



## Implant Technique Tips to Consider when using Extendable/Retractable Active Fixation Leads

The following implant technique tips were collected from recent discussions with a number of implanting physicians regarding unique / incremental techniques that they have used to help reduce the risk of cardiac perforation and / or “micro-perforation”. Please note that these “tips” are only considered to be helpful suggestions that you may want to review with your physician customers, may not themselves prevent perforations which are influenced by many factors, and are not presented in any specific order.

**Note:** This is not an exhaustive list of techniques that experienced implanters use to enhance lead implantation safety. Other techniques can be found in the references below. Some implanting physicians may use techniques that are very different from those listed here. Furthermore, certain techniques that may decrease the risk for myocardial perforation may, in some patients, affect other outcomes (ie pacing, sensing and defibrillation thresholds). Thus, the implanting physician will need to consider several factors when determining the optimal implantation technique for a given patient.<sup>1</sup>

- Slow down the implant process for the RV ICD or Brady active fixation lead.
- Use the new softer stylet with the longer taper when inserting the lead into the cardiac chambers.
- Pull the stylet back (at least several cm) just prior to engaging tissue with the lead tip and when extending the helix.
- Try to avoid placing the lead’s tip deep into the RV apex, which is a very thin walled site. Also, numerous clinical studies now indicate that pacing at the RV apex site may be a suboptimal site taking into consideration the cardiac stimulation wavefront.<sup>2</sup> The newer advanced technology, smaller leads are much easier to push deeper into the RV apex than older, larger diameter leads. Thus, consider placing the lead tip up into the RVOT first (or up the RV septal wall), and then slowly “walk” the lead tip down towards the apex, but stop short of the lead moving into the apex itself. Instead, consider positioning the lead tip in the lower RV septal wall. Once achieving a low RV septal wall position with the lead tip, pull the stylet back at least several centimeters (e.g. 8 to 10 cm) and advance the lead tip very gently and slowly towards the lower RV septal wall until the lead tip is seen on fluoroscopy to just begin bending as it engages the wall. Then, fixate the helix by rotating the connector pin, carefully counting the number of pin rotations until the helix is ascertained to be fully extended and fully embedded.
- Avoid rotating the connector pin quickly; and suggest rotating the pin uniformly (e.g. approximately 1 rotation per second).
- Once the helix appears fully extended on fluoroscopy, assess whether the helix is fully embedded (refer to the next bullet). Manually, a very gentle pull on the lead should result in feeling a slight resistance while observing a stable tip position on fluoroscopy once the helix is fixated.
- Avoid excessive connector pin rotations or whole lead body rotations that can lead to excessive helix rotations which could result in tissue damage.
- Avoid turning the whole lead body after helix extension as a means to “tighten” the helix in the tissue.

- For any lead tip position and lead body orientation, make sure a gentle strain relief curve exists on the lead from the lead's tip as it extends away from the helix fixation site to provide for easier flexing and a less aggressive pushing motion of the lead tip into the RV wall tissue.
- Once the helix appears to be fully extended and fully embedded, allow the lead's torque build-up to relax for a minute or two; then reconfirm the helix's position and fixation, prior to obtaining final electrical measurements.

### Other Key Points to Consider

- Consider using the RVOT Septum site as it may provide for more optimal hemodynamic and electrical activation vs. other RV sites – especially the RV apex. Should the RVOT Septum not be an option, your customer may want to consider placing the lead tip in the lower RV septal wall as described previously. Recent published articles suggest there are better suited positions than the RV Apex for pacing leads.<sup>2,3,4</sup>
- Look for an injury current waveform in the ST segment of the ECG (an elevated ST segment is typically seen after helix fixation) to confirm that the helix is embedded.
- Once the helix is fully embedded, further rotation of the connector pin to extend the helix can result in additional helix rotations that can potentially cause tissue damage and reduced pacing impedance. This can be the precursor to a full perforation, or to a “micro-perforation” that usually is only evidenced by deteriorating pacing electrical parameters soon (e.g. 12 to 72 hours) after the implant. (Evidence for micro perforation may be poorer sensing as a result of diminished R-wave amplitudes and / or increasing capture thresholds).<sup>5</sup>
- Lastly, during the system (device and leads) insertion into the pocket, the implanting physician should be cognizant of how excess lead length is wrapped and placed in the pocket. It is suggested that excess lead be rolled-up in a way that avoids creating additional torque that could be transferred down the lead body, potentially allowing further helix rotation. Failure to sufficiently secure the suture sleeve may also enable the lead body to rotate and transfer torque to the helix. This additional torque could, depending on the direction that the lead is wrapped, cause the helix to rotate further or the lead tip to move further into tissue (possibly causing a perforation) or allow the helix to back out of the tissue, resulting in dislodgement.

### References:

<sup>1</sup> Belott P.H. and Reynolds D.W.; *Permanent Pacemaker and Implantable Cardioverter-Defibrillator Implantation*; in Ellenbogen K.A., Kay G.N., Lau C.P., Wilkoff B.L., Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 3<sup>rd</sup> Edition, Saunders Elsevier, 2007; 561 – 651.

<sup>2</sup> Antonis S. Manolis; The Deleterious Consequences of Right Ventricular Apical Pacing: Time to Seek Alternate Site Pacing; PACE, March 2006; Vol. 29; 298 – 315.

<sup>3</sup> Mond, H.G., Hillock R.J., Stevenson I.H., McGavigan A.D.; The Right Ventricular Outflow Tract: The Road to Septal Pacing; PACE, April 2007, Vol. 30; 482 – 491;

<sup>4</sup> Vlay S.C.; Right Ventricular Outflow Tract Pacing: Practical and Beneficial. A 9-Year Experience of 460 Consecutive Implants; PACE, October, 2006; Vol. 29; 1055 – 1062;

<sup>5</sup> Laske T.G., Vincent S.A., Skagsberg N.D., Iaizzo P.A.; High Pacing Impedances: Are You Overtorquing Your Leads?; PACE, Vol. 28: 894\_898, 2005.