

CRHF CITATIONS

CRHF/CRM IMPLANTABLES: COBALT CROME ICD & CRT-D

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CRHF/CRM IMPLANTABLES: MYCARELINK HEART™ MOBILE APP

- Varma N. Remote monitoring of patients with CIEDs following the updated recommendations — Easing or adding to postimplant responsibilities? Cont. Cardiol Educ. December 2016;2(4):198-204.
- Fowles JB, Terry P, Xi M, Hibbard J, Bloom CT, Harvey L. Measuring self-management of patients' and employees' health: further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. Patient Educ Couns. October 2009;77(1):116-12
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TAVR – EVOLUT™ PRO, PRO+ TRANSCATHETER AORTIC VALVE REPLACEMENT SYSTEM

1. Gleason TG, Reardon MJ, Popma JJ, et al. 5-year Outcomes from the Randomized CoreValve US Pivotal HighRisk Trial: Final Results, J AM Coll Cardiol. September 2015;72(13 Supp.).
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3. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. May 2, 2019;380(18):1706-1715.
4. Testa L, Fiorina C, Giannini C, et al. Valve performance and echocardiographic data throughout 8 years follow up after TAVR. Presented at EuroPCR 2019; Paris, France.
5. Ring ME, Jin R, Parrish R, et al. Comparison of Echocardiographic Outcomes Following Trans Catheter Aortic Valve Replacement with Edwards S3 23 mm versus Medtronic Evolut 26 mm Valves. Poster presented at ACC 2020 Virtual.
6. Rashid HN, Gooley RP, Nerlekar N, et al. Bioprosthetic aortic valve leaflet thrombosis detected by multidetector computed tomography is associated with adverse cerebrovascular events: a meta-analysis of observational studies. EuroIntervention. February 2, 2018;13(15):e1748-e1755.
7. Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA. 2014;312:162-170.
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10. Data from STS/ACC TVT Registry. Data on file.
11. IFU, Study Enrollment Criteria

CITATIONS

PELVIC HEALTH–INTERSTIM™ SYSTEMS

1. In the U.S. alone, 37.5 million people are living with overactive bladder.

- Stewart WF, et al. Prevalence and burden of overactive bladder in the United States. World J Urol. 2003 May;20(6):327-336.
- United Nations, Department of Economic and Social Affairs, Population Division (2011). World Population Prospects: The 2010 Revision, CD-ROM Edition.

2. Of those, 4.5 million are indicated for a third line therapy and only 5% pursue treatment.

- Medtronic data on file. (See attached slide: "OAB severely under-treated")

3. We have taken advances in battery technology and microelectronics to develop a rechargeable system that is smaller, faster, and better than the Axonics' system.

- Add fair balance statement: The most common adverse events experienced during clinical studies include pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms

4. It's faster because our battery has the fastest recharge speed – from zero to 100% in less than an hour.*

- *Based on appropriate recharger placement

5. It's better because our battery has zero fade*

- *Under standard patient therapy settings

6. And, let's not forget ... we have a new basic evaluation lead. It's designed to move less than the trial lead by Axonics, providing patients with a BETTER chance to move on to an implant.

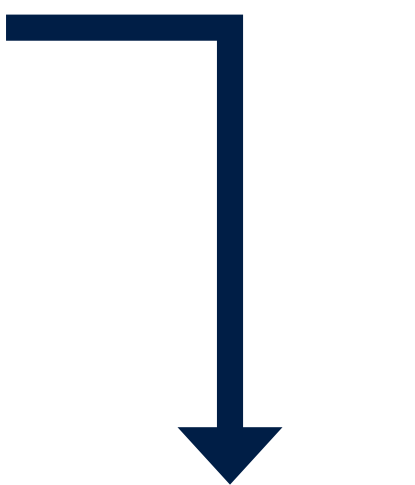
- Add fair balance statement: Complications can occur with the evaluation, including tissue damage, infection, and technical problems with the device. Patients should be instructed on operating the programmer and given precautions related to the evaluation.
- For the Medtronic vs Axonics lead video, the reference is: Medtronic data on file.

OVERACTIVE BLADDER IS SEVERELY UNDER-TREATED

37.5M
Total US OAB
Population

US data for illustration -
drop-out rates are similar
globally

- More than **40%** of adults with OAB don't ask for help ⁷
- Women experience OAB symptoms for **6.5** years before being diagnosed. ⁷
- Fewer than **10%** of urologists specialize in OAB. ⁸



22M
Non-Responders to
1st Line Therapy

4. "Real-world patterns of care for the overactive bladder syndrome in the U.S.", Goldman et al., Urology 2016;87:64-9.

5. Long-term patterns of use and treatment failure with anticholinergic agents for OAB", Chancellor, et al., Clinical Gherapeutics. 2013;35(11)

17.5M
Non-Adherent to
2nd Line
Medications

6. "Persistence and adherence in the treatment of overactive bladder syndrome with anticholinergic therapy: a systematic review of the literature", Sexton, et al, Int'l J Clin Pract, May 2011, 65, 5, 567-585

4.5M
Indicated for
3rd Line

~225k
currently treated
in 3rd line

OAB population is significantly under-treated with high fallout from continuum

- Medications have harsh side effects and limited efficacy
- Patients reluctant to move to third line therapies (*invasiveness, side-effects & inconvenience*)
- Most urologists unwilling to offer third line therapies (*difficult to integrate in practice*)

7. Leede Research. "Views on OAB: A Study for the National Association of Continence" Dec 16, 2015
8. AUA Member Census 2018 <https://www.auanet.org/research/research-resources/aua-census/census-results>

CITATIONS

NEUROMODULATION

- NEUROMODULATION – DTM Segment

- Market Size data: “100M Americans suffer from chronic pain, >\$500B Annual Cost”

- ¹ Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education, and research. Washington DC, United States: The National Academies Press; 2011

- Market Size data: “Chronic pain is costlier than diabetes, heart disease and cancer”

- ² Gaskin DJ, Richard P. The economic costs of pain in the United States. J Pain. 2012;13(8):715-724

- DTM 3 month data publication:

- Fishman M, Cordner H, Justiz R et al. Randomized Controlled Clinical Trial to Study the Effects of DTM-SCS in Treating Intractable Chronic Low Back Pain: 3 Month Results. Presentation at NANS 2020, Las Vegas, Nevada

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RENAL DENERVATION – SYMPPLICITY SPYRAL™ MULTI-ELECTRODE RENAL DENERVATION

1. World Health Organization. Hypertension fact sheet. 13 September 2019. <https://www.who.int/news-room/fact-sheets/detail/hypertension> Accessed January 24, 2020.
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5. Medtronic Renal Denervation Research Synthesis. June 2019.
6. Kandzari DE, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomized trial. *Lancet*. 2018 Jun 9;391(10137):2346-2355.
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CAS: ARCTIC FRONT™ FAMILY OF CARDIAC CRYOABLATION CATHETERS

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MICRA/EV-ICD: MICRA AV & VR TPS PORTFOLIO

- 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*. December 2018;15(12):1800-1807.
- Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. February 11, 2016;374(6):533-541.
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