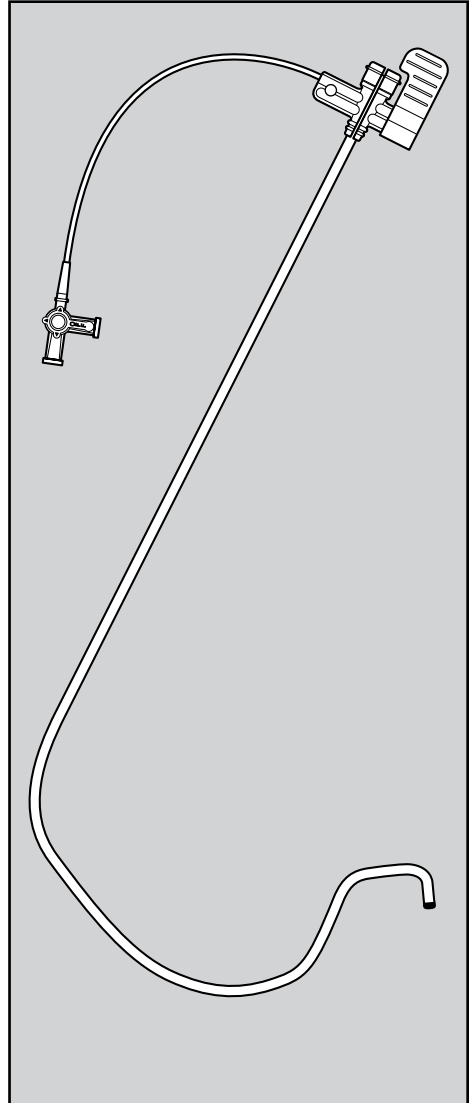


H. Lee
SafeSheath® **Worley LVI**
Lateral Vein Introducers

**Hemostatic Braided Sliceable
Lateral Vein Introducer System
with Infusion Side Port**



Manufactured by

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The H. Lee SafeSheath® CSG® splittable and SafeSheath® CSG® Braided sliceable hemostatic sheaths are protected by Patent Insurance through 2011.
USA Patents 5125904, 5,312,355, 5,409,463 and 6,966,896.
Canadian Patent 2,112,394.
European Patent EP0593685.
The Braided Sheath Cutter is covered by USA Patent 6,497,681.
Other patents pending.

SafeSheath and CSG are registered trademarks of Pressure Products, Inc.

Directions 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 or defibrillator leads and catheters.

Braided Lateral Vein introducers are designed for sub-selective coronary sinus venography and/or the placement of pacemaker leads in specific coronary sinus tributaries.

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.**
- Infusion through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular inserter tool (TVI) can cause air embolism and back bleeding.

Precautions

- Do not alter this device in any way.
- Federal law (U.S.A) restricts this device to sale by or on the order of a physician.
- 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 pacing lead, or dilator wire.
- Dilator wires, 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.
- When injecting or aspirating through the sheath, use the side port only.
- When using the transvalvular insertion tool (TVI), lead size may not exceed 6.2F.
- When using the TVI always keep the exposed proximal end covered to prevent air embolization and back bleeding.

Use Sterile Technique *A suggested procedure:*

1. After placement of either a Braided or Peel Away SafeSheath 9F CSG in the mid coronary sinus, occlusive balloon venography is performed preferably in both the RAO and LAO projections. An appropriate posterolateral coronary sinus tributary is then selected.
2. Depending upon the take-off angle of the venous tributary, an appropriate 7F SafeSheath Braided Telescopic Lateral Vein introducer is selected.

3. A guide wire is advanced to a position in the coronary sinus beyond the chosen lateral vein and the 7F Telescopic Braided introducer is advanced to the desired location.
4. Advance the 5 French catheter over the retained wire through the LVI.
5. Using fluoroscopy and small 'puffs' of contrast material manipulate the tip of the 5 French catheter into the target vein. Sub-selective venography may then be performed if desired.
6. Advance the LVI over the 5 French catheter into the target vessel.
7. Remove the 5 French catheter leaving the LVI in the target vessel.
8. If a stylet driven pacing lead is chosen, it is then advanced through the LVI Telescopic introducer and tested.
9. If an over the wire lead is used, the angioplasty wire is advanced through the LVI Telescopic introducer as far as it will go in the sub-selected vessel. The 'over the wire' lead is then advanced over the angioplasty wire to the desired pacing location.
10. In either case, when the lead position is correct fluoroscopically and electrically, the Lvi Telescopic introducer is withdrawn into the SafeSheath CSG while lead position is observed fluoroscopically.
11. Use either the Cutter (Model #CUT) or a Medtronic Slitter (Model #6228SLT) to remove the braided introducer from the lead. For the Cutter, see "Cutter Directions for Use" on the next page.

Note: The Cutter or Medtronic Slitter is to be used after pacing lead or catheter is in the desired location and the sheath introducer is ready to be removed. It is suggested the lead stylet or angioplasty wire be retained during sheath removal.

Note: The Telescopic introducer should always be removed prior to removal of the CSG sheath.

Cutter Directions for Use

To aid in removal of a braided sliceable introducer after it has been used to place a pacemaker lead or catheter.

All Cutter materials are bio-compatible, latex-free and PVC-free.

Precautions

Do not alter this device in any way.

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

As specified in the following chart, use an introducer sheath and pacing lead within the parameters listed in the chart below.

Largest Introducer Size	Largest Lead Size
4.0mm/12F	2.0mm/6F

Suggested Directions for Use

The Cutter is to be used after pacing lead or catheter is in the desired location and the sheath introducer is ready to be removed. It is suggested a lead stylet or stiffening wire be retained in the pacing lead during sheath removal.

■ If cutting a SafeSheath CSG Braided Series Sheath:

1. Open package and place contents on sterile field.
2. It is suggested that the braided sheath be withdrawn to the furthest extent possible prior to splitting the sheath valve and cutting the sheath.

NOTE: The lead tip and lie of the lead along the RA floor should be carefully observed fluoroscopically as the braided sheath is withdrawn and cut, to avoid inadvertent lead dislodgment.

3. Manually split the handles of the sheath valve. One half of the valve will remain attached to the braided sheath. Dispose of the other valve section. (see Figure 1)
4. Position the distal 'C' section of the Cutter under the sheath tubing, distal to the sheath hub. (see Figure 2)
5. Place the blade hook into the 'V' notch of the tubing at the proximal end of the sheath. (see Figure 3)
6. **Thread the pacing lead over the notch at the back end of the Cutter and compress the lead with your thumb**, while holding the Cutter in a 'pistol grip' fashion. (see Figure 4)
7. While holding the Cutter and the lead with one hand, slowly withdraw the braided sheath over the Cutter blade with the other hand. As the sheath is withdrawn it is cut away from the lead in the process. (see Figure 4)

■ If cutting a braided Lateral Vein Introducer (LVI) within a CSG sheath:

1. Open package and place contents on sterile field.
2. With a stabilizing stylet or stiffening wire in place, and while holding the lead in place, under fluoroscopic control, withdraw the LVI into the distal end of the SafeSheath CSG. (see Figure 5)

NOTE: The lead tip should be carefully observed fluoroscopically as the LVI sheath is withdrawn and cut, to avoid inadvertent lead dislodgment. The outer CSG sheath should be stabilized by an assistant grasping the CSG distal to the CSG hub as the LVI is withdrawn and cut to prevent inadvertent dislodgment of the CSG outer sheath from the mid CS.

3. Manually split the handles of the LVI sheath valve. One half of the valve will remain attached to the braided LVI. Dispose of the other valve section. (see Figure 6)
4. Position the distal 'C' section of the Cutter under the LVI sheath tubing distal to the sheath hub. (see Figure 7)
5. Place the blade hook into the 'V' notch of the LVI tubing at the proximal end of the LVI guide. (see Figure 3)
6. While maintaining the LVI Guide, pacing lead and CSG Sheath in position, hold the Cutter in 'pistol grip' fashion and cut the LVI by advancing the Cutter toward the CSG sheath until the distal 'C' portion of the Cutter engages the CSG hub. (see Figure 8)

NOTE: Make sure the pacing lead, LVI guide and CSG sheath are not advanced or withdrawn with the Cutter during this step of the procedure.

7. **After the Cutter has engaged the CSG hub, thread the pacing lead over the notch at the back end of the Cutter and compress the lead with your thumb.** (see Figure 9)
8. While holding the Cutter engaged with the CSG hub and lead with one hand, slowly withdraw the LVI sheath over the Cutter blade with the other hand. As the LVI is withdrawn it is cut away from the lead in the process. (see Figure 9)

NOTE: The outer CSG sheath should continue to be stabilized distal to the CSG hub as the LVI is withdrawn and cut to prevent inadvertent dislodgment of the CSG outer sheath from the mid CS.

9. After the LVI is cut and removed the CSG is removed as described above under the heading "If cutting a SafeSheath CSG Braided Series Sheath," or in the appropriate DFU.

Figures

