

## Use of the Transvalvular Insertion (TVI) Tool with ENDOTAK RELIANCE® G/SG Leads

### BACKGROUND INFORMATION

The TVI tool is designed for use with ENDOTAK RELIANCE® G/SG defibrillation leads that are implanted or repositioned using tear-away introducers with hemostatic valves (such as SafeSheath®). The tool protects the integrity of the lead coil(s) during passage through the valve portion of the introducer. The tool is available in 9 Fr and 11 Fr sizes. Physicians utilizing a non-retained guidewire technique may use either size tool, depending upon preference, but the 11 Fr tool must be used if the lead is implanted utilizing a retained guidewire technique. TVI tool sizing is independent of the size of the SafeSheath lead introducer used.

This article was first published as a *Product Update* on May 2, 2005.

CRM PRODUCTS REFERENCED\*  
Transvalvular Insertion (TVI) Tool,  
hemostatic tear-away introducer,  
ENDOTAK RELIANCE G/SG

\*Products referenced herein may not be approved in all geographies.

### CRM CONTACT INFORMATION

Technical Services – U.S.  
1.800.CARDIAC (227.3422)  
[Tech.Services@quidant.com](mailto:Tech.Services@quidant.com)

Technical Services – Europe  
+32 2 416 7222  
[eurtechservice@quidant.com](mailto:eurtechservice@quidant.com)

LATITUDE Clinician Support  
1.800.CARDIAC (227.3422)  
[latitude@quidant.com](mailto:latitude@quidant.com)

Patient Services  
1.866.484.3268 – U.S. and Canada  
001.651.582.4000 – International

### What is the purpose of the TVI tool?

The TVI tool (Figure 1) temporarily dilates the hemostatic valve to protect the integrity of the GORE ePTFE<sup>1</sup>-covered defibrillation coil(s) during passage through the valve.



Figure 1. 11 Fr TVI tool.

To realize the full benefit of ePTFE-covered defibrillation coils, Boston Scientific recommends using the TVI tool to:

- Facilitate free passage of the coil(s) through the valve of the hemostatic introducer
- Prevent exposure of the coil(s) to the oil-based non-conductive lubricant used in silicone hemostatic valves

### When is the TVI tool needed?

The TVI tool should always be used when implanting or repositioning a RELIANCE G/SG defibrillation lead in conjunction with a hemostatic tear-away introducer (such as SafeSheath). The tool should be used *any time coil passage through a hemostatic introducer occurs, which includes:*

- At initial implant (advanced forward through the valve)
- During lead repositioning, either during the original implant or subsequent lead revision procedure (retracted backward through the valve and advanced forward again)

Failure to use the tool may result in damage to the ePTFE covering.

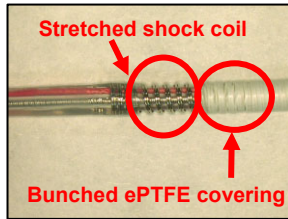
### What are the possible effects of passing a RELIANCE G/SG lead through a hemostatic valve without using the TVI tool?

Possible effects of not using the TVI tool include:

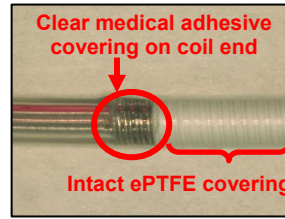
- Bunching of the ePTFE covering when passing through the tight valve. This may result in exposed coil(s) as shown in Figure 2A, making it susceptible to tissue ingrowth (similar to defibrillation leads that do not have an ePTFE covering).
- ▶ By design, the ends of the coil(s) are not completely covered with ePTFE; instead, a clear medical adhesive covering is used to facilitate a smooth transition to the ePTFE (Figure 2B). **This small section of clear medical adhesive should not be mistaken for bunched ePTFE.**

<sup>1</sup>GORE is a trademark of W.L. Gore and Associates. ePTFE is an acronym for expanded polytetrafluoroethylene.

- **Stretched shock coil(s).** If coil stretching occurs *in conjunction* with ePTFE bunching (Figure 2A), the coil(s) may be more susceptible to tissue ingrowth. (Tissue ingrowth susceptibility also applies to non-ePTFE covered coils that become stretched.)



**Figure 2A. Bunched ePTFE covering and stretched shock coil.**



**Figure 2B. Intact ePTFE covering and shock coil.**

- Temporary increase in shock impedances. If the ePTFE covering comes into contact with the oil-based lubricant used within the valve, microscopic pores in the ePTFE covering may become clogged, resulting in a slight initial increase in shocking impedance.

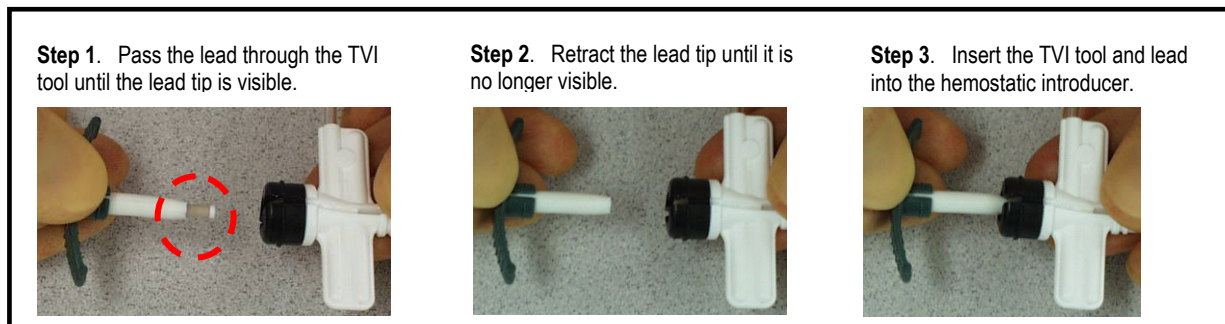
Therefore, to fully realize the benefits of ePTFE, Boston Scientific recommends use of the TVI tool during implant and/or lead repositioning to protect the coil(s) during passage through the hemostatic valve.

#### **Does use of the TVI tool defeat the purpose of utilizing a hemostatic introducer?**

The TVI tool only *briefly* dilates the hemostatic valve to facilitate passage of the shocking coil(s) through the valve.

#### **What can be done to minimize the time that hemostasis is temporarily interrupted?**

Holding a thumb over the proximal exposed opening of the tool significantly limits the potential for air embolization and/or back-bleeding. Additionally, when implanting without a retained guidewire, pre-loading the TVI tool onto the lead before inserting the tool into the hemostatic valve can further reduce this time (Figure 3).



**Figure 3. Pre-loading the TVI tool onto the lead prior to insertion into the hemostatic introducer.**

#### **Should the TVI tool be peeled away once the coils have passed through the hemostatic valve?**

No. Instead, the tool should be slid back along the lead body toward the terminal end and remain on the lead until final positioning has been achieved (Figure 4). Should lead repositioning require passage of the coil(s) through the hemostatic valve, the TVI tool should be reinserted into the hemostatic introducer valve before attempting to retract/advance the lead coil(s) through the introducer valve. The tool should be used to dilate the valve any time the coil(s) is passed through the valve *but only until the coil(s) has passed through the valve* (to minimize hemostasis interruption). Once final lead positioning is achieved, the tool must be peeled away.



**Figure 4. TVI tool retracted from introducer and remaining on lead body.**

**What if a RELIANCE G/SG lead has already passed through a hemostatic valve without using the TVI tool?**  
Physicians should be aware that the integrity of the ePTFE-covering might be compromised and therefore unable to fully protect against fibrotic tissue ingrowth (similar to defibrillation leads that do not have an ePTFE covering).

**What are the sizes in which the TVI tool is available, and when should each size be used?**

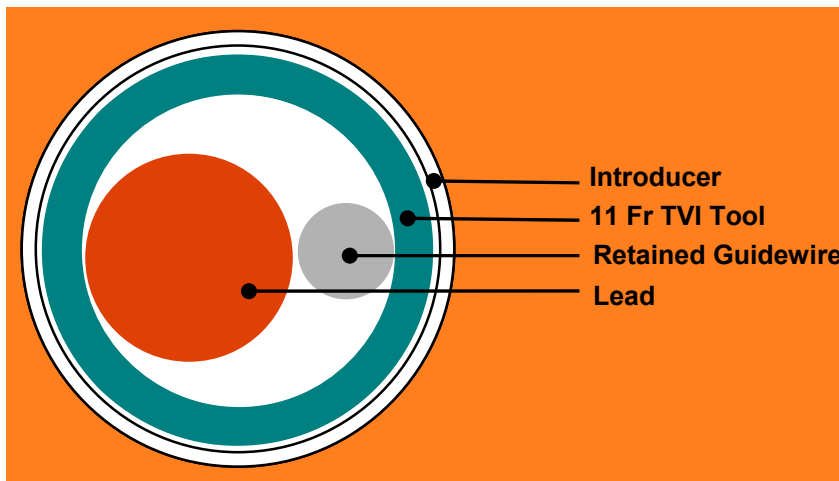
The TVI tool is available in two sizes (9 Fr/white handle and 11 Fr/green handle). One 11 Fr TVI tool is packaged with each RELIANCE G/SG lead. Additionally, an Accessory Kit (Model 7600) containing both the 9 Fr and 11 Fr tools is available. The size of the TVI tool to be used depends on technique and physician preference.

Non-retained guidewire technique: May use either 9 Fr or 11 Fr TVI tool

- Physicians utilizing a non-retained guidewire implant technique may prefer the 9 Fr tool to further limit back-bleeding and/or air embolization.

Retained guidewire technique: **MUST use 11 Fr TVI tool**

- 11 Fr tool is needed to accommodate both the lead and the retained guidewire (Figure 5).



**Figure 5. Cross-section of introducer, 11 Fr TVI tool and lead with a retained guidewire.**

- **The size of the TVI tool to be used is independent of the size of the SafeSheath lead introducer utilized.** This is because SafeSheath introducers (ranging from 7 Fr to 14 Fr) all have the same valve size; the sizing difference is accomplished via tapering from the valve region to the introducer body, and the TVI tool does not extend beyond the valve region.

---

**Summary of Implant Steps Using TVI Tool:**

1. Insert the TVI tool into the hemostatic introducer.
  - To minimize hemostasis interruption, cover the proximal exposed TVI tool opening or pre-load the tool onto the lead.
2. Pass the coil(s) through the hemostatic introducer valve.
3. Slide the TVI tool back along the lead body; reinsert as needed until final lead positioning is achieved.
4. Peel away and discard the TVI tool.