## Managing leads. Leading change. A new era in lead management. References

- 1. Fields, Michael E., et al. How to select patients for lead extraction. Heart Rhythm, Vol 4, Issue 7, July 2007.
- 2. 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.
- 3. 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.
- 4. iData, MRG, Eucomed, EHRA White Book, Product Performance Reports (Biotronik, Boston Scientific, Medtronic, and St. Jude Medical), and internal estimates / analysis on file.
- 5. Philips data on file. Case log book, 2012-2019.
- 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. Sprint Fidelis Lead Performance information, physician communication, Downloaded May 2014 http://www.medtronic.com/product-advisories/physician/sprint-fidelis/6949-LEAD-PERFORMANCE
- 9. Wilkoff, Bruce L., et al. How to treat and identify device infections. Heart Rhythm, Vol 4, No 11, 2007, 1467-1470.
- 10. Hauser, Robert, et. al., The Increasing Hazard of Sprint Fidelis Implantable Cardioverter-Defibrillator Lead Failuree, Heart Rhythm, Vol. 6, No 5, May 2009.
- 11. Worley, Seth J. Implant Venoplasty: Dilation of Subclavian and Coronary Veins to Facilitate Device Implantation: Indications, Frequency, Methods, and Complications. Journal of Cardiovascular Electrophysiology Vol. 19, No. 9, September 2008, 1004-7.
- 12. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
- 13. 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
- 14. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
- 15. Philips data on file. D021403 Infection Infographic.
- 16. Tarakji, K, et al. Cardiac implantable electronic device infections: presentation, management, and patient outcomes, Heart Rhythm, Vol. 7, No. 8, 2010: 1043-7.
- 17. Chua, J.D., et al. (2000). Diagnosis and management of infections involving implantable electrophysiologic cardiac devices. Annals of Internal Medicine, 133(8): 604-608.
- 18. del Rio A, Anguera I, Miro JM, et al. Surgical treatment of pacemaker and defibrillator lead endocarditis: the impact of electrode lead extraction on outcome. Chest 2003;124:1451–9.
- 19. Klug, D., et al. (2004). Local symptoms at the site of pacemaker implantation indicate latent systemic infection. Heart, 90(8), 882-886.
- 20. Sohail MR, et al. Management and outcome of permanent and implantable cardioverter-defibrillator infections. J Am Coll Cardiol. 2007;49:1851–1859.
- 21. Margey, R. et al. Contemporary management of and outcomes from cardiac device related infections Europace (2010) 12 (1): 64-70 first published online November 11, 2009 doi:10.1093/europace/eup362
- 22. 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.

- 23. 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.
- 24. Erkapic, Damir, et al. Insulation Defect of Thin High-Voltage Leads: An Underestimated Problem? Journal of Cardiovascular Electrophysiology, published online April 1, 2011.
- 25. Abdelhadi, RH et,al. Independent multicenter study of Riata and Riata ST implantable cardioverterdefibrillator leads. Heart Rhythm. 2013 Mar;10(3):361-5. doi: 10.1016/j. hrthm.2012.10.045. Epub 2012 Nov 2.
- 26. Steinberg, C, et.al. 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. doi: 10.1093/europace/eus339. Epub 2012 Nov 1.
- 27. 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 May 19. pii: euu079. [Epub ahead of print]
- 28. 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
- 29. 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).
- 30. 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
- 31. Medtronic, Product-Advisories, Medtronic Website, Downloaded July, 2019, http://wwwp.medtronic. com/productperformance/model/6949-sprint-fidelis.html
- 32. Lovelock JD et al. Generator exchange is associated with an increased rate of Sprint Fidelis lead failure, Heart Rhythm 2012 Oct;9(10):1615-8. doi: 10.1016/j.hrthm.2012.06.009. Epub 2012 Jun 6.
- 33. Kallinen L, et al., Lead integrity alert decreases inappropriate shocks in patients who have Fidelis pacesense conductor fractures, Heart Rhythm, Vol. 7, No. 8, August 2010, pp. 1048-55.
- 34. 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.
- 35. 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.
- 36. 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.
- 37. Dr. Kutalek Occlusion Case Study, D030926. Data on file.
- 38. Marco, CB, et al, Clinical Applications of cardiovascular MRI, CMAJ 2006: 175:911-7
- 39. Roguin, Ariel et al, Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices, Europace 2008:10, 336-346.
- 40. Levine, G, et al, "Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Devices: AHA statement from the Committee on diagnostic and interventional cardiac catherization, council on clinical cardiology, and the council on cardiovascular radiology and intervention. Circ 2007, pp 2878-2891
- 41. Acharya, Raj, et al, "Biomedical Imaging Modalities: A Tutorial, Computerized Medical Imaging and Graphics, 1995, Vol 19: 1-23
- 42.http://www.diffen.com/difference/CT\_Scan\_vs\_MRI
- 43. Nazarian S, Reynolds MR, Ryan MP et al. Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. J Magn Reson Imaging. Published online June 27, 2015.

- 44. Schellinger, P. D. et al. (2010). Evidence-based guideline: The role of diffusion and perfusion MRI for the diagnosis of acute ischemic stroke Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology, 75(2), 177-185. Viewed at https://www.neurology.org/content/75/2/177.full
- 45. Bohm, Adam, et al. Complications Due to Abandoned Noninfected Pacemaker Leads. PACE, Vol 24, No 12, 2001, 1721-1724.
- 46. 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
- 47. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
- 48. Chua, J.D., et al. (2000). Diagnosis and management of infections involving implantable electrophysiologic cardiac devices. Annals of Internal Medicine, 133(8): 604-608.
- 49. Klug, D., et al. (2004). Local symptoms at the site of pacemaker implantation indicate latent systemic infection. Heart, 90(8), 882-886.
- 50. Sohail, MR, et al. Management and outcome of permanent and implantable cardioverterdefibrillator infections. J Am Coll Cardiol. 2007;49:1851–1859.
- 51. Margey, R. et al. Contemporary management of and outcomes from cardiac device related infections Europace (2010) 12 (1): 64-70 first published online November 11, 2009 doi:10.1093/europace/eup362.
- 52. del Rio, A, Anguera I, Miro JM, et al. Surgical treatment of pacemaker and defibrillator lead endocarditis: the impact of electrode lead extraction on outcome. Chest 2003;124:1451–9.de Bie, Mihály K., et al. "Cardiac device infections are associated with a significant mortality risk." Heart Rhythm 9.4 (2012): 494-498
- 53. Lead Extraction for Treatment of Cardiac Device Infection: A 20-Year Single Centre Experience. Gomes S, Heart Lung Circ. 2016 Aug: S1443-9506(16)31534-7.
- 54. Byrd, CL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. PACE 1999; 22:1348-1357.
- 55. Raitt, Merritt H. "Implantable cardioverter-defibrillator shocks." (2008): 1366-1368.
- 56. Philips data on file and IMS data 2016.
- 57. Goto Y, Abe T, Sekine S, Sakurada T. Long-term thrombosis after transvenous permanent pacemaker implantation. Pacing Clin Electrophysiol 1998;21:1192–1195.
- 58. Suga C, Hayes DL, Hyberger LK, Lloyd MA. Is there an adverse outcome from abandoned pacing leads? J Interv Card Electrophysiol 2000;4:493–9.
- 59. 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.
- 60. 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.
- 61. Philips post market surveillance. Data on file. 2018.
- 62. 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.
- 63. 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.
- 64. Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.
- 65. Elrod, Jodia. Use of Bridge™ Occlusion Balloon in Lead Extraction: Interview with Dr. Roger Carrillo. EP Lab Digest. November, 2016.

- 66. Data on file at Philips. Lead Extraction Survey, conducted by in2ition for Philips. January 2010.
- 67. 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
- 68. 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.
- 69. Kern M. SCAI Interventional Cardiology Board Review Book. Lippincott Williams & Wilkins 2006; p.165.
- 70. 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.
- 71. 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.
- 72. Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. Circ Arrhythm Electrophysiol. 2016; 9(8)."
- 73. 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.
- 74. Hussein et al. Microbiology of Cardiac Implantable Electronic Device Infections. J Am Coll Cardiol EP 2016;2:498–505 Circ Arrhythm Electrophysiol.
- 75. Chamis AL., et al. Staphylococcus aureus Bacteremia in Patients with Permanent Pacemakers or Implantable Cardioverter-Defibrillators. Circulation. 2001;104:1029-1033. doi:10.1161/hc3401.095097.
- 76. Centers for Medicare & Medicaid Services. Decision Memo for Magnetic Resonance Imaging (MRI) (CAG-00399R4). April 10, 2018. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=289&bc=AAAAAAAAAAAAAAA
- 77. Math is an extrapolation using the following study: Hussein AA, Tarakji KG, Martin DO, Gadre A, Fraser T, Kim A, Brunner MP, Barakat, AF, Saliba WI, Kanj M, Baranowski B, Cantillon D, Niebauer M, Callahan T, Dresing T, Lindsay BD, Gordon S, Wilkoff BL and Wazni OM. Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes with Previously Abandoned Leads. JACC Clin Electrophysiol. -2017;3: 1-9 Use of the data in the paper stating 23% had abandoned hardware and applying that to 3.3 million patients. That equals 759,000. We're using 600,000 to be conservative based on the extrapolation.
- 78. Barakat, Amr F., et al. "Transvenous lead extraction at the time of cardiac implantable electronic device upgrade: Complexity, safety, and outcomes." Heart rhythm 14.12 (2017): 1807-1811.
- 79. 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
- 80. 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
- 81. Peacock Jr, James E., et al. "Attempted salvage of infected cardiovascular implantable electronic devices: Are there clinical factors that predict success?." Pacing and Clinical Electrophysiology 41.5 (2018): 524-531.
- 82. Hot Topics call with Dr. John Piccini September 11, 2017. Philips data on file, 2018.
- 83. Kutalek et al. HRS 2018 presentation: Yikes! The Veg is Bigger than I Thought! Drexel University Experience and Clinical Results. http://education.hrsonline.org/common/media-player. aspx/30/35/2565/21097
- 84. 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.
- 85. Barbanti M, Petronio AS, Capodanno D, et al. Impact of balloon post-dilation on clinical outcomes after transcatheter aortic valve replacement with the self-expanding CoreValve prosthesis. JACC Cardiovasc Interv 2014;7:1014–21. 10.1016/j.jcin.2014.03.009

- Boshi R, Decter DH, Meraj P. Incidence of arrhythmias and impact of permanent pacemaker implantation in hospitalizations with transcatheter aortic valve replacement. Clin Cardiol. 2018;41:640– 645.
- 87. Culler, SD, Cohen, DJ, Brown, PP. Trends in aortic valve replacement procedures between 2009 and 2015: has transcatheter aortic valve replacement made a difference? Ann Thorac Surg 2018; 105: 1137–1143.
- 88. Elayi CS, Darrat Y, Suffredini JM, et al. Sex differences in complications of catheter ablation for atrial fibrillation: Results on 85,977 patients. J Intervent Cardiac Electrophysiol. 2018:1-7.
- 89. Khan MN, et al. Pulmonary-vein isolation for atrial fibrillation in patients with HF. N Engl J Med 2008;359(17):1778–1785.
- 90. Jones DG, et al. A randomized trial to assess catheter ablation versus rate control in the management of persistent atrial fibrillation in HF. J Am Coll Cardiol 2013; 61(18):1894–1903.
- 91. Hummel J, et al. Phased RF ablation in persistent atrial fibrillation. Heart Rhythm 2014;11(2):202–209.
- 92. Lakkireddy, D, Rao, A, Theriot, P. et al. Contemporary Management of Cardiac Implantable Electronic Device Infection: The American College of Cardiology COGNITO Survey. JACC Adv. 2024 Feb, 3 (2) . https://doi.org/10.1016/j.jacadv.2023.100773
- 93. Pokorney SD, Zepel L, Greiner MA, et al. Lead Extraction and Mortality Among Patients With Cardiac Implanted Electronic Device Infection. JAMA Cardiol. Published online October 18, 2023. doi:10.1001/jamacardio.2023.3379