

Using the Pressure Products SafeSheath CSG Worley with Radio Opaque Soft-Tipped Braided Core

The components of the SafeSheath CSG Worley with Braided Core include the guide wire, the straight dilator, the 40 cm 11F OD/9F ID SafeSheath CSG Worley peel away sheath with hemostatic valve and the 50 cm 9F OD/7F ID Braided Core with radio opaque soft tip. The 50 cm Braided Core replaces the 40 cm curved plastic dilator of the previous model.

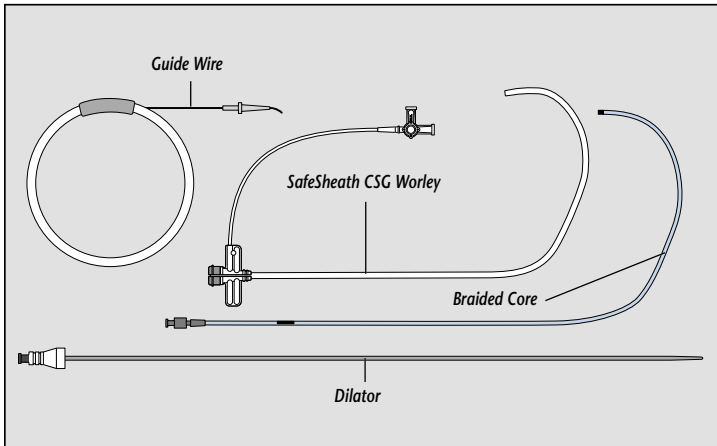


Figure 1 New SafeSheath CSG Worley with Braided Core. The component pieces are labeled in the figure. The braided core replaces the curved dilator used in the previous model.

Before describing how the SafeSheath CSG Worley with Braided Core is used to cannulate the CS it is important to understand the advantages of the braided core over the curved plastic dilator and how it is used with the SafeSheath CSG Worley. The braided core replaces the curved dilator of the previous model of the SafeSheath CSG Worley. The curved dilator did not have a radio opaque soft tip like the tip of the braided core. In addition, the curved plastic dilator did not provide one to one torque control. Thus the tip of the sheath did not respond well to counterclockwise torque delivered to the hub. Further, the curved plastic dilator was only 40 cm and could not be advanced out the tip of the sheath if needed. The braided core is shown in more detail in Figure 2.

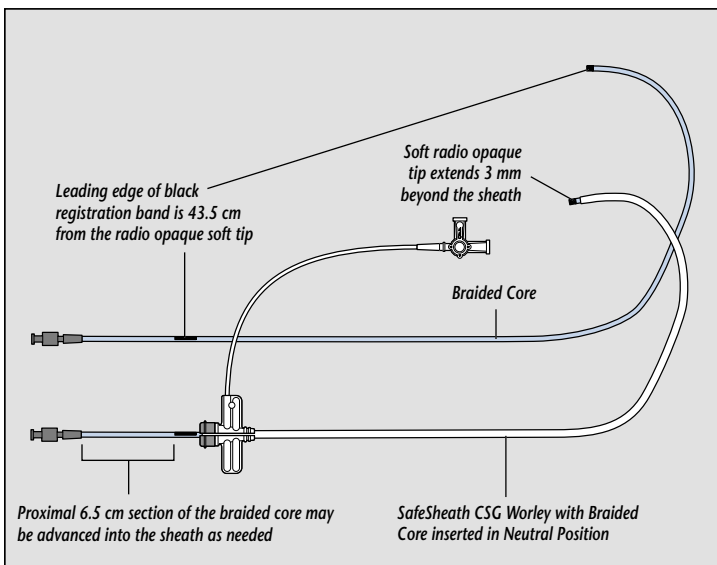


Figure 2 The 50 cm Braided Core alone and inserted into the 40 cm SafeSheath CSG Worley with hemostatic valve

There is a black registration band 43.5 cm from the soft radio opaque tip. When the braided core is inserted into SafeSheath CSG Worley with the leading edge of the black registration band at the hemostatic valve, the tip extends 3 mm beyond the sheath. An additional 6.5 cm of braided core remains proximal to the hemostatic hub. When the braided core is in the sheath, as shown in Figure 2, it is in the "neutral position."

The effect of advancing the braided core into the SafeSheath CSG Worley beyond the black band is demonstrated in Figure 3. A continuum of shapes can be created as the proximal core is advanced into the sheath. In addition, the trajectory of the tip can be varied depending on whether the core and sheath are advanced as a unit or the sheath held in place and the core advanced. The ability to vary the trajectory of the tip may facilitate cannulation in some cases.

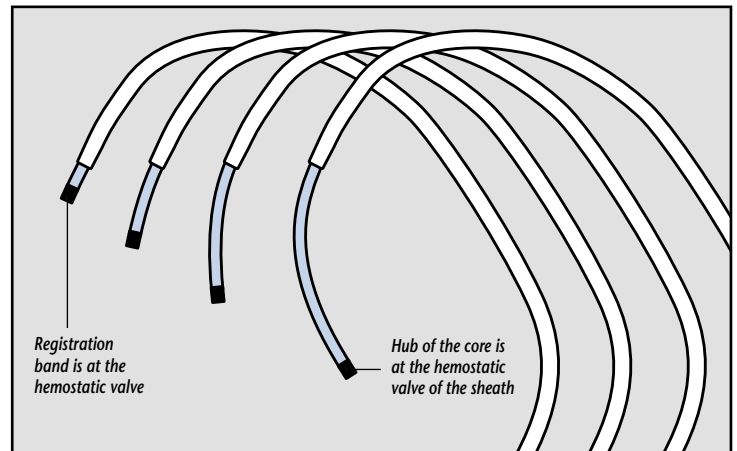


Figure 3 Variable shapes created by advancing the proximal 6.5 cm of the Braided Core into the SafeSheath CSG Worley

This and other instruction manuals, product specifications, and ordering information is available on the Pressure Products, Inc. website at www.pressure-products.com.

Recommended Procedure for Cannulating the CS Using the SafeSheath CSG Worley with Radio Opaque Soft-Tipped Braided Core

Step 1 Obtain venous access and advance the guide wire included in the package until the tip is located at the mid RA level.

Step 2 Insert the long straight dilator into the flushed SSCSG-W until the hub locks over the hemostatic valve.

Step 3 Advance the dilator and sheath as a unit over the guide wire until the tip of the dilator reaches the SVC/RA junction (Figure 4A).

Step 4 Hold the dilator and wire in place at the SVC/RA junction and advance the sheath over the dilator and wire into the RA with the sheath tip pointed toward the RV (Figure 4B). Remove the wire and dilator then flush the sheath.

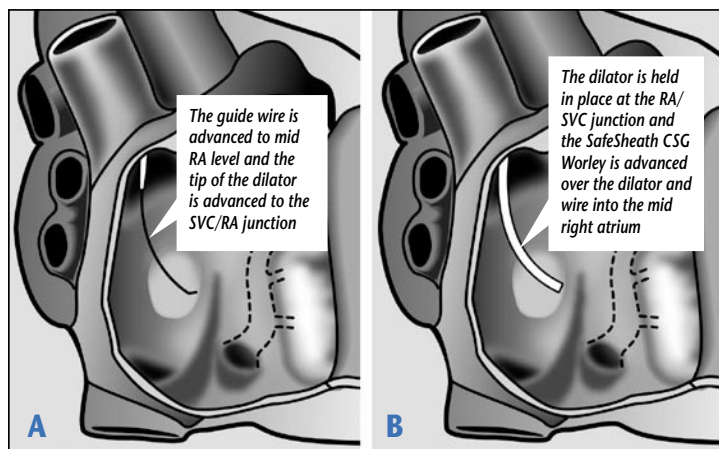


Figure 4 Initial placement of the SafeSheath CSG Worley into the heart.

Step 5 Connect a hemostatic Y adapter to the hub of the braided core with an injection system attached (Figure 5). Remember, the braided core does not have a hemostatic valve. Connect the open side of the Y adapter to a contrast injection system. Close the hemostatic valve and flush the core flushed with either saline or contrast. The contrast/flush system shown in Figure 5 is assembled from materials readily available in the lab. It is composed of the hemostatic Y adapter, extension tubing 18 to 24 inches in length, a 3 way stop cock, a 30 ml reservoir syringe and a 12 ml control syringe.

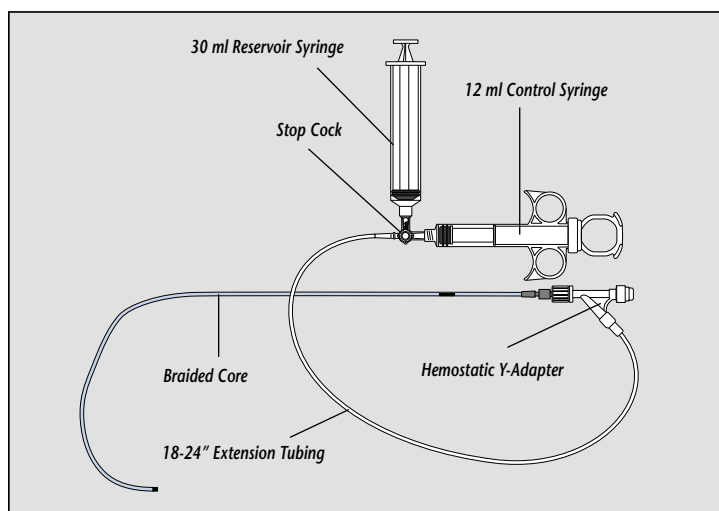


Figure 5 The braided core shown attached to a Y adapter with a hemostatic valve.

Step 6 Insert the braided core into the SafeSheath CSG Worley until the leading edge of the black registration band is even with the hemostatic valve (Figure 6A). The SafeSheath CSG Worley with radio opaque soft tipped Braided Core extending 3mm beyond the sheath will be resting in the RA (Figure 6B). The braided core can be used to change the shape at the tip of the sheath and facilitate CS cannulation (Figure 3).

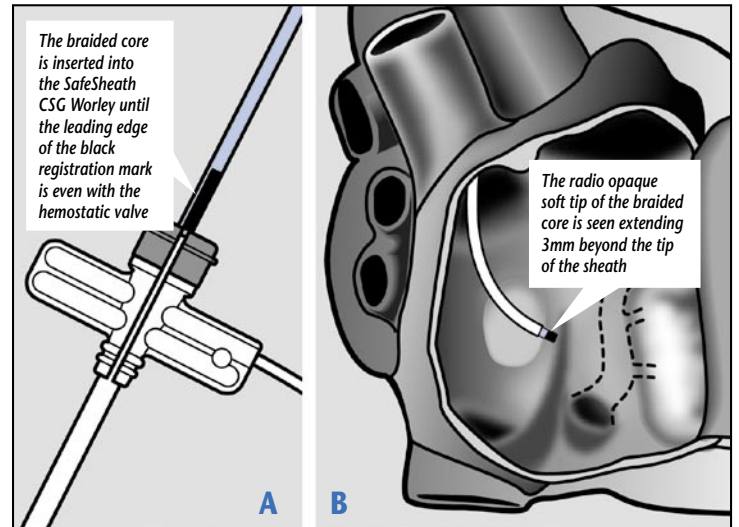


Figure 6 Braided Core registration marker and position of the radio opaque soft tip.

Step 7 Insert the guide wire through the hemostatic valve of the Y adapter into the braided core (Figure 7) and advance the wire under fluoroscopy until the wire exits the tip of the core.

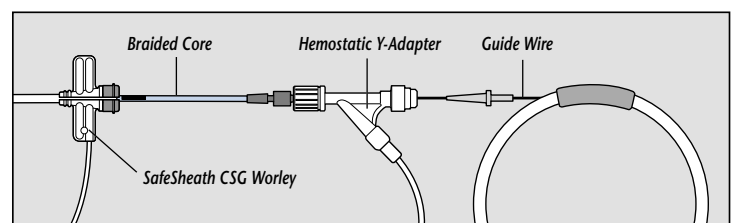


Figure 7 Guide Wire Inserted into the hemostatic valve of the Y Adapter.

Step 8 Hold the tip of the SafeSheath CSG Worley at the mid RA level and advance the guide wire from the tip of the core into the RV (Figure 8A). In some cases the guide wire will be directed by the tip of the sheath into the CS rather than the RV. This will be apparent by the lack of PVC's and direction of the wire in the LAO view. When the wire enters the CS instead of the RV simply advance the braided core over the wire followed by the SafeSheath CSG Worley.

Step 9 With the guide wire in the RV advance the SafeSheath CSG Worley and Braided Core as a unit over the wire into the RV. Once in the RV the guide wire is withdrawn into the braided core (Figure 8B).

Step 10 Grasp the hub of the braided core with the right hand and the wings of the hemostatic valve with the left hand. Apply 45 degrees of counter clockwise torque to the hub of the braided core with the right hand while stabilizing the wings of the hemostatic valve with the left hand. This will direct the SafeSheath CSG Worley posterior. Inject 2 to 3 cc of contrast to confirm the location of the tip of the core.

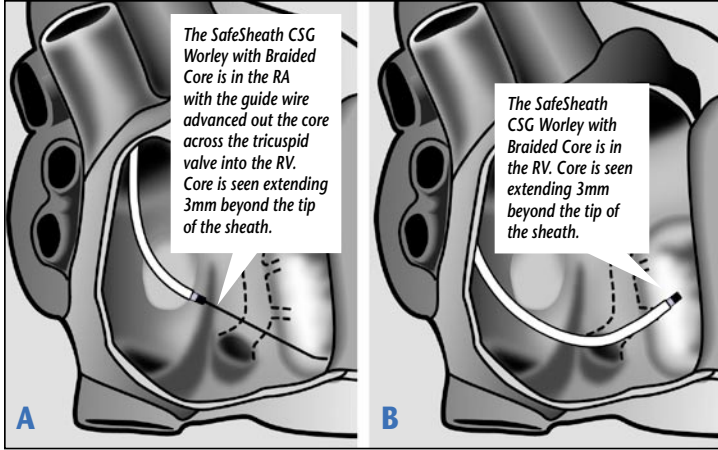


Figure 8 Advancement of the Braided Core SafeSheath CSG Worley into the RV.

Step 11 While maintaining 45 degrees of counterclockwise torque on the core, gradually withdraw the core and sheath as a unit until the tip of the core is on the tricuspid annulus. Inject one ml puffs of contrast to confirm tip location as the core/sheath is withdrawn under counterclockwise torque. Frequently the CS OS is visualized and/or the tip of the core will drop into the CS OS as the unit is withdrawn from the RV toward the tricuspid annulus.

Step 12 If the tip of the core reaches the tricuspid annulus without identification of the CS OS (Figure 9A) do not withdraw the sheath and core further. Keep the tip of the core on the tricuspid annulus and add an additional 90 degrees of counterclockwise torque to the core to direct the tip inferior and toward the RA while maintaining the posterior direction of the tip. The tip will slide inferior and posterior under the effect counterclockwise torque (Figure 9A, locations 2 and 3). Inject one ml puffs of contrast and watch for the OS of the CS as counterclockwise torque is applied.

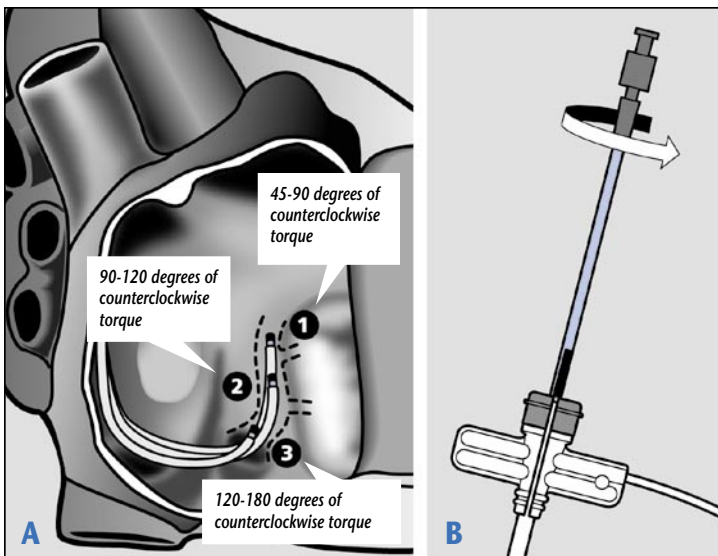


Figure 9 Effect of counterclockwise torque applied to the Braided Core on the position of the SafeSheath CSG Worley. In Panel A, the position of the tip of the sheath and core on the tricuspid annulus is demonstrated with varying degrees of counterclockwise torque. In Panel B, counterclockwise torque is shown applied to the core alone. Without advancing or withdrawing the core sheath combination, progressive counterclockwise torque on the core directs the tip inferior and toward the RA (Panel A, 1-3).

Step 13 Once the CS OS is identified, advance the wire followed by the core then the sheath gently into CS (Figure 10). As the wire and core are advanced into the CS one ml puffs of contrast are injected to confirm the tip location and identify venous side branches that might catch the tip of the core and prevent the core from advancing beyond the OS into the CS. In some cases the wire or core will not advance beyond the CS OS due to an anatomic variant. Anatomic variants that prevent the wire and or core from easily passing beyond the CS OS are readily identified with contrast injection. The most common include the large proximal venous branch that catches the tip of the catheter, the extreme vertical CS and the sigmoid CS. Once the anatomic variant is identified specific maneuvers can be applied to overcome the obstacle.

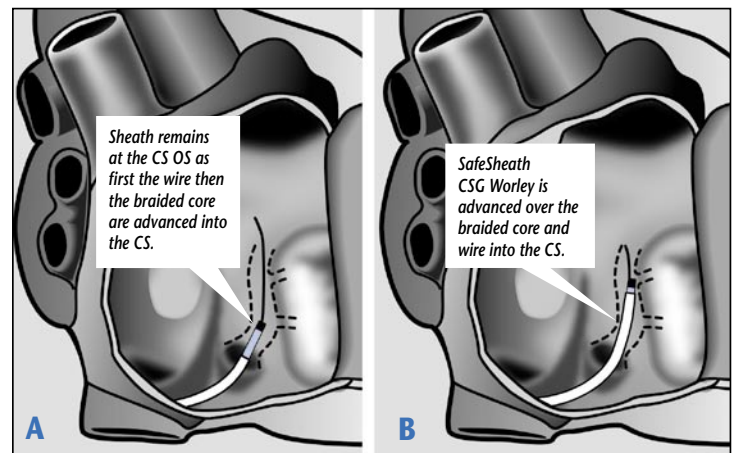


Figure 10. Guide wire and SafeSheath CSG Worley with Braided Core cannulate the CS.

Step 14 When the braided core reaches mid CS level, hold it in place and advance the SafeSheath CSG Worley over the braided core to the mid CS.

Step 15 With the SafeSheath CSG Worley at mid CS level, withdraw the wire and braided core and flush the sheath.

Tips on Removal of the SafeSheath CSG Worley to Prevent Lead Dislodgment and Reduce Back Bleeding.

Tip 1 Use a soft curved stylet to support the LV lead

Once the LV pacing lead is in place and before the SafeSheath CSG Worley is removed insert a gently curved soft stylet to support the pacing lead as the sheath is withdrawn. Once the sheath is removed the stylet must be removed without displacing the LV pacing lead. To prevent the process of removing the stylet from displacing the LV lead it is important that the stylet be curved similar to the curve on the SafeSheath CSG Worley. For comparison, the curve on a straight stylet in the coronary sinus is maintained by pressure against the CS. As the stylet is withdrawn within the pacing lead the curve continues to be supported by the CS until the stylet exits the CS still within the pacing lead. When the curve on the straight stylet is no longer supported by the CS it straightens and drops to the floor of the RA pulling the LV lead out of place. However, if the stylet is pre curved to fit the CS (similar to the curve on the SafeSheath CSG Worley) the curve on the stylet is intrinsic, not maintained by pressure on the CS. As the stylet exits the CS within the pacing lead, it does not straighten, fall to the floor of the RA and pull the LV lead out of place.

Tip 2 Withdraw the sheath as far as possible before peeling

Always watch the LV lead under fluoroscopy while the sheath is withdrawn. As the SafeSheath CSG Worley is withdrawn from the CS it may be necessary to advance or withdraw the LV lead to keep the position constant and the lead tip in place. Because of the wide curve on the SSCSG-W, the tip of the sheath will elevate, not drop to the floor of the RA, as it clears the CS OS (Figure 11). Sometimes, an operator will crack the hemostatic hub first and peel the sheath as it is withdrawn. However, when peeling and withdrawing are done simultaneously, it is difficult to watch the LV lead and add or remove slack as needed which can result in lead dislodgement. If the sheath is withdrawn first then peeled as a separate step (Figures 12-13), the lead length can be adjusted as needed while the sheath is withdrawn out of the CS over the lead. With the hemostatic hub intact, the sheath can be withdrawn slowly without bleeding. Waiting to crack the valve and peel the sheath until the hemostatic hub is at the IS-1 connector and the sheath tip high in the RA also reduces the impact of cracking and peeling on the LV lead position. Waiting to crack the hemostatic valve until the sheath is withdrawn to the lead connector reduces back bleeding and the risk of air embolism.

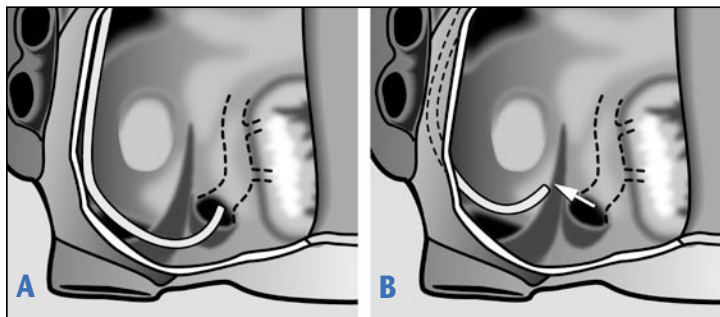


Figure 11 As the SafeSheath CSG Worley is withdrawn from the coronary sinus, the tip elevates toward the SVC rather than falling to the floor of the RA and dislodging the LV lead.

Tip 3 Pinch the LV lead between the walls of the sheath where it exits the body during peeling

Because withdrawing and peeling are done as separate steps, the LV lead can be stabilized where it exits the body by an assistant. With the hemostatic valve withdrawn to the IS-1 connector, an assistant firmly pinches the walls of the sheath against the LV pacing lead in the pocket where they exit the body. Pinching the lead between the walls of the sheath both stabilizes the lead and reduces bleeding during peeling (Figure 14). With the lead stabilized, the operator grasps the wings of the hemostatic valve, breaks the valve and peels the sheath rapidly from the IS-1 connector to fingers of the assistant (Figure 15). Peeling can be done rapidly without fear of lead dislodgement reducing back bleeding. Pinching the LV lead between the sides of the sheath where it exits the body not only stabilizes the lead but also reduces back bleeding and the risk of air embolization.

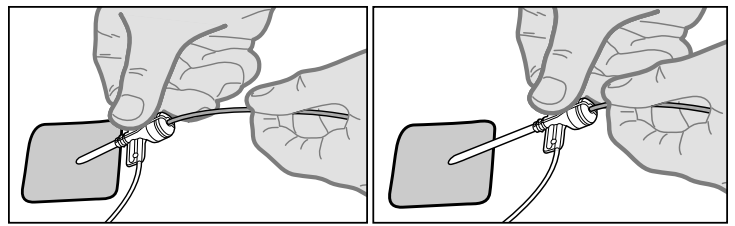


Figure 12 Withdrawing the SafeSheath CSG Worley over the LV pacing lead before cracking the hemostatic valve. As the sheath is withdrawn, the slack on the lead can be adjusted.

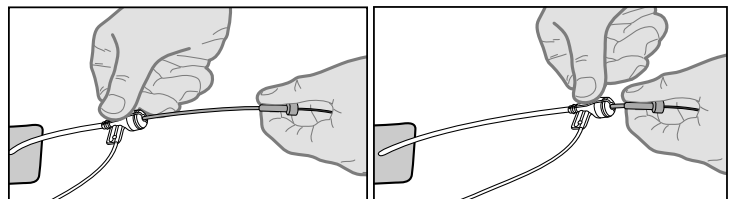


Figure 13 Continued withdrawal of the SafeSheath CSG Worley to the IS-1 connector before cracking the hemostatic valve. As the sheath is withdrawn, the slack on the lead can be adjusted.



Figure 14 Stabilizing the LV pacing lead and SafeSheath CSG prior to cracking the hemostatic valve.

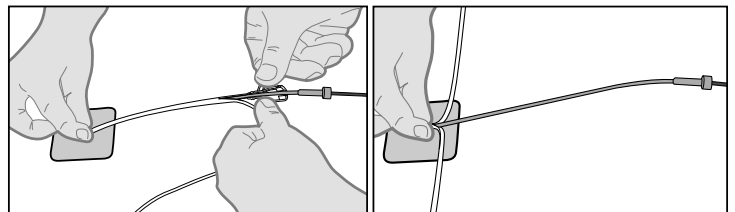


Figure 15 Cracking the hub and peeling the stabilized SafeSheath CSG Worley.

© Copyright Pressure Products, Inc., all rights reserved

Second Edition
First Printing March 2005

Copying or duplicating this manual or any part thereof is a violation of the law. No part of this manual may be reproduced or transmitted in any form or by any means, electronic or mechanical, including but not limited to photocopying, without written permission from Pressure Products, Inc.



Pressure Products, Inc.
1861 N. Gaffey Street
Suite B
San Pedro, CA 90731

Phone: (310) 547-4973 (800) 547-4973
Fax: (310) 547-4760
www.pressure-products.com

Pressure Products, the Double-P logo, SafeSheath and CSG are registered trademarks of Pressure Products, Inc. Other product names mentioned herein are used for identification purposes only, and may be trademarks of their respective companies.

Printed in the USA.