

References

S-267

1. Haight PJ, Stewart RE, Saarel EV, et al. Lateral thoracotomy for epicardial pacemaker placement in patients with congenital heart disease. *Interact Cardiovasc Thorac Surg.* 2018;26(5):845-851.
2. Harake DE, Shannon KM, Aboulhosn JA, Moore JP. Transvenous pacemaker implantation after the bidirectional Glenn operation for patients with complex congenital disease. *J Cardiovasc Electrophysiol.* 2018;29(3):497-503.
3. FDA Executive Summary Memorandum. General Issues: Leadless pacemaker devices prepared for the February 18, 2016 meeting of the Circulatory System Devices Advisory Panel; Gaithersburg, MD. 2016; Accessed February 6, 2020
4. Statement of the American Heart Association to the Food and Drug Administration Circulatory System Devices Panel February 18, 2016: Leadless Cardiac Pacemaker Devices. 2016; Accessed February 6, 2020
5. Reddy VY, Miller MA, Knops RE, et al. Retrieval of the leadless cardiac pacemaker: A multicenter experience. *Circ Arrhythm Electrophysiol.* 2016;9(12):
6. Lakkireddy D, Knops R, Atwater B. et al. A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker. *Heart Rhythm.* 2017;14(12):1756-1763.
7. Sperzel J, Defaye P, Delnoy PP, et al. Primary safety results from the LEADLESS observational study. *Europace.* 2018;20(9):1491-1497.
8. Circulatory System Devices Panel Meeting: Leadless Pacemakers. FDA Presentation. 2016; Accessed February 6, 2020
9. Tjong FVY, Beurskens NEG, de Groot JR, et al. Health-related quality of life impact of a transcatheter pacing system. *J Cardiovasc Electrophysiol.* 2018;29(12):1697-1704.
10. Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. *N Engl J Med.* 2016;374(6):533-41.

11. Lloyd M, Reynolds D, Sheldon T, et al. Rate adaptive pacing in an intracardiac pacemaker. *Heart Rhythm*. 2017;14(2):200-205.
12. Summary of Safety and Effectiveness Data (SSED): Micra Transcatheter Pacing System (PMS P150033). 2016. Accessed February 6, 2020.
13. Centers for Devices and Radiological Health Medical Devices Advisory Committee. 2016. Accessed February 6, 2020.
14. Meet Micra (brochure). n.d. Accessed February 6, 2020
15. Grubman E, Ritter P, Ellis CR, et al. To retrieve, or not to retrieve: System revisions with Micra transcatheter pacemaker. *Heart Rhythm*. 2017;14(12):1801-1806.
16. Roberts PR, Clementy N, Al Samadi F, et al. A leadless pacemaker in the real-world setting: The Micra transcatheter pacing system post-approval registry. *Heart Rhythm*. 2017;14(9):1375-1379.
17. El-Chami MF, Al-Samadi F, Clementy N, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart Rhythm*. 2018;15(12):1800-1807.
18. Duray GZ, Ritter P, El-Chami M, et al. Long-term performance of a transcatheter pacing system 12-month results from the Micra transcatheter pacing study. *Heart Rhythm*. 2017;14(5):702-709.
19. El-Chami MF, Johansen JB, Zaidi A, et al. Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra post-approval registry. *J Cardiovasc Electrophysiol*. 2019;30(4):569–574.
20. Decision Memo for Leadless Pacemakers (CAG-00448N). 2017. Accessed February 6, 2020.
21. Tjong FVY, Knops RE, Neuzil P, et al. Midterm safety and performance of a leadless cardiac pacemaker: 3-year follow-up to the LEADLESS trial (Nanostim safety and performance trial for a leadless cardiac pacemaker system). *Circ*. 2018;137:633-635.

22. Hayes, Inc. Hayes Health Technology Assessment. *Micra transcatheter pacing system (Medtronic Inc.) for single-chamber pacemaker indications*. Lansdale, PA: Hayes, Inc.; 12/31/2019.
23. El-Chami MF, Soejima K, Piccini JP, et al. Incidence and outcomes of systemic infections in patients with leadless pacemakers: Data from the Micra IDE study. *Pacing Clin Electrophysiol*. 2019;42(8):1105-1110.
24. Asirvatham RS, Vaidya VR, Thome TM, et al. Nanostim leadless pacemaker retrieval and simultaneous Micra leadless pacemaker replacement: A single-center experience. *J Interv Card Electrophysiol*. 2020;57(1):125-131.