The Tempo® Temporary Pacing Lead

Innovation Designed to Eliminate Complications and Reduce Costs

BioTrace MEDICAL

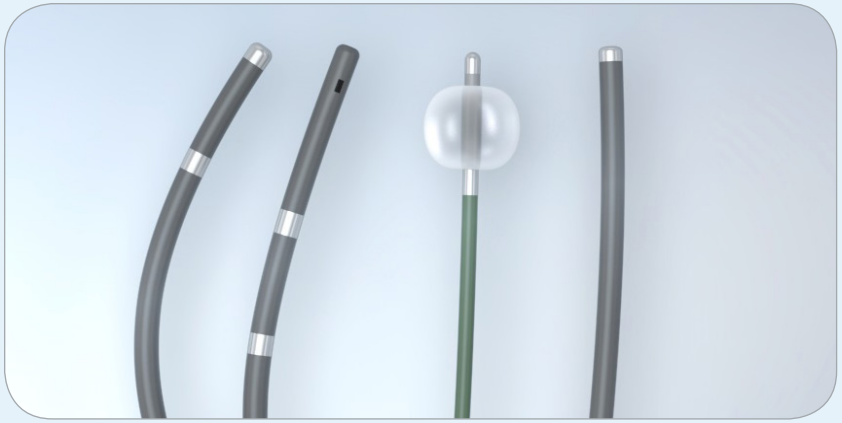
Limitations of Common Temporary Pacing Leads

Common temporary pacing leads are associated with serious complications[1] including:

0.6%-4.0%
cardiac perforation and/or tamponade

10%-37%
dislodgment with loss of pace capture

Recent clinical studies of patients undergoing TAVR have confirmed the previously documented complications related to temporary pacing.[1]



Standard temporary pacing leads have two electrodes mounted on the distal end with one rigid metal electrode at the distal tip. The rigid distal tip predisposes the lead to myocardial perforation. The design also does not include any fixation mechanism to secure the pacing electrodes to the myocardium.

The Tempo Lead Advantage

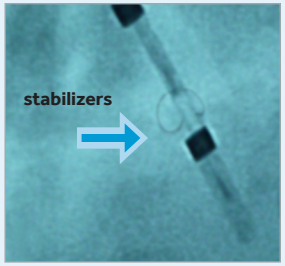
The Tempo Lead delivers proven secure and stable pacing[2, 3] to reduce complications and allow patients to ambulate sooner after procedures.

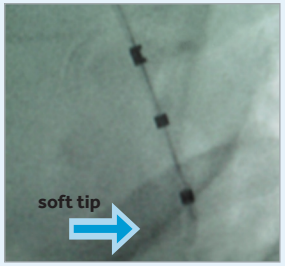
In over 4,500 US Tempo Lead placements to date, there have been only two reported cardiac perforations.[4]

0.04%
cardiac perforation rate[4]

0.04%
dislodgment with loss of pace capture[4]

The Tempo Lead's thin flexible stablizer loops provide secure fixation and maintain stable pace capture; a unique soft tip mitigates perforation.





Fluoroscopic view of the Tempo Lead demonstrating the deployed active fixation stabilizer loops and soft tip in the right ventricular apex,

References

1. Metkus, et al. Chest. 2019; Lopez, et al. Rev Esp Cardiol. 2004; Betts, Postgrad Med J. 2003; Jowett, et al. Postgrad Med J. 1989; Austin, et al. Am J Cardiol. 1982; Gammage, Heart 2000; Lumia et al. Chest 1973
2. Nazif TM, Chen S, Codner P, et al. The initial U.S. experience with the Tempo active fixation temporary pacing lead in structural heart interventions. Catheter Cardiovasc Interv. 2019;1–6. https://doi.org/10.1002/ccd.28476.
3. Webster M, Pasupati S, Lever N, Stiles M. Safety and Feasibility of a Novel Active Fixation Temporary Pacing Lead. J Invasive Cardiol 2018;30:163-167.
4. Company data on file, as of September 2019.

APM032-01 Rev B