Riata and Fidelis 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 United States: 1996 through 2003. JACC Vol. 48, No. 3, 2006: 590-1.
- 4. Kleeman Thomas, et al. Annual Rate of Transvenous Defibrillation Lead Defect in Implantable Cardioverter-Defibrillators over a Period of >10 Years. Circulation 2007; 115:2474-2490.
- 5. Philips data on file. Case Log 2012-2017.
- 6. Wilkoff, Bruce, L., et al. Pacemaker Lead Extraction with the Laser Sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. JACC, Vol 33, No. 6, May 1999.
- 7. 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.
- 8. Downloaded on January 21, 2013 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ ucm314930.htm
- St Jude Medical, Product Advisories, St Jude Website, Downloaded July 15, 2011: http://www. sjmprofessional.com/Media/DownloadResource.aspx?id=%7B59163A28-D8BA-4310-AECD-6ECB40A28C53%7D
- 10. Erkapic, Damir, et al. Insulation Defect of Thin High-Voltage Leads: An Underestimated Problem? Journal of Cardiovascular Electrophysiology, published online April 1, 2011.
- 11. Carrillo, R., Riata Issues and Solutions presented at Miami Lead Extraction Symposia January 2012.
- 12. Theuns, Dominic AMJ, et al. "Nationwide Longitudinal Follow-Up of Riata Leads Under Advisory at 3 Annual Screenings: Report From the Netherlands Heart Rhythm Association Device Advisory Committee." JACC: Clinical Electrophysiology (2017).
- 13. Erkapic, Damir, et al. Insulation Defect of Thin High-Voltage Leads: An Underestimated Problem? Journal of Cardiovascular Electrophysiology, published online April 1, 2011.
- 14. Goyal, SK., Ellis, CR, Rottman, JN, Whalen, SP, et al. (2013) Lead Thrombi Associated with Externalized Cables on Riata ICD leads: A Case Series, abstract, Journal of Cardiovascular Electrophysiology
- 15. Ricciardi D, et el; A case of in vivo thrombogenicity of an externalized Riata ST lead, Europace. 2013 Mar;15(3):428. doi: 10.1093/europace/eus395
- 16. Larsen, JM. MD, Prospective Nationwide Fluoroscopic and Electrical Longitudinal Follow-up of Recalled Riata Defibrillator Leads in Denmark, Heart Rhythm, http://dx.doi.org/10.1016/j.hrthm.2014.07.003
- 17. 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
- Abdelhadi RH, Saba SF, Ellis CR, Mason PK, Kramer DB, Friedman PA, et al. Independent multicenter study of Riata and Riata ST implantable cardioverter-defibrillator leads. Heart rhythm. 2013 Mar;10(3):361-365.
- 19. Steinberg C, Sarrazin JF, Philippon F, Bouchard MA, O'Hara G, Molin F, Nault I, Blier L, Champagne J. Detection of high incidence of Riata lead breaches by systematic postero-anterior and lateral chest X-ray in a large cohort. Europace. 2013 Mar;15(3):402-8.
- 20. Demirel F, Adiyaman A, Delnoy PP, Smit JJ, Ramdat Misier AR, Elvan A. Mechanical and electrical dysfunction of Riata implantable cardioverter-defibrillator leads. Europace. 2014 Dec;16(12):1787-94.
- 21. Zeitler, Emily P., et al. Cable externalization and electrical failure of the Riata family of implantable cardioverter-defibrillator leads: A systematic review and meta-analysis. Heart Rhythm 12.6 (2015): 1233-1240.

- 22. Downloaded 9/18/2013 http://professional.sjm.com/resources/product-performance/riata-importantinfo/physician-information/riata-lead-performance
- 23. D016929-02 Extraction Considerations for Silicone Riata Leads. On file with Philips.
- 24. Richardson TD, Kolek MJ, Goyal SK, Shoemaker MB, Lewis AA, Rottman JN, Whalen SP, Ellis CR. Comparative outcomes of transvenous extraction of sprint fidelis and riata defibrillator leads: a single center experience. J Cardiovasc Electrophysiol. 2014 Jan;25(1):36-42.
- 25. Medtronic Physician Letter. Downloaded 9/18/2013 http://www.medtronic.com/wcm/groups/ mdtcom_sg/@mdt/documents/documents/pdf-fidelis-phys-letter07.pdf
- 26. Medtronic, Product-Advisories, Medtronic Website, Downloaded on June 15, 2018, http://wwwp. medtronic.com/productperformance/model/6949-sprint-fidelis.html
- 27. Lovelock JD, Patel A, Mengistu A, Hoskins M, El-Chami M, Lloyd MS, Leon A, DeLurgio D, Langberg JJ. Generator exchange is associated with an increased rate of Sprint Fidelis lead failure. Heart Rhythm. 2012 Oct;9(10):1615-8.
- 28. Kallinen L, et al., Lead Integrity alert decreases inappropriate shocks in patients who have Fidelis pacesense conductor fractures, Heart Rhytm, Vol.7, No. 8, August 2010, pp. 1048-55
- 29. Sweeney, M., et al., Differences In Effects of Electrical Therapy Type for Ventricular Arrhythmias on Mortality in Implantable Cardioverter-Defibrillator Patients, Heart Rhythm, Volume 7, Issue 3, March 2010: 353-60
- 30. Raltt, M., Implantable Cardioverter-Defibrillator Shocks; A Double-Edged Sword? JACC, Volume 51, Issue 14, April 8, 2008; 1366-8
- 31. Byrd, Charles, et al. Clinical Study of the Laser Sheath for Lead Extraction: The Total Experience in the United States. Journal of Pacing and Electrophysiology. Vol I25, No. 5, May 2002.
- 32. 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
- 33. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
- 34. 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.
- 35. 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.
- 36. 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.
- 37. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
- 38. Elrod, Jodia. Use of Bridge™ Occlusion Balloon in Lead Extraction: Interview with Dr. Roger Carrillo. EP Lab Digest. November, 2016.
- 39. Cappato R, Calkins H, Chen SA, et al. Worldwide Survey on the Methods, Efficacy, and Safety of Catheter Ablation for Human Atrial Fibrillation. Circulation 2005; 111:1100-11105
- 40. Cappato R, Calkins H, Chen SA, et al. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation. J Am Coll Cardiol 2009; 53:1798-1803.
- 41. Kern M. SCAI Interventional Cardiology Board Review Book. Lippincott Williams & Wilkins 2006; p.165.
- 42. Poole, J. et. al., Complication Rates Associated with Pacemaker and ICD Generator Replacements when Combined with Planned Lead Addition or Revision, American Heart Association, November 15, 2009.

- 43. Brignole, M. et. al., Defibrillation testing at the time of implantation of cardioverter defibrillator in the clinical practice: a nation-wide survey, Europace 2007 Vol. 9 No. 7: 540-543.
- 44. Data on file Philips. Lead Extraction Survey, conducted by in2ition for Philips. January 2010.
- 45. Pokorney SD, Mi X, Lewis RK, Greiner M, Epstein LM, Carrillo RG, Zeitler EP, Al-Khatib SM, Hegland DD, Piccini JP. Outcomes Associated With Extraction Versus Capping and Abandoning Pacing and Defibrillator Leads. Circulation. 2017 Oct 10;136(15):1387-1395.
- 46. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
- 47. 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.
- 48. 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.
- 49. 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.
- 50. 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
- 51. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
- 52. 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
- 53. D026882-00 Preparing for Lead Extarction, John Piccini Duke University. Philips data on file.