

InVaMed Technologies, Inc.

9955 Titan Park Circle / Littleton, CO 80125

Phone 303-346-5300 Fax 303-346-9120

Instructions for Use

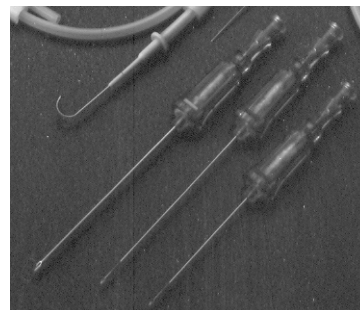
SP-Pro™ GWI

Sterile, non-pyrogenic, single patient use

Sharps Safety Guide-Wire Introducer (GWI) Needle:

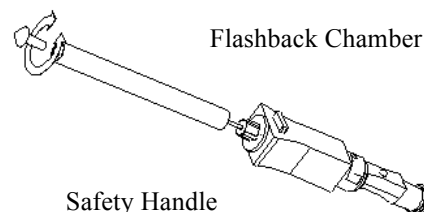
Do not use if package is damaged or open. Do not re-sterilize.

Use Sterile Technique - A suggested procedure:



Preparation for Use

1. Open package and place needle on sterile field.
2. Grip the clear safety handle and remove needle guard.
3. Follow standard hospital practice for veni-puncture and placement of guide-wire.

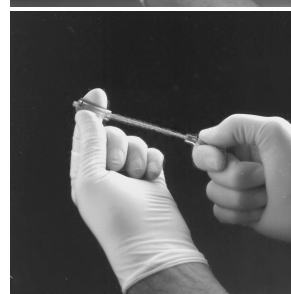
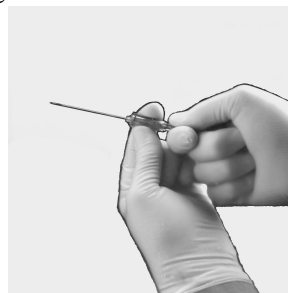


4. Remove SP-Pro™ needle from vessel and guide-wire. Keep hands behind needle at all times prior to deployment of safety feature.

Caution: Do not withdraw the guide-wire back into the cannula as this may result in separation of the guide-wire. The SP-Pro™ needle should be removed first from the guide-wire.

Deploying the Sharps Injury Prevention Feature

5. While holding the safety handle (luer toward user), rotate the needle flashback chamber counter-clockwise to unlock the safety handle from the flashback chamber and pull back.
6. Pull back on the flashback chamber until the needle tip disappears into the safety handle and locks securely into needle handle as indicated by an audible “click” and feel. Hearing loss and dexterity may hamper these signs of activation. Follow the next step carefully!
7. Deployment of Sharps Injury Prevention Feature is confirmed by gently pushing the needle flashback chamber forward while securely holding the safety handle to verify that the needle tip is securely locked inside the needle handle. If needle is not locked into handle repeat locking procedure. If for any reason safety mechanism does not deploy use extreme caution and proceed to step 8. Please report any occurrence of non-deployment to InVaMed.



Needle Disposal

8. The needle should be disposed of in accordance with policies and procedures for contaminated sharps disposal. Do not attempt to override or defeat the locking safety mechanism. Single Use Only.