This guide contains recommendations as provided by Dr. Seth Worley, MD
1. Advance dilator and CSG over 0.035” wire until dilator tip reaches the SVC.

2. Holding dilator stationary, advance CSG sheath to the Tricuspid Valve or into the RV. Then remove the wire and dilator.
3 Connect injection system to Braided Core & flush with full strength contrast to remove any air.

4 Insert Braided Core to tip of CSG using black marking.
5 Holding Braided Core stationary, withdraw CSG until only 1cm remains between CSG and Braided Core hub: withdrawing in this manner maximizes safety.

6 Using left hand, cradle CSG between 3rd & 4th finger. Then grasp Braided Core with thumb and index fingers.
7 Placing right hand palm up, grasp rotating hemostatic valve of injection system with thumb and index finger.

8 Using index thumb and index finger of BOTH hands, apply counterclockwise torque on Braided Core ONLY (not the CSG):

- Using both hands to torque the catheter will prevent kinking of Braided Core near hub.

- If PVC’s occur, system is too far into RV. Maintain gentle torque and withdraw both CSG and Braided Core as a unit until PVC’s no longer occur.
9 While applying additional counterclockwise torque, slightly withdraw both Braided Core and CSG as a unit until Braided Core is at annulus. With the additional torque the Braided Core will drop toward the CS and will stop when it reaches the ostium.

10 Request small puff of contrast to confirm tip is in CS ostium and not in a side branch.

11 Hold counterclockwise torque while gently advancing Braided Core into proximal CS.

- If resistance is encountered with minimal effort, STOP and inject contrast to determine if the tip has engaged a side branch.
- A 0.035” wire can be added to redirect if needed.
12 Advance CSG and Braided Core as a unit into CS until Braided Core is at mid CS. Then advance CSG over Braided Core.

13 Holding CSG stationary, withdraw Braided Core.
en-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 certain other leads and catheters.

Contraindications
Use of the Coronary Sinus Guide / Lateral Vein Introducer (CSG/LVI) systems is contraindicated for the following:
- Patients with an existing or possible occlusion of the coronary vessels or unstable anatomy of the coronary veins
- Patients with active systemic infection

Possible Negative Side Effects / Adverse Events
Coronary Sinus Guide / Lateral Venous Introducer (CSG. LVI) systems should be used by physicians familiar with percutaneous catheter introduction. Complications which may be associated with the use of catheter introducer systems include, but are not limited to, the following:
- Air embolism
- Allergic reaction to contrast media
- Arterial wall damage
- Bleeding
- Cardiac arrhythmias
- Cardiac tamponade
- Chemodenervation
- Damage to the heart valves
- Hematoma at the puncture site
- Infection
- Local tissue response, fibrotic tissue formation
- Myocardial damage
- Myocardial infarction
- Plateau dislodgement
- Premature closure
- Stroke and death
- Thrombus formation/emboli
- Vascular occlusion
- Vascular spasm
- Venous or cardiac perforation

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.

- Inflation through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular insertion tool (TVI) can cause air embolism and back bleeding.
- Do not use this device in patients who cannot be appropriately anticoagulated. When tested in non-anticoagulated sheep, this device has shown thrombus formation, however, heparinized studies alleviated the concern.

Precautions
- Do not alter this device in any way.
- Single Use Devices: This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-stereilization, or reuse.
- 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, pacing lead, 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.
- 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. Peel open package and place contents on sterile field.
2. Prep skin and drape in area of anticipated venipuncture as desired.
3. Distein the subclavian vein. The subclavian vein is difficult to locate unless it is distended by raising the patient's legs to a 45 degree angle or by using the Trendelenburg position. The vein will be much easier to locate if the patient is well hydrated.
4. Insert needle into vessel. The needle position should be verified by observing venous blood return.
5. The angle of the needle should be adjusted depending on the patient's build: shallower in a thin person, deeper in a heavy-set person. Use an 18g needle, 2cm (2-3/4 in.) long.
6. Aspirate the puncture needle using the 12cc syringe. Remove the syringe and insert soft tip of guide wire through the introducer needle into the vessel. Advance guide wire guide to 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 superior vena cava and right atrium 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 the straight vessel dilator into the sheath until the dilator cap folds up over the valve housing and secures the dilator on the sheath assembly.
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 is admissible. Attaching a clamp or hemostat to the proximal end of the guide wire will prevent a twisting motion inadvertently advancing the guide wire entirely into the patient.
11. Once assembly is fully introduced into the venous system, separate the dilator cap from the sheath valve housing by rocking the dilator cap off the hub. (see Figure 1)
12. Slowly retract the dilator, leaving the sheath and wire in position. The hemostasis valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
13. Remove the curved braided core from the package and thread the exposed proximal portion of the retained guide wire into the distal end of the braided core.
14. Feed the guide wire through the curved braided core or braided sheath until the proximal end of the guide wire can be secured with either a clamp or hemostat before advancing the curved dilator into the interventional sheath.
15. Do not advance the braided core into the sheath until the guide wire has been completely passed through the core and the wire is secured with a hemostat or clamp in order to prevent inadvertently advancing the guide wire entirely into the patient.
16. Advance the braided core into the sheath and observe fluoroscopically as the wire and distal end of the core extend past the distal end of the sheath and are positioned in the right atrium.
17. Make the distal end of the guide wire or sheath into the desired location (coronary sinus etc.) by combining a twisting motion of the guide wire or sheath with the inadvertent aspiration of air through the sheath.
18. Manipulate the distal end of the guide wire or sheath into the desired location (coronary sinus etc.) by combining a twisting motion of the guide wire or sheath with the gentle probing of the guide wire or sheath itself. Fluoroscopy in the left anterior oblique (LAO) position is helpful. Advance the CSG sheath into the mid coronary sinus and establish its position by injecting contract material through the side port.
19. Once the guide wire is in the desired location advance the sheath over the wire until the tip rests in the desired location. It is advisable to leave a short segment of wire extending past the distal end of the tip to minimize any potential blunt trauma to the surrounding tissues.
20. Holding the wire and braided core securely in place advance the sheath over the core until the sheath rests in the desired location. While advancing the sheath into position observe the sheath fluoroscopically to minimize any unwanted movement or dislodgement of the tip or wire.
21. Once the sheath is in the desired location slowly retract the braided core and wire and remove them from the retained sheath. Injecting contrast material through the side port is useful in establishing that the sheath is correctly positioned.
22. Aspirate all air from the sheath valve assembly by using a syringe connected to the side port. Flush the introducer through the flush port. If the introducer is to remain in place during lead positioning and testing, flushing the introducer via the side port periodically with heparinized saline is advised.
23. A 7F. transvalvular insertion tool (TVI) is provided with the CSG kit. It is to be used by the physician's discretion to open the valve for ease of lead placement. Load these greater than a 6.2F, may not be used with the TVI.
24. Caution! When the TVI is inserted into the CSG valve housing all hemostasis is lost and the risk of air embolization and back bleeding exists. Always keep the proximal exposed end of the TVI covered with your thumb while the TVI is in use.
25. To use the TVI, insert the distal end of the TVI into the valve housing by gently pushing the TVI into the sheath.
26. Hold your thumb over the proximal exposed opening of the TVI to prevent air embolization or back bleeding.
27. Advance the pacemaker lead through the TVI and into the sheath.
28. As soon as the pacar lead is resting inside the sheath pull the TVI back out of the sheath valve housing.
29. The TVI may then either be peeled away or it may be temporarily left resting on the shaft of the pacemaker lead.
30. Once the TVI has been withdrawn from the sheath, aspirate the sheath, through the sideport, until any air which may have entered the sheath during the procedure is removed and again flush with heparinized saline.
31. Advance the pacemaker lead into the desired location of the heart.
32. When lead position is correct fluoroscopically and electrically, flush sheath with 5 cc of saline immediately before peeling or skinning the sheath away in order to minimize back-bleeding. If multiple leads are to be positioned, the sheath and lead may correctly positioned.
33. When the sheath is to be removed, withdraw sheath and valve over the lead or catheter and from the vessel, while keeping the lead in place.
34. Sharply snap the tabs of the valve housing down in a plane perpendicular to the long axis of the sheath to split the valve housing. (see Figure 2)
35. Separate the handles of the sheath and peel sheath tubing apart longitudinally while withdrawing from vessel. Caution should be used not to withdraw catheter during removal.
36. A retained guide wire technique may be used for dual lead implantation. The valve will remain hemostatic with both the lead and guide wire inserted through it; however, extreme caution must be used when manipulating the lead in order to prevent accidental advancement of the guide wire into the patient. Again, a hemostat attached to the guide wire proximal end is advised.
37. If a cephalic vein cut-down approach is used, the procedure is identical once the guide wire is placed in the vein through a venotomy and advanced fluoroscopically to the level of the right atrium.