

Your bridge to surgery

References

1. iData, MRG, Eucomed, EHRA White Book, Product Performance Reports (Biotronik, Boston Scientific, Medtronic, and St. Jude Medical), and internal estimates/analysis on file.
2. SPNC data on file 2017. Current Trends in Lead Management D014953-10.
3. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
4. Spectranetics data on file and IMS data 2016.
5. Le KY, Sohail MR, Friedman PA, et al. Impact of timing of device removal on mortality in patients with cardiovascular implantable electrophysiologic device infections. Heart Rhythm 2011;8:1678 – 85.
6. Bohm, Adam, et al. Complications Due to Abandoned Noninfected Pacemaker Leads. PACE, Vol 24, No 12, 2001, 1721-1724.
7. Mattei, E., Gentili, G., Censi, F., Triventi, M. and Calcagnini, G. (2015), Impact of capped and uncapped abandoned leads on the heating of an MR-conditional pacemaker implant. Magn Reson Med, 73: 390–400. doi: 10.1002/mrm.25106
8. Maytin, M. MD, et al. Multicenter Experience with Extraction of the Riata™/Riata™ ST ICD Lead, Heart Rhythm, <http://dx.doi.org/10.1016/j.hrthm.2014.05.014>
9. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
10. Azarrafiy R, Tsang DC, Boyle TA, Wilkoff BL, Carrillo RG, Compliant Endovascular Balloon Reduces the Lethality of Superior Vena Cava Tears During Transvenous Lead Extractions, Heart Rhythm. doi:10.1016/j.hrthm.2017.05.005
11. Wazni, O et. al. Lead Extraction in the Contemporary Setting: The LEXIcon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579-586.
12. Spectranetics Post Market data, data on file. 2017.
13. Brunner, Outcomes of patients requiring emergent surgical or endovascular intervention for catastrophic complications during transvenous lead extraction
14. Document on file, D027561. When deployed, the Bridge occlusion balloon reduces blood loss by up to 90%, on average, in an animal model of an SVC tear. Testing was conducted in a heparinized porcine model which has shorter SVC length than is typical in humans. A balloon design scaled for use specifically in the porcine model was used in generating this data.
15. Document on file, D027562.
16. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
17. Document on file, D026203. The balloon will cover the length and diameter of the SVC in 90% of the population as determined by analysis of 52 patients (N=52, % Male=48.1, Average Age 47.1 ± 16.5, Age Range 63 (18 to 81 years), Average Height 170.8cm ± 10.6, Height Range 40.6cm (152.4 to 193cm), Average BMI 29.8 ± 7.2, BMI Range 32.1 (18.2 to 50.3)).
18. D027564 (Marketing Claims Summary Report for Bridge, Project #1338).
19. Azarrafiy R, Tsang DC, Boyle TA, Wilkoff BL, Carrillo RG, Compliant Endovascular Balloon Reduces the Lethality of Superior Vena Cava Tears During Transvenous Lead Extractions, Heart Rhythm. doi:10.1016/j.hrthm.2017.05.005
20. Ryan Azarrafiy, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circulation: Arrhythmia and Electrophysiology, August 2019.
21. Brunner, Wilkoff et al: Heart Rhythm 2014;11:419-25