# New CIED Technologies Not Avaliable in Korea

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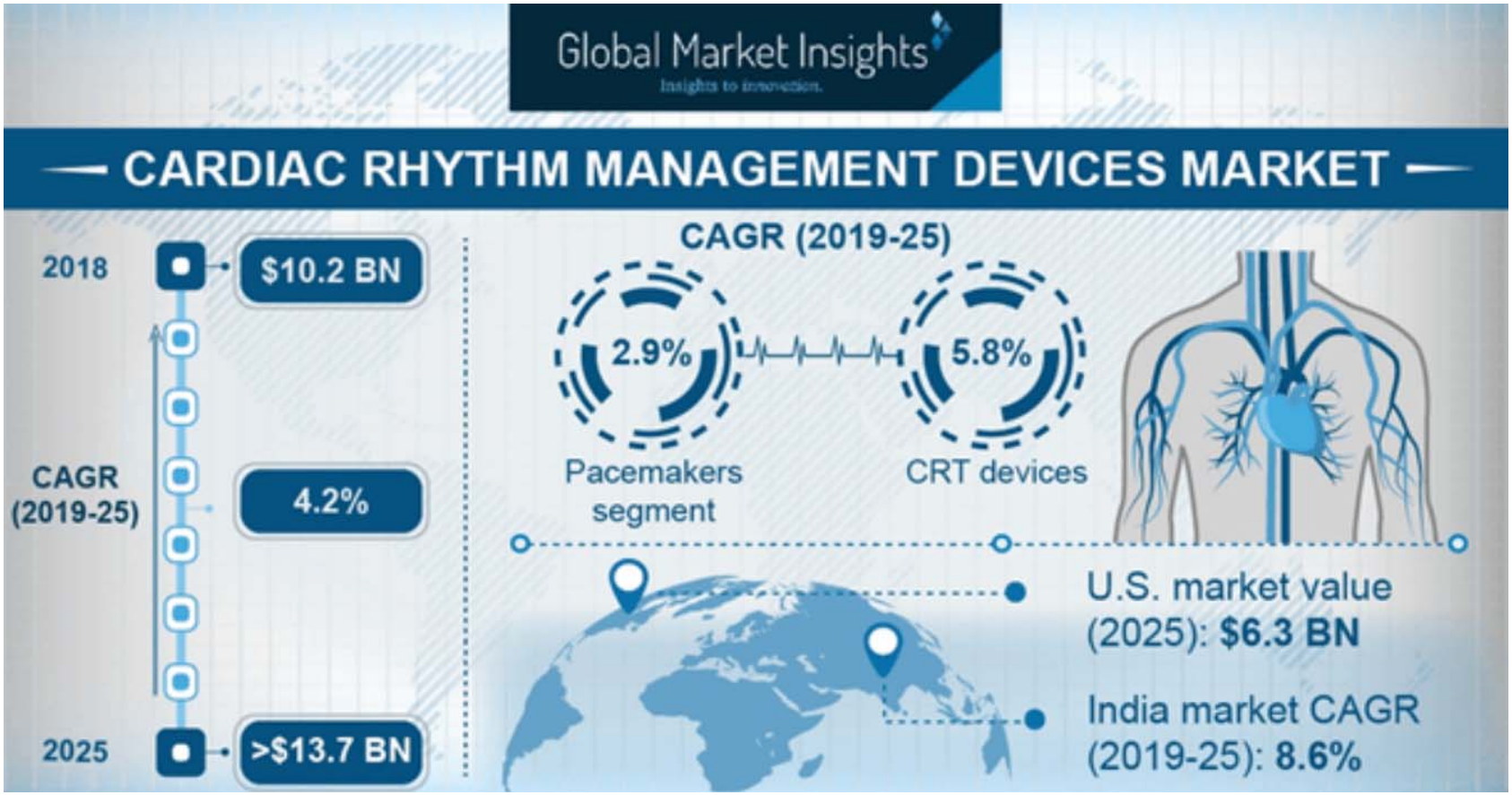
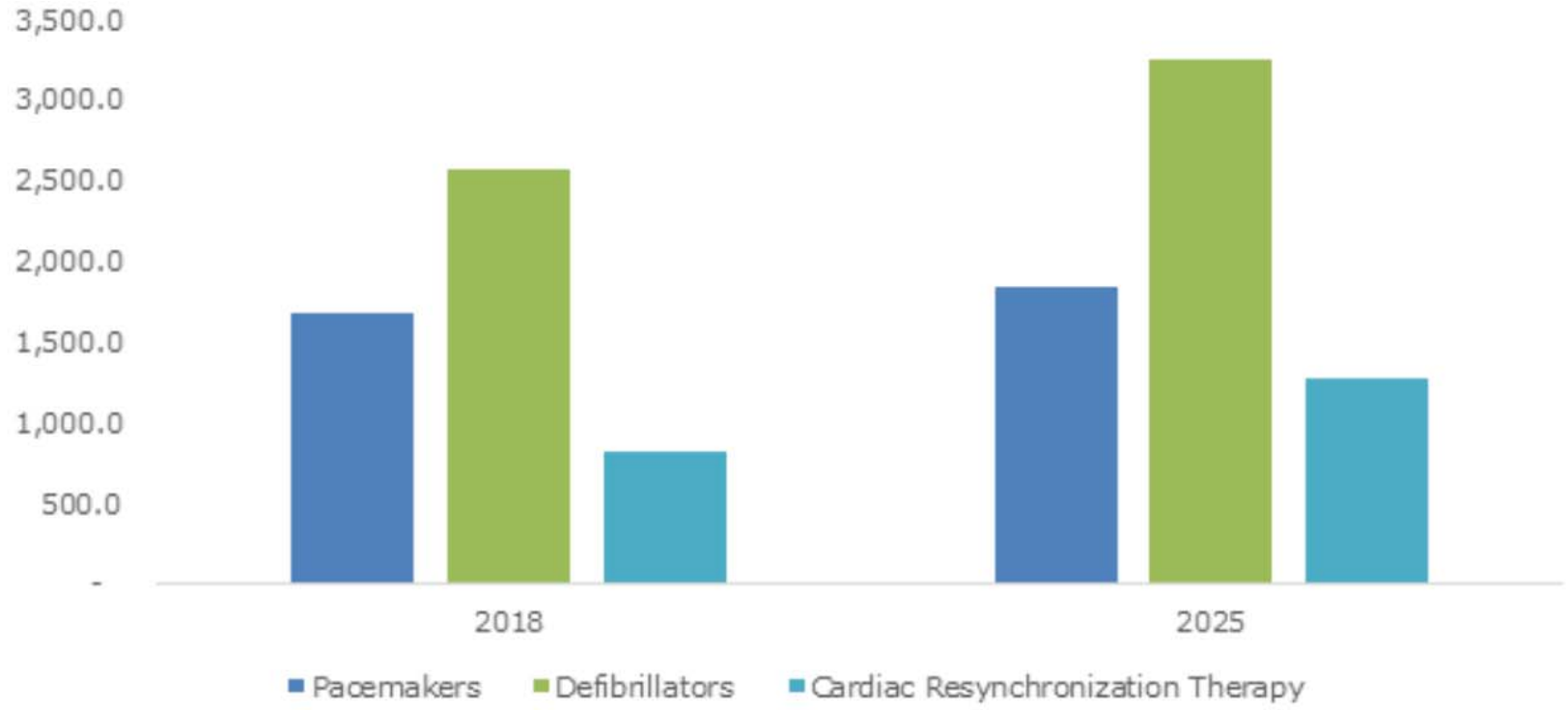
# Cardiac Rhythm Management Devices Market




Compounded Annual Growth Rate

# U.S. cardiac rhythm management devices market, by product, 2018 & 2025 (USD Million)



# New ICD Technologies

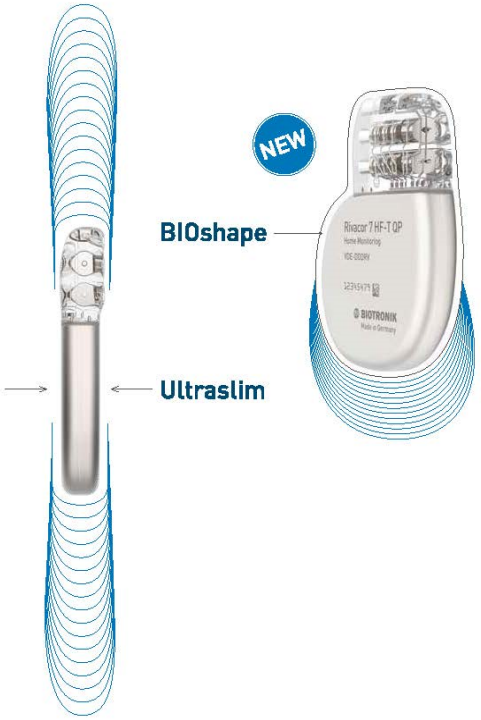
- The biggest trends in ICDs : **smaller devices**, **simplified implantation**, **reducing or eliminating leads implanted in the veins or the heart**, and a **movement toward MRI-conditional labeling**.

New hybrid ICDs feature increased longevity, smooth BIOshape and simplified DF4 header configuration

When implanted with Biotronik's Plexa ProMRI S DX lead,

- the **hybrid ICD Acticor systems offer dual-chamber diagnostics** without the need for an atrial lead.
- Importantly, all three Acticor DX devices feature a new DF4 header configuration with **a penta-polar electrode lead cable design** that simplifies the implant procedure for physicians.
- Acticor is **approved for use in full-body, 3.0T MRI scans**.
- The new devices measure **10 mm thin**, with a smooth, rounded shape that eases implantation and increases patient comfort.
- The devices have **improved battery longevity of nearly 14 years** for Acticor DX, and 11 years for both Rivacor CRT and Acticor CRT-DX.

# Biotronik Launches Acticor and Rivacor ICD and CRT-D Devices in Europe

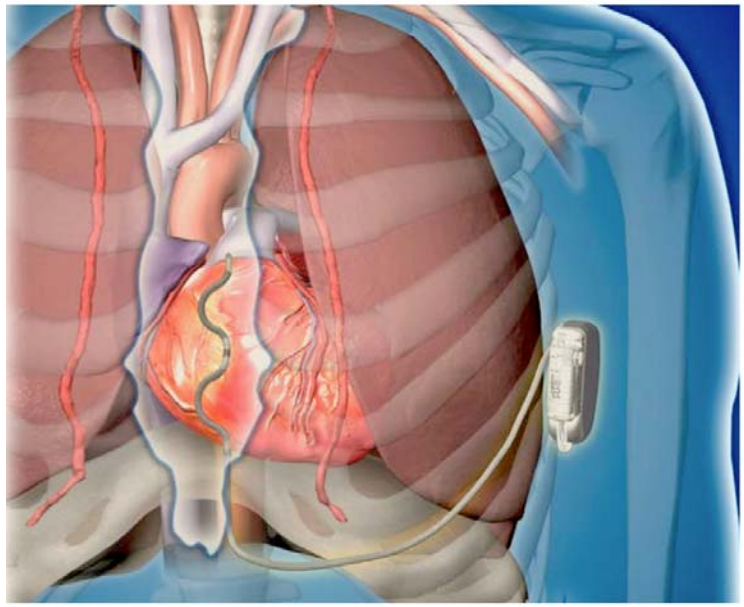



- **Device families feature ultraslim BIOshape as well as extended battery life and warranty**

- Devices in the Acticor and Rivacor families are **only 10 mm slim**, with a smooth and elliptical BIOshape that facilitates the insertion procedure.
- Besides their body-friendly shape, Acticor and Rivacor devices feature an extended battery life, **with up to 15 years for ICDs3 and nine years for CRT-Ds4**

- **With Biotronik Home Monitoring**, cardiovascular data from an Acticor or Rivacor device can be **transmitted to the physician on a daily** basis with programmable alerts about relevant changes in patient health and device status.

# Advancements in Subcutaneous ICD Technology



Medtronic's investigational Extravascular (EV) ICD system

- The FDA cleared the first subcutaneous ICD a few years ago, Boston Scientific's Emblem S-ICD.
- Medtronic is now developing a **subcutaneous ICD** which it called **the Extravascular (EV) ICD system**.

**May 13, 2019 – A first-in-human pilot study of Medtronic's investigational Extravascular (EV) ICD system** showed it can be implanted with no major complications, **and can sense, pace and defibrillate the heart.** Results from the pilot study were presented during a late-breaking session at Heart Rhythm 2019, the Heart Rhythm Society's 40th Annual Scientific Sessions.

- The device uses a lead is placed outside of the heart and veins **to deliver lifesaving defibrillation and anti-tachycardia pacing therapy in one system**, **with a device the same size(33 cc) as traditional**, transvenous ICDs.

# The First-in-Human Chronic Implant Experience of the Substernal Extravascular ICD

**Enrollment**

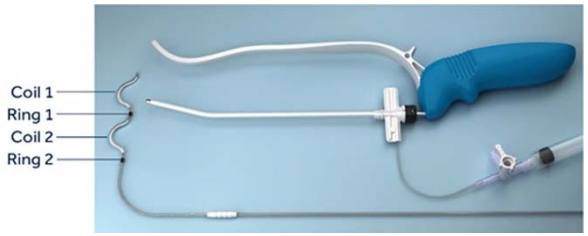
26 patients with Class I or IIa indication

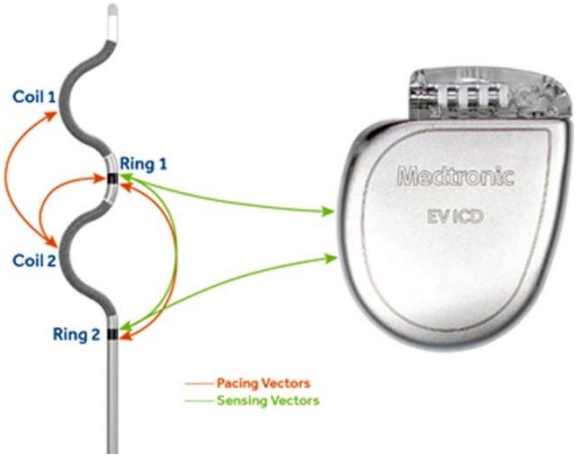
**Implant Attempted**

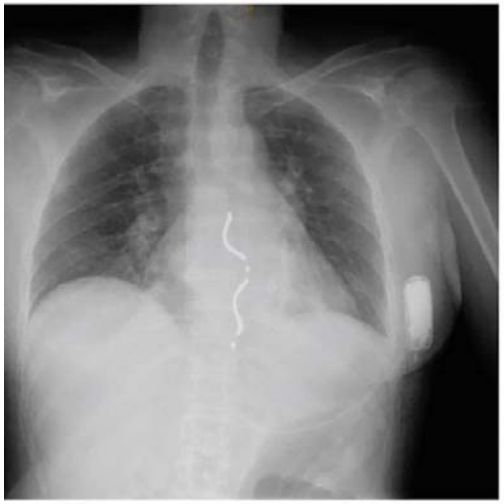
21 patients (81% male; ages 22-77 years)

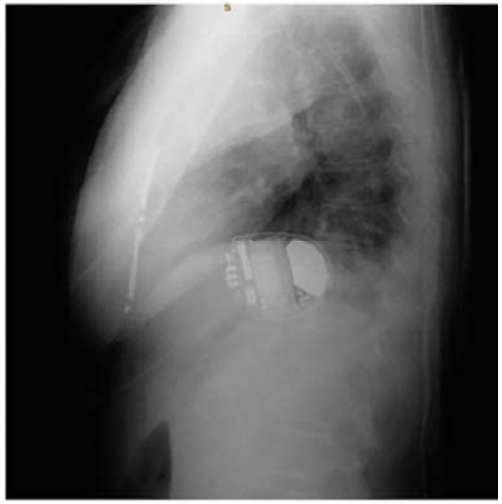
**Actue Implant Testing**

20 patients





**Defibrillation**

90% successful with ≥ 10 J safety margin

Median energy for defibrillation: 15 J

**Pacing**

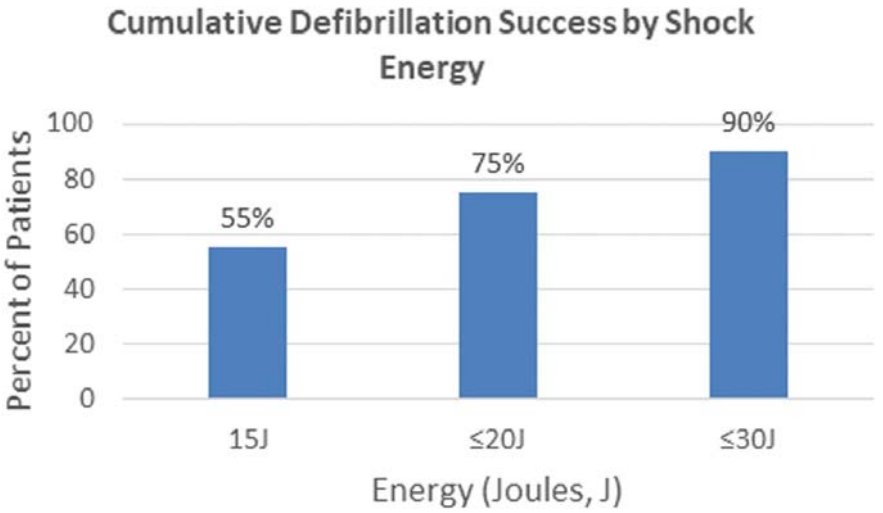
5.4 ± 2.2 V mean pacing threshold (acute)

95% of patients with successful pacing capture at ≤ 10 volts

**Sensing**

3.4 ± 2.0 mV mean R-wave amplitude

Successfully detected VF with ≥ 0.3 mV sensitivity in all patients



### WRAP-IT: Antibacterial Envelope to Prevent Cardiac Implantable Device Infection

multicenter, randomized, controlled, prospective, single-blind

AMERICAN COLLEGE of CARDIOLOGY

Objective: To assess the safety and efficacy of an absorbable, antibiotic-eluting envelope in reducing the incidence of infection associated with cardiac implantable electronic devices (CIED) implantations.

Patients with CIEDs → Absorbable, antibiotic eluting envelope → Clinical outcomes

**6,983** patients undergoing CIED generator replacement or a system upgrade with or without new leads, those undergoing CIED pocket or lead revision, and those undergoing an initial CRT-D procedure.

| CIED envelope (n=3,495) | Control group (n=3,488) |
|---|---|

**Primary Outcome**

| 0.7% | Infection, long-term antibiotic therapy with infection recurrence, or death, within 12 months | 1.2% |
|---|---|---|

HR 0.60; 95% CI, 0.36 to 0.98; P=0.04

**Secondary Outcome**

| 6.0% | Procedure-related or system-related complications within 12 months | 6.9% |
|---|---|---|

HR 0.87; 95% CI, 0.72 to 1.06; P<0.001 for noninferiority

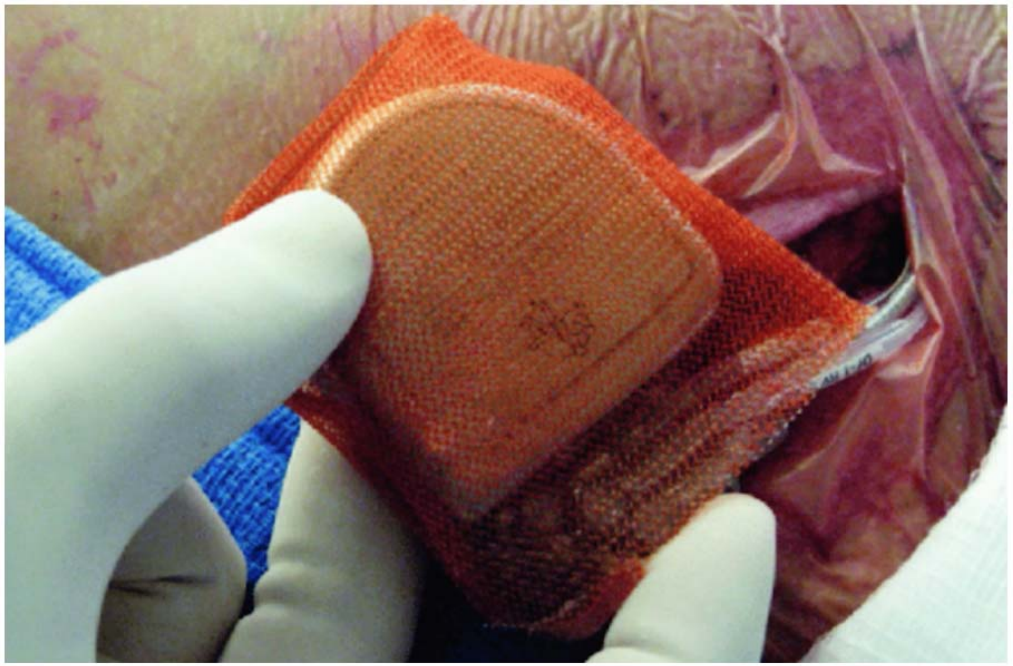
| 32 | Major CIED-related infections (n) | 51 |
|---|---|---|

HR 0.63; 95% CI, 0.40 to 0.98

Adjunctive use of an antibacterial envelope significantly lowers incidence of major CIED infections than standard-of-care infection prevention strategies alone, without a higher incidence of complications.

Tarakji KG, et al. NEJM 2019 Mar 17

# Mitigating ICD Infection Risks

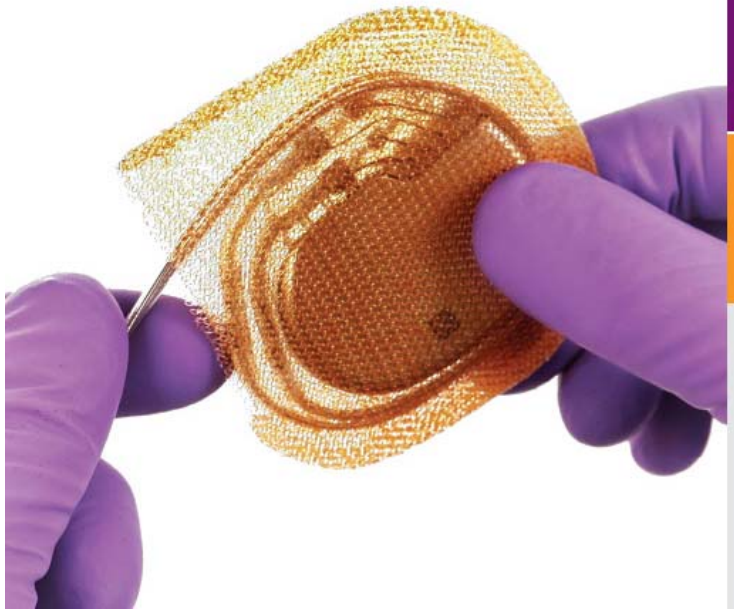


## The TYRX Absorbable Antibacterial Envelope

- A single-use device, stabilizes CIED
- **Absorbable multifilament knitted mesh**
- **Polymer-controlled antibiotic elution**
- Locally delivered minocycline and rifampin **sustained for 7 days**
- **Fully absorbed in about 9 weeks**

# WRAP-IT : Largest global cardiac device trial

**6,983 patients | 181 centers | 25 countries**



**Patients undergoing cardiac implantable electronic device (CIED) procedures randomized 1:1 to:**

| Standard-of-care infection prevention | Standard of care + TYRX™ antibiotic-eluting envelope to surround CIED |
|---|---|

**After 12 months…**

- 40% relative reduction in major CIED infections in envelope group
- Comparable rates of complications in envelope and no-envelope groups

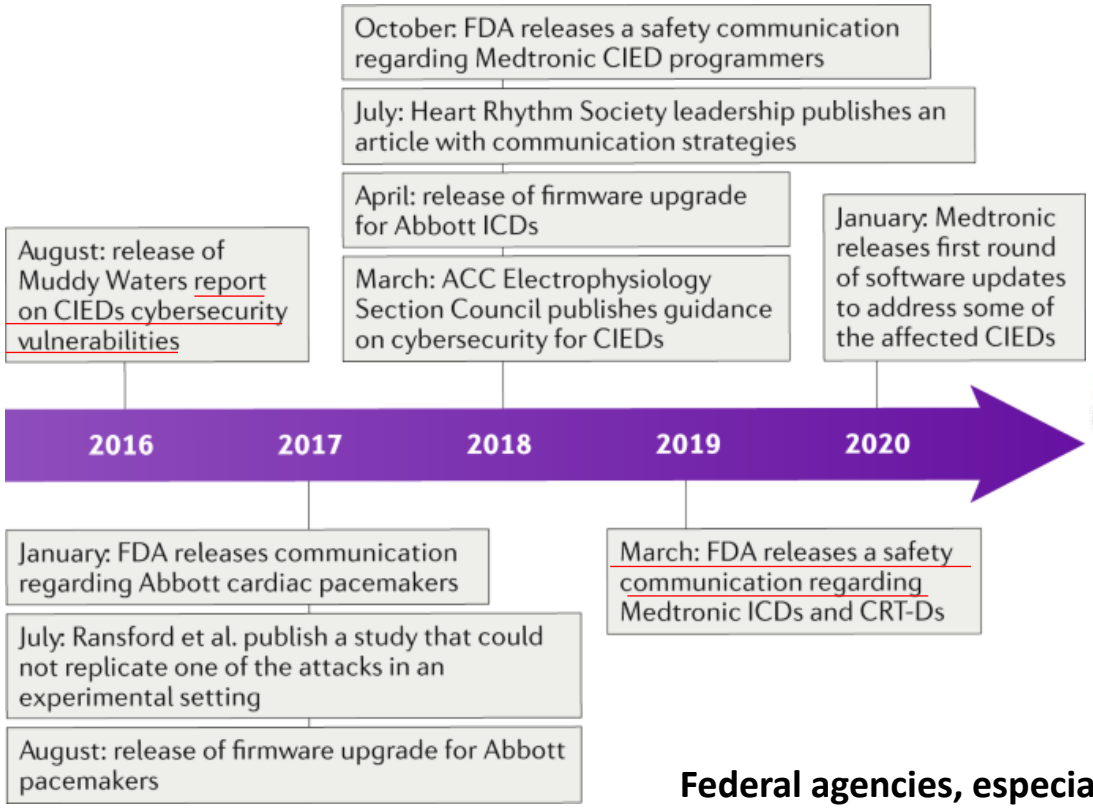
- **With > 1 million people worldwide receiving CIEDs annually**, the antibiotic envelope is an effective strategy **for reducing risk of devastating CIED infections**.

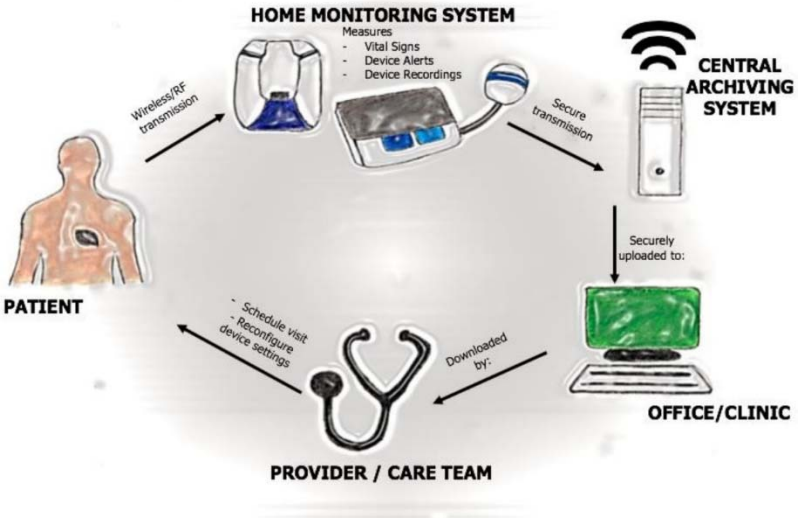
# FDA Issues Safety Alert on Cybersecurity Vulnerabilities of Medtronic ICD, CRT Devices


**ICD Cybersecurity Concerns**

- The alert concerns Medtronic's ICDs and CRT-Ds, devices that provide pacing **for slow heart rhythms and electrical shocks or pacing to stop dangerously fast heart rhythms**.
- Concerto CRT-D and Virtuoso ICD implantable cardiac devices are among several Medtronic electrophysiology devices included **in a safety alert because of their lack of cybersecurity measures to avoid hacking**, according to the FDA

**In March 2019, the FDA issued a safety communication to alert** healthcare providers and patients **about the cybersecurity vulnerabilities** identified in a wireless telemetry technology used for communication between Medtronic's ICDs, CRT-Ds, clinic programmers and home monitors.




**Federal agencies, especially the FDA, should play a critical role in acting as the gatekeeper of such discussions and should monitor companies for prompt redressal of these security concerns**. Involving physicians in the discussion will help foster a better understanding on their part of such security issues, which will translate into better patient communication and increase adherence **to firmware and other security updates put forth** by manufacturers.

# FDA Clears Abbott Gallant ICD and CRT With Bluetooth Connectivity and Continuous Remote Monitoring


- **Next-generation Gallant implantable cardioverter defibrillator family of devices offers Bluetooth capability for a more meaningful connection between patients and their doctors**

- **July 13, 2020 - The U.S. FDA has approved Abbott's next-generation Gallant ICD and CRT-D devices.**
- The devices offer **good battery longevity** and **MRI compatibility.**
- In addition, **the new devices offer Bluetooth technology and a new patient smartphone app for improved remote monitoring**, allowing for increased patient/physician engagement and streamlined communications.

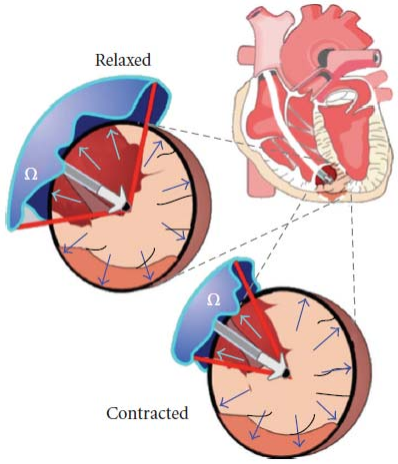
# Severe Fainting Can Be Treated with Cardiac Pacing Supported by Closed Loop Stimulation

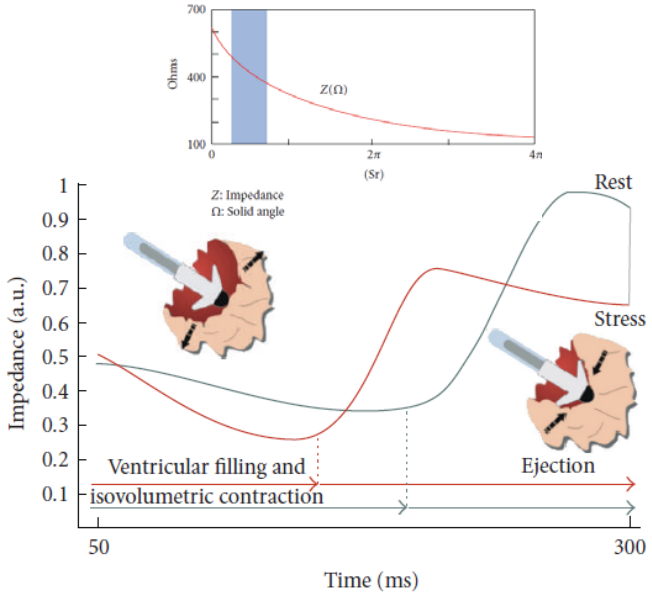

**September 8, 2020 - A new study presented at the 2020 European Society of Cardiology (ESC)** Congress shows that **Biotronik's closed loop stimulation (CLS)** technology helps reduce unexplained fainting in patients with recurrent episodes due to skipped heartbeats.

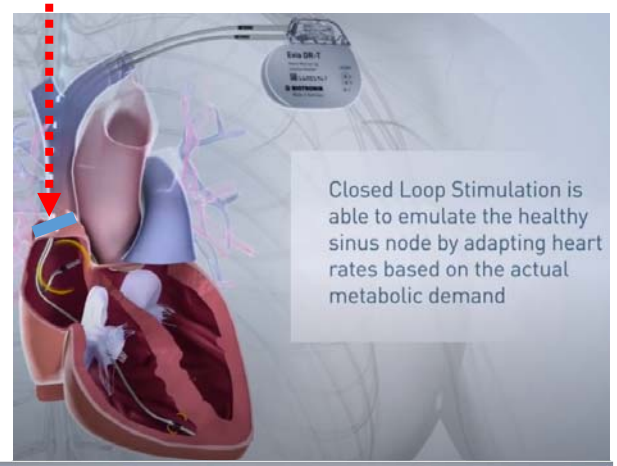
- For more than 20 years, patients with pacemakers or defibrillators have benefitted from **the Closed Loop Stimulation (CLS)** sensor, offered only by BIOTRONIK.
- **This intelligent cardiac sensor** can be activated by clinicians to help patients live **a normal life during physical and emotional situations.**
- CLS is available in IPGs and more recently in ICDs as well as CRTs.

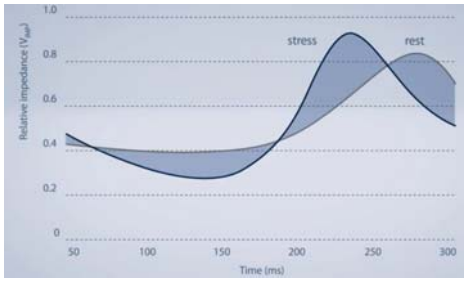
# A new era of physiological rate regulation

## The CLS sensor measures the contraction dynamics of the myocardium and translates them into proper heart rate adaptation, thus delivering proven physiological therapy

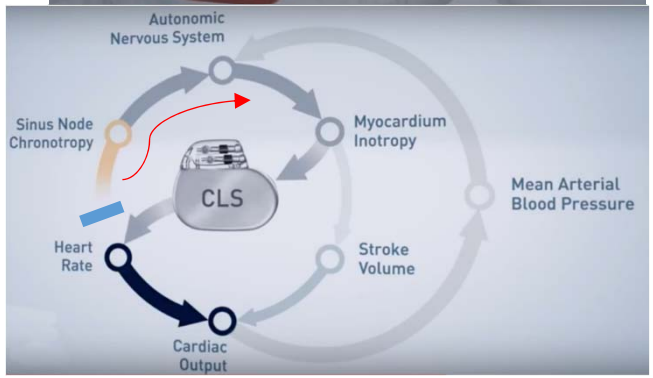



- **Adjusting pacing rates** delivered by the pacemaker based on the differences between the impedance curves
- Evaluating real-time changes **between impedance curve at rest and under physical and emotional stress**

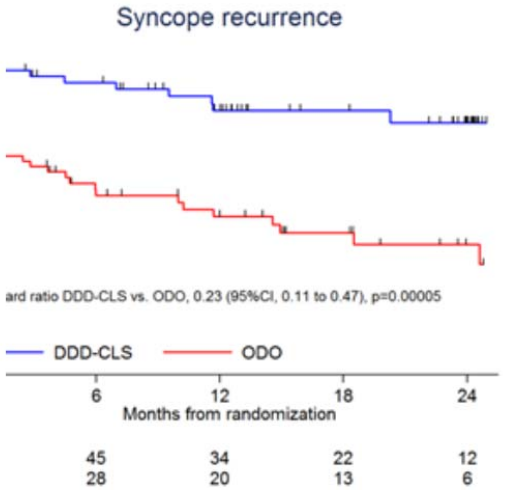





Article *in* Cardiology Research and Practice · March 2011 DOI: 10.4061/2011/925653 · Source: PubMed

## Why would your patients need a comprehensive physiologic sensor, like CLS?

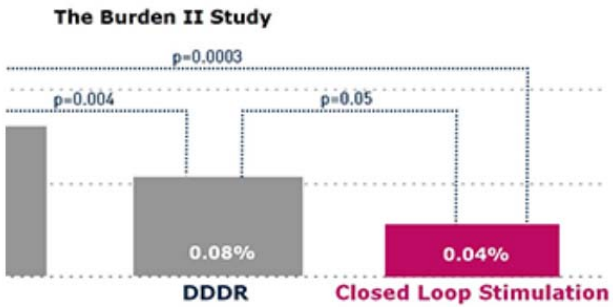
- **CLS can improve the quality of life of Chronotropic Incompetence(CI) patients as well as those suffering from vasovagal syncope.**
- **Thanks to CLS rate adaptation, pacemaker patients are also supported during emotional stress.**




## Which patients can benefit from CLS?

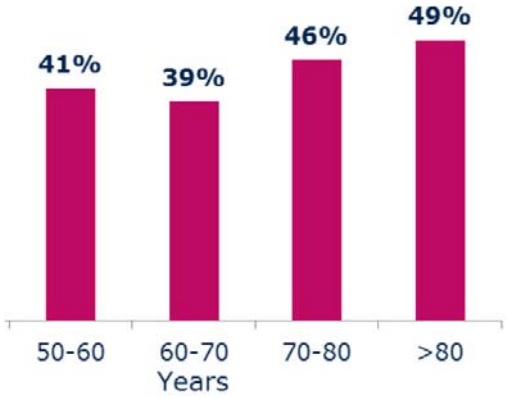
- CLS is beneficial for **patients with CI and VS as well as patients with AF.**

: For patients suffering from CI, the PROVIDE study showed that 75% of patients programmed with DDD-CLS experienced significant improvement compared to only 22% of patients programmed in DDDR



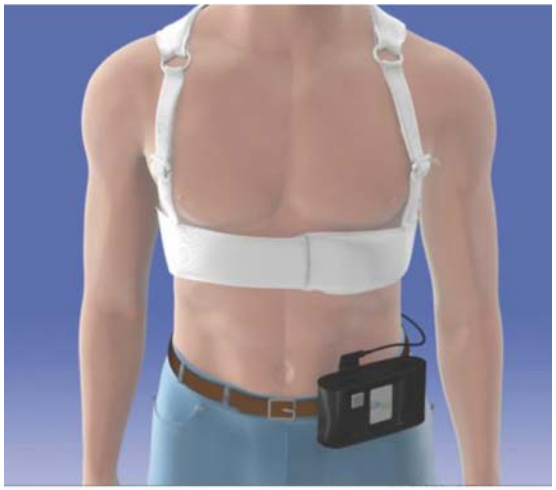

- Multicenter BIOSync CLS study demonstrated a **reduction of syncope recurrence rate after two years by 77% with CLS pacing versus placebo**.
- **CLS has also been shown to reduce the burden for atrial tachycardia patients compared with other modes.**

: **The BURDEN study I** demonstrated that patients with CLS sensor had on average 0.11 min/day of AT burden while with DDDR mode patients had on average 10.9 min/day of AT burden.[4] Subsequently, **the BURDEN Study II** equally showed a lower AT burden with the CLS sensor

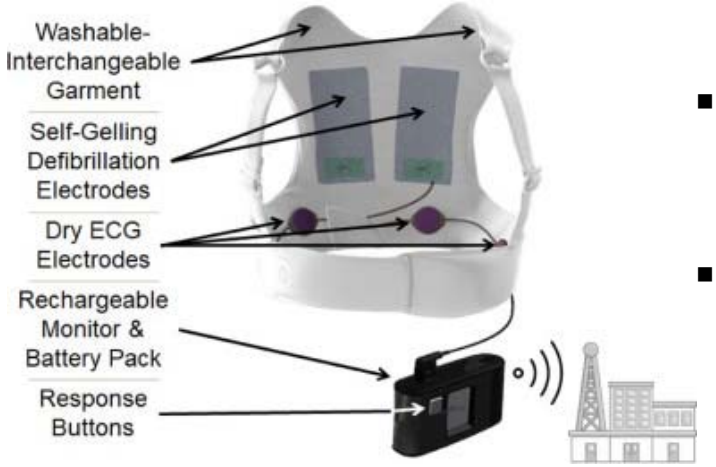



- About **40% of your pacemaker patients between 70 and 80 years old suffer from chronotropic incompetence.**

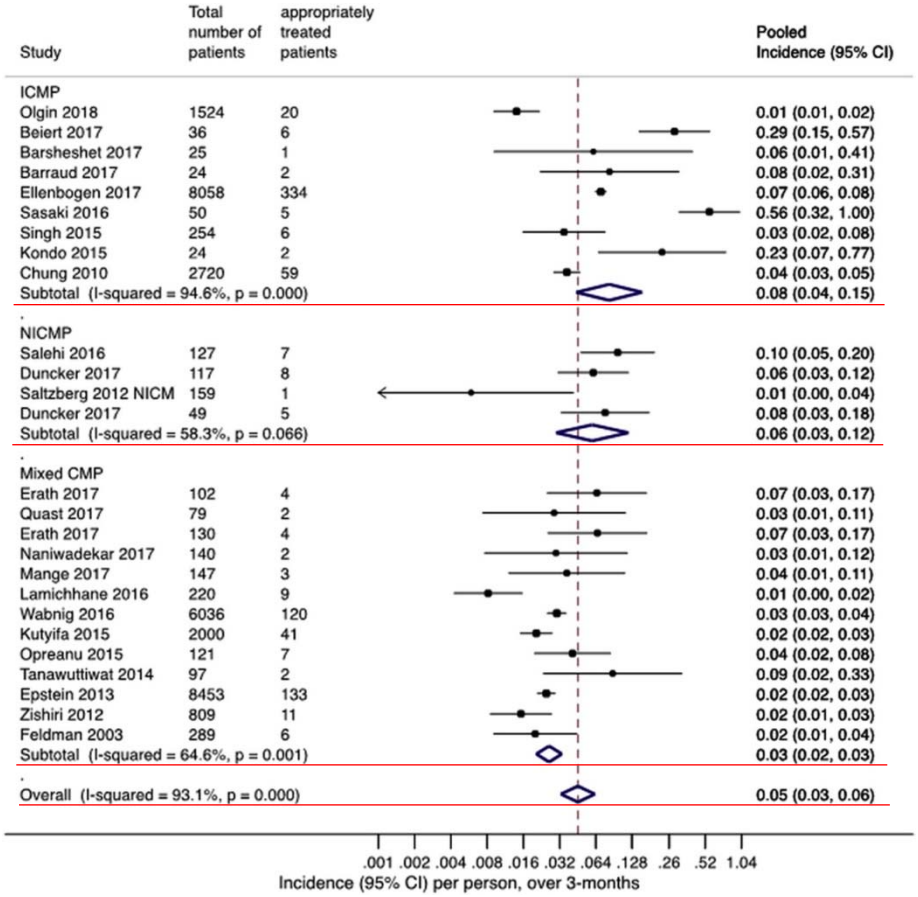
# Wearable Defibrillator Offers a Bridge Therapy



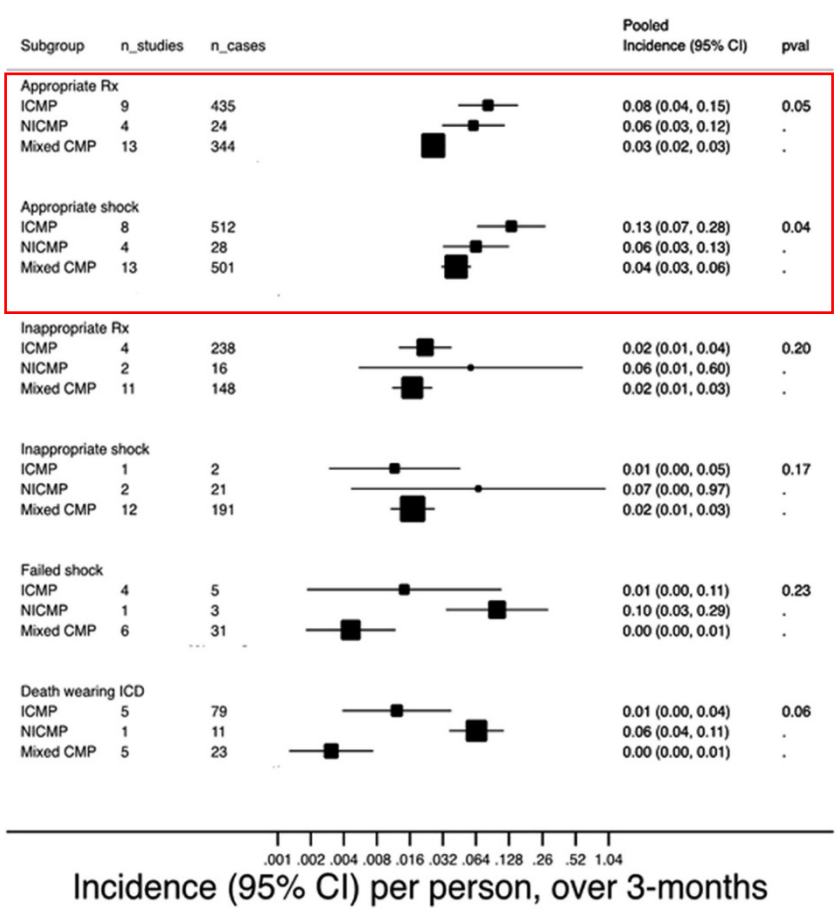
Zoll LifeVest buys time for assessment




- **For patients at risk for sudden cardiac arrest (SCA)** who are being evaluated for a permanent ICD, Zoll offers the LifeVest wearable defibrillator (WCD) **as a temporary solution**.
- It allows **a physician more time to assess a patient's long-term arrhythmic risk and make appropriate plans.**
- The LifeVest continuously monitors the patient's heart and, if a rapid life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.
- If a rapid life-threatening heart rhythm (VT or VF) is detected, the device **alerts bystanders and delivers a treatment shock** to restore normal heart rhythm.
- The entire event, from detecting a life-threatening arrhythmia to automatically delivering a treatment shock, **usually occurs in less than a minute.**
- including following a heart attack and **before or after bypass surgery or stent placement**, as well as for those with cardiomyopathy or CHF that places them at particular risk.

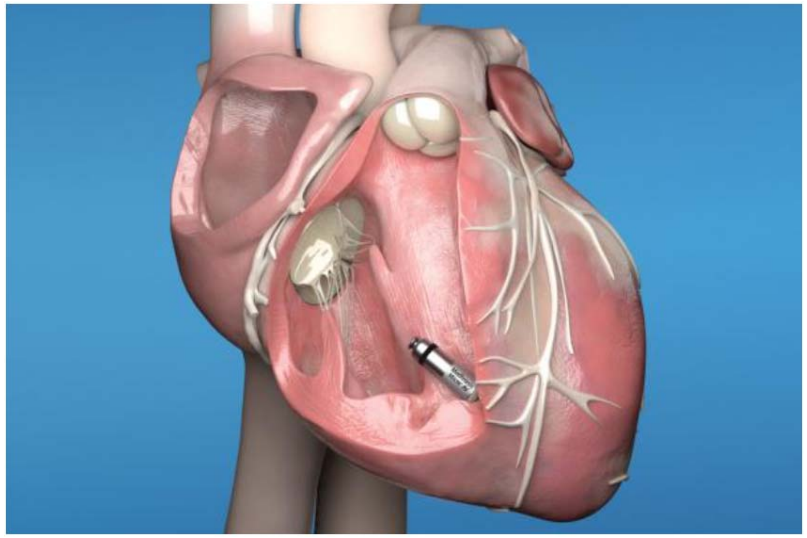


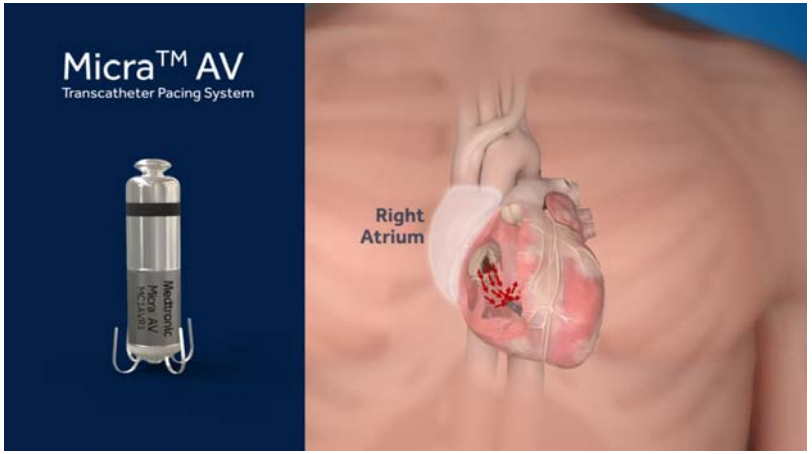

## Meta-Analysis of Appropriate Treatment by the Wearable-Cardioverter Defibrillator, Subgrouped by Cardiomyopathy Type




## Subgroup Analyses by Cardiomyopathy Type

# FDA Clears Medtronic Micra AV to Treat AV Block

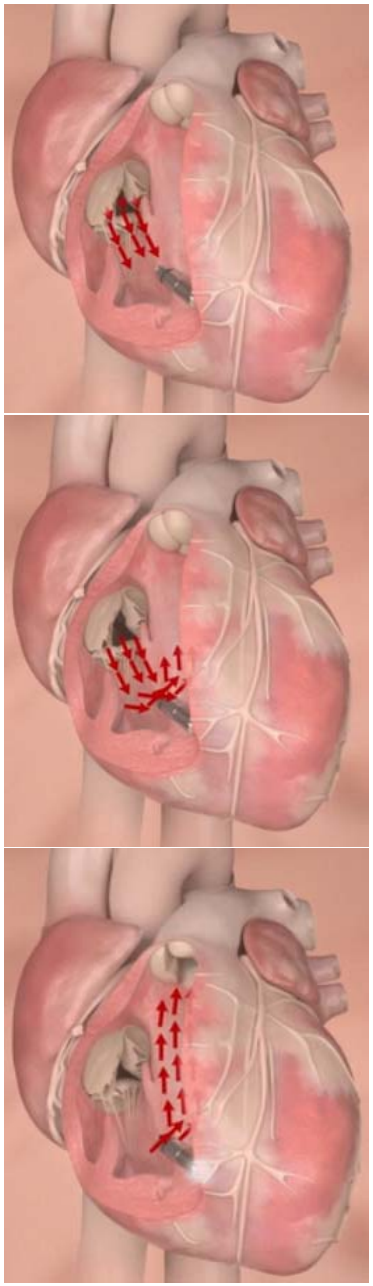




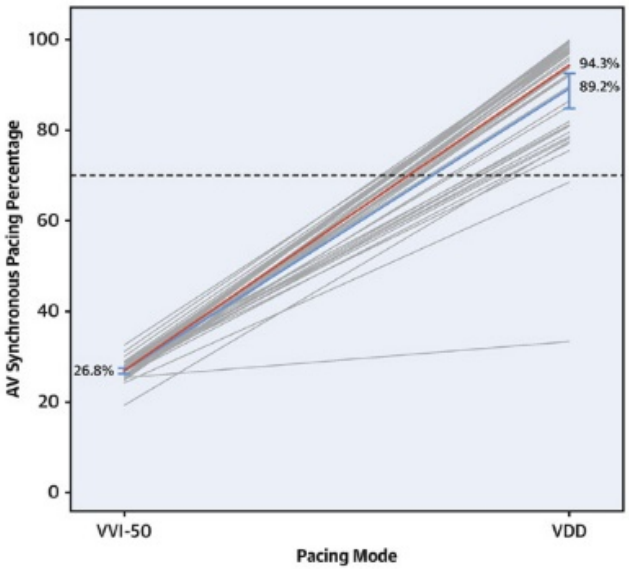

- February 13, 2020 — The U.S. Food and Drug Administration (FDA) has approval of **Micra AV, the world's smallest pacemaker with atrioventricular (AV) synchrony.**
- The leadless Micra AV device is indicated for the treatment **of patients with AV block**, a condition in which the electrical signals between the chambers of the heart (the atria and the ventricle) are impaired.

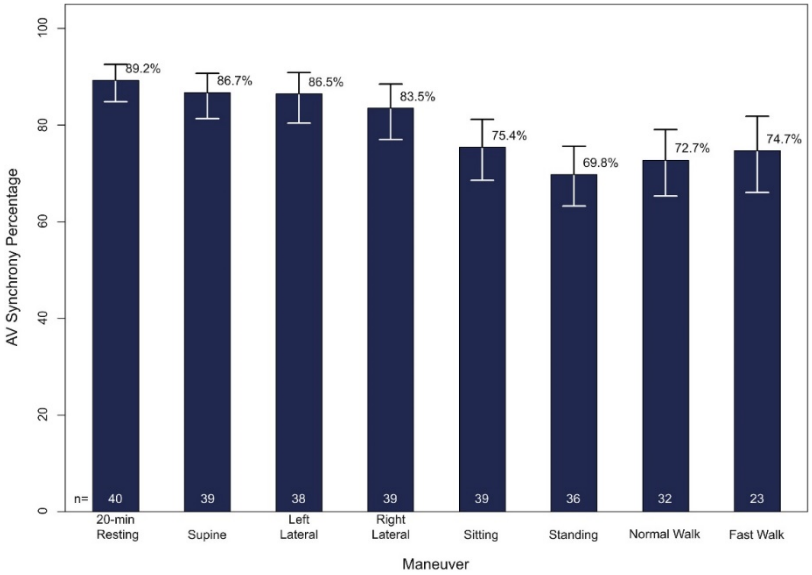
**MARVEL 2 Data Supported FDA Clearance Mica AV to Coordinate Pacing Between the Atrium and Ventricle**

- **Accelerometer-based atrial sensing** with a novel, automated, enhanced algorithm **significantly improved AV synchrony and stroke volume in pts with sinus rhythm and AV block** implanted with a single-chamber leadless pacemaker in the RV.



# AV Synchronous Pacing Percentage



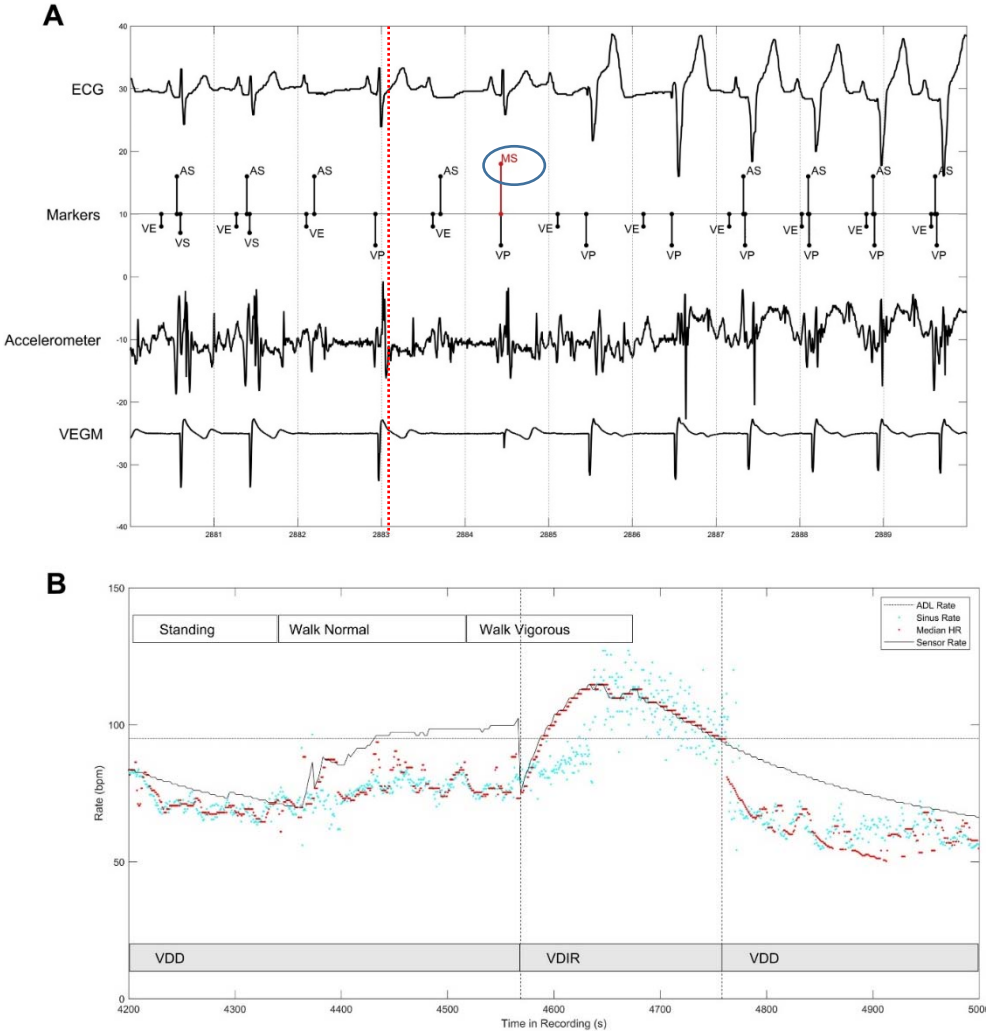

- The **Micra AV approval** is based on data from **the MARVEL 2** (Micra Atrial Tracking Using A Ventricular accELerometer) study, which evaluated **the safety and effectiveness of accelerometer-based atrial sensing algorithms**.

- The study evaluated the ability of the **Micra's internal sensor to monitor and detect atrial contractions and enable coordinated pacing** between the atrium and ventricle, thereby providing AV synchrony.



**JACC: Clinical Electrophysiology** Volume 6, Issue 1, January 2020, Pages 94-106

# AV Conduction Mode Switch and Activity Mode Switch




(A) AV conduction mode switch in pts with intermittent third-degree AV block. Before the mode switch at 2,884 s, the patient exhibits AV conduction in VVI-40 mode. The patient then goes into second-degree AV block, and the device mode-switches to VDD.

**Two cycles after the mode switch**, the device begins **tracking the atrium** in VDD mode.

(B) **Activity mode switch** in patient with CAVB and NSR. **During the standing and/or walking maneuvers, good AV synchrony is indicated by the similarity of median HR and sinus rate.** Mode switch to VVIR occurs when the sensor rate diverges from the pacing rate. The sensor rate decreases to the median HR and gradually increases to minimize large rate changes.

After the activity ceases, the mode returns to VDD promoting AV synchronous pacing.

ADL = activities of daily living; AS = atrial sense; ECG = electrocardiogram; MS = mode switch; VE = ventricular end; VEGM = ventricular electrogram; VP = ventricular pace; VS = ventricular sense;

# Conclusions

- The biggest trends in ICDs : **smaller devices**, **simplified implantation**, **reducing or eliminating leads implanted in the veins or the heart**, and a **movement toward MRI-conditional labeling**.
- The new devices offer Bluetooth technology and a new patient smartphone app for improved remote monitoring, allowing for increased patient/physician engagement and streamlined communications.
- This intelligent cardiac sensor can be activated by clinicians to help patients live a normal life during physical and emotional situations.
- **Zoll LifeVest** allows **a physician more time to assess a patient's long-term arrhythmic risk and make appropriate plans.**
- The leadless Micra AV device is indicated for the treatment **of patients with AV block.**

# Thank You For Your Attention !