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray with accessories necessary for a percutaneous microintroducer introduction (Modified Seldinger technique or Seldinger technique).

General Information and Warnings

The product described here may be used only by specialist physicians who are familiar with the techniques used in diagnostic and interventional cardiology. These instructions for use and the information on the packaging should be read carefully before each use.

WARNINGS:

- 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 quickly or 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 re-sterilize the catheter or accessories by any method.
- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
- STERILIZED BY ETHYLENE OXIDE
- 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.

IMPORTANT INFORMATION PERTAINING TO POWER INJECTION

WARNINGS:

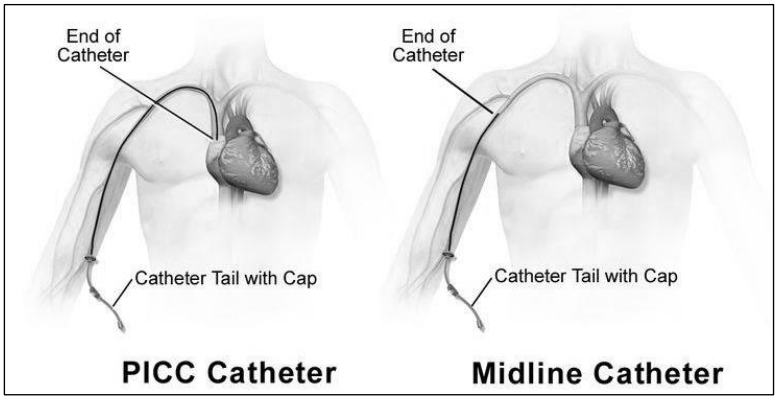
- Contrast media should be warmed to body temperature prior to power injection. Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the THINLINE® PICC catheter using a 10cc or larger syringe and sterile normal saline prior to and immediately 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.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Use only lumens marked "Power Injectable" for power injection of contrast media.
- Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
- Do not exceed the maximum flow rate printed on the catheter.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.

- Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.
- THINLINE® PICC 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.

CATHETER PRECAUTIONS

- Small syringes will generate excessive pressure and may damage the catheter. Ten (10) cc or larger syringes are 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 luer(s) and hub of the catheter.
- Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps; use only the in-line clamp(s) provided
- 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 uses.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Repeated over tightening of luer lock connections, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Confirm catheter tip position by x-ray prior to use. Monitor tip placement routinely per institution policy.

INSERTION SITES



The basilic, brachial, or cephalic vein may be used. Ultrasound guidance is considered the safest method for needle guidance and insertion.

WARNING: THINLINE® PICC features a reverse-taper catheter design. Placement of a larger catheter at or below the antecubital fossa may result in an increased incidence of phlebitis. Placement of the THINLINE® PICC catheter above the antecubital fossa is recommended.

Indications

The THINLINE® PICC is indicated for short or long term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, and power injection of contrast media. The THINLINE® PICC has a maximum recommended infusion rating of 5cc/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 or vein 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.
- There has been past irradiation of prospective insertion site.
- There have been previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- There are local tissue factors that may prevent proper device stabilization and/or access.
- Skin conditions that prevent insertion through an unaffected area.

Possible Complications

Insertion of these devices requires training consistent with the Standards of Practice. Ensure that you are familiar with the below complications and their emergency treatment should any occur.

- Air Embolism
- Accidental Arterial Access
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Breakage
- Catheter Erosion through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Inadvertent Vessel Puncture
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Myocardial Erosion
- Mediastinal widening
- Perforation of Vessels or Viscus
- Phlebitis
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

Directions for Use

DIRECTIONS FOR SafetyNET® GUIDEWIRE INTRODUCER USE

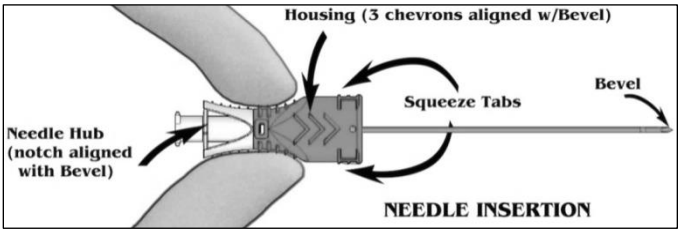
SafetyNET®Guidewire introducers are intended to introduce a guidewire into a patient for general surgery or into the vascular system, and to provide a means of protecting the needle point after use to reduce the risk of accidental needle stick injury.

1. Remove guidewire introducer needle, taking care to not remove needle cover until you are ready to use needle.
2. Using aseptic technique, prepare the patient for the procedure. Select the desired vessel entry site.
3. Grasp clear needle hub or the base (proximal end) of the colored housing. With other hand, grasp middle of needle cover on the annular rings and pull cover straight off needle.
4. A syringe may be attached to needle's clear luer hub at discretion of user.

NOTE: Do not grasp distal end of colored housing to manipulate needle during procedure. Doing so may inadvertently deploy the spring-loaded needle Safety Guard and disrupt the procedure.

CAUTION: Never attempt to disable, manipulate, or re-set the spring-loaded Safety Guard once it has been deployed. Injury may result.

5. Needle insertion: While gripping clear needle hub, or base (proximal end) of colored housing, needle may be inserted into tissue to desired location. The iECHO® needle includes an echogenic feature at the distal tip allowing pinpoint placement of the needle into the vessel under ultrasound guidance. The clear hub has a "bevel up" notch, and the colored housing has three raised chevrons aligned with top of needle bevel to allow proper bevel orientation during the procedure. Clear needle hub allows visualization of blood flashback. **See Figure below** for product features and proper gripping position during needle insertion.



6. Advancing a guidewire: A guidewire, with a maximum diameter as specified on the package label, may be threaded through needle to the desired location.

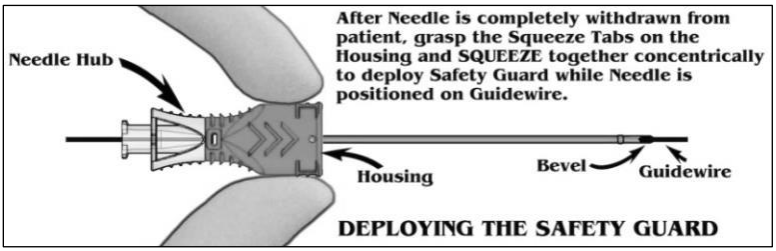
   CAUTION: To avoid guidewire damage, do not withdraw guidewire through needle.

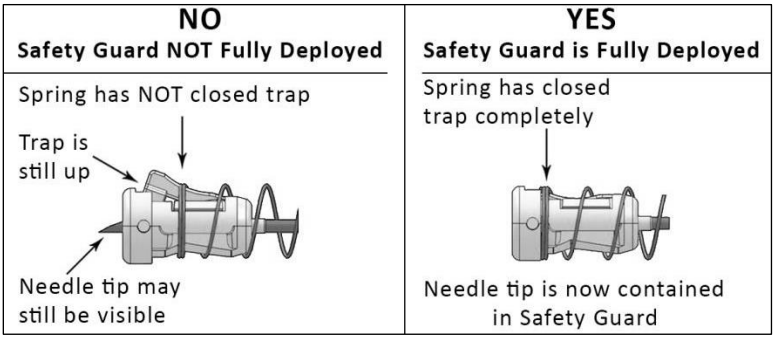
7. Removing the needle: While gripping clear needle hub or proximal portion of colored housing with the dominant hand, pull needle back until it has exited tissue a short distance but is still on guidewire. Use non-dominant hand to stabilize guidewire and control bleeding.

   CAUTION: To ensure proper operation of Safety Guard, do not deploy Safety Guard until needle point has fully exited patient.

8. Deploying the Safety Guard: While keeping needle on guidewire, grasp the Squeeze Tabs at distal end of colored housing with thumb and forefinger. Squeeze the tabs together (concentrically) to release the spring-loaded Safety Guard. Safety Guard should move forward to cover end of needle point, but trap will not close and Guard will not lock into place until needle has been pulled off guidewire completely.

   CAUTION: If Safety Guard does not release and/or move forward to end of needle, do not attempt to manipulate Safety Guard. Injury may result. For clarification, see illustration on page 6.





9. Needle disposal: Withdraw needle completely off guidewire. Safety Guard's trap should close, and spring should move forward to end of Safety Guard to lock Guard into place. Handle and dispose of used needle according to institutional policies and procedures for contaminated sharps.

   CAUTION: Always treat used needle as a contaminated sharp, even if the Safety Guard has been deployed. The presence of a safety feature is not a substitute for good technique. If Safety Guard does not fully deploy or appear to lock into place, do not try to manipulate Safety Guard, but dispose of used needle immediately per institutional policies and procedures

DIRECTIONS FOR MODIFIED SELDINGER INSERTION

1. Examine the package carefully before opening to confirm its integrity, presence of all components, and that the expiration date has not passed.
2. Read instructions carefully before using this device.
3. 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.
4. 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.
5. 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
- Size of the vein and catheter appropriate for the diameter of the vein
- Unusual anatomical variables
- Type and purpose of IV therapy
- Anticipated dwell time of catheter

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

PREPARE CATHETER

1. Pre-flush catheter, needleless access port(s), and stylet

WARNINGS:

- Attach saline filled syringe to lumen of catheter. If using dual lumen catheter, attach needleless access port to remaining extension. Attach saline filled syringe to the needleless access port and completely flush catheter lumen. Remove syringe from needleless access port prior to clamping extension.
- Attach saline filled syringe to the luer lock fitting of the flush through stylet hub. Inject enough solution to wet the stylet surface entirely. Remove the stylet from its holder and insert into the catheter. If the catheter has been trimmed, only advance the stylet to the distal end of the catheter. The catheter stylet assembly can now be introduced as described in the following information

CAUTION:

- Never close clamp on catheter stylet; stylet and catheter damage may result.
- 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

2. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask.
3. Apply tourniquet to arm above anticipated insertion site to distend the vein.
4. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement. Release tourniquet.
5. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Insert the flexible end of marked guidewire into needle so that only the end of the guidewire is visible. Advance guidewire with forward motion into and past the needle hub into the target vein.

   CAUTION: The length of the wire inserted is determined by the size of the patient and should not be advanced past the shoulder except when fluoroscopic guidance is available. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.
   NOTE: For alternate insertion method, see Directions for Seldinger Insertion Section.

6. Remove needle, leaving guidewire in the target vein. For clarification, see page 4 DFU. Thread sheath/dilator over the proximal end of the guidewire into target vein. If necessary, nick the skin with the PenBlade safety scalpel for easier advancement of the dilator.

   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. If necessary, nick the skin with the PenBlade safety scalpel for easier advancement of the dilator.

7. Withdraw stylet back beyond the point where the catheter is to be trimmed by at least ¼ inch (1cm). With the included PenBlade safety scalpel, cut catheter to length determined by marked guidewire.

NOTE: Cut catheter at the desired length by inserting catheter tube perpendicular to blade into the distal blade cavity of the PenBlade safety scalpel when the blade is retracted. To extend blade, press orange slide proximally until an audible click is heard and the slide locks into place. To retract blade, press retraction button situated above the blade until an audible click is heard, and then release.
CAUTION: Never attempt to cut stylet.
CAUTION: Always withdraw stylet back beyond the tip of the catheter prior to insertion

8. Once proper catheter length and stylet position has been achieved, remove dilator from sheath.
9. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
10. 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.

    CAUTION: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage and skin laceration, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time. Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

11. Make any adjustments to catheter under X-ray or fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction
12. 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. Attach saline filled syringe to needleless access port, or lumen and aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

    CAUTION: To avoid difficulty and/or bunching of the catheter lumens while removing the stylet, flush catheter prior to removal. The catheter may need to be repositioned to allow for removal of the stylet.
    CAUTION: Do not attempt to reinsert stylet once it has been withdrawn.
    CAUTION: Never leave stylet in place after catheter insertion; injury may occur. Remove stylet after insertion.

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.
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.
16. Confirm and document proper tip placement with X-ray or fluoroscopy prior to use. The distal tip should be positioned at the level of the caval atrial junction.

    CAUTION: Failure to verify catheter placement may result in serious trauma or fatal complications.
    NOTE: If there is no blood return, correct the catheter position before use.

CATHETER SECUREMENT AND WOUND DRESSING:

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

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

DIRECTIONS FOR SELDINGER INSERTION

1. Follow directions for Modified Seldinger Insertion, up to step #4.
2. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism.
3. Insert guidewire into hub of introducer needle and thread desired length
4. Remove needle, leaving guidewire in the targeted vein. For clarification, see page 4 DFU. Advance the guidewire until it reaches the caval atrial junction and confirm with fluoroscopic verification. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire
5. Cut catheter to length determined by marked guidewire.
   NOTE: Cut catheter at the desired length by inserting catheter tube perpendicular to blade into the distal blade cavity of the PenBlade safety scalpel when the blade is retracted. To extend blade, press orange slide proximally until an audible click is heard and the slide locks into place. To retract blade, press retraction button situated above the blade until an audible click is heard, and then release.

6. Insert proximal end of wire into distal tip of catheter lumen. Feed catheter lumen into the vessel following the guidewire. Make sure the guidewire comes out of the hub end of the catheter before advancing the wire in the vessel to avoid wire emboli, or wire advancing towards the heart. Then, advance catheter along the guidewire until the distal tip is correctly positioned in the target vein. Maintain control of the wire external to the catheter hub at all times. The distal tip should be positioned at the level of the caval atrial junction.

   CAUTION: A skin nick may be required to feed the catheter smoothly into the vessel.

7. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.
8. Remove the wire from the catheter. Remove by applying gentle pressure with one hand above the insertion site while grasping the wire with the other hand and pulling slowly back with a constant motion.
9. Follow directions for Modified Seldinger Insertion, from step # 14 on.

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the THINLINE® PICC catheter.
2. Using a 10cc or larger syringe(s), aspirate for blood return and flush catheter lumen to assure free flowing patency. 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.
4. Detach syringe.
5. Attach the power injection device to the THINLINE® PICC catheter per manufacturer's recommendations.

   WARNING: Always use injectable luer locking 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 of 300 psi at 5 ml/sec.
7. Disconnect the power injection device.
8. Flush the THINLINE® PICC catheter with 10cc of sterile normal saline, using a 10cc or larger syringe. For multi-lumen catheters, flush all lumens after power injection.
9. Replace the injection/needleless cap on the THINLINE® PICC 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.

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: When using alcohol or alcohol containing antiseptics with the THINLINE® PICC, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

WARNINGS:

- Alcohol should not be used to soak or declot the THINLINE® PICC because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Acetone and polyethylene glycol containing ointments should not be used with the THINLINE® PICC, as these may cause failure of the device.
  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 by imaging method.
- Flushing and Heparinization - Follow institutional policy for flushing frequency and heparin concentration.
- The catheter should be flushed with normal saline prior to drug administration to remove heparin solution.
- After drug administration each lumen should be flushed again with normal saline and then locked with heparin to maintain patency
- Injection cap(s) or needleless access port(s) should be changed per institutional policy.

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 and notify the physician.
5. If no resistance is felt- Resume removal procedure.
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

Disposal after Use

Always treat used needle as a contaminated sharp, even if the Safety Guard has been deployed. The presence of a safety feature is not a substitute for good technique. If Safety Guard does not fully deploy or appear to lock into place, do not try to manipulate Safety Guard, but dispose of used needle immediately per institutional policies and procedures. After use, medical products and accessories pose a potential biological hazard. For this reason, the products and their accessories should be handled and disposed of in accordance with recognized medical procedure, and in compliance with the relevant legal regulations and local ordinances.

WARRANTY

FRONTLINE MEDICAL PRODUCTS 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.

Explanation of the symbols on label and packaging

REF	Reference Number
LOT	Lot Number
	Read Instructions for Use Carefully
	Protect from Direct Sunlight
	Store in a Dry Place
	Expiration Date
	For Single Use
	Do Not Resterilize
STERILE EO	Sterilized by Ethylene Oxide
	Do Not Use if Packaging is Damaged
	Manufacturer
$\mathbf{R}_{\mathbf{only}}$	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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