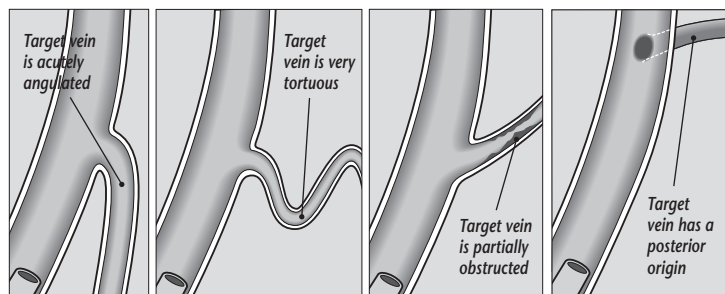


# Using the Pressure Products SafeSheath® Worley Telescopic Lateral Vein Introducers to Optimize LV Lead Placement



**Figure 1** Coronary venous anatomy that can make LV lead placement difficult even with over the wire leads.

The most efficient way to deliver a pacing lead to a lateral wall target vein is to place the tip of a guide or sheath in the target vein. With the guide in the target vein, the lead has no choice but to go directly into the vein when the lead is advanced. To accomplish this end, a telescoping system must be used. The Pressure Products SafeSheath Worley Telescopic LV introducer system is composed of two parts:

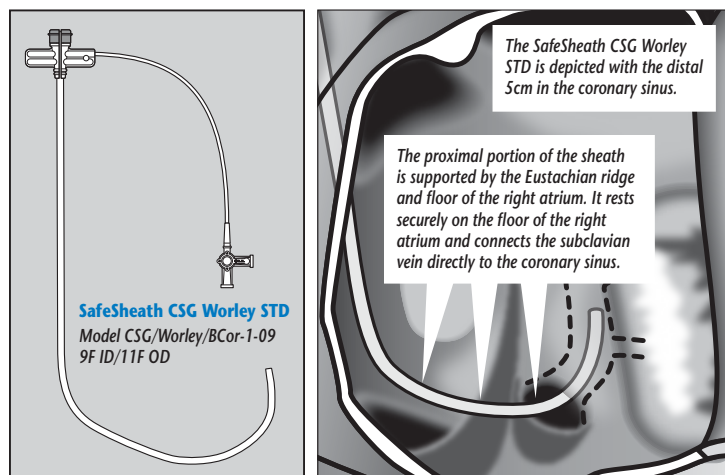
**The Staging Platform** (Pressure Products SafeSheath CSG Worley with radio opaque soft tipped braided core), a sheath that rests securely on the floor of the right atrium and connects the subclavian vein directly to the coronary sinus. Details of the Staging Platform are contained in the document "How to Use the Pressure Products SafeSheath CSG Worley with Radio Opaque Tipped Braided Core," available from Pressure Products, Inc., at [www.pressure-products.com](http://www.pressure-products.com).

**The Telescopic Guide** (Pressure Products SafeSheath Worley Telescopic Braided Lateral Vein Introducer), a catheter that fits through the platform sheath and into the target vein. The guiding catheter must be large enough to accept the pacing lead. The shape of the telescopic guiding catheter is determined by the requirements of the coronary venous anatomy.

The components and use of the Pressure Products Worley Telescoping System is outlined below.

## The Staging Platform for Pressure Products SafeSheath Worley Telescopic LV introducer system

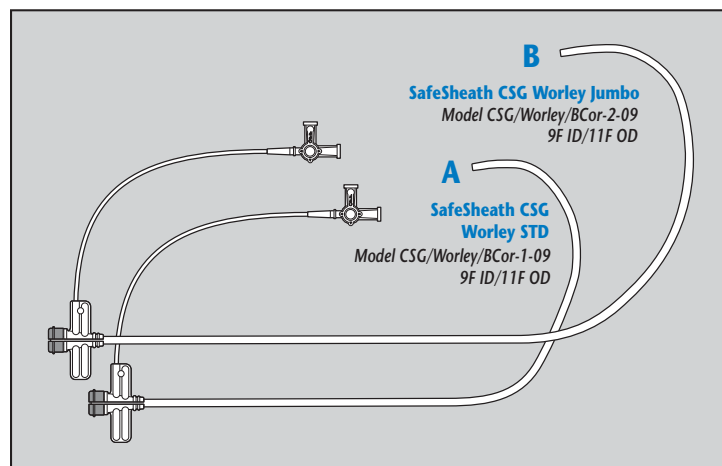
### The Platform for 85-90% of Patients with CHF



**Figure 2** The 9F SafeSheath CSG Worley STD is the platform for telescoping delivery system in most patients with CHF.

The SafeSheath CSG Worley STD is a long standard 9F sheath (11F OD/9F ID) shaped to rest in the coronary sinus without kinking.

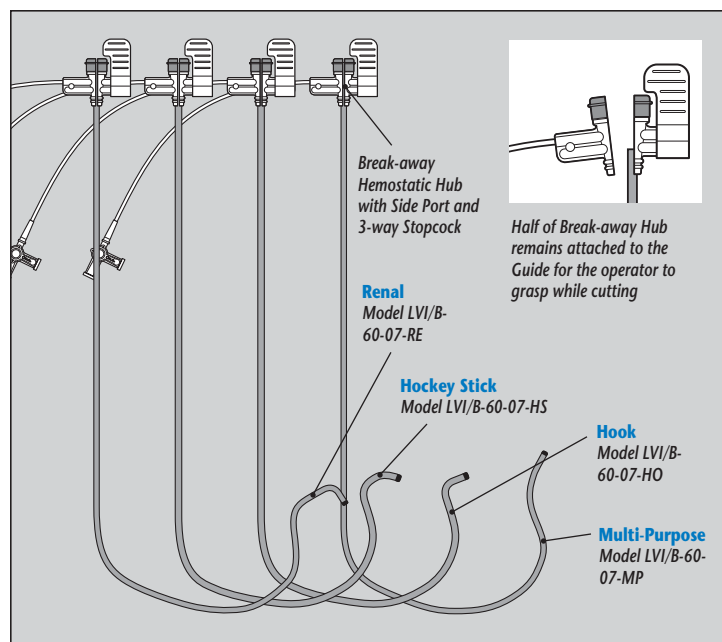
### The Platform for 10-15% of Patients with CHF



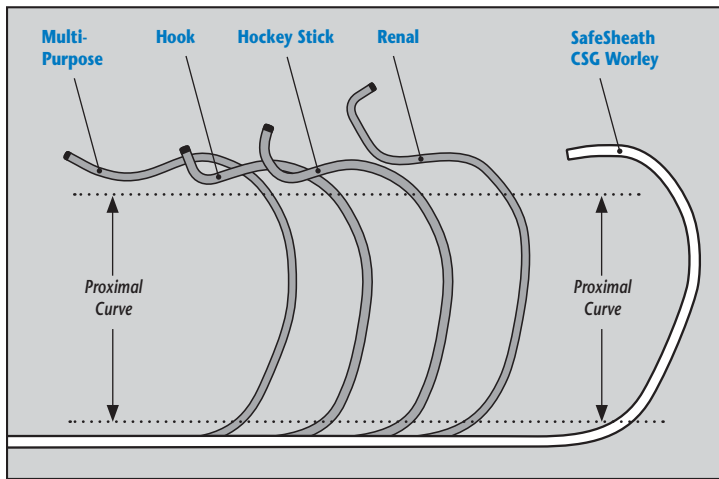
**Figure 3** The SafeSheath CSG Worley Jumbo in comparison to the CSG Worley STD. The jumbo is the required platform for a telescoping delivery system in 10-15% of patients.

The SafeSheath CSG Worley is available in two sizes, Standard (A) and Jumbo (B). The standard size is appropriate for 85-90% of patients with class 3-4 CHF. The Jumbo size is appropriate for large patients with massively dilated right heart structures, particularly those with permanent atrial fibrillation.

## The Guiding Catheters for Pressure Products SafeSheath Worley Telescopic LV introducer system

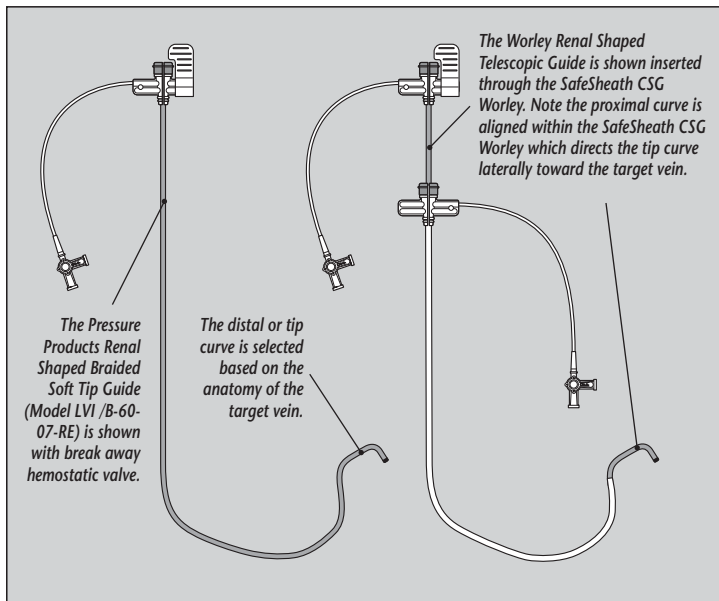


**Figure 4** The family of curves of the Pressure Products SafeSheath Worley Telescopic LV introducer system.

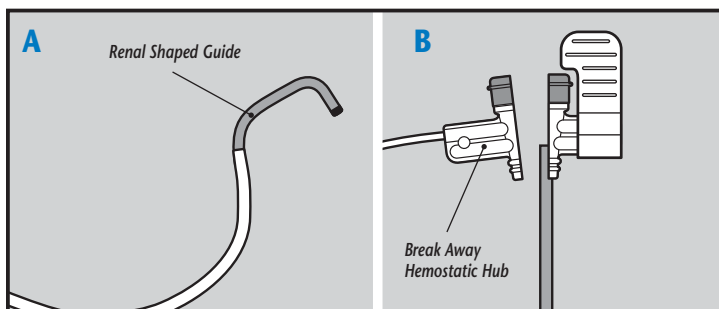


**Figure 5** The 9F (9F OD/7F ID) Braided Soft Tip Guiding Catheters designed to be inserted through the 9F (9F ID/11F OD) SafeSheath CSG Worley Platform.

The proximal curve on all three shapes is the same and is designed to align within the SafeSheath CSG Worley platform. The distal or tip curve is aligned 180 degrees from the proximal curve to direct the tip laterally toward the target vein. The tips of the guides are designed for direct cannulation and delivery of the pacing lead to a variety of target veins with difficult anatomy. Each shape is designed for a specific anatomy lateral wall target vein anatomy



**Figure 6** Insertion of the Renal Shape 9F (9F OD/7F ID) Braided Soft Tip Guiding Catheter Into the 9F (9F ID/11F OD) SafeSheath CSG Worley STD.

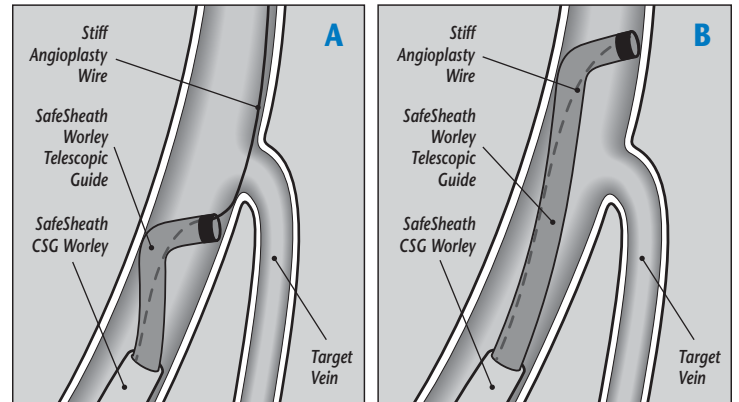


**Figure 7** Details of the 9F (9F OD/7F ID) Braided Soft Tip Guiding Catheter for Cannulation of the Target Vein and Direct Delivery of Pacing Lead to the Target Vein.

Panel A is a close up of the Renal Shape guide that demonstrates the soft non traumatic tip of the guide.

Panel B shows a close up of the hemostatic valve of the braided guide. Once the lead is in place in the target vein through the guide, the hub is cracked. Half of the hub remains attached to the guide and serves as a handle to cut the guide away. The other half of the hub with the tubing and stopcock detaches.

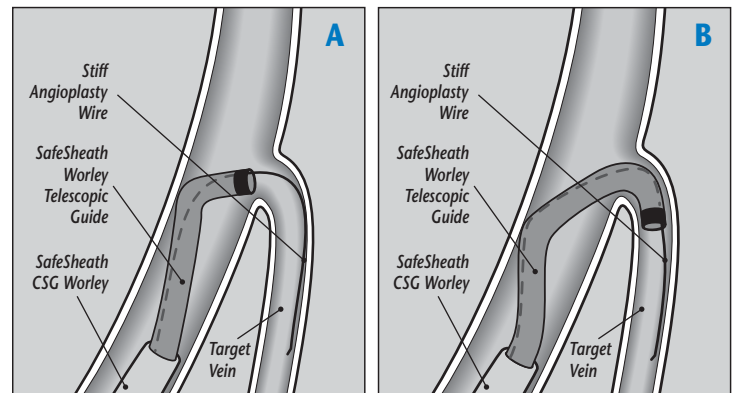
## Inserting the Pressure Products **SafeSheath Worley Telescopic Lateral Vein Introducer**



**Figure 8** The Tip of the SafeSheath Worley Telescopic Lateral Vein Introducer is advanced over the stiff angioplasty wire beyond the target vein. The wire is withdrawn into the Telescopic Guide and the Guide is then withdrawn toward the CS.

In Panel A the stiff angioplasty wire is advanced into the distal CS. The Telescopic Guide is advanced out the SafeSheath CSG Worley over the wire into the CS.

In Panel B the Telescopic Guide is advanced over the wire beyond the target vein. Once the tip of the guide is beyond the target vein, the wire is withdrawn into the sheath.



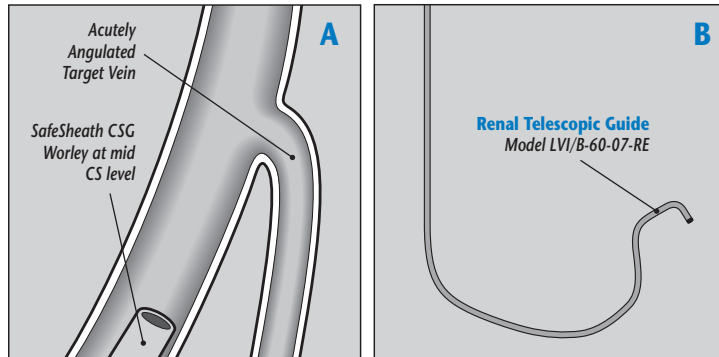
**Figure 9** The position of the tip of the Telescopic Guide is confirmed with a puff of contrast. From there the angioplasty wire is advanced into the target vein. The telescopic Guide is then advanced over the wire into the target vein.

In Panel A the Telescopic Guide is gently withdrawn with the wire inside until a puff of contrast confirms the tip approximates the target vein. The wire is then advanced from the guide into the target vein.

In Panel B the Telescopic Guide is then advanced over the stiff angioplasty wire into the target vein.

## Choosing the Best Lateral Vein Introducer Shape for Specific Coronary Venous Anatomy

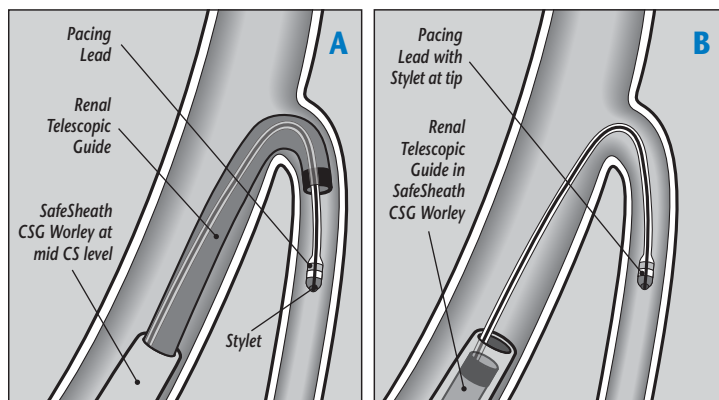
### Renal Shape for Acutely Angulated Target Veins



**Figure 10** The Renal Shape Braided Guide for Acutely Angulated Target Veins.

Panel A depicts an acutely angulated target vein with the sheath at mid CS level. It will be difficult to direct a pacing lead into the target vein from the position of the sheath.

In Panel B the Renal Shape Braided Guide designed for this type of anatomy is shown.

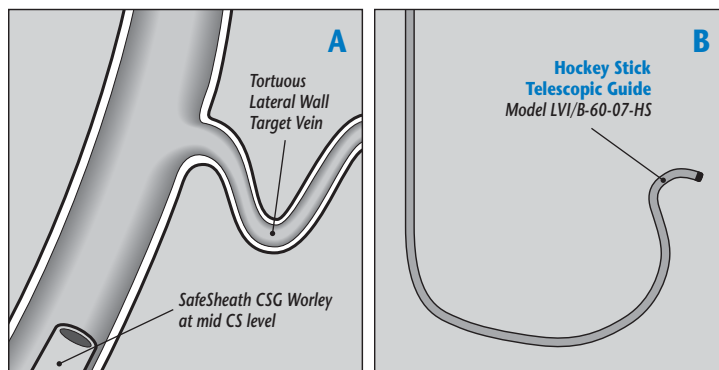


**Figure 11** The Renal Shape Braided Telescopic Guide advanced into sheath Acutely Angulated Target Veins.

Panel A shows the Renal Shape Braided Telescopic Guide advanced through the sheath. The tip of the guide rests in the mouth of the target vein. The pacing lead is inserted directly into the vein through the guide and over the stylet.

In Panel B the Telescopic Guide is withdrawn into the sheath. As long as the stylet does not move the lead remains in position.

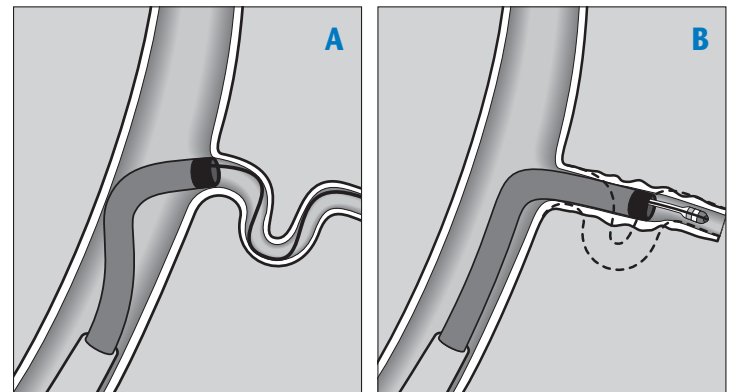
### Hockey Stick Shape for Tortuous Lateral Vein Anatomy



**Figure 12** The Hockey Stick Shape Telescopic Guide for tortuous lateral wall target vein anatomy.

In Panel A the tortuous lateral wall target vein is depicted with the sheath at mid CS level. It will be difficult to advance the lead into the target vein and through the tortuous segment without buckling the lead or displacing the sheath out of the coronary sinus as attempts are made to advance the lead from the mid CS level.

In Panel B the Hockey Stick Telescopic Guide is shown. When the guide is inserted into the sheath the tip of the guide will extend laterally and advance through the tortuous segment. The guide then provides support and a smooth low friction conduit for the lead from the sheath to beyond the tortuous vein segment.

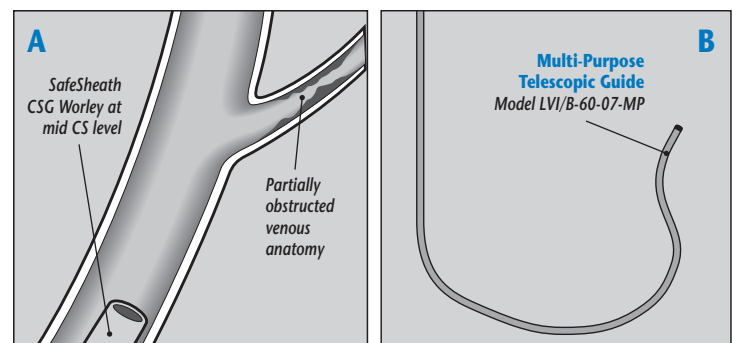


**Figure 13** Illustration of the use of the Hockey Stick Telescopic Guide to provide a smooth low friction conduit for the Pacing Lead.

In Panel A, the tip of the Hockey Stick Telescopic Guide is at the mouth of the target vein. The direction of the guide is used to advance and support a wire through the tortuous vein segment.

In Panel B, the guide is advanced over the wire through the tortuous vein segment until the tip of the guide is beyond the tortuous segment. The pacing lead now has a smooth, low-friction environment to traverse between the skin and the tip of the sheath.

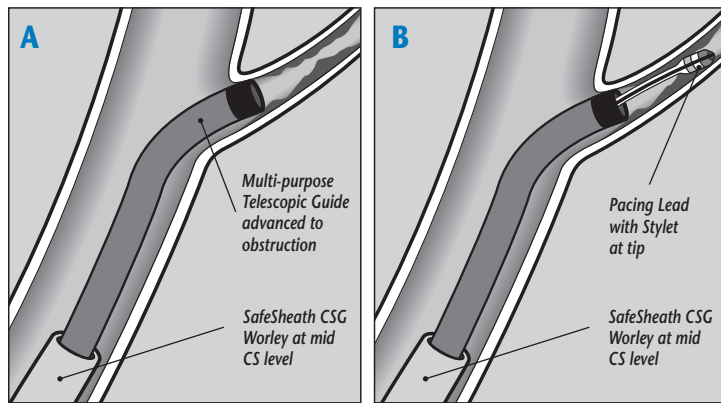
### Multi-purpose Shape for Partially Obstructed Venous Anatomy



**Figure 14** Multi-purpose Telescopic Guide to provide support for partially obstructed venous anatomy.

In Panel, A the sheath is shown resting in the mid coronary sinus. The angle of the lateral wall target vein is not acute, however, there is an obstruction in the vein that will inhibit lead placement. The lead may buckle between the sheath and the obstruction.

In Panel B, the Multi-purpose Telescopic Guide is shown. When this guide is inserted into the sheath, the tip of the guide will rest in the mouth of the target vein. Because the pacing lead is supported by both the sheath and the guide up to the point of obstruction, it will be less likely to buckle. The multipurpose shape can also be used to selectively cannulate lateral wall target veins with origins near the OS of the coronary sinus.

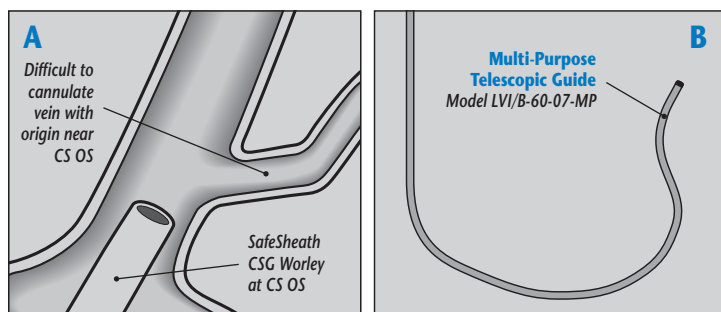


**Figure 15** Multi-purpose Telescopic Guide is used to advance lead beyond the obstruction.

In Panel A, the Multi-purpose Telescopic Guide is advanced to the obstruction providing additional support. With the guide in the target vein, the stylet may be used in pacing lead to advance beyond obstruction.

In Panel B, the pacing lead is supported by both the sheath and the guide past the point of obstruction.

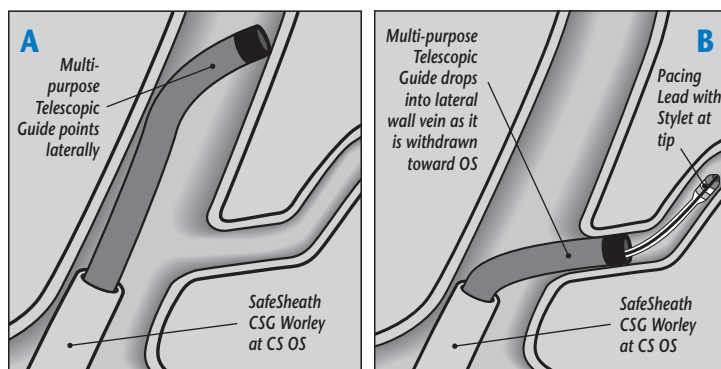
### Multi-purpose Shape for Difficult to Cannulate Vein with Origin Near Coronary Sinus OS



**Figure 16** Multi-purpose Telescopic Guide is used to access difficult to cannulate vein with origin near coronary sinus OS.

In Panel A, the sheath is shown resting near the OS of the coronary sinus. The difficult to cannulate target vein with its origin near the OS of the coronary sinus is shown. It can be difficult to advance a lead from the sheath without loss of CS access.

In Panel B, the Multi-purpose Telescopic Guide is shown pointing laterally.

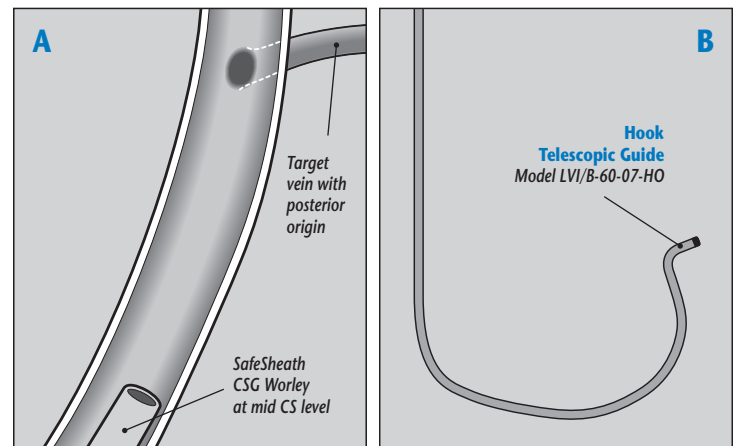


**Figure 17** Multi-purpose Telescopic Guide shown accessing lateral wall vein near CS OS.

In Panel A, with the sheath near the OS of the coronary sinus, the Multi-purpose Telescopic Guide is advanced into the CS over a wire, beyond the take off of the lateral wall vein.

In Panel B, the Multi-purpose Telescopic Guide is withdrawn inside the sheath with small puffs of contrast. Because the tip is directed laterally by the proximal curve, the tip will easily locate and cannulate the vein without loss of CS access.

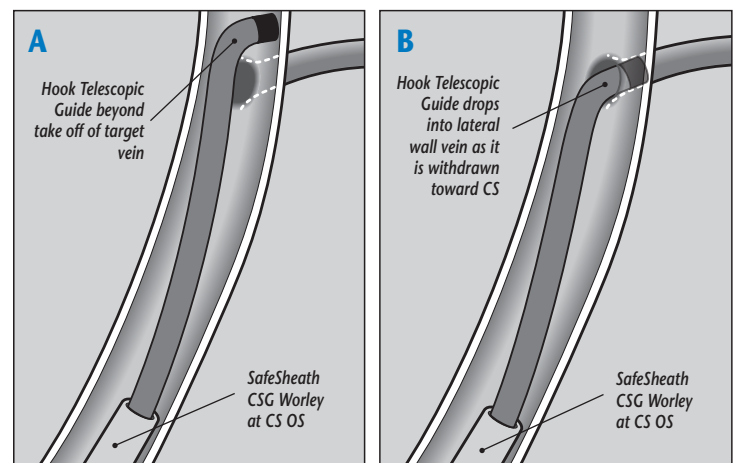
### Hook Shape to Cannulate Lateral Wall Target Veins with Difficult to Locate Ostia



**Figure 18** The Hook Telescopic Guide can be used to selectively cannulate lateral wall target veins with difficult to locate ostia, such as a vein with a posterior take off.

In Panel A, the sheath is shown resting at the mid coronary sinus. A target vein with a posterior origin is shown. It can be difficult to cannulate this vein with a PTCA wire or pacing lead from the sheath in the mid coronary sinus.

In Panel B, the Hook Telescopic Guide is shown .



**Figure 19** Hook Telescopic Guide shown locating and cannulating lateral wall vein with posterior take off.

In Panel A, the Hook Telescopic Guide has been advanced over a wire beyond the take off of the target vein.

In Panel B, the Hook Telescopic Guide is withdrawn with counterclockwise torque and small puffs of contrast to locate and selectively cannulate the target vein.

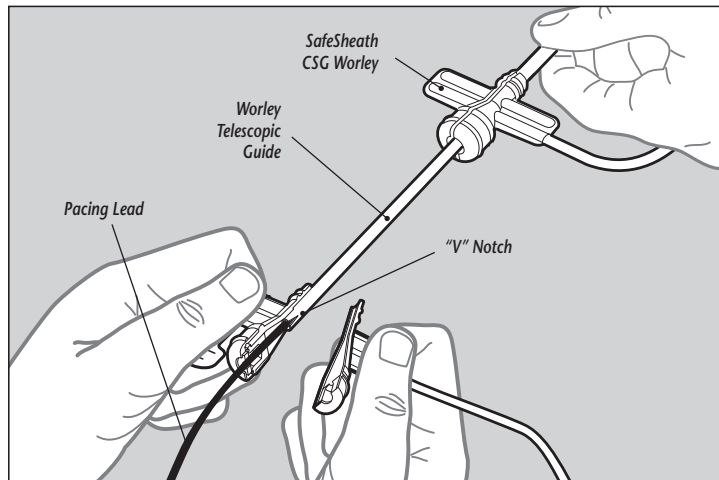
**This and other instruction manuals, product specifications, and ordering information is available on the Pressure Products, Inc. website at [www.pressure-products.com](http://www.pressure-products.com).**



## Removing the Telescopic LVI Guide

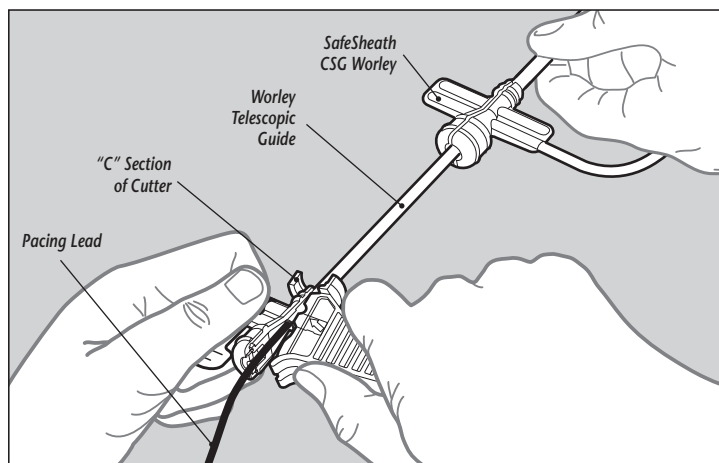
Once a stabilization styllet is at the tip of the LV pacing lead, the Telescopic Guide can be removed. Before removing the LVI, be certain the SafeSheath CSG Worley is at mid CS level. The tip of the CSG sheath must be at mid CS level to straighten and support the Telescopic Guide, stabilizing the lead as the LVI is removed. If the CSG is not securely in the CS, removal of the Telescopic Guide may displace the lead as it falls out of the CS unsupported.

Once it is clear that the tip of the CSG is in the CS, an assistant grasps the CSG sheath distal to the CSG hub in order to maintain stability as the Telescopic Guide is cut away. The hemostatic hub of the LVI is cracked and a Cutter is used to remove the Telescopic Guide (see Figure 20). As the LVI is cut away, the sheath maintains CS access and helps support the lead.



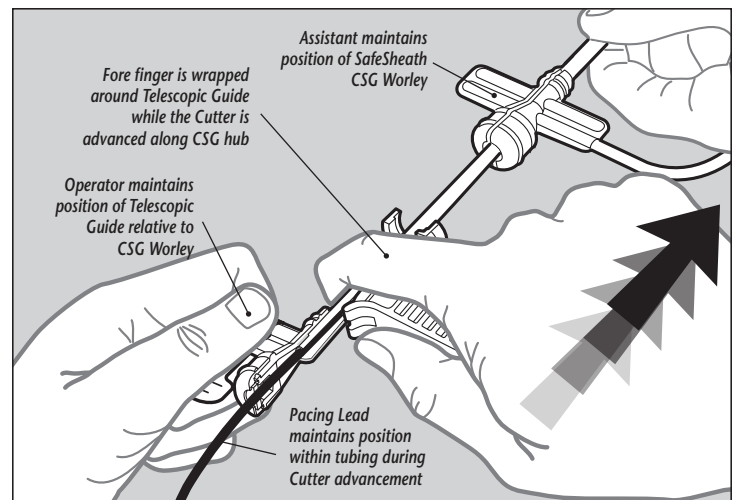
**Figure 20** Cutting the Worley Braided Telescopic Guide. The assistant holds the SafeSheath CSG Worley in position at mid CS level. The operator breaks the hemostatic valve. Half of the hub remains attached to the Telescopic Guide as a handle for cutting, enabling removal of the LVI without the need to slice through the hub.

Position the distal "C" section of the Cutter under the Telescopic Guide distal to the LVI hub as shown in Figure 21. Insert the Cutter blade hook into the "V" notch (see Figure 20) of the tubing at the proximal end of the Telescopic Guide as shown below.



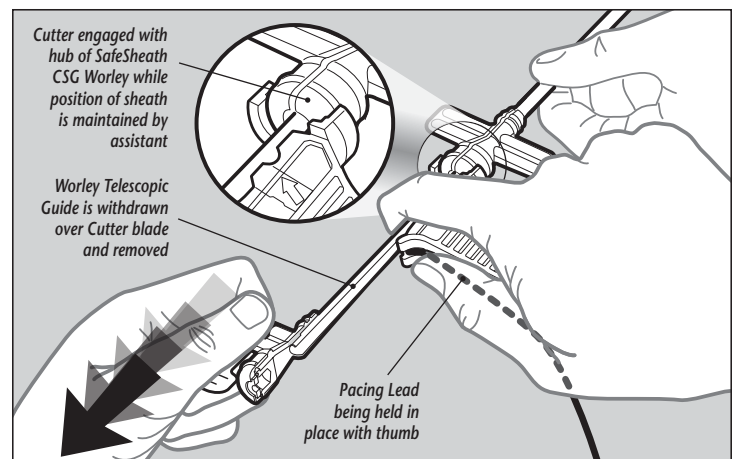
**Figure 21** Preparing to cut the Worley Braided Telescopic Guide

While holding the pacing lead, Telescopic Guide and CSG Worley in position, cut the LVI by advancing the Cutter toward the SafeSheath CSG (see Figure 22) until the distal 'C' portion of the Cutter engages the CSG hub. Wrapping the fore finger over the guide helps to prevent the Cutter blade from disengaging during cutting. Make sure the pacing lead, Telescopic Guide and CSG Worley are not advanced or withdrawn with the Cutter during this part of the procedure.



**Figure 22** The Worley Braided Telescopic Guide is cut by advancing the Cutter along the LVI tubing toward the CSG hub while making sure to maintain position of CSG Worley, Telescopic Guide and Pacing Lead

After the Cutter has engaged the CSG hub, thread the lead over the notch at the back of the Cutter. Compress the lead between your thumb and the Cutter while continuing to keep your fore finger wrapped around the Telescopic Guide as shown in Figure 23. While keeping the lead and Cutter engaged with the CSG hub with one hand, slowly withdraw the Telescopic Guide over the Cutter blade with the other hand. As the Telescopic Guide is withdrawn it is cut away from the lead in the process. Make sure the assistant continues to hold the SafeSheath CSG Worley distal to the hub, maintaining its position in the mid CS during cutting and removal of the LVI Guide. The peel-away SafeSheath CSG Worley continues to provide CS access and stability for the pacing lead during the LVI Guide cutting procedure.



**Figure 23** Removing the Worley Braided Telescopic Guide

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