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


Ziegler PD, et al. Accuracy of Atrial Fibrillation Detection in Implantable Pacemakers. Presented at HRS 2013 (PO02-08); Denver, CO.


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


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.

CRHF CITATIONS
CRHF/CRM IMPLANTABLES: LINQ II ICM CITATIONS


CRHF CITATIONS
CRHF/CRM IMPLANTABLES: MYCARELINK HEART™ MOBILE APP

CITATIONS

TAVR – EVOLUT™ PRO, PRO+ TRANSCATHETER AORTIC VALVE REPLACEMENT SYSTEM


11. IFU, Study Enrollment Criteria
1. In the U.S. alone, 37.5 million people are living with overactive bladder.

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

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

22M
Non-Responders to 1st Line Therapy

- 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)

17.5M
Non-Adherent to 2nd Line Medications

2. The Prevalence of Lower Urinary Tract Symptoms (LUTS) and Overactive Bladder (OAB) by Racial/Ethnic Group and Age: Results From OAB-POLL.
4. Real-world patterns of care for the overactive bladder syndrome in the U.S.
5. Long-term patterns of use and treatment failure with anticholinergic agents for OAB.

~225k currently treated in 3rd line

4.5M
Indicated for 3rd Line

8. AUA Member Census 2018 https://www.auanet.org/research/research-resources/aua-census/census-results
NEUROMODULATION – DTM Segment

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


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


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
CITATIONS

RENNAL DENERVATION – SYMPLICITY SPYRAL™ MULTI-ELECTRODE RENAL DENERVATION


CAS CITATIONS

CAS: ARCTIC FRONT™ FAMILY OF CARDIAC CRYOABLATION CATHETERS


CAS CITATIONS
CAS: ARCTIC FRONT™ FAMILY OF CARDIAC CRYOABLATION CATHETERS


- Su WW, et al. Cryoballoon Ablation of Pulmonary Veins for Persistent Atrial Fibrillation: Results From the Multicenter STOP Persistent AF Trial. *Heart Rhythm*. Published online June 23, 2020.
CRHF CITATIONS
MICRA/EV-ICD: MICRA AV & VR TPS PORTFOLIO


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


