

The Tempo® Temporary Pacing Lead

Cost-Effective Safety, Stability, and Ambulation for TAVR and Other Cardiac Procedures

Temporary pacing is an important and necessary adjunct to support patients undergoing a wide variety of cardiovascular procedures, including transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve replacement (TMVR). However, temporary pacing for TAVR can be associated with complications such as valve embolization, cardiac tamponade, or conduction defects requiring new pacemaker implantation.¹ With the expansion of TAVR to low-surgical-risk patients, the resultant increase in procedure volume and corresponding resource demands will make the importance of safe, temporary cardiac pacing even more critical. The unique design of the Tempo Temporary Pacing Lead assures stable intra- and post-procedural temporary pacing without the risk of perforation, thereby improving outcomes and reducing procedural costs.

RETHINKING THE TEMPORARY PACING LEAD

The standard design of temporary pacing leads consists of two rigid metal electrodes mounted at the distal tip of a simple catheter. This design has been associated with cardiac perforation and tamponade in 2% to 7.5% of cases and lead dislodgment with loss of capture in 10% to 37% of patients.¹⁻⁵ In addition, conventional temporary pacing leads restrict patient mobilization, which may delay postprocedural rehabilitation, prolong intensive care unit (ICU) and hospital length of stay (LOS), and as a result, increase costs.⁶

BioTrace Medical's Tempo Temporary Pacing Lead represents the only significant

advance in temporary pacing since the technology was introduced decades ago. The Tempo Lead's unique design features a novel rapidly deployable stabilizing fixation mechanism and a soft tip (Figures 1 and 2) that mitigates the risks of dislodgment and perforation during and after procedures. The design provides safe lead placement while avoiding intraprocedural complications such as valve embolization during rapid pacing or cardiac tamponade. In postprocedural temporary pacing, the safety and stability delivered by the Tempo Lead enable direct



Figure 1. The Tempo Lead features a novel active fixation mechanism designed to enhance pacing stability and a soft tip to reduce the risk of right ventricular perforation. Active fixation is accomplished via small retractable stabilizer loops deployed into the myocardium. An elastomeric balloon aids passage through the venous vasculature and provides apposition of the loops to the right ventricular myocardium.

TEMPO TEMPORARY PACING LEAD HIGHLIGHTS

- Only active fixation temporary pacing lead available
- Unique design assures safe and reliable pace capture without perforation risk
- Proven performance in a United States multicenter study and over 4,000 cases to date
- Enables postprocedural ambulation and suitable for SDUs

transfer to step-down units (SDUs), bypassing the ICU or cardiac care unit (CCU) and allowing earlier initiation of physical therapy, ambulation, and discharge.

The Tempo Lead is cleared by the FDA and holds CE Mark certification for use in all transvenous temporary pacing applications, including TAVR, TMVR, electrophysiology procedures, cardiac surgery, reversible symptomatic bradycardia, and other procedures such as alcohol septal ablations, pacemaker infections/extractions, and pacemaker generator changes.

INTRAPROCEDURAL SAFETY AND EFFECTIVENESS OF THE TEMPO LEAD

Data from a multicenter United States retrospective study of 224 transcatheter procedures demonstrated no perforations, pericardial effusions, or sustained device-related arrhythmias.⁷ “The clinical study results have demonstrated that the Tempo Lead is safe and effective for temporary cardiac pacing, provides stable peri- and postprocedural pacing support, and facilitates postprocedure ambulation” said Susheel K. Kodali, MD, Director of the Structural Heart & Valve Center at NewYork-Presbyterian/Columbia University Medical Center in New York, New York. “By virtue of its unique soft tip and flexible stabilizers, the innovative Tempo Lead improves pacing reliability and reduces the risk of ventricular perforation,” he said.

“The innovative design and demonstrated safety differentiate the Tempo Lead from traditional pacing leads,” said Samir Kapadia, MD, Chairman of the Department

of Cardiovascular Medicine and the Heart & Vascular Institute at Cleveland Clinic in Cleveland, Ohio. “The Tempo Lead’s soft tip and unique fixation mechanism result in safe and reliable pacing.” The study data are further validated by the subsequent real-world experience with the Tempo Lead, which has been used in more than 4,000 procedures in the United States to date, with an outstanding safety and performance record.⁸

COST BENEFITS OF SAFE POSTPROCEDURAL AMBULATION

Bypassing the ICU/CCU

An increasing number of TAVR patients are placing more strain on already overburdened ICUs. Nevertheless, many hospitals have developed policies that prohibit the transfer of patients with standard temporary leads in place to less costly SDUs due to perforation and dislodgment risks. Furthermore, conventional lead designs prevent the nursing team from ambulating patients or initiating physical therapy with leads in situ, which can prolong ICU and overall hospital LOS while standard temporary pacing leads are in place.

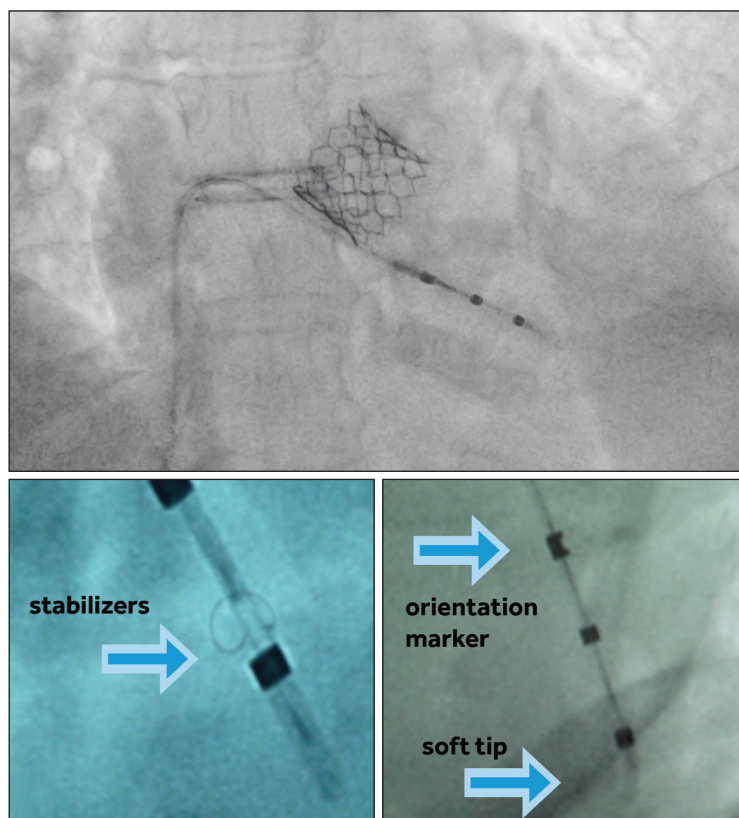


Figure 2. Fluoroscopic views of the Tempo Lead demonstrating the soft tip in the right ventricular apex, the orientation marker, and the deployed active fixation stabilizer loops.

“The innovative design of the Tempo Lead eliminates the need for restrictive temporary pacing or patient ambulation policies,” stated Stanley J. Chetcuti, MD, Professor of Cardiovascular and Director of the Cardiac Catheterization Laboratory at the University of Michigan in Ann Arbor, Michigan. “The Tempo Lead’s active fixation design eliminates off-hour callbacks to reposition leads and assures same-day ambulation, making it appropriate for SDU environments,” Dr. Chetcuti added.

Reducing LOS

After implementing the Tempo Lead into its TAVR program, OhioHealth/Riverside Methodist Hospital was able to reduce LOS by 45% for TAVR patients at risk for post-TAVR conduction abnormalities.⁹ “Our goal was to send patients to physical therapy on day 0; however, hospital policy prohibited ambulation of patients with traditional pacing leads in place,” stated Steven Yakubov, MD, System Chief, Advanced Structural Heart Disease at OhioHealth/Riverside Methodist Hospital in Columbus, Ohio. “The Tempo Lead allowed early ambulation and physical therapy for these patients, helping us reduce their LOS from 3.1 to 1.7 days.”

Facilitating Watchful Waiting to Reduce Unnecessary PPM Implantation

Studies have shown that 10% to 40% of TAVR patients require permanent pacemaker (PPM) implantation due to TAVR-related complications,¹⁰ yet 50% or more of these patients are not using their PPMs for pacing even 30 days post-TAVR.¹¹ Pacemaker implantation post-TAVR has been shown to increase both the length and cost of the index TAVR hospitalization and expose patients to potential complications such as pneumothorax, bleeding, and heart failure.^{12,13}

The ongoing expansion of TAVR to aortic stenosis patients at low surgical risk will place a spotlight on early PPM implantation in this population.^{14,15} These patients will be younger and have a longer life expectancy than those at intermediate or high surgical risk, making them more susceptible to the long-term increased morbidity and mortality associated with PPM implantation after TAVR.¹⁶

FDA cleared for temporary implantation for up to 7 days, the Tempo Lead enables “watchful waiting” post-TAVR, potentially avoiding PPM implantation in patients with transient conduction disturbances that could resolve in a few days. “The Tempo Lead can assure safe temporary pacing with ambulation while we observe the progression of postprocedural conduction disturbances in low-risk TAVR patients,” said Dr. Chetcuti.

CONCLUSION

The only significant temporary pacing innovation in decades, the Tempo Lead complements advancements and growth in minimally invasive cardiac procedures. Clinical results and real-world experience demonstrate that the Tempo Lead’s excellent safety and efficacy profile can have a significant impact on patient outcomes and cost in the rapidly burgeoning field of transcatheter structural heart interventions. ■

1. Ali N, Patel PA, Lindsay SJ. Recent developments and controversies in transcatheter aortic valve implantation. *Eur J Heart Fail*. 2018;20:642-650.
2. Bosmans JM, Kefer J, De Bruyne B, et al. Procedural, 30-day and one-year outcome following CoreValve or Edwards transcatheter aortic valve implantation: results of the Belgian national registry. *Interact Cardiovasc Thorac Surg*. 2011;12:762-767.
3. Grube E, Buellesfeld L, Mueller R, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve Revalving system. *Circ Cardiovasc Interv*. 2008;1:167-175.
4. Piazza N, Onuma Y, Jessorun E, et al. Early and persistent intraventricular conduction abnormalities and requirements for pacemaker after percutaneous replacement of the aortic valve. *J Am Coll Cardiol Interv*. 2008;1:310-316.
5. El Masry H, Breall JA. Alcohol septal ablation for hypertrophic obstructive cardiomyopathy. *Curr Cardiol Rev*. 2008;4:193-197.
6. Cribier A, Elchaniouff H, Tron C, et al. Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience. *J Am Coll Cardiol*. 2006;47:1214-1223.
7. Nazif T, Sanchez C, Whisenant B, et al. Analysis of the initial U.S. experience with the BioTrace Tempo Temporary Pacing Lead in TAVR and other cardiac procedures. *J Am Coll Cardiol*. 2018;71(11 suppl):A1285.
8. BioTrace Medical, Inc.; company data on file as of July 2019.
9. Yakubov S. How to manage pacemakers with TAVR, temporary and permanent indications. Presented at: 2017 Transcatheter Cardiovascular Therapeutics (TCT) congress (virtual session); October 29–November 2, 2017; Denver, Colorado.
10. Auffret V, Puri R, Urena M, et al. Conduction disturbances after transcatheter aortic valve replacement: current status and future perspectives. *Circulation*. 2017;136:1049-1069.
11. Nazif TM, Dizon JM, Hahn RT, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of Aortic Transcatheter Valves) trial and registry. *JACC Cardiovasc Interv*. 2015;8(1 pt A):60-69.
12. Fadahunsi OO, Olowoyeye A, Ukaigwe A, et al. Incidence, predictors, and outcomes of permanent pacemaker implantation following TAVR: analysis from the US Society of Thoracic Surgeons/American College of Cardiology TVT Registry. *JACC Cardiovasc Interv*. 2016;9:2189-2199.
13. Kotsakou M, Kioumis I, Lazaridis G, et al. Pacemaker insertion. *Ann Transl Med*. 2015;3:42.
14. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706-1715.
15. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695-1705.
16. Aljabbar T, Qiu F, Masih S, et al. Association of clinical and economic outcomes with permanent pacemaker implantation after transcatheter aortic valve replacement. *JAMA Netw Open*. 2018;1:e180088.



BioTrace Medical Inc.

3925 Bohannon Drive Suite 200 | Menlo Park, CA 94025

www.biotracemedical.com | cs@biotracemedical.com

P: 650.779.4999 | F: 650.779.4746

©2019 BioTrace Medical Inc. All rights reserved. Tempo® is a registered trademark of BioTrace Medical Inc. US and foreign patents issued and pending. <https://www.biotracemedical.com/patents>.