Pro-Lock™ CT Safety Infusion Set

To Be Used With Implanted Vascular Access Ports

DEVICE DESCRIPTION:
The Pro-Lock™ CT Safety Infusion Set is composed of a Huber style needle for port septum access having a safety feature designed to prevent accidental needle sticks and automatically activate during needle removal. The needle is connected to a conventional style extension set for attachment to standard IV/Drug infusion line sets.

The proximal end of the extension tubing attaches to a female luer connector with removable dust cap creating a fluid path from the needle tip thru the female luer. A non-removable pinch clamp is located between the female luer and needle cannula. The pinch clamps are designed that when engaged, fluid flow is restricted thru the extension tubing.

The needle cannula is constructed with a Huber style needle. The cannula is stainless steel and is shielded by a removable star needle guard of plastic construction.

INDICATIONS FOR USE:
The Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through implanted vascular access ports. The Pro-Lock™ CT Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 20 gauge non-coring Huber style needles.

CONTRAINDICATIONS:
- **DO NOT USE,** if local tissue factors will prevent proper device stabilization and/or access.
- **DO NOT USE,** when the presence of device related infection, bacteria, or septicemia is known or suspected.

Directions: ***Use Aseptic Technique***

TO ACCESS OR INSERT SAFETY NEEDLE:

1. Prepare port site for sterile needle insertion.
2. Attach 10cc syringe containing normal saline to the proximal Luer lock connection of the safety infusion set.
3. Grasp the wings between thumb and forefinger (Fig. 1).
4. Remove needle guard (Fig. 2).
5. Prime and flush infusion set.
6. Using the forefinger and middle finger, locate and stabilize the vascular access port. Position the needle over the port and insert needle perpendicular into vascular access port by pressing down with thumb and index finger of the dominant hand while aiming for the port septum (Fig. 3).
7. Advance needle through the skin and septum into the port reservoir (Fig. 4).
   NOTE: Depending on the length of the needle used the base may not rest flush against the skin.
8. Aspirate and flush to verify patency.
9. Dress and secure site per institutional protocol.
10. Fill port in accordance with institutional protocol.
11. Do not use syringes less than 10cc.

TO DE-ACCESS OR REMOVE SAFETY NEEDLE:

1. **Position forefinger and middle finger onto Pro-Lock's base from side opposite of extension tubing.** With available hand, firmly grasp wings between thumb and forefinger (Fig. 5).
2. While maintaining Pro-Lock base against patient, pull wings up vertically to remove the needle from the port. Fully retract the needle to ensure the needle point is positioned within the protective well. USER WILL HEAR AND FEEL LOCKING MECHANISM LOCK IN PLACE (Fig. 6).
3. Dispose of the Pro-Lock™ CT Safety Infusion Set per institutional protocol.

CAUTIONS:
- Leakage may occur when disconnecting components.
- Place in sharps container.
- Change set according to CDC guidelines.
- Rx only.
- Select an appropriate needle length based on port reservoir depth and tissue thickness.
- Port used for power injection must be indicated for power injection. Power injection or high pressure in a non-power injectable port may cause leakage or damage.
- Inspect package and the product. Do not use if the package is damaged or open.
- STERILIZED BY ETHYLENE OXIDE. STERILE EO
- Single use product - Do not resterilize or re-use.
- After use, this product may be a potential biohazard. Handle and dispose in accordance with institutional protocol regarding local, state and federal laws and regulations.
- Dispose of needle set in a sharps container per institutional protocol.

TO POWER INJECT WITH SAFETY NEEDLE:

1. Verify the implanted port is a power injection rated port.
2. Access the port with the Pro-Lock™ CT Safety Infusion Set. Make certain that the needle tip is inserted fully within the port.
   Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.
3. Attach a syringe filled with sterile normal saline.
4. Instruct the patient to assume the position they will be in during the power injection procedure,before checking for patency. If possible, the patient should receive power injection with his or her arm vertically above the shoulder with the palm of the hand on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
5. Aspirate for adequate blood return and vigorously flush the port with at least 10 ml of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
6. Detach syringe.
7. Ensure contrast media is at proper viscosity prior to power injection. Refer to contrast agent manufacturer recommendations.
8. Attach the power injection device to the Pro-Lock™ CT Safety Infusion Set ensuring connection is secured. Check indicated flow rate of safety infusion set and confirm CT settings.

Gauge Size	20G
Device Color	Yellow
Maximum Flow Setting	5 ml/sec
Maximum Pressure Setting	325 psi

9. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
10. Inject contrast, taking care not to exceed the flow rate limits.
    Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
    Warning: Exceeding the maximum flow rate may result in Pro-Lock™ CT Safety Infusion Set failure, implanted port failure and/or catheter tip displacement.
11. Disconnect the power injection device.
12. Flush the Pro-Lock™ CT Safety Infusion Set with 10 ml of sterile normal saline.
13. Perform heparin lock procedure.
    Note: Some patients are hypersensitive to heparin or suffer heparin induced thrombocytopenia. These patients must not have their port primed with heparinized saline.
14. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of flush solution.
15. Stabilize port by placing two fingers on the base of the Pro-Lock™ CT Safety Infusion Set from side opposite of extension tubing (Fig. 5).

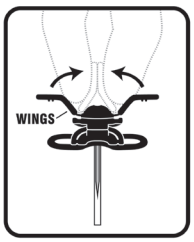

Figure 1

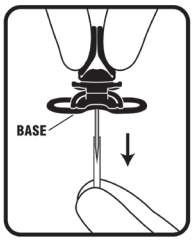

Figure 2

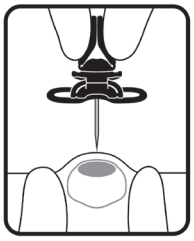
Figure 3

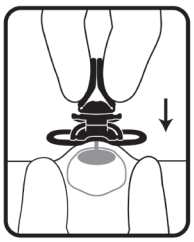
Figure 4

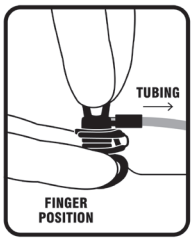

Figure 5

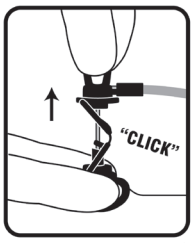

Figure 6

16. With available hand, firmly grasp wings between thumb and forefinger, while maintaining Pro-Lock base against patient, pull wings up vertically to remove the needle from the port. Fully retract the needle to ensure the needle point is positioned within the protective well. USER WILL HEAR AND FEEL LOCKING MECHANISM LOCK IN PLACE (Fig. 6).
17. Dispose of the Pro-Lock™ CT Safety Infusion Set per institutional protocol.
Warning: Do not exceed a 325 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the Pro-Lock™ Safety Infusion Set.

MRI SAFETY INFORMATION

The **Pro-Lock™ CT Safety Infusion Set** is MR Conditional
Non-clinical testing demonstrated that the Pro-Lock™ CT Safety Infusion Set is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

·Static magnetic field of 1.5 T or 3 T.
·Maximum spatial gradient magnetic field of 1,900 Gauss/cm (19 T-m).
·Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg in the Normal Operating Mode.

MRI-Related Heating
Under the scan conditions defined above, the Pro-Lock™ CT Safety Infusion Set is expected to produce a maximum temperture rise of 3°C after 15 minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the Pro-Lock™ CT Safety Infusion Set extends approximately 20-mm from this device when imaged using a gradient echo pulse sequence and a 3 T MRI system.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATEMENT, 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 without notice.

Medcomp® is a registered trademark of Medical Components, Inc.

Pro-Lock™ is a trademark of Medical Components, Inc.

SYMBOL TABLE

5.1.1 	Manufacturer *
5.2.3 	Sterilized Using Ethylene Oxide *
5.2.6 	Do Not Resterilize *
5.6.3 	Non-pyrogenic *
5.3.4 	Keep Dry *
5.3.2 	Keep Away from Sunlight *
5.2.8 	Do Not Use if Package is Damaged *
	MR Conditional - 3 Tesla ****
Rx Only	Prescription Use Only ***
5.1.5 LOT	Batch/Lot Number *
5.1.4 	Use-by Date *
5.1.6 REF	Catalogue Number *
5.4.2 	Do Not Re-use *

***This symbol is in accordance with ISO, 15223-1**
**** Not a recognized symbol.**
***** FDA guidance Use of Symbols in Labeling.**
******This Symbol is in accordance with ASTM F 2503-20**


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