Current trends in implantable cardioverter-defibrillator (ICD) and advisory leads 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. Fields, Michael E., et al. How to select patients for lead extraction. Heart Rhythm, Vol 4, Issue 7, July 2007.
- 3. Voight, Andrew, et al. Rising Rates of Cardiac Rhythm Management Device Infections in the UnitedStates: 1996 through 2003. JACC Vol. 48, No. 3, 2006: 590-1.
- 4. Kleeman Thomas, et al. Annual Rate of Transvenous Defibrillation Lead Defect in ImplantableCardioverter-Defibrillators over a Period of >10 Years. Circulation 2007; 115:2474-2490.
- 5. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
- 6. Pokorney et al. Outcomes Associated with Extraction versus Capping and Abandoning Pacing and De brillator Leads Circulation 2017 Oct 10;136(15):1387-1395. doi: 10.1161/CIRCULATIONAHA.117.027636. Epub 2017 Aug 22.
- 7. Sohal, M. et al. (2014). Laser lead extraction to facilitate cardiac implantable electronic device upgrade and revision in the presence of central venous obstruction. Europace, 16(1), 81-87.
- 8. Oginosawa Y, Abe H, Nakashima Y. The incidence and risk factors for venous obstruction after implantation of transvenous pacing leads. Pacing Clin Electrophysiol 2002;25:1605–1611.
- 9. Kutarski, A., Pietura, R., Młynarczyk, K., Małecka, B., & Głowniak, A. (2012). Pacemaker lead extraction and recapture of venous access: technical problems arising from extensive venous obstruction. Cardiology journal, 19(5), 513-517.
- 10. de Cock CC, et al. Long-term outcome of patients with multiple (> or = 3) noninfected leads: a clinical and echocardiographic study. PACE, Vol 23, No 4, 2000, 423-6
- 11. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
- 12. 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
- 13. Maytin, M, et al., Multicenter Experience with Extraction of the Sprint Fidelis Implantable Cardioverter-Defibrillator Lead, J. Am. Coll. Cardiol. Published online June 30, 2010; doi:10.1016/j.jacc.2010.03.058
- 14. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
- 15. Wilkoff BL, Love CJ, Byrd CL, Bongiorni MG, Carrillo RG, Crossley GH 3rd, Epstein LM, Friedman RA, Kennergren CE, Mitkowski P, Schaerf RH, Wazni OM; Heart Rhythm Society; American Heart Association. Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). Heart Rhythm. 2009 Jul;6(7):1085-104.
- 16. Data on file Philips. Lead Extraction Survey, conducted by in2ition for Philips. January 2010.
- 17. 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.
- 18. Roger G. Carrillo, MD; Darren C. Tsang, BS; Ryan Azarra y, BA; Thomas A. Boyle, BS. Multi-Year Evaluation of Compliant Endovascular Balloon in Treating Superior Vena Cava Tears During Transvenous Lead Extraction. EHRA late-breaking trial, March 19, 2018.
- 19. Erkapic, Damir, et al. Insulation Defect of Thin High-Voltage Leads: An Underestimated Problem? Journal of Cardiovascular Electrophysiology, published online April 1, 2011.
- 20. 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 heparinzed 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.

- 21. Document on file D027562. Bridge can be fully deployed in under one minute (53 seconds) in an animal model when pre-positioned on a guidewire, or in under two minutes (1 minute, 46 seconds) when not pre-positioned.
- 22. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
- 23. Elrod, Jodia. Use of Bridge™ Occlusion Balloon in Lead Extraction: Interview with Dr. Roger Carrillo. EP Lab Digest. November, 2016.