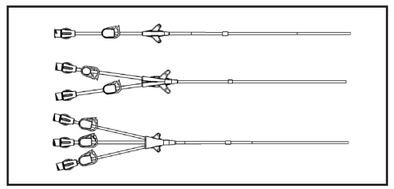
medCOMP®

PRO-LINE® CT CENTRAL VEIN ACCESS CATHETER

INSTRUCTIONS FOR USE

DESCRIPTION:

- The Pro-Line® CT family of centrally inserted catheters is made from specially formulated biocompatible medical grade materials. They are packaged in a tray with accessories necessary for percutaneous insertion using a microintroducer (Modified Seldinger or Seldinger technique).



INDICATIONS FOR USE:

- The Medcomp® Pro-Line® CT Power Injectable CVC is indicated for short or long term access to the central venous system. It is designed for administering I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the Pro-Line® CT Power Injectable CVC may not exceed 300psi.
- The Medcomp® 6F Triple Pro-Line® CT Power Injectable CVC is indicated for short or long term access to the central venous system. It is designed for administering I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal, allows for central venous pressure monitoring and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the Pro-Line® CT Power Injectable CVC may not exceed 300psi.
- Catheter testing included 10 power injection cycles.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein.
- Alternate insertion sites include the subclavian vein.

IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:

- Contrast media should be warmed to body temperature prior to power injection. **Warning:** Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the Pro-Line® CT 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. **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 of 5cc/sec. **Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter. **Warning:** Exceeding the maximum flow rate of 5cc/sec may result in catheter failure and/or catheter tip displacement.
- **Warning:** Pro-Line® CT 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.

CONTRAINDICATIONS:

- The presence of device related infection, bacteremia, or septicemia is known or suspected.
- This catheter is intended for short or long-term vascular access and should not be used for any purpose other than indicated in these instructions.
- The patient is known or is suspected to be allergic to materials contained in the device.

POSSIBLE COMPLICATIONS:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Laceration of the Vessels or Viscus
- Myocardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- 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

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

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 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 resterilize the catheter or accessories by any method.
- Re-use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
STERILIZED BY ETHYLENE OXIDE
STERILE | EO
- 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.

Note: Discard biohazard according to facility protocol.

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.
- 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 overtightening 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.
- The catheter allows for blood draws, power injection of contrast media, intravenous therapy, and infusion of medications into the central venous system. Refer to standards of practice and institutional policies for compatible infusion agents for central venous access.
- Follow all contraindications, warnings, precautions, and instructions for all infusates including contrast media as specified by their manufacture.

INSERTION SITES:

When placing catheters through percutaneous introducers, caution should be exercised to avoid inadvertent penetration of vital structures in the thorax. Catheters placed percutaneously or through a cut-down should be inserted into the subclavian vein at the angle of the outer third of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to severing or damaging of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

Internal Jugular Vein

- Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Subclavian Vein

- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- Avoid medial catheter placement into subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the subclavian vein.[1]

[1] Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1994; 148:633-636.

DIRECTIONS FOR MODIFIED SELDINGER INSERTION

- 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.

PREPARE CATHETER:

1. Preflush catheter, sideport adaptor, and needleless access port(s).
- Attach saline filled syringe to luer of sideport adaptor and flush adaptor and catheter. Clamp sideport extension and remove syringe. If using a multi-lumen catheter, attach needleless access ports to remaining extensions. Attach saline filled syringes to the needleless access ports and completely flush catheter lumens. Remove syringe from access port prior to clamping extension.

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

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:

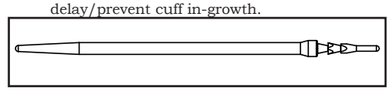
2. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The operating room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask.
3. The selection of the appropriate cannula french size is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

TUNNELING:

4. Administer sufficient local anesthetic to completely anesthetize the insertion and exit site.

   Note: A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the hub of the catheter from entering the exit site.
5. Make a small incision at the exit site. Make a second incision at the insertion site. Make the incision at the exit site wide enough to accommodate the cuff, approximately 0.5cm.
6. Use blunt dissection to create the subcutaneous tunnel opening. Do **NOT** tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.

   Warning: Do **NOT** over-expand subcutaneous tissue during tunneling. Over-expansion may delay/prevent cuff in-growth.



7. Loosen locking collar of sideport adaptor and withdraw stylet until tip is approximately 1 inch inside the catheter tip. Tighten locking collar to keep stylet in place. Slide distal end of the catheter over the barbed end of the tunneler.
8. Barbs must be completely covered by the catheter tip to adequately secure the catheter as it is pulled through the tunnel.
9. Advance tunneler through the subcutaneous layer from the exit site to the insertion site.
10. Lead catheter into the tunnel gently. Do **NOT** pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion.

    Caution: Do not attempt to pull catheter lumen off tunneler. After reaching the insertion site, the lumen must be cut from the tunneler. Cut catheter squarely (with no points) in such a manner that produces a clean, smooth surface.

VEIN ACCESS:

11. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement.
12. 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 .018" guidewire back into advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. 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. 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. Do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

    Note: For alternate insertion method, see Directions for Seldinger Insertion Section.
13. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into target vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire. Remove the guidewire leaving the sheath and dilator in the 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, regrasp 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.
14. Loosen locking collar of sideport and withdraw stylet back beyond the point where the catheter is to be trimmed by at least ¼ inch (1cm). Cut catheter to length determined by marked guidewire.

    Note: Lumen depth markings are from the zero mark at the hub to the distal end of the catheter. To achieve proper tip placement be sure to account for length of catheter lumen inside tunnel.

    Note: The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper measurement and trimming are important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

    Caution: Never attempt to cut stylet.

    Caution: Always withdraw stylet back beyond the tip of the catheter prior to insertion.
15. Once proper catheter length and stylet position has been achieved, tighten locking collar to keep stylet in place.
16. Remove dilator from sheath.
17. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
18. Remove the tearaway sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

    Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
19. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.

    Caution: 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.

20. Remove the catheter stylet and sideport adaptor. First loosen the locking collar of the sideport adaptor. Applying gentle pressure above the exit site with one hand while grasping the stylet handle with the other, slowly withraw the stylet with a constant motion. Clamp catheter extension and remove sideport adaptor. Install needleless access port. Unclamp catheter extension and attach saline filled syringes to needleless access port. Aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

    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 both stylet and sideport adaptor after insertion.

21. 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.

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

    Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten (10)cc or larger syringes are recommended.

23. 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.

24. Confirm and document proper tip placement with 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, verify catheter position before use.

CATHETER SECUREMENT AND WOUND DRESSING:

25. Suture insertion site closed. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

    Caution: Care must be taken when using sharp objects on needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

26. Cover the insertion and exit site with occlusive dressings.

27. Catheter must be secured/sutured for entire duration of implantation.

28. 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 and including step #12.

2. Remove needle, leaving guidewire in the targeted vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire.

3. Remove stylet from catheter.

4. Cut catheter to length determined by marked guidewire.

    Note: Lumen depth markings are from the zero mark at the hub to the distal end of the catheter. To achieve proper tip placement be sure to account for catheter lumen inside tunnel.

    Note: The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper measurement and trimming are important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

5. It may be necessary to dilate the insertion site. To achieve this, remove the dilator from the provided sheath/dilator. Thread dilator over the proximal end of the guidewire into the target vein until insertion site has been sufficiently dilated. Remove the dilator.

6. Insert proximal end of wire into distal tip of catheter lumen. Feed catheter lumen into the vessel following the guidewire. Advance catheter lumen along the guidewire until the distal tip is correctly positioned in the target vein. The distal tip should be positioned at the level of the caval atrial junction.

    Caution: A skin knick 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.

    Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use serrated forceps; use only in-line clamps provided.

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 #21 on.

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the Pro-Line® CT catheter.

2. Using a 10cc or larger syringe(s), aspirate catheter lumen(s) to assure patency and remove heparin. 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 Pro-Line® CT catheter per manufacturer's recommendations.

    Warning: Always use connector 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. **Warning:** Exceeding the maximum flow rate of 5cc/sec may result in catheter failure and/or catheter tip displacement.

7. Disconnect the power injection device.

8. Flush the Pro-Line® CT catheter with 10cc of sterile normal saline, using a 10cc or larger syringe. For multi- lumen catheters, flush all lumens.

9. Replace the injection/needleless cap on the Pro-Line® CT 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.
- Necessary remedial action must be taken prior to the continuation of the treatment.

Note: Excessive blood loss may lead to patient shock.

CENTRAL VENOUS PRESSURE MONITORING

- For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.
- Prior to conducting central venous pressure (CVP) monitoring:

    - Ensure proper positioning of the catheter tip.

    - Flush catheter vigorously with normal saline.

    - Ensure pressure transducer is at the level of the right atrium.

- It is recommended that a continuous infusion of saline (3 ml/hr) is maintained through the catheter while measuring CVP to improve the accuracy of the results.
- Use your institution's protocols for central venous pressure monitoring procedures.

Warning: CVP monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

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: 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 Locking** - Flush and lock catheter according to your institutional policy.
- The catheter should be flushed with normal saline prior to drug administration to remove locking solution.
- After drug administration, each lumen should be flushed again with normal saline and then locked to maintain patency.

Injection Caps - Injection cap(s) or needleless access port(s) should be changed per institutional policy. If using the supplied needleless access port(s), do not exceed 100 actuations.

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 physician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

No resistance should be felt when withdrawing catheter from vein. If resistance is encountered, do not continue pulling against resistance since this may cause catheter breakage and air embolism. Free up resistance before proceeding.

1. Palpate the catheter exit tunnel to locate the cuff.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
3. Make a 2cm incision over the cuff, parallel to the catheter.
4. Dissect down to the cuff using blunt and sharp dissection as indicated.
5. When visible, grasp cuff with clamp.
6. Clamp catheter between the cuff and the insertion site.
7. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.
8. Remove the remaining section of catheter (i.e. portion in tunnel) through the exit site.

    Warning: Do **NOT** pull distal end of catheter through incision as contamination of wound may occur.

9. Apply pressure to proximal tunnel approximately 10-15 minutes or until bleeding stops.
10. Suture incision and apply dressing in a manner to promote optimal healing.
11. Check catheter for integrity and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

Pro-Line®				
Catheter Size	Gravity Flow		Full Length Priming Volume	
5F X 60CM SINGLE w/Cuff @ 2cm	28.4 cc/min		0.79cc	
5F X 60CM SINGLE w/Cuff @ 5cm				
5F X 55CM DUAL w/Cuff @ 2cm	9.96 cc/min		0.60cc	
5F X 55CM DUAL w/Cuff @ 5cm				
6F X 60CM SINGLE w/Cuff @ 2cm	54.3 cc/min		1.06cc	
6F X 60CM SINGLE w/Cuff @ 5cm				
6F X 60CM DUAL w/Cuff @ 2cm	11.75 cc/min		0.67cc	
6F X 60CM DUAL w/Cuff @ 5cm				
	17 Ga	19 Ga	17 Ga	19 Ga
6F X 60CM TRIPLE w/Cuff @ 5cm	16.4 cc/min	6.4 cc/min	0.70cc	0.40cc
7F X 60CM SINGLE w/Cuff @ 5cm	108.11 cc/min		1.39cc	
7F X 60CM DUAL w/Cuff @ 5cm	26.65 cc/min		0.82cc	

WARRANTY

Medcomp® 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.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents in accordance with all relevant regulatory requirements.

SYMBOL TABLE

5.1.1	Manufacturer *
5.3.4	Keep Dry *
5.4.2	Do Not Re-use *
5.6.3	Non-pyrogenic *
5.3.2	Keep Away from Sunlight *
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *
5.2.8	Do Not Use if Package is Damaged *
5.1.4	Use-by Date *
5.2.6	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
Rx Only	Prescription Use Only ***
5.1.2 EC REP	Authorized Representative in the European Community*
5.4.4	Caution, consult Accompanying Documents *
5.3.8	Upper Limit of Temperature *

*** This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

Note: Temperature symbols : "This symbol only applies to kits with drugs".

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