

Transvalvular Insertion (TVI) Tool and ENDOTAK RELIANCE[®] G/SG Leads

SUMMARY

The TVI tool is designed for use with pacing and defibrillation leads (such as ENDOTAK RELIANCE[®] G/SG) that are implanted or repositioned using splittable/peel-away introducers with hemostatic valves (such as SafeSheath^{®1}). The tool is intended to open the valve portion of the introducer for ease in passing the lead and protecting lead integrity.

Products Referenced

Transvalvular Insertion (TVI) Tool,
hemostatic splittable/peel-away introducer,
ENDOTAK RELIANCE G/SG

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator

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What is the intended use of the TVI tool?

The Transvalvular Insertion tool (Figure 1) can be used to temporarily open (dilate) a hemostatic introducer valve for ease of lead passage. Use of the TVI tool:

- facilitates free passage of the GORE[®] ePTFE² - covered coils through the SafeSheath^{®1} hemostatic introducer valve
- limits lead coil exposure to the oil-based non-conductive lubricant used in some silicone hemostatic valves.



Figure 1. 11 Fr TVI tool.

When should the TVI tool be used?

The TVI tool should be used any time ENDOTAK RELIANCE G/SG defibrillation lead coils or porous tip pass through a hemostatic introducer valve (e.g., at implant or repositioning).

What type of damage can occur if the TVI tool is not used when passing a RELIANCE G/SG lead through a hemostatic valve?

- **Bunching and Stretching** - If a lead is passed through a non-dilated hemostatic introducer valve, the ePTFE covering could become bunched or the shock coils could become stretched.
- **Temporary increase in shock impedance** - A slight initial increase in shocking impedance may be seen if the ePTFE covering comes into contact with oil-based lubricants sometimes used within hemostatic introducer valves.

An introducer with a hemostatic valve helps to prevent back bleeding while implanting a pacing or defibrillation lead. Does use of the TVI tool defeat the purpose of utilizing a hemostatic introducer?

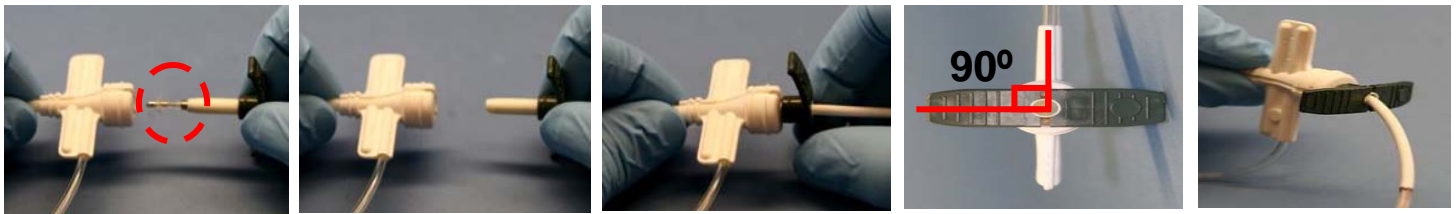
The TVI tool only *temporarily* dilates the hemostatic valve to facilitate passage of the shocking coil(s) through the introducer valve. Holding a thumb over the proximal exposed opening of the tool limits the potential for air embolization and/or back bleeding. Additionally, when implanting without a retained guidewire, pre-load the TVI tool onto the lead before inserting the tool into the hemostatic valve.

¹ SafeSheath is a registered trademark of Pressure Products, Inc.

² GORE is a trademark of W.L. Gore and Associates. ePTFE is an acronym for expanded polytetrafluoroethylene.

How is the TVI tool inserted and positioned?

The technique described below can be used for inserting and positioning the TVI tool (Figure 2). While placed within the hemostatic introducer, the maximum valve dilation (largest insertion diameter) is achieved when the tool's peel-away grips are perpendicular to the wings on the introducer.



Pass the lead through the TVI tool until the lead tip is visible.

Retract the lead tip until it is no longer visible.

Insert the TVI tool and lead into the hemostatic introducer.

For maximum valve dilation, position and maintain the tool's peel-away grip perpendicular to the wings on the introducer.

Figure 2. Inserting and positioning the TVI tool.

After the lead shocking coils have passed through the valve, how do you remove and peel away the TVI tool?

Slide the TVI tool back along the lead body toward the terminal end and leave the TVI tool on the body of the lead until final positioning has been achieved. **NOTE:** Should lead repositioning require passage of the coil(s) through the hemostatic valve, the TVI tool should be reinserted into the hemostatic introducer valve. The tool should be used to dilate the valve any time a coil is passed through the introducer valve. Once final lead positioning is achieved, the tool should be peeled away.

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:** Requires use of an 11 Fr TVI tool to accommodate both the lead and the retained guidewire (Figure 3).

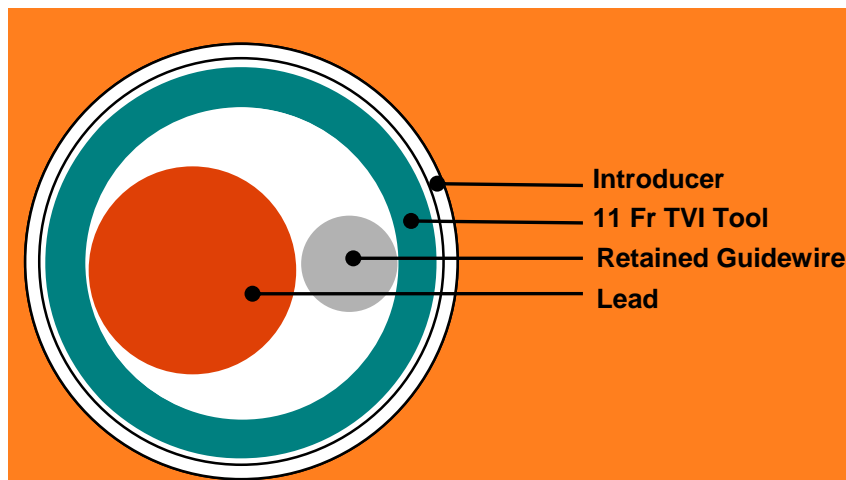


Figure 3. Cross-section of introducer, 11 Fr TVI tool, and lead with a retained guidewire.

NOTE: Refer to the specifications section of ENDOTAK RELIANCE G/SG instructions for use for recommended lead introducer sizes when using the TVI tool.