H. Lee SafeSheath® ULTRALITE

STERILE EO

30°C 5°C

For U.S.-California Only.
Proposition 65, a State of California voter initiative, requires the following notice:
WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

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ANGIODYNAMICS®

Technical Manual

en-Instructions for Use

This device is intended for one time use only. Read instructions prior to use.

Indications
For the introduction of various types of pacing leads and catheters.

Warnings
This product is sensitive to light. Do not use if stored outside the protective outer carton. Store in a cool, dark, and dry place.

Precautions
- Do not alter this device in any way.
- Dilator tip must be inserted into the center of the sealing membrane. Do not force the dilator through the membrane if resistance is met.
- Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation.
- Indwelling introducer sheaths should be internally supported by a catheter, electrode, or dilator.
- Dilators, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.

Use Sterile Technique *A suggested procedure:*

1. Peel open package and place contents on sterile field.
2. Prep skin and drape in area of anticipated puncture as desired.
3. The angle of the needle should be adjusted depending on the Patient's build: shallow in a thin person, deeper in a heavyset person.
4. Insert needle into vessel. The needle position should be verified by blood return.
5. Aspirate the puncture needle using the syringe.
6. Remove the syringe and insert soft tip of guide wire through the introducer needle into the vessel. Advance the guide wire to the required depth. Leave an appropriate amount of guide wire exposed.

   At no time should the guide wire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding. Fluoroscopic verification of the guide wire's entrance into the vessel is suggested.
7. Hold guide wire in place and remove introducer needle. Do not withdraw the guide wire back into the cannula as this may result in separation of the guide wire. The cannula should be removed first.
8. Insert vessel dilator into sheath and rotate the dilator cap over valve housing to secure the dilator onto sheath assembly. **At no time should the dilator be advanced through the sealing membrane when resistence is met.**
9. Thread the dilator/sheath assembly over the guide wire.
10. Advance the dilator and sheath together with a twisting motion over the guide wire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guide wire will prevent inadvertently advancing the guide wire entirely into the patient.
11. Once assembly is fully introduced into the vascular system, separate the dilator cap from the sheath valve housing by rotating the dilator cap off the hub. *(see figure 1)*
12. Slowly retract the guide wire and dilator, leaving the sheath in position. The hemostasis valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
13. Introduce the catheter through the hemostasis valve/sheath and advance it into position.
14. First, withdraw the sheath from the vessel. Then remove the sheath by sharply snapping the tabs of the valve housing in a plane perpendicular to the long axis of the sheath to split the valve and peel the sheath apart. *(see figure 2)*

Figure 1

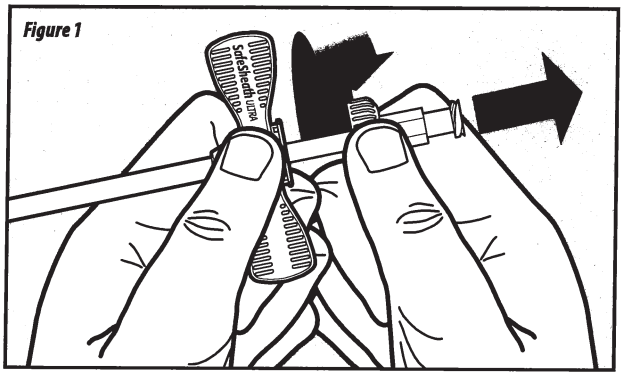
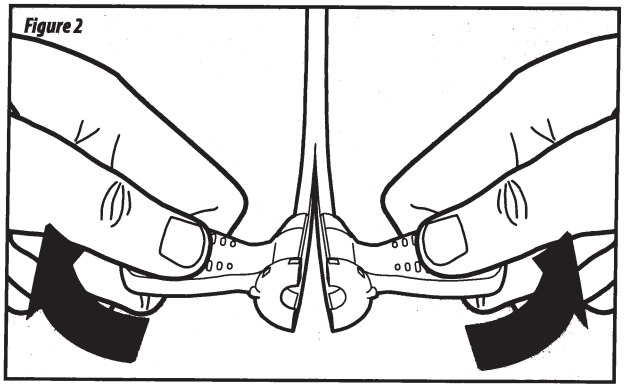


Figure 2



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