Medtronic

Engineering the extraordinary

Cardiac Rhythm Management for enthusiasts

Sep 2022

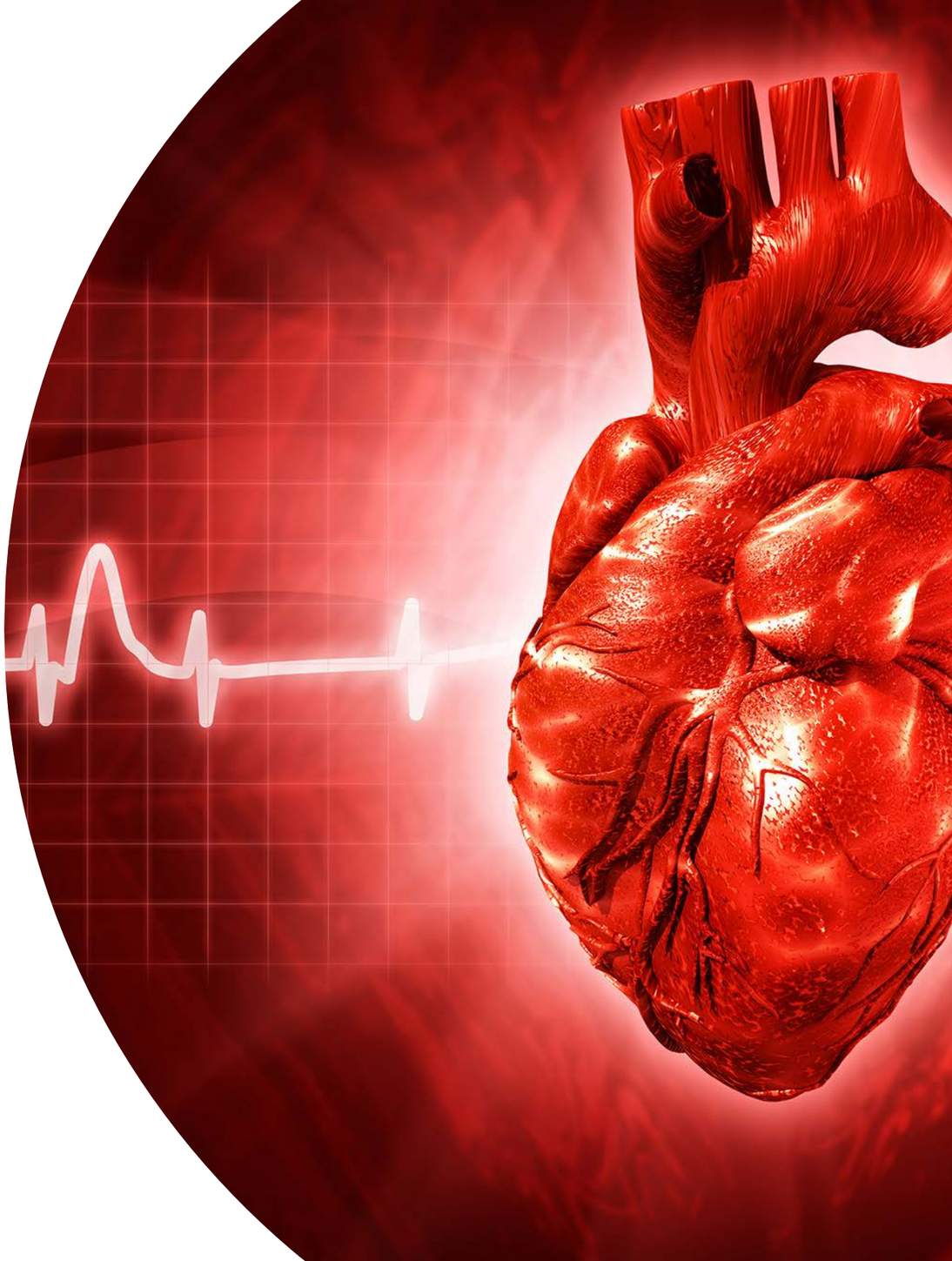
Ela Vidović

Medtronic

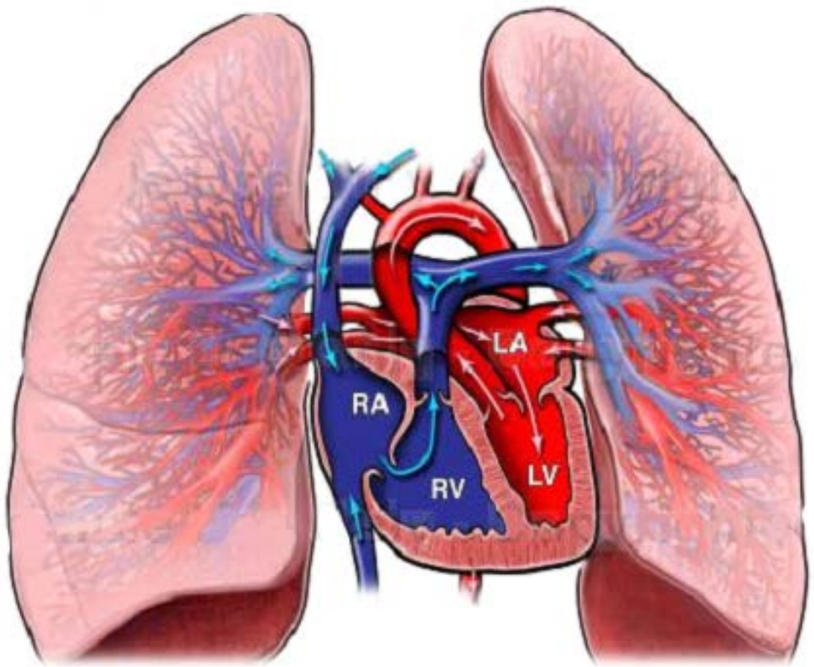
Engineering the extraordinary

Rhythm disorders

... and CRM therapies

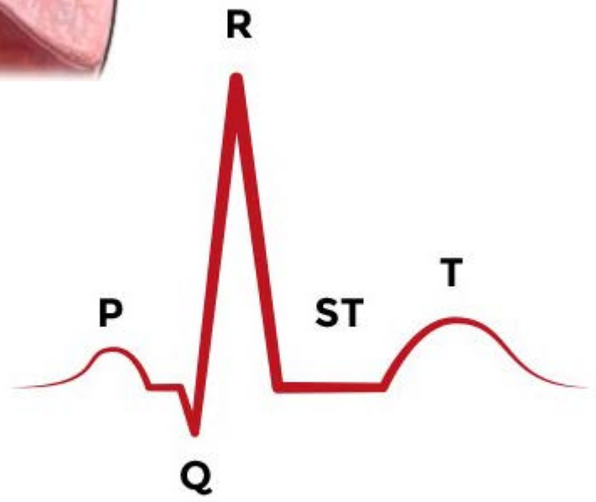


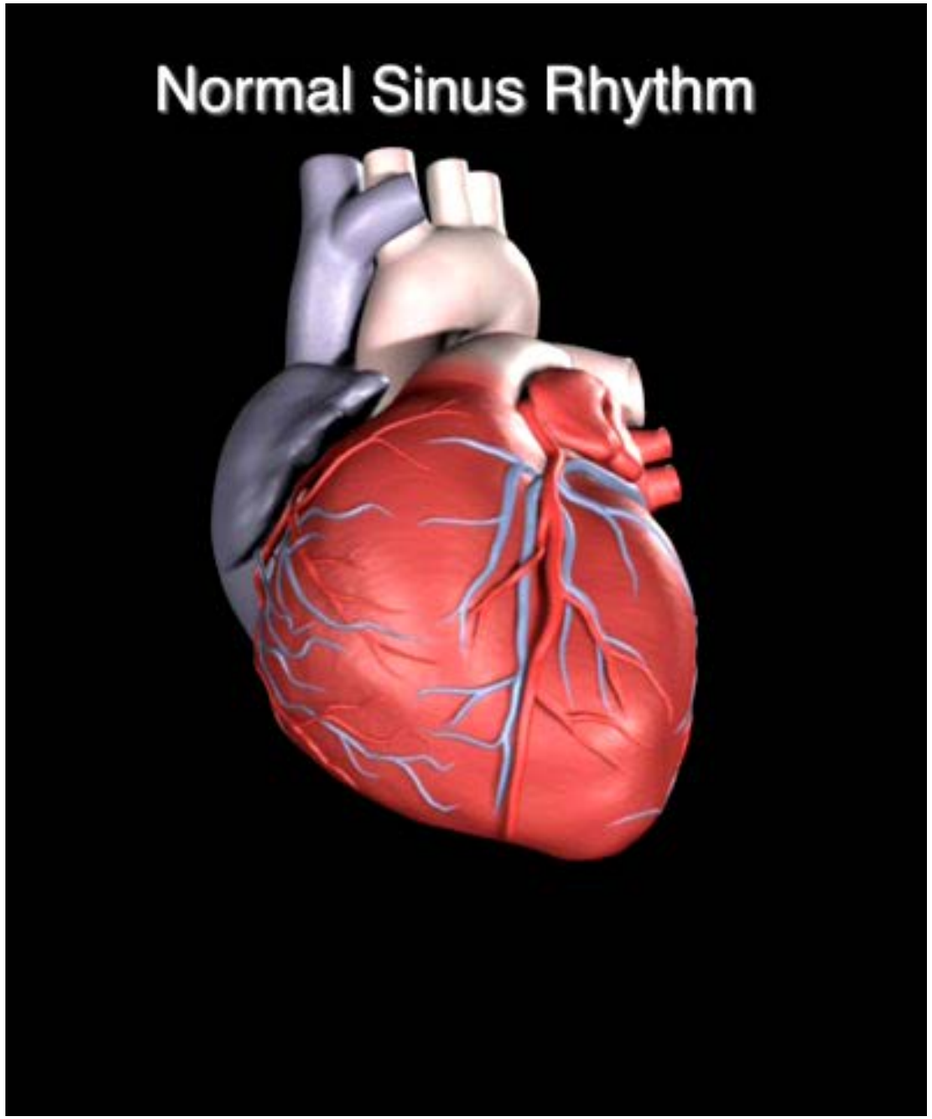
Heart is a pump



RA = Right Atrium
RV = Right Ventricle

LA = Left Atrium
LV = Left Ventricle





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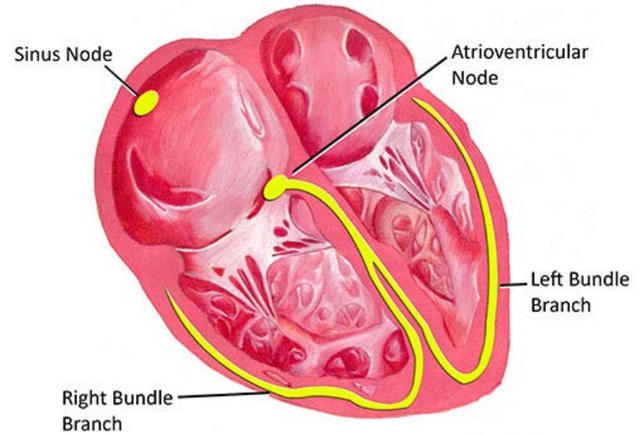
Conduction system

Main heart rhythm disorders



Slow ventricular rhythm

Bradycardia

Sinus or AV Node problem

IPG
Pacemaker

Fast ventricular rhythm

- VT - V. tachycardia (regular)
- VF - V. fibrillation (irregular)

Directly **life-threatening**, blood is not pumped into heart/brain!

ICD
Defibrillator

Heart failure

Insufficient pumping of the blood into the body.

Often de-synchronized ventricles.

CRT
Cardiac Resynchr. Th

Fast atrial rhythm

- AT - A.tachycardia (regular)
- AF - A. fibrillation (irregular)

Not directly **life-threatening**. Build-up clots can lead to stroke.

AF Mgmt Algorithms

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Cardiac Rhythm Management

Focus areas

Brady

Pacemakers (IPG)

If the heart beats slowly

Tachy

Defibrillators (ICD)

If the heart beats fast

Heart Failure

Cardiac Resynchronization Therapy (CRT)

Treat heart failure patients

Patient Management

To manage patients
(in-person or remotely)

Procedure Innovation

To reduce infections

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Cardiac Rhythm Management

Key products

Brady

Pacemakers (IPG)

If the heart beats slowly

Tachy

Defibrillators (ICD)

If the heart beats fast

Heart Failure

Cardiac Resynchronization Therapy (CRT)

Treat heart failure patients

Patient Management

To manage patients
(in-person or remotely)

Procedure Innovation

To reduce infections

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Pacemakers

Brady

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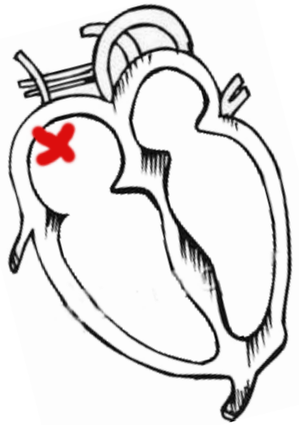
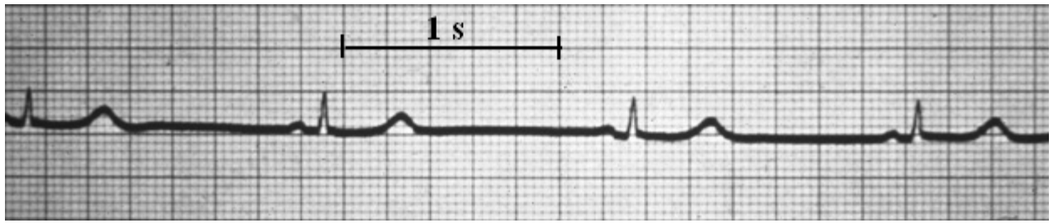
Slow rhythms

Synus Bradicardia

Regular heart contractions

Slow rhythm: heart rates less than 60bpm of caused by sinus node disease



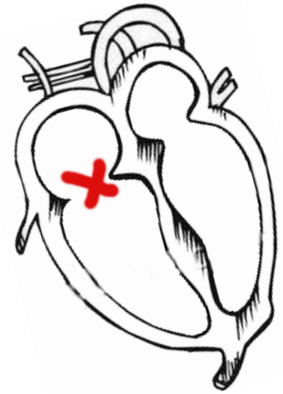


AV Block

Conduction disorders between atria and ventricles

Atria contract normally

Ventricles contract at very slow rate and with no relation to the atria



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Pacemaker

Patients with sinus node disease, AV block and some other heart rhythm problems resulting in bradycardia or asystole are indicated for pacemaker implant.

Pacemaker = IPG (Implantable Pulse Generator)

After the battery depletion, leads are kept and only device is replaced.

- The pacemaker battery lasts usually 8-10 years but there are lot of factors influencing the longevity.

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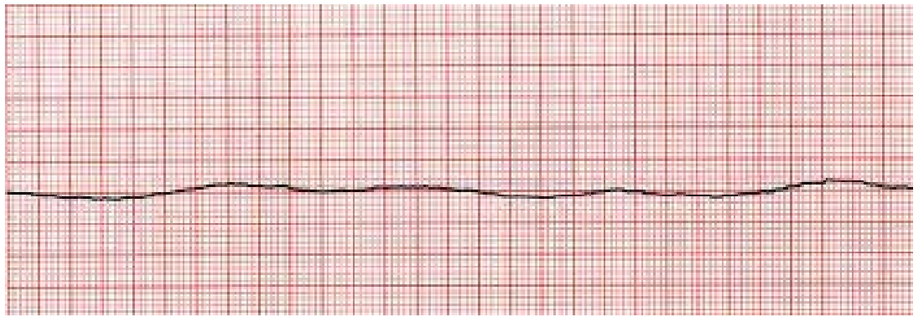
Pacemaker therapy can be

Life saving

In case there’s no intrinsic activity

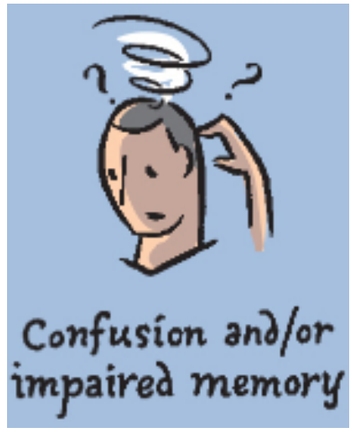
Resulting in asystole



Improving quality of life

Some intrinsic activity exists

Insufficient to meet the needs of the body to live full life



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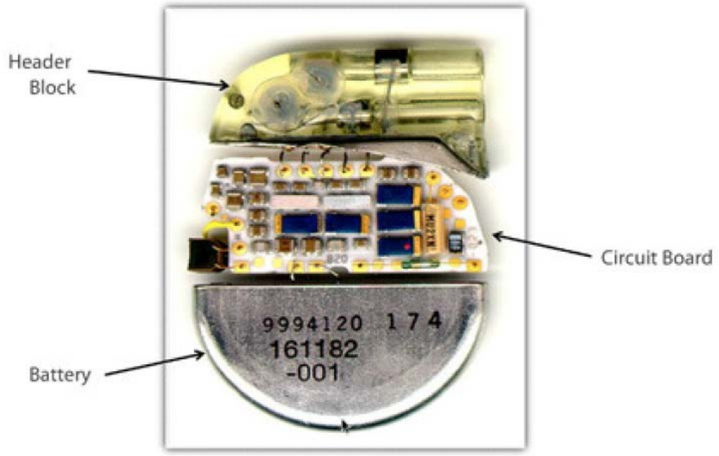
Implantable Pacemaker Circuit

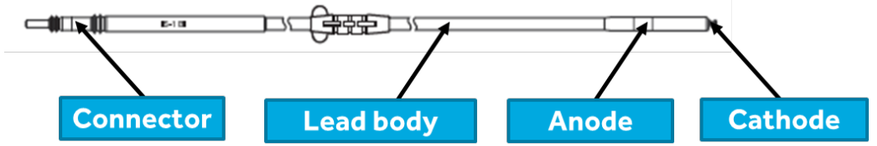
Implantable pulse generator (IPG)

- Battery (lithium-iodine)
- Electrical circuitry
- Microprocessor and memory
- Connector(s)

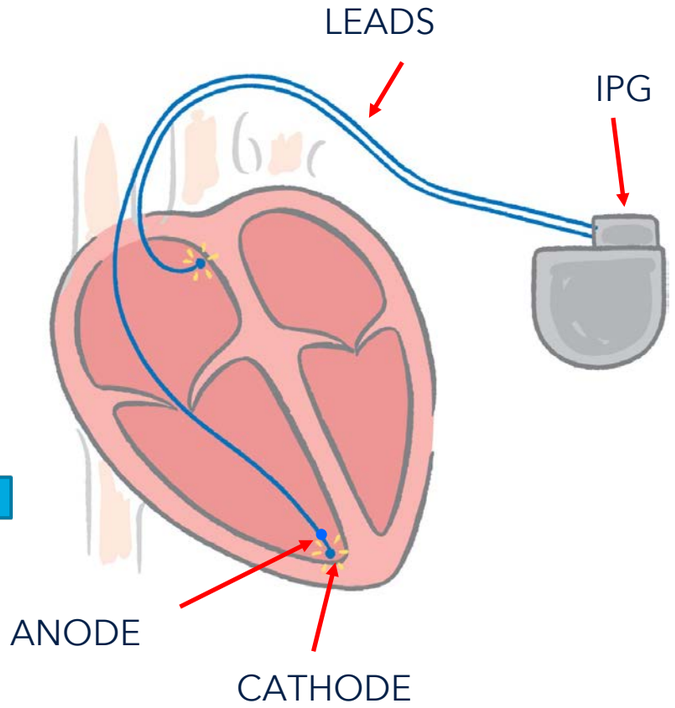


Leads (wires)

- Cathode (negative electrode)
- Anode (positive electrode)
- Lead body
- Connector



Body tissue



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History of pacemakers

5800

1958

First External Pacemaker

5858

1970

Pediatric Asynchronous Pulse Generator

Activitrax®

1986

Rate Response

MicroMinix®

1990

Radically smaller size

Thera ®

1995

1st Microprocessor-based, MS

EnPulse®

2004

Full Automaticity

Advisa MRI®

2009

2nd MRI-Conditional

Astra XT MRI™

2017

Azure XT and S MRI™

2018

1st app connected pacemaker

1960

First Implantable Pacemaker

1979

1989

Dual chamber rate response

1991

1998

Rate response via activity & MV

2005

MVP, Full Automaticity

2015

Transcath. Pacing

2017

2020

Transcath. Pacing

Chardack-Greatbatch

Byrel®

Synergist™

Elite™

Kappa®

Adapta™

Micra™

Attesta MRI™

Micra™ AV

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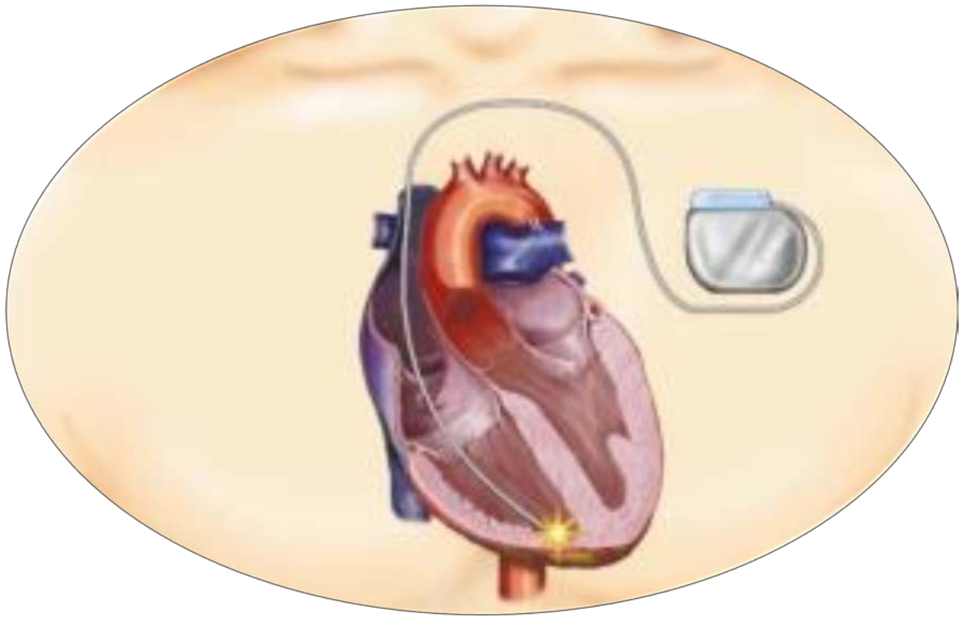
Pacemaker systems

Basic classification

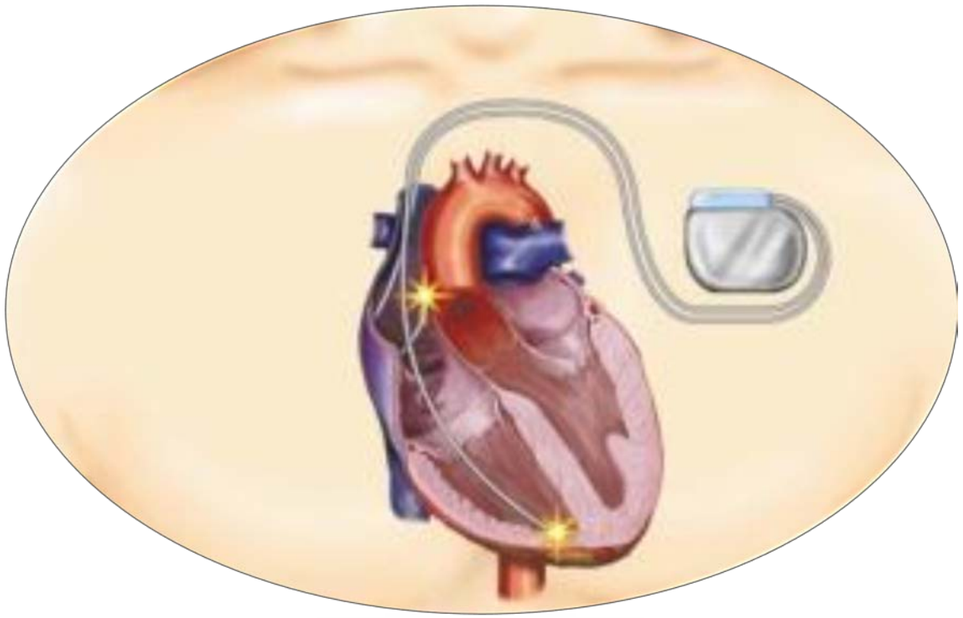
Single chamber

- Implanted one lead only
- Usually in the right ventricle



Dual chamber

- One lead implanted in right atrium and one in the right ventricle



Pacemaker implant

Procedure video

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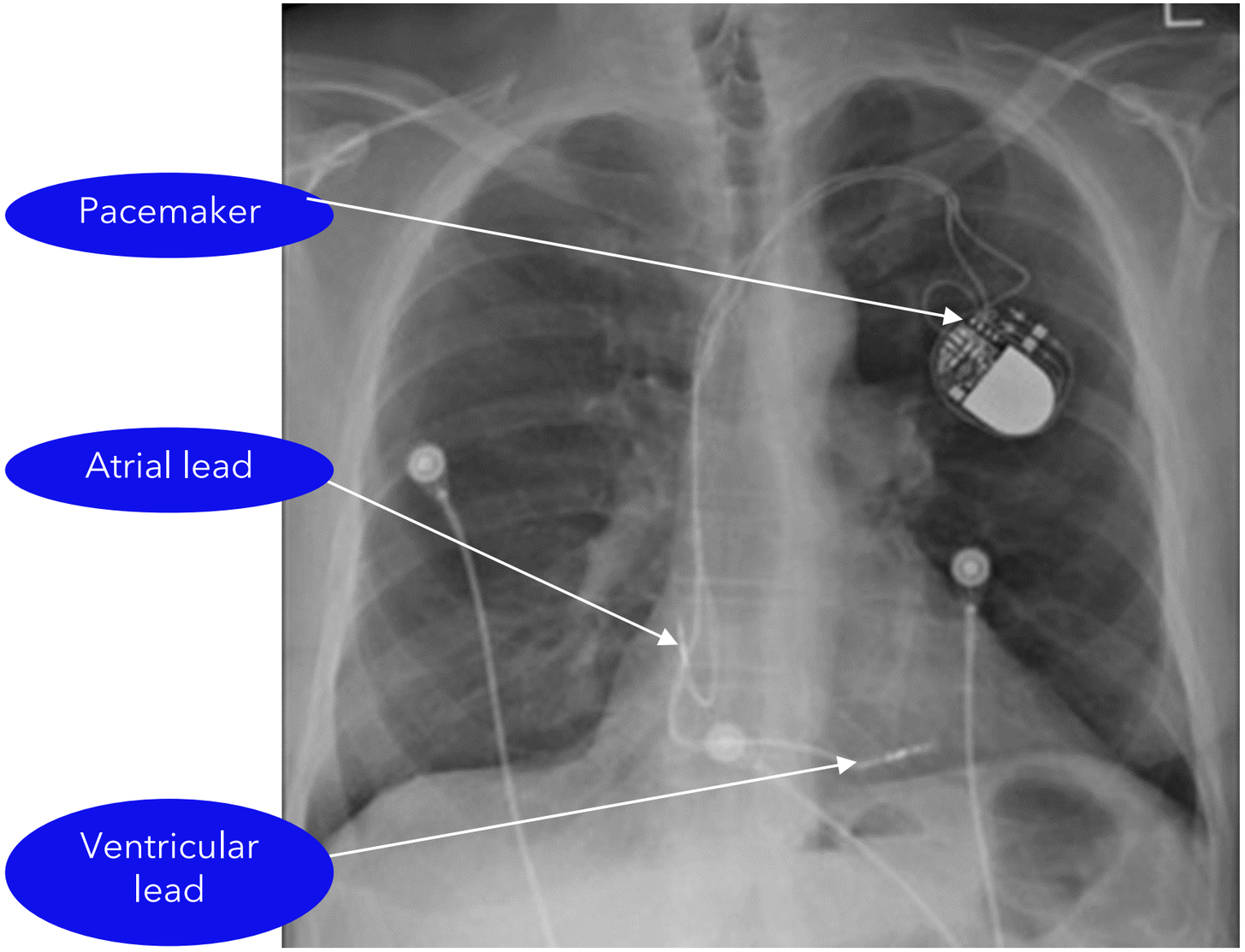
Pacemaker implant

X-ray check



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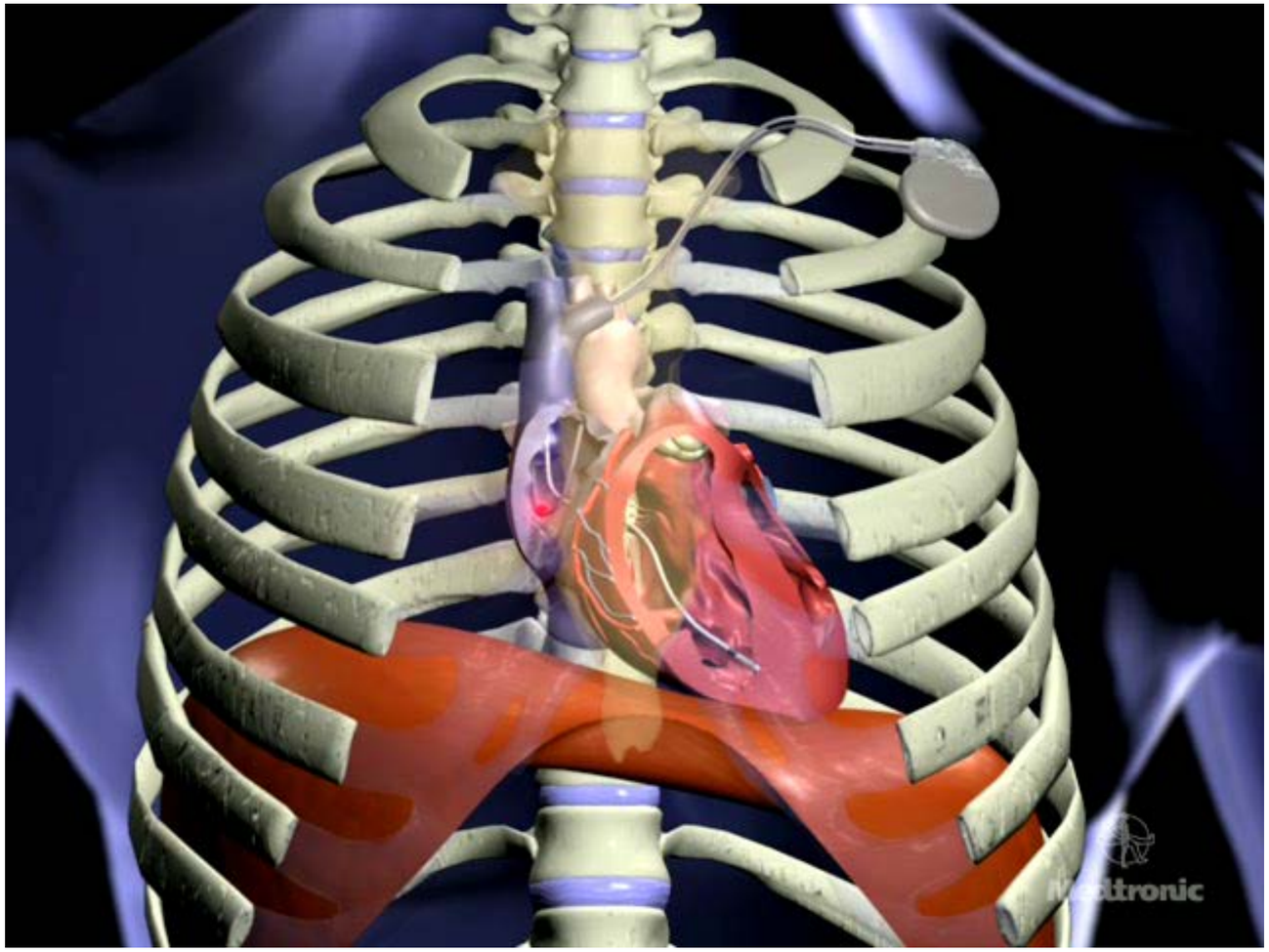
Stimulated heart

Dual chamber pacing system video



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Paing leads

Low voltage leads

Passive

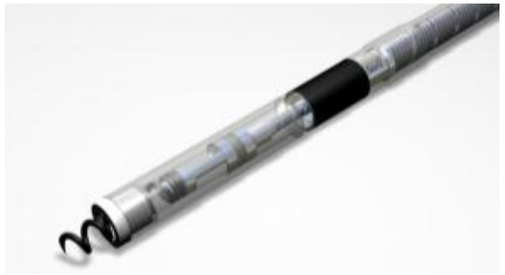
Fixated by silicone tines in the heart tissue

ventricle

atrium

Active

Fixated with (retractable) helix into the heart muscle



atrium and ventricle

Typical lead lengths:

- Atrium: 53cm (or 45cm)
- Ventricle: 58 or 65 cm

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THANK YOU FOR 20 YEARS **OF TRUST**

CapSureFix Novus MRI™
SureScan™* 5076 lead

Sprint Quattro Secure™

LIFETIME WARRANTY ☑

More than
6.8 million CapSure Fix Novus
and **1.6 million** Sprint Quattro
implanted since 2000[1,2]

1. Menard C. CapSureFix Novus 5076 global sales. February 2021. Medtronic data on file.
2. Heveling N. Sprint Quattro 6935, 6935M, 6946M, 6947, 6947M global sales. February 2021. Medtronic Data on file

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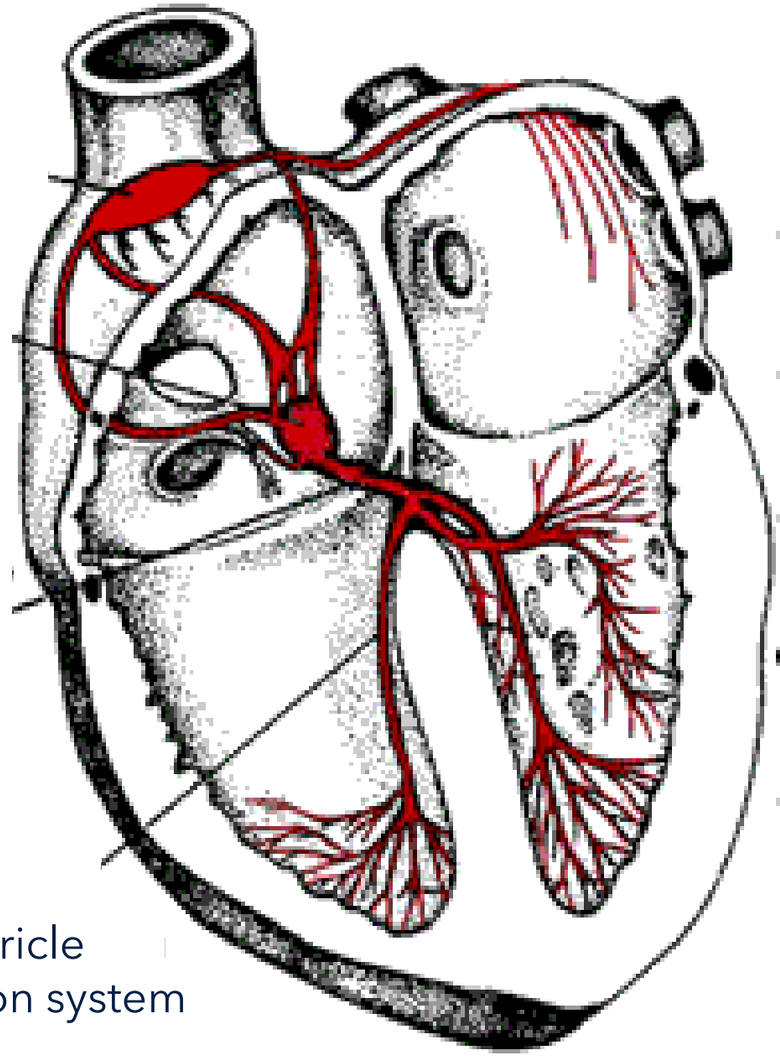
Heart conduction system

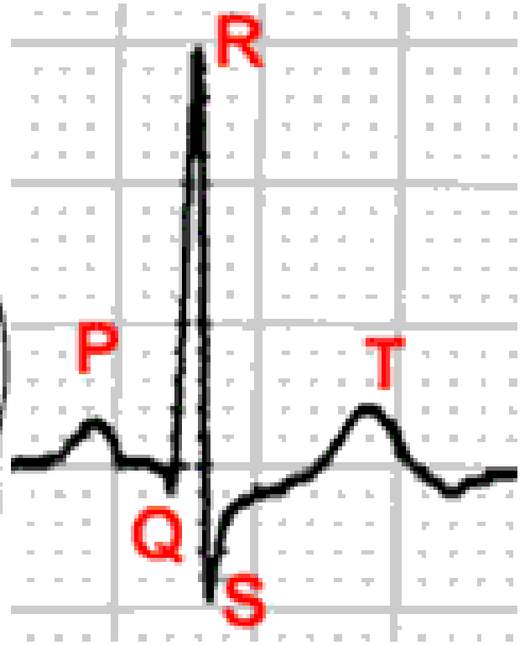
Sinus node

AV node

HIS Bundle

Ventricle
conduction system





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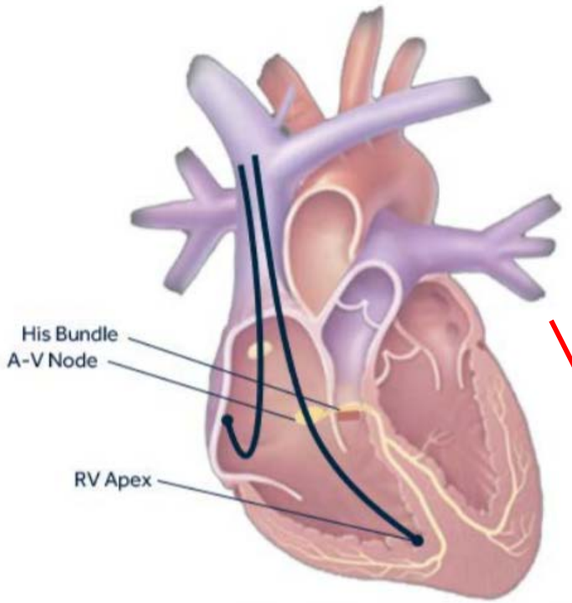
Why His Bundle Pacing?

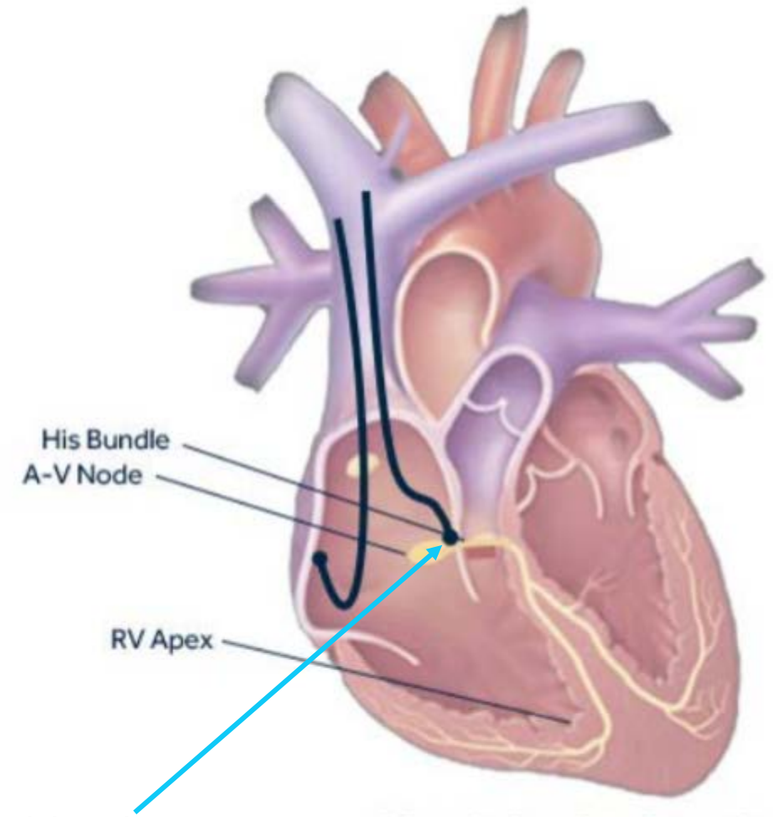
Long-term RV apical pacing creates a non-physiologic activation pattern and may lead to worsened systolic and diastolic function in a subset of patients



Ventricular Lead at Right Ventricular Apex

Intrinsic signal travels this way

So ventricular lead placed higher would be “more physiologic”



Ventricular Lead at His Bundle‡

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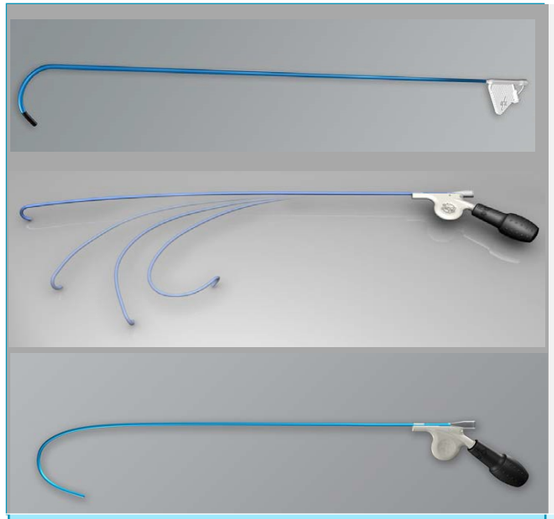
Medtronic HBP Portfolio

Delivery Systems

Options for variances in anatomy
- C315
- SelectSite™C304-HIS
- SelectSite™ C304

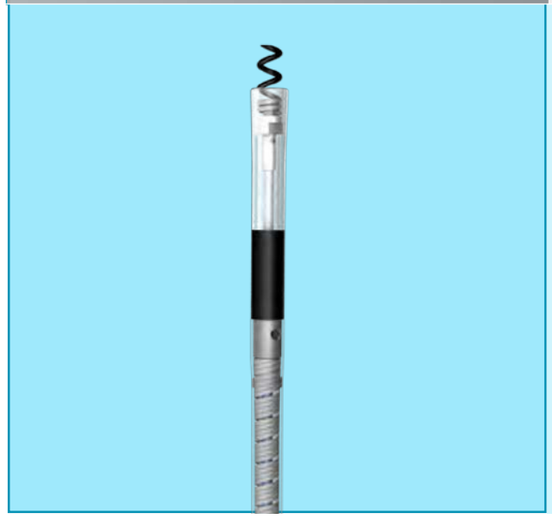


Pacemakers

Options in sensitivity settings and longevity
- Azure™
- Astra™
- Attesta™ L

Pacing Lead

Only CE approved lead for His-bundle pacing
- 3830 SelectSecure™



Pacing System Analyzer

For visual analysis of small amplitude components
- CareLink SmartSync™ with EGM high gain feature

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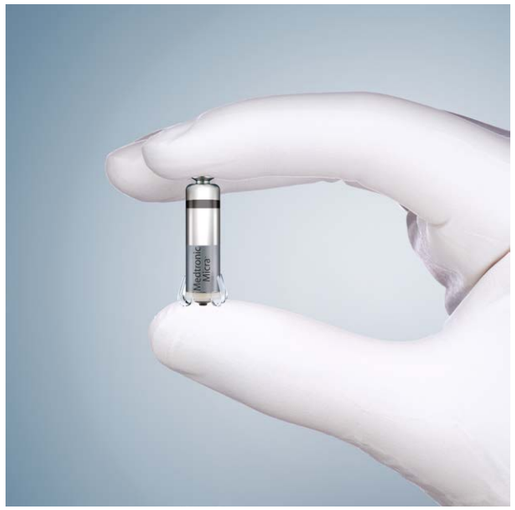
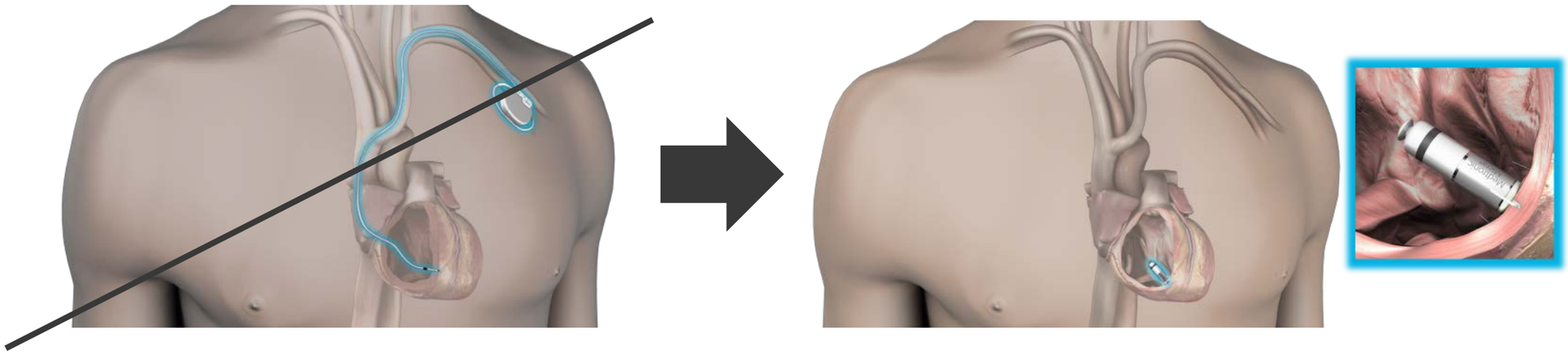
Micra

Transcatheter Pacing System (“Leadless”)

Parameter	Micra
Pacing Mode	VVIR
Mass	2.0 g
Cathode Surface Area	2.5 mm[5]
Anode Surface Area	22 mm[5]
Volume	0.8 cc





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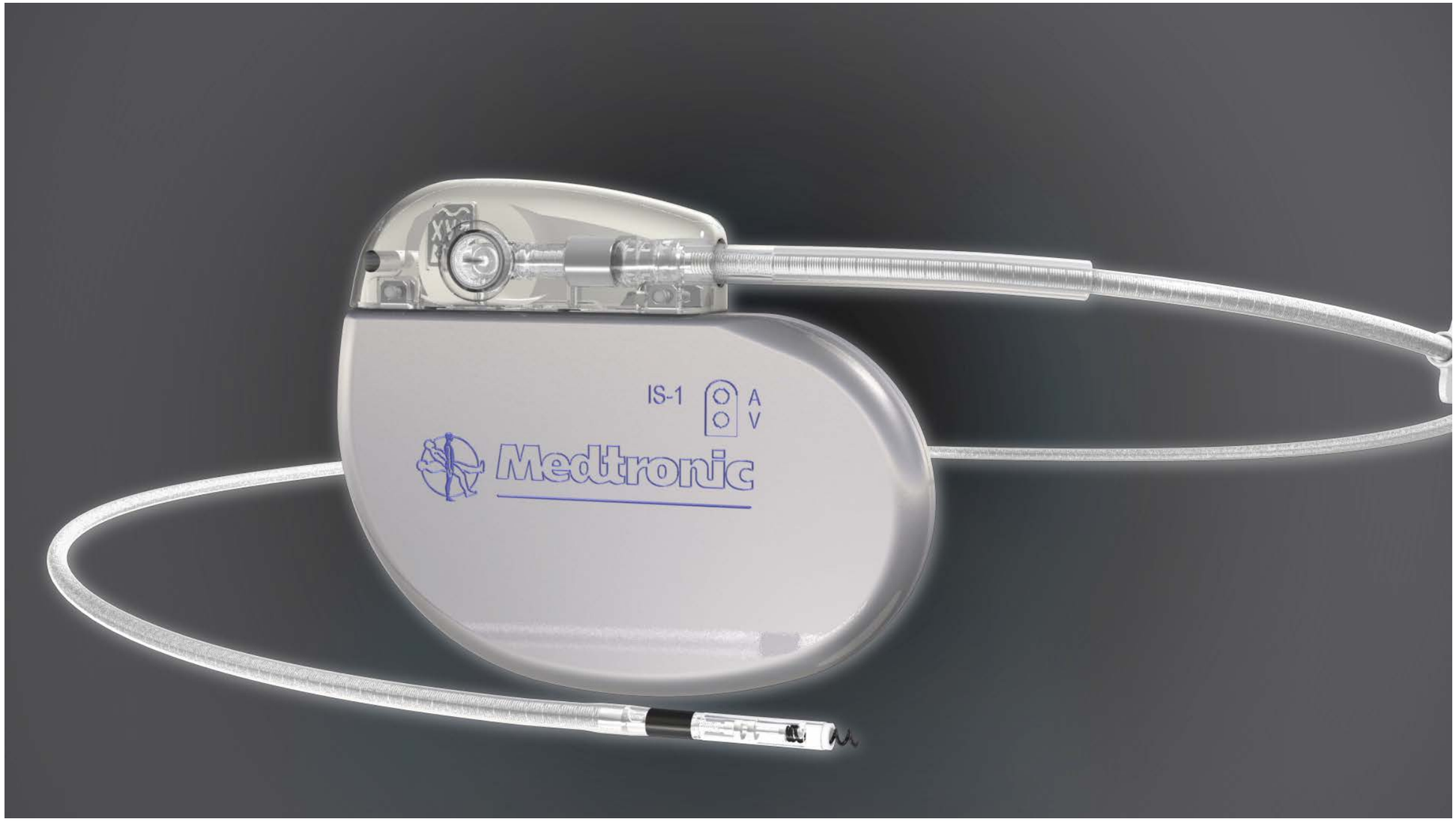
Micra

Transcatheter Pacing System (“Leadless”)



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Micra

Now offering two leadless pacing options

- The world's smallest pacemaker
  - **93% smaller** vs traditional pacemakers[1]
- 99% implant success rate[2,3]
- 63% reductions in major complications[2]
- Leadless pacing option now for 45% of pacing population[4]

1 Williams E, Whiting J. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic data on file; 2 El-Chami MF, 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; 3 Reynolds D, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med. 2016; 4 Lewis D, Whiting J. Bradycardia Indication Breakdown. January 2020. Medtronic data on file.

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Scan or not to scan?

Importance of MRI compatibility for implantables devices

MRI is becoming an irreplaceable imaging modality

Traditional implantable systems were contraindicated to MRI – strong magnetic fields may interact with the system and cause

- Inhibition of the therapy and/or delivery of unwanted therapy
- Damage of the implantable system
- Damage of the heart tissue (due to lead-tip heating)

Medtronic has developed and designed CRM/CDS systems that are MRI conditional (SureScan devices & leads)

- Big part of MDT portfolio has now (MRI) SureScan labelling
  - With **simple** conditions
  - For **all** SureScan devices and leads
  - In **any** combination

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Unmatched MRI access for all device patients

CRM/CDS portfolio

- Astra XT MRI™ IPGs
- Advisa MRI™ IPGs
- Ensura MRI™ IPGs
- Attesta MRI™ IPGs
- Sphera MRI™ IPGs
- Vitatron G-series MRI IPGs
- Vitatron Q-series MRI IPGs

- Percepta MRI ™ CRT-Ps
- Serena MRI ™ CRT-Ps
- Solara MRI ™ CRT-Ps

- Cobalt XT MRI™ ICDs
- Cobalt MRI™ ICDs
- Crome MRI™ ICDs
- Evera MRI™ ICDs
- Visia AF MRI™ ICDs
- Primo MRI™ ICDs
- Mirro MRI™ ICDs

- Cobalt XT HF MRI™ CRT-Ds
- Cobalt HF MRI™ CRT-Ds
- Crome HF MRI™ CRT-Ds
- Claria MRI™ CRT-Ds
- Amplia MRI™ CRT-Ds
- Compia MRI™ CRT-Ds

- Micra™ VR and AV Transcatheter Pacemakers

- Reveal LINQ™ and LINQ™ II ICMs

- SureScan™ Pacing Leads

- SureScan™ Defibrillation Leads (DF-4 & DF-1)

- SureScan™ Left-Heart Quadripolar and Bipolar Leads

Same conditions **across the portfolio**

- Full body 1.5T &3T
- No MRI exclusion zone
- No MRI duration restriction
- No patient height restrictions
- No patient conditions restrictions (e.g. fever)
- SureScan™ devices and leads work in any combination
- DF1/DF4, IS1/IS4 leads & connectors

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Defibrillators

Tachy

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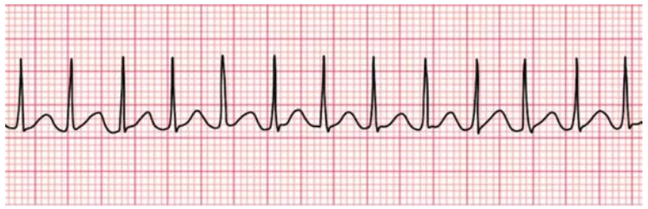
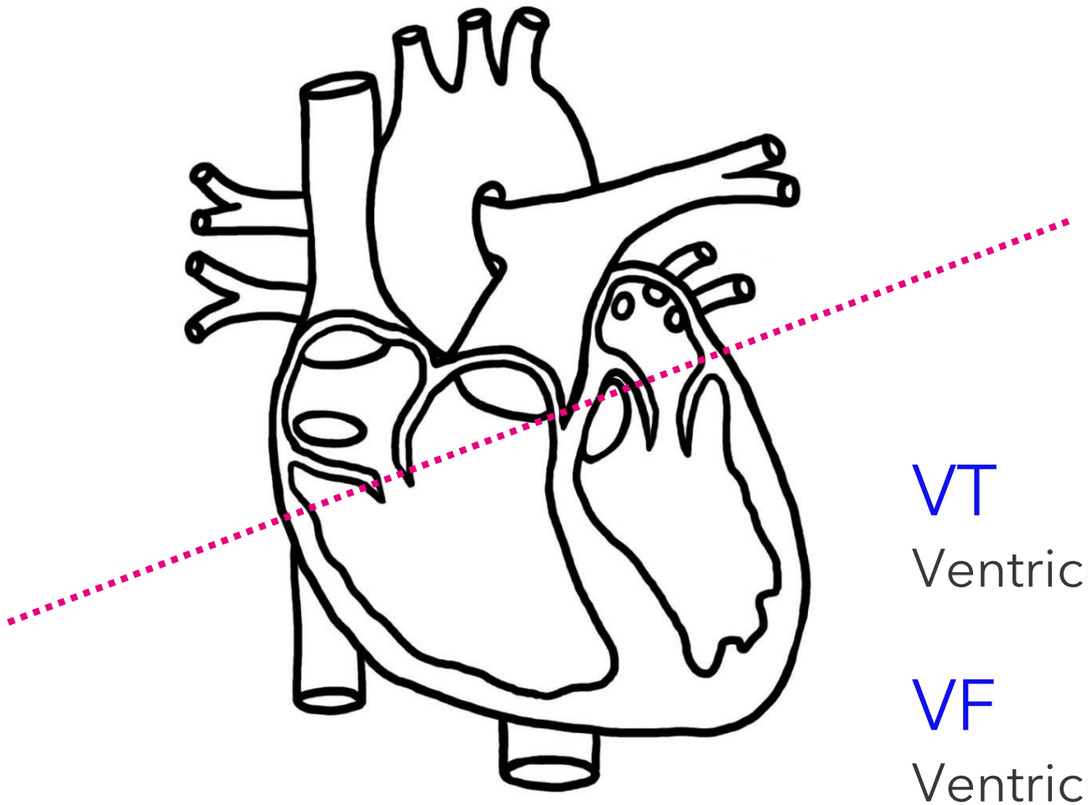
Clasification of tachyarrhythmias

SVT

Supraventricular tachycardia

- from above
- the ventricles
- fast heart rate





VT

Ventricular tachycardia

VF

Ventricular fibrillation

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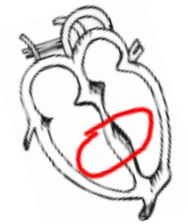
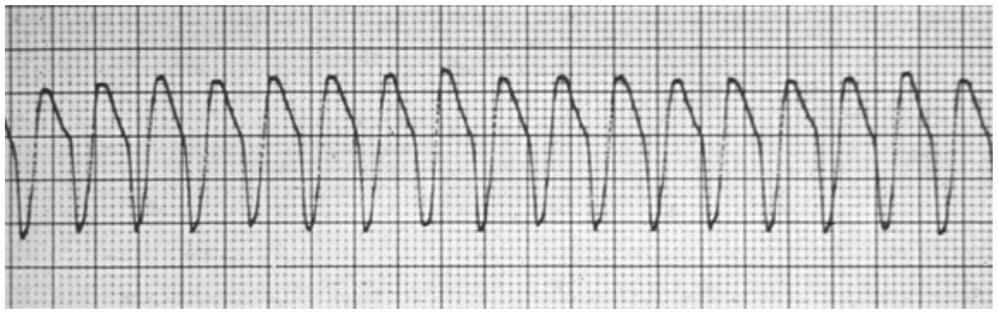
Ventricular arrhythmias



VT

Ventricular tachycardia

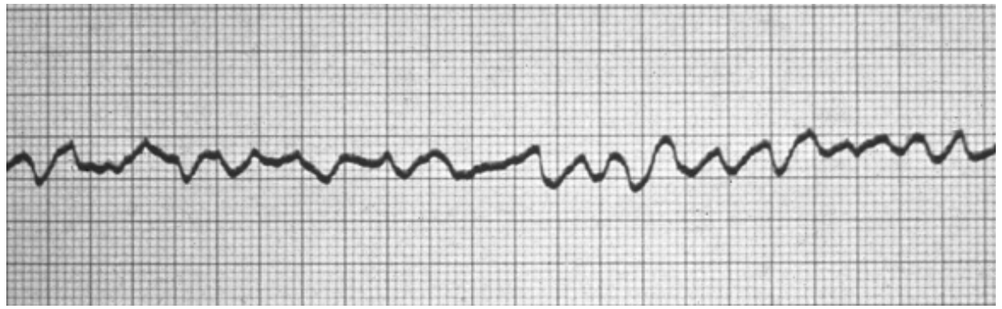
- Fast
- 150-250 bpm
- Regular



VF

Ventricular fibrillation

- Very fast
- >200 bpm
- Irregular



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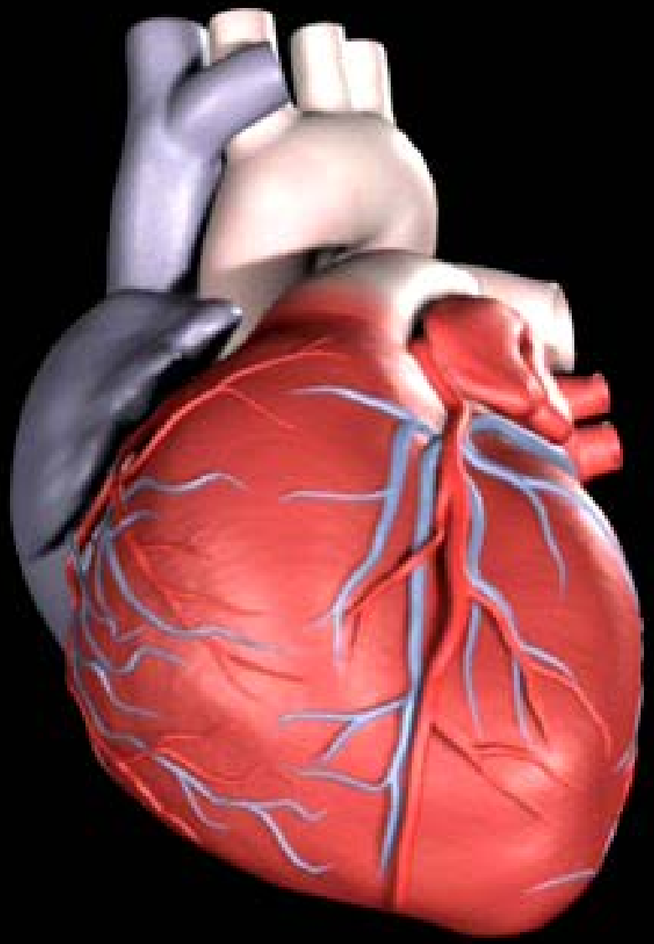
Ventricular Fibrillation (VF)



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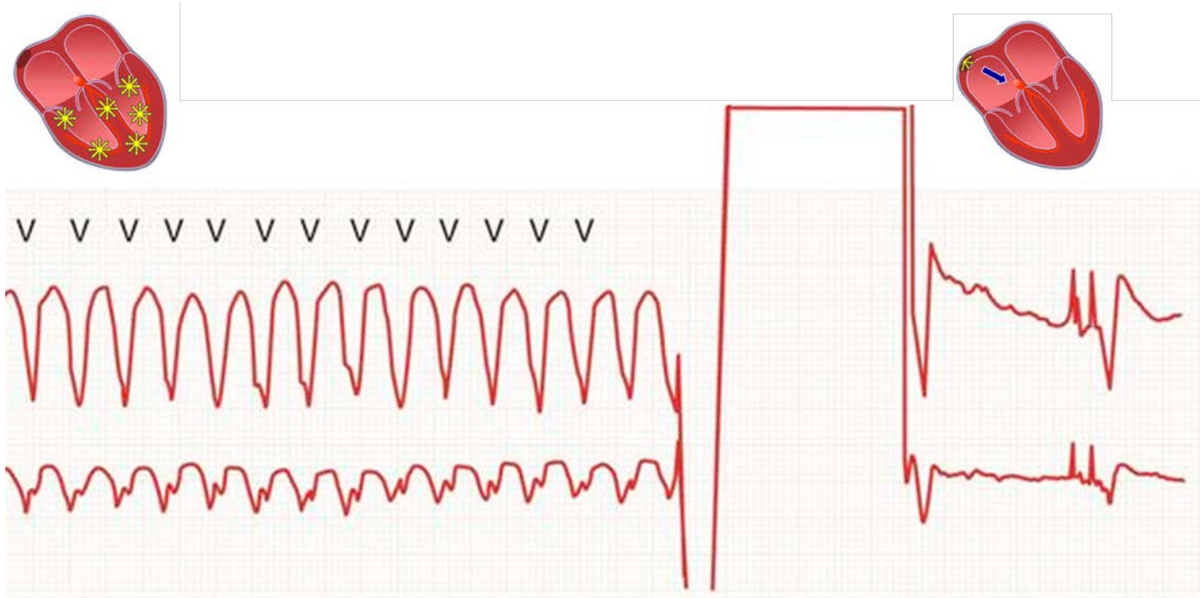
Defibrillation

- The only effective treatment for ventricular fibrillation (VF) that would otherwise result in cardiac arrest
- Resets the heart with an electrical discharge



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Cardioverter-Defibrillators

“High-voltage” devices

External Defibrillator

- Delivers 360J
- Not in CRM portfolio
  - PhysioControl (former MDT)

Implantable Cardioverter-Defibrillator

- Delivers 35-40J directly to the heart
- For this capacitors need to be charged to ~800V

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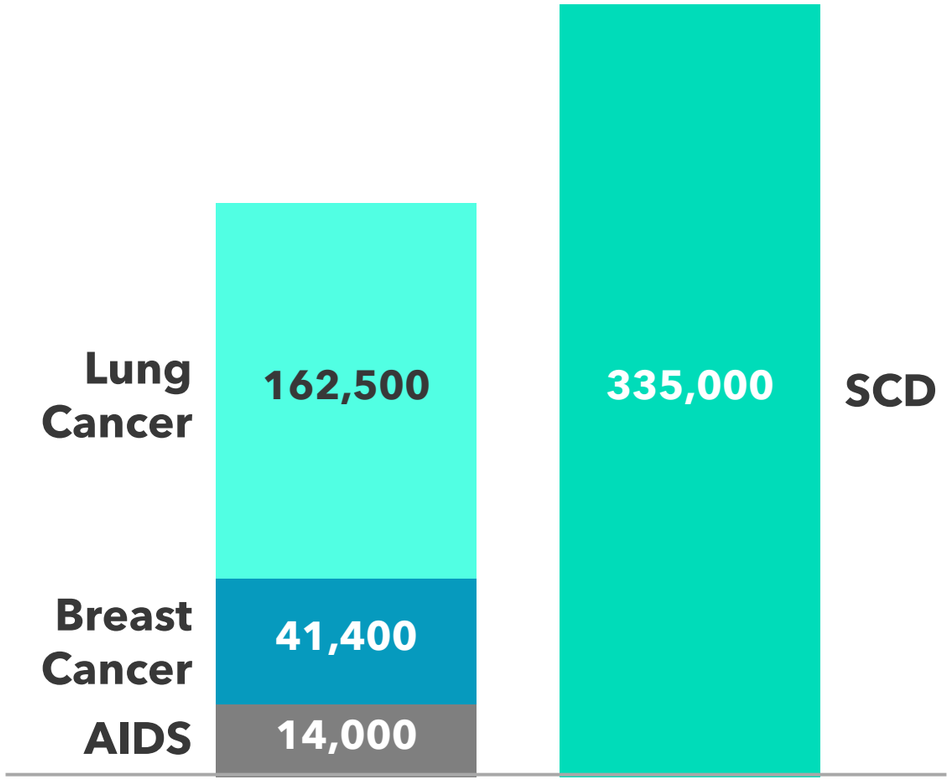
Save Sudden Cardiac Death Victims

Hungarian National Heart Foundation

Sudden cardiac arrest / death

SCD claims more lives than lung cancer, breast cancer, and AIDS combined



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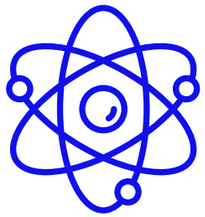
Sudden cardiac arrest / death

SCD claims more lives than lung cancer, breast cancer, and AIDS combined

80%

due to VF or fast VT



40%

happens when alone

<5%

survival

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Implantable Cardioverter-Defibrillator (ICD)

Is ICD a cure?

- ICD will not cure a patient's underlying condition
- ICD terminates patient's arrhythmias when they occur and saves lives

What does ICD do?

Constantly checks the patient’s rhythm and works the same as a pacemaker

Additionally, in case of detecting fast ventricular rhythm, it delivers specific therapy in order to terminate it

- Antitachycardia Pacing (ATP)
- Defibrillation shock

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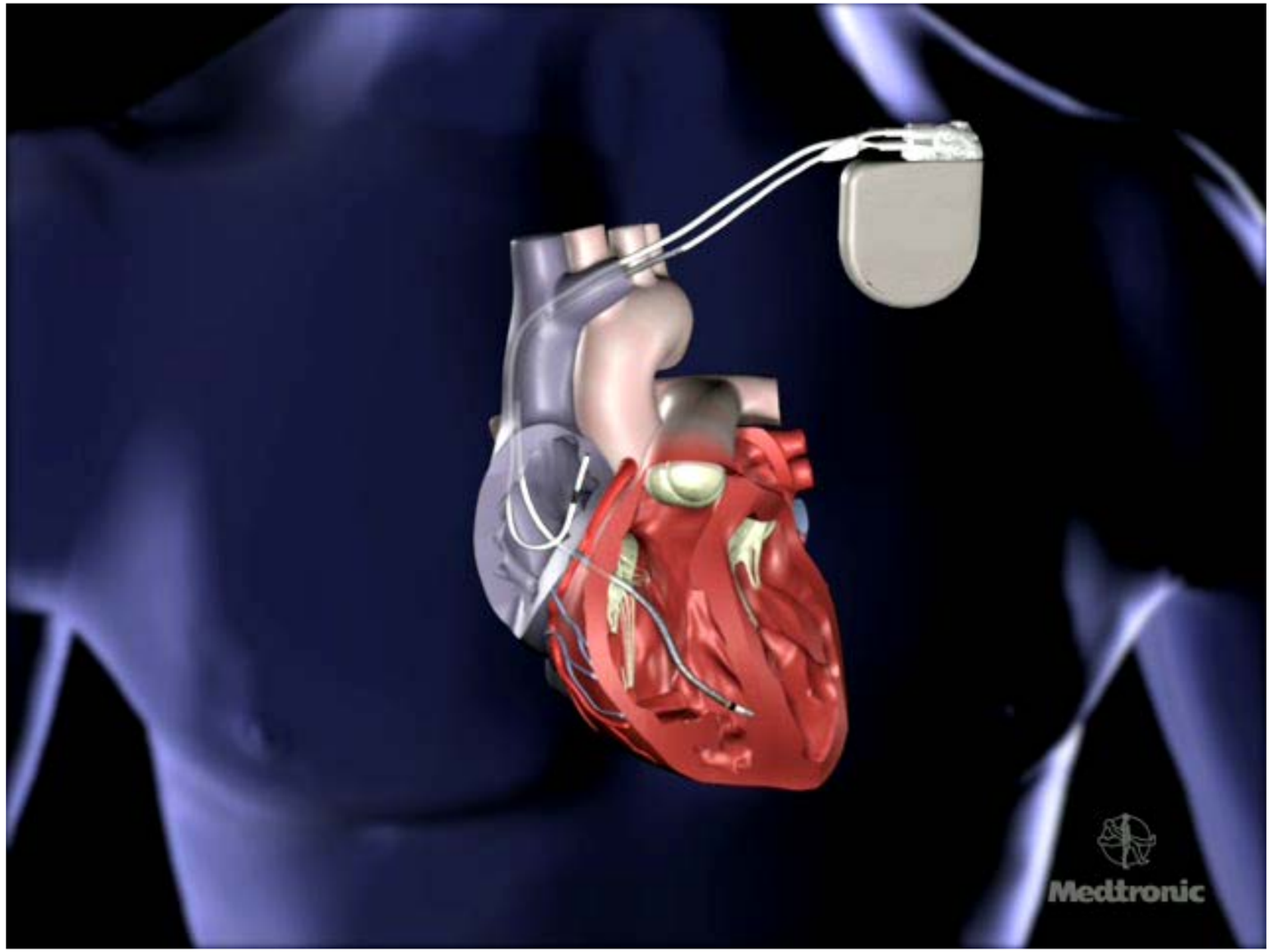
How ICD works

Defibrillation shock



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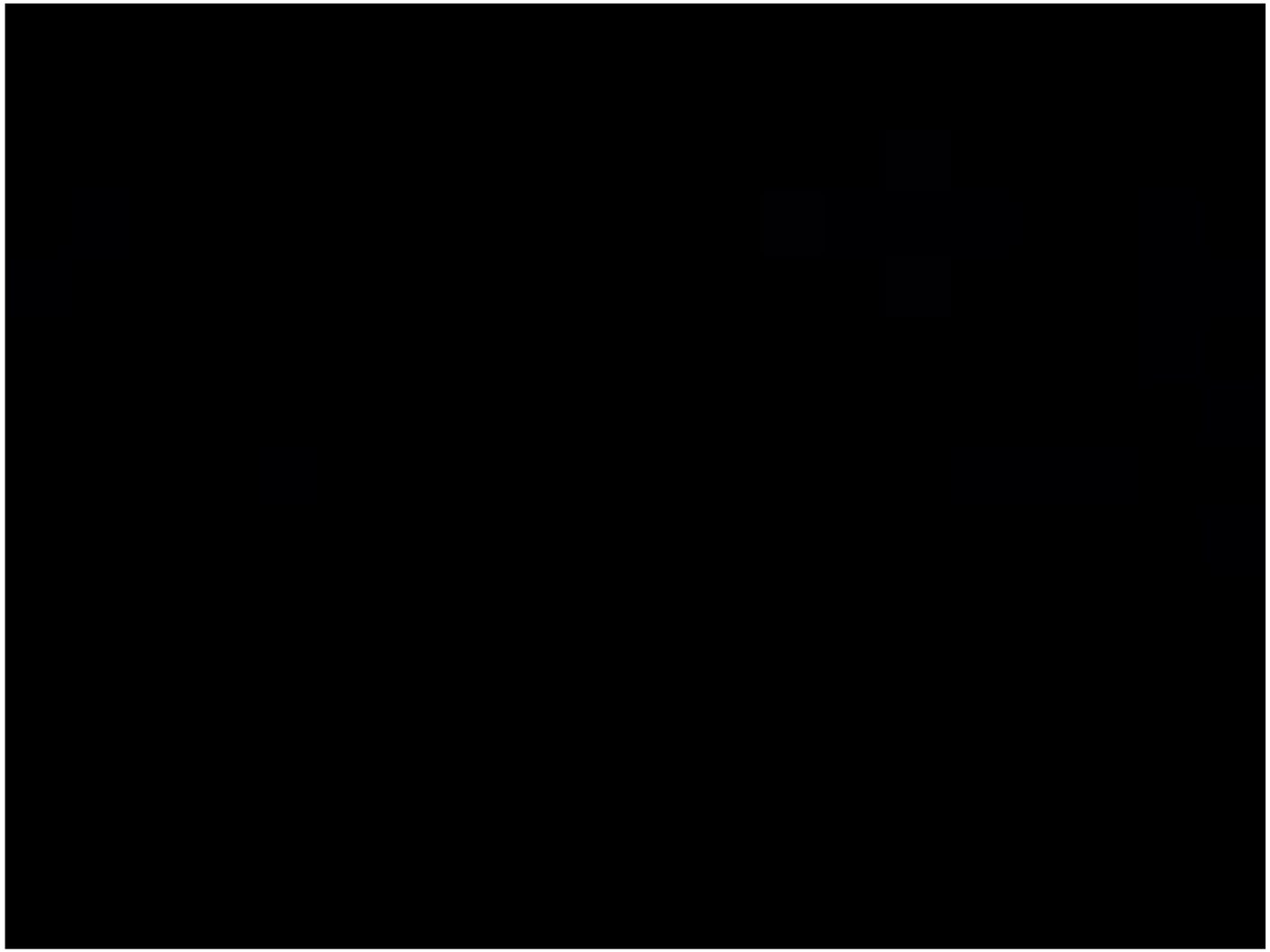
It is important to shock only when it's needed...

Because IT HURTS!



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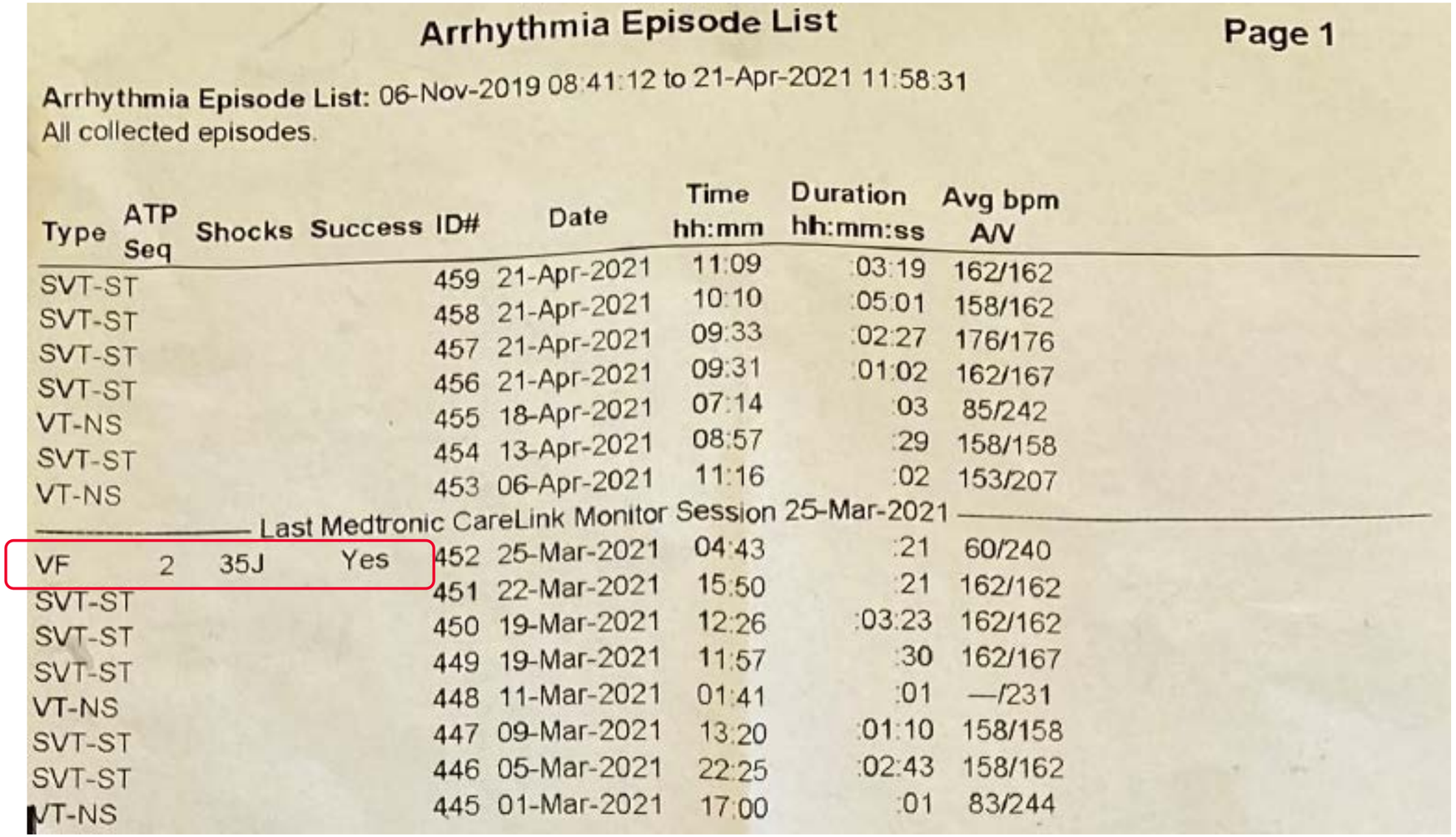
What does the device see?



Arrhythmia Episode List Page 1

Arrhythmia Episode List: 06-Nov-2019 08:41:12 to 21-Apr-2021 11:58:31
All collected episodes.

Type	ATP Seq	Shocks	Success	ID#	Date	Time hh:mm	Duration hh:mm:ss	Avg bpm A/V
SVT-ST				459	21-Apr-2021	11:09	:03:19	162/162
SVT-ST				458	21-Apr-2021	10:10	:05:01	158/162
SVT-ST				457	21-Apr-2021	09:33	:02:27	176/176
SVT-ST				456	21-Apr-2021	09:31	:01:02	162/167
VT-NS				455	18-Apr-2021	07:14	:03	85/242
SVT-ST				454	13-Apr-2021	08:57	:29	158/158
VT-NS				453	06-Apr-2021	11:16	:02	153/207
Last Medtronic CareLink Monitor Session 25-Mar-2021								
VF	2	35J	Yes	452	25-Mar-2021	04:43	:21	60/240
SVT-ST				451	22-Mar-2021	15:50	:21	162/162
SVT-ST				450	19-Mar-2021	12:26	:03:23	162/162
SVT-ST				449	19-Mar-2021	11:57	:30	162/167
VT-NS				448	11-Mar-2021	01:41	:01	—/231
SVT-ST				447	09-Mar-2021	13:20	:01:10	158/158
SVT-ST				446	05-Mar-2021	22:25	:02:43	158/162
VT-NS				445	01-Mar-2021	17:00	:01	83/244

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VERY simplified indication criteria

Secondary prevention

- Sudden Cardiac Arrest (SCA/SCD) survivors

Primary prevention

Patients with risk factors who never experienced SCA or VT/VF

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Why shock only to save lives?

Shocks save lives but impact patient outcomes and healthcare spending

Patient pain and anxiety caused by defibrillation shocks can lead to decreased quality of life and participation in normal activities.

Patients with ventricular arrhythmia (VA) episodes who receive shocks have higher mortality than patients with VA treated only with ATP.

Shocks can lead to unnecessary hospital admissions, which result in increased costs and resource usage.

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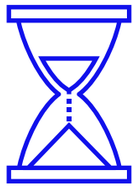
Did you know?

...the following on Medtronic

10

years of SmartShock technology



20+

years of studying shock reduction

14

prospective clinical trials

>15k

patients enrolled

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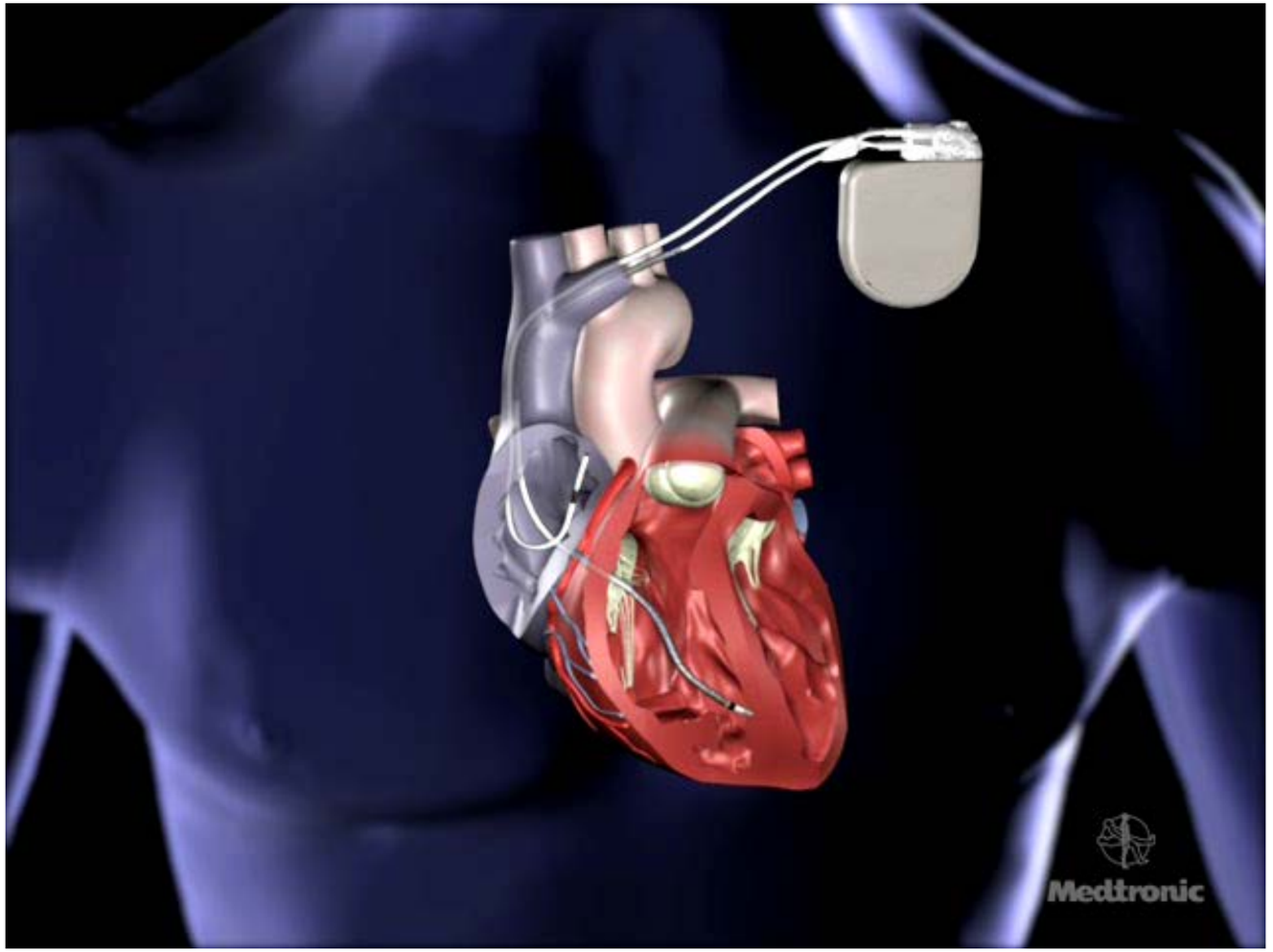
Painless therapy

Antitachicardia pacing (ATP)



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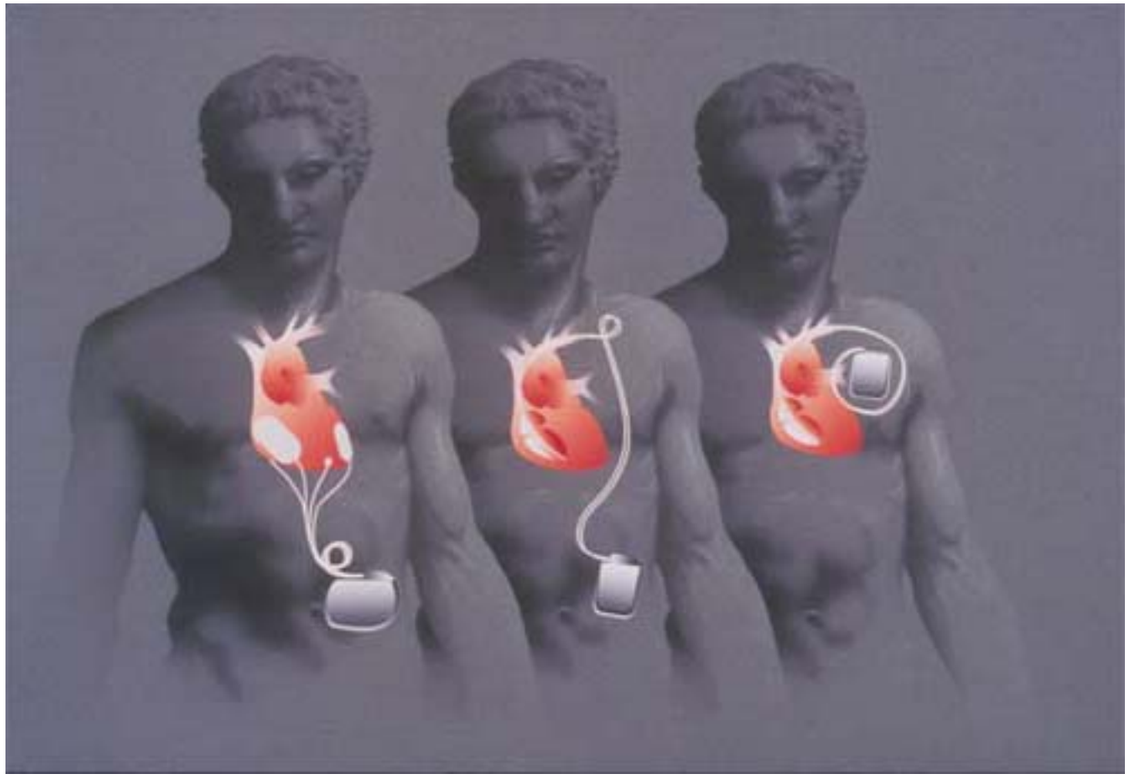
ICD Evolution



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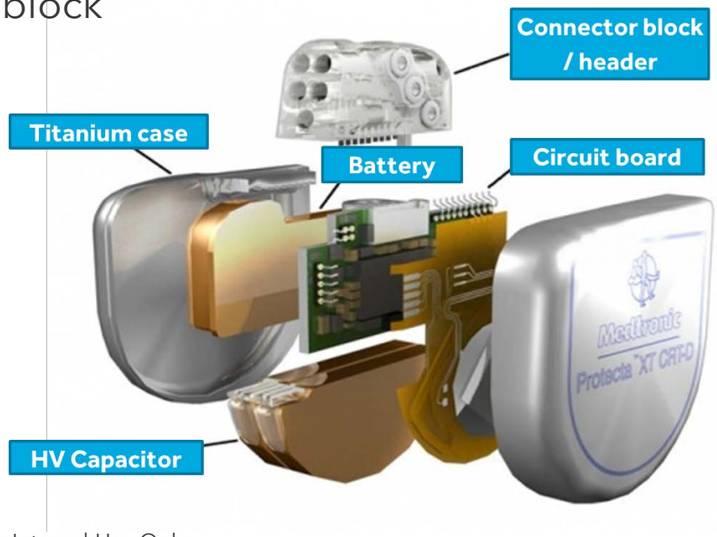
ICD system components

ICD

Implantable cardioverter-defibrillator

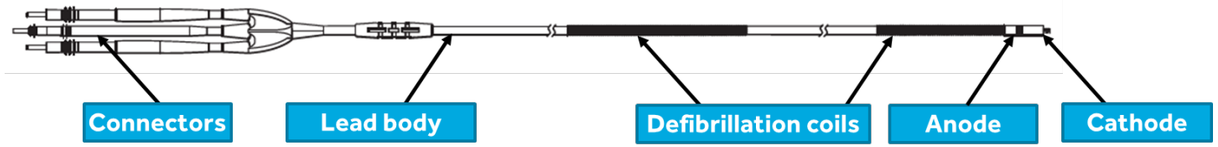
- Battery (lithium silver vanadium oxide)
- Electrical circuitry
- Microprocessor and memory
- HV Capacitor
- Connector block



Lead

Lead

- Cathode – negative electrode
- Anode – positive electrode
- Defibrillation coil(s)
- Lead body
- Connector



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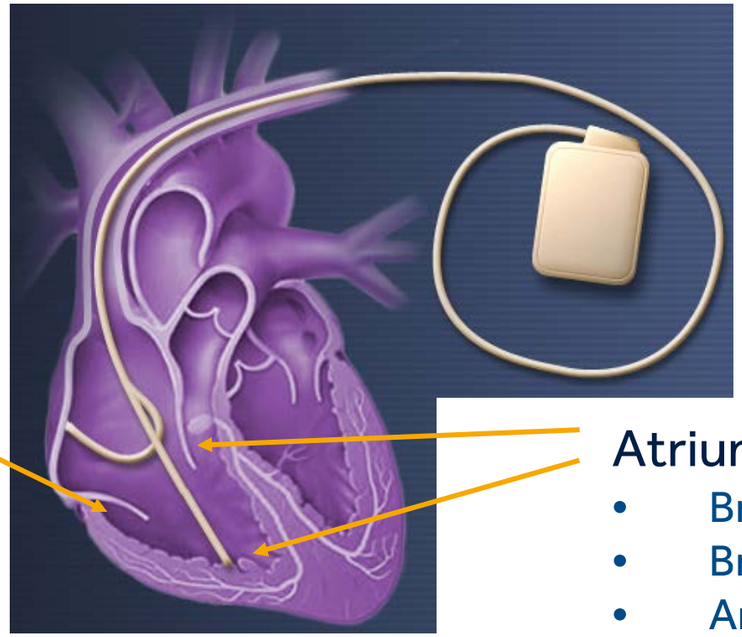
ICD system

How it works

Ventricle

- VT prevention
- Cardioversion
- Defibrillation



Atrium & Ventricle

- Bradycardia sensing
- Bradycardia pacing
- Antitachycardia pacing

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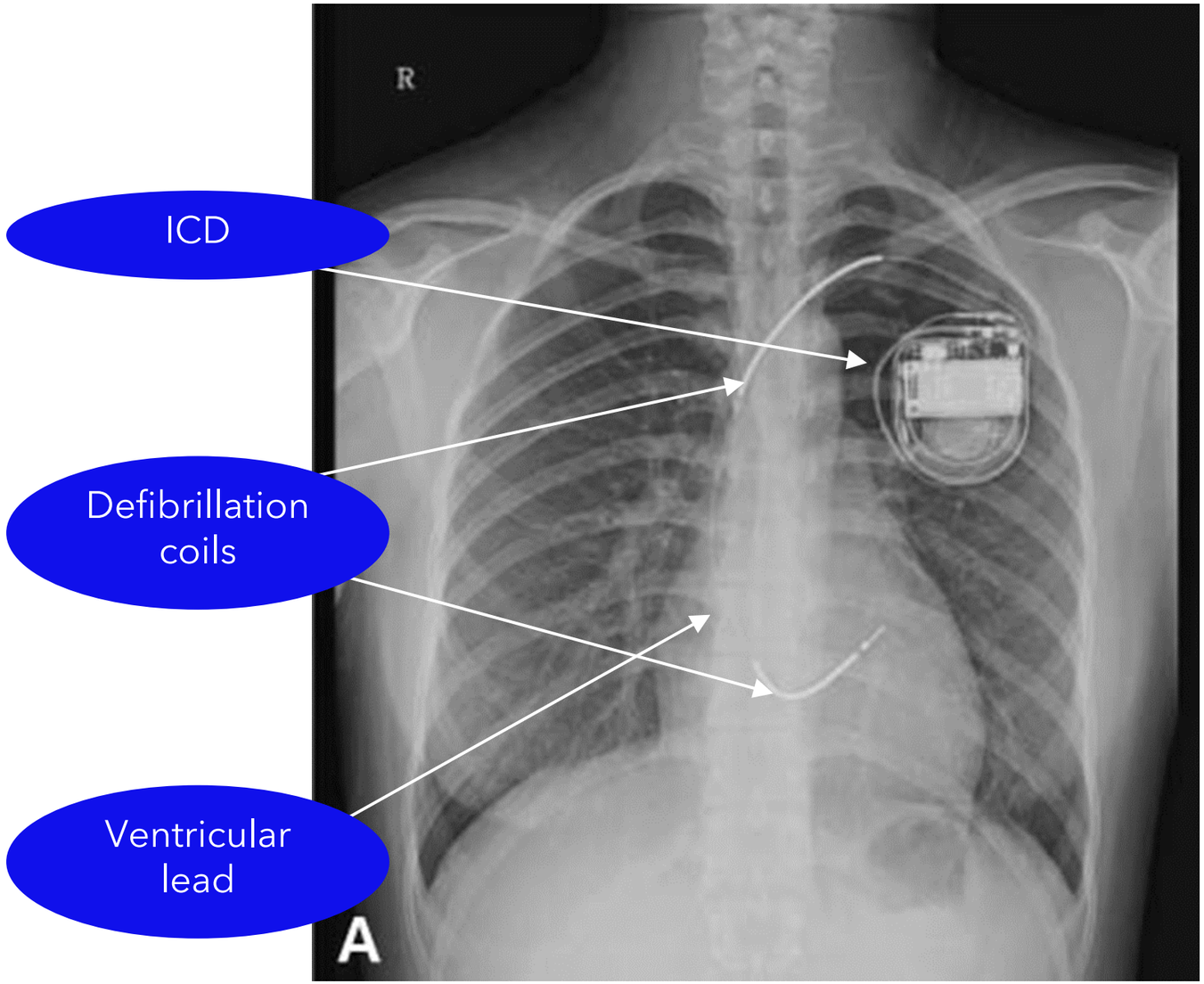
ICD implant

X-ray check



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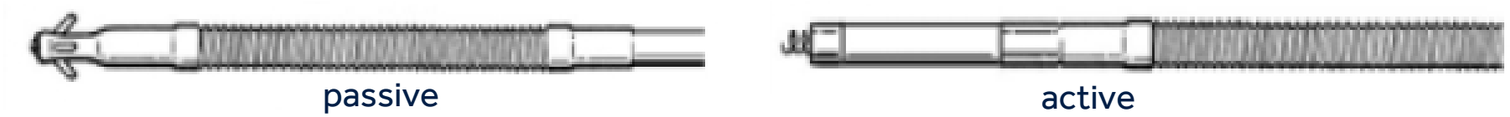
‘Standard’ (endocardial) leads categorization

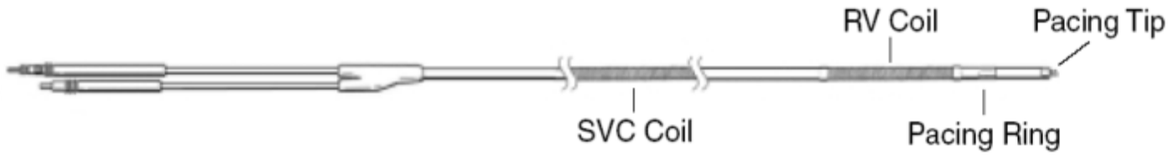
can be made according to:

Fixation Mechanism



Number of Shocking Coils

- Sing
- Doul



Connector Type

- DF1: trifurcation dividing the lead into 2-3 connectors: pacing/sensing, defib RV, defib SVC
- DF4: single connector

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Special leads

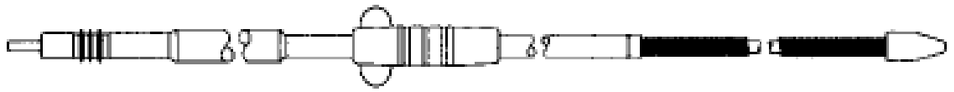
All are DF1, all just defibrillate (no pace/sense)

Epicardial patch 6721 S/M/L

- Placed on the heart surface

Subcutaneous: 6996 SQ

- Placed in the tunnel under the skin



Into Coronary Sinus: Transvene 6937

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An implanted defibrillator saved
a young soccer player's life yesterday.

Cardiac Resynchronization Therapy

Heart Failure

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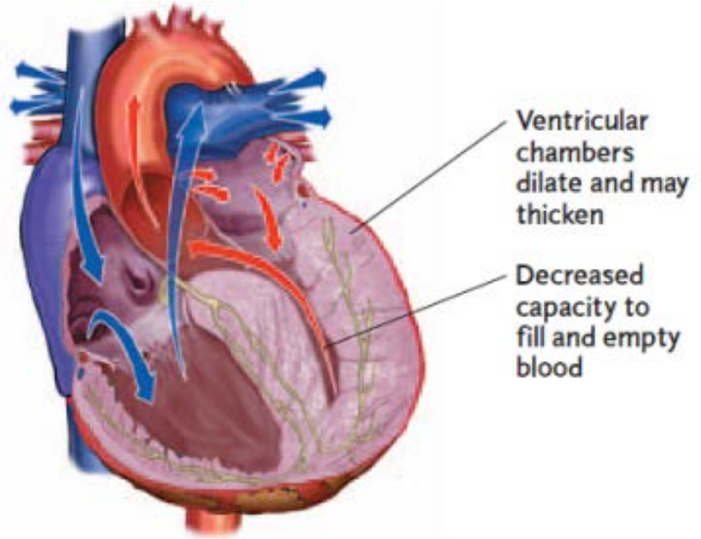
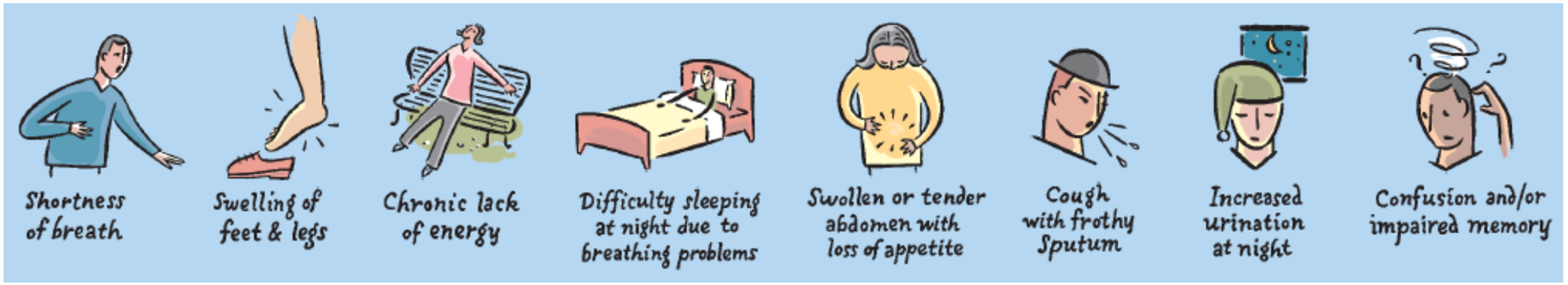
Chronic Heart Failure (CHF)

Is not a single illness, it's a condition

- Heart muscle is weakened
- Heart enlarges and becomes "baggy"
- Reduced oxygen delivery to organs such as the brain and kidneys



Symptoms:



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HF Classification

Symptoms[1]

NYHA Class = New York Heart Association Classification

Class I	Class II	Class III	Class IV
No symptoms Can perform ordinary activities without any limitations	Mild symptoms Occasional swelling Somewhat limited in ability to exercise or do other strenuous activities No symptoms at rest	Noticeable limitations in ability to exercise or participate in mildly strenuous activities Comfortable only at rest	Unable to do any physical activity without discomfort Symptoms at rest

1. The Criteria Committee of the NYHA .Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256

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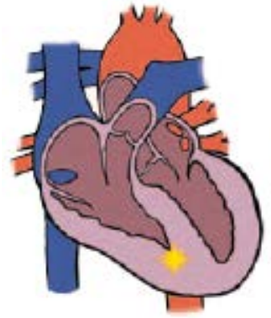
Treatment of CHF

CHF = Congestive Heart Failure



Right ventricle contracts first

Followed by contraction of the left ventricle

Standard treatment

- Lifestyle changes
- Rest and exercise
- Medications

Surgery

- Heart transplant
- Valve repair / replacement

CRT

For Mild to Severe HF Patients with low ejection fraction (EF≤35%) and ventricular dyssynchrony (long QRS)

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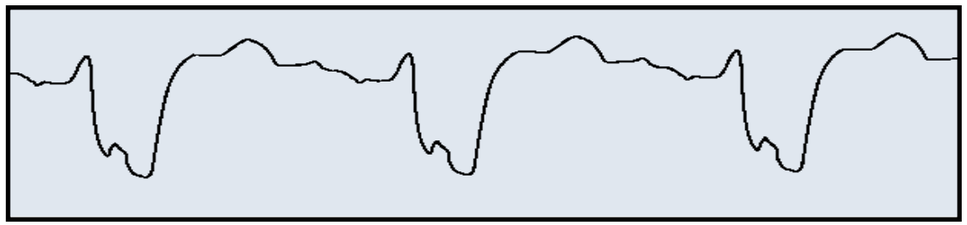
Ventricular dyssynchrony & CRT

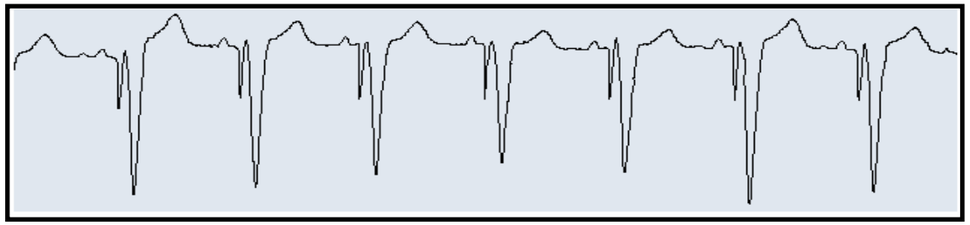
Ventricular Dyssynchrony[1]

- Electrical
- Structural
- Mechanical



CRT

- Therapeutic intent of atrial synchronized biventricular pacing
- Complement to optimal medical therapy



1. Tavazzi L. Eur Heart J 2000;21(15):1211-1214

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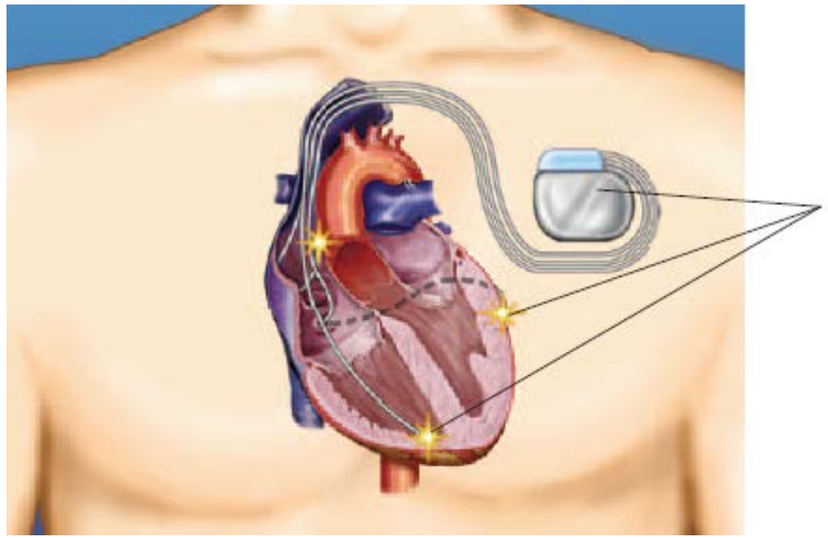
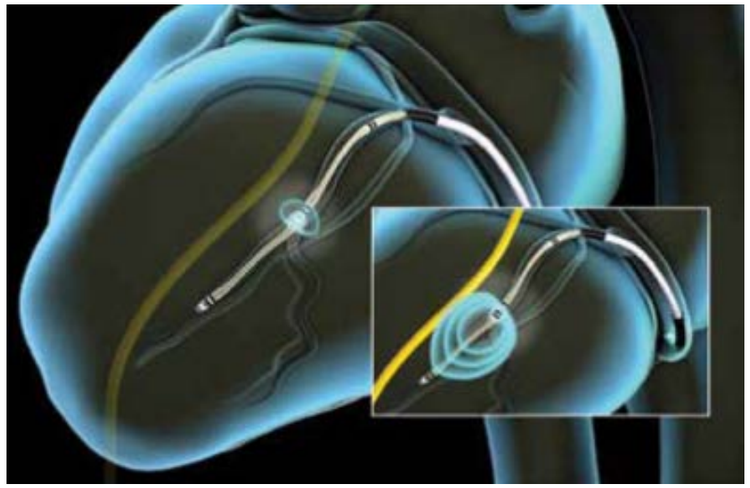
Cardiac Resynchronization Therapy



CRT causes both ventricles to beat together while paced from both right and left ventricle



Potential Benefits of the Therapy:

- Reduced mortality
- Improved Quality of Life
- Reduced heart failure symptoms
- Increased ability to exercise and perform other physical activities

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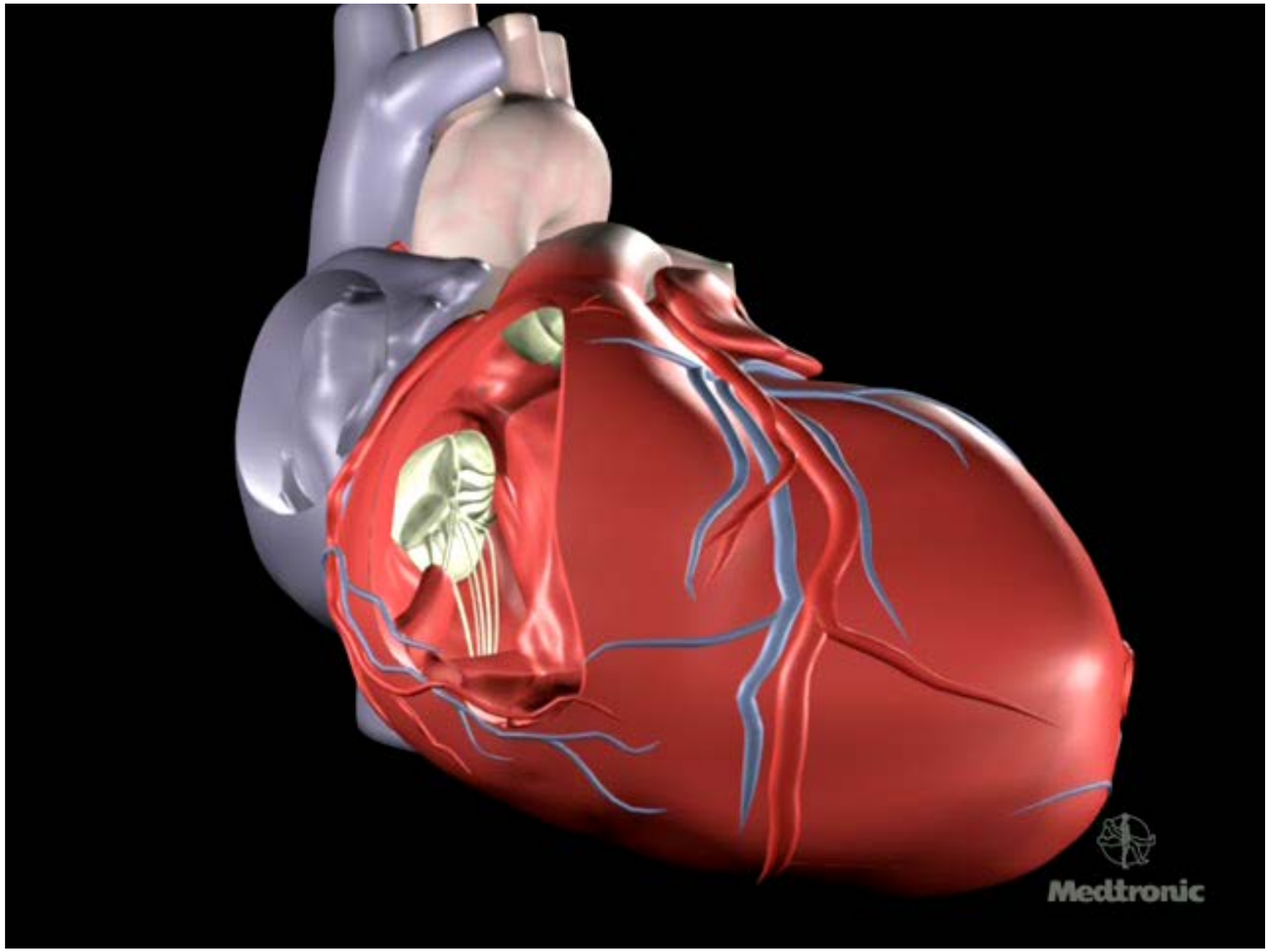
CRT implant procedure

More complex than IPG/ICD



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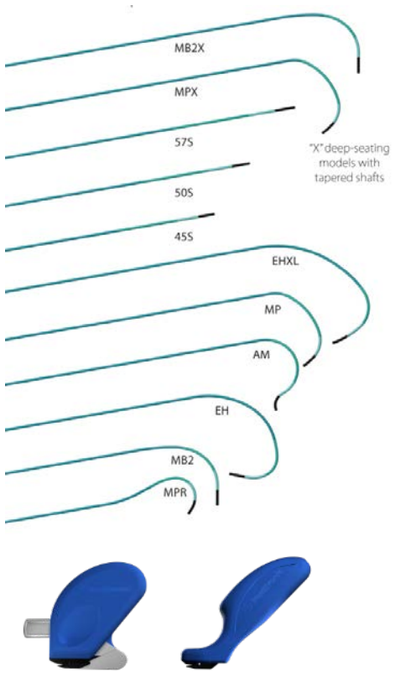
CRT implant procedure

The tools

CRT system

- CRT device (CRT-P or CRT-D)
- 3 leads: pacing for RA, pacing or defib for RV and pacing for LV
- Introducers
- Accessories to place LV lead
  - Delivery catheter kit (catheters, dilators, slitters, valves, wire)
  - Venogram balloon
  - Guidewires



Additional catheters, subselecting catheters, slitters, valves, guidewires, stylets, …

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Left heart leads

Also called LV – left ventricle lead

Special leads used for pacing LV from the coronary veins

- with 2-electrodes (IS1-connector), or
- with 4-electrodes, so called ‘Quad’ or ‘Quadpole’ (IS4-connector)

Family	Attain Ability		Attain Performa			Attain Stability	
Model #	4196	4396	4296	4598	4398	4298	4796	4798
Connector	IS-1	IS-1	IS-1	IS-4	IS-4	IS-4	IS-1	IS-4

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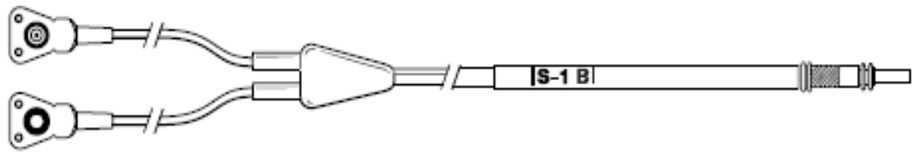
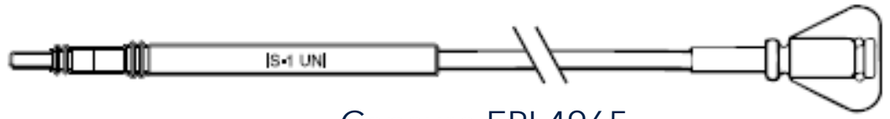
Epicardial pacing leads

~5-10% of LV leads have to be placed epicardially

- e.g. on the heart surface
- if not possible to find good location in coronary veins



Capsure EPI 4968



Capsure EPI 4965

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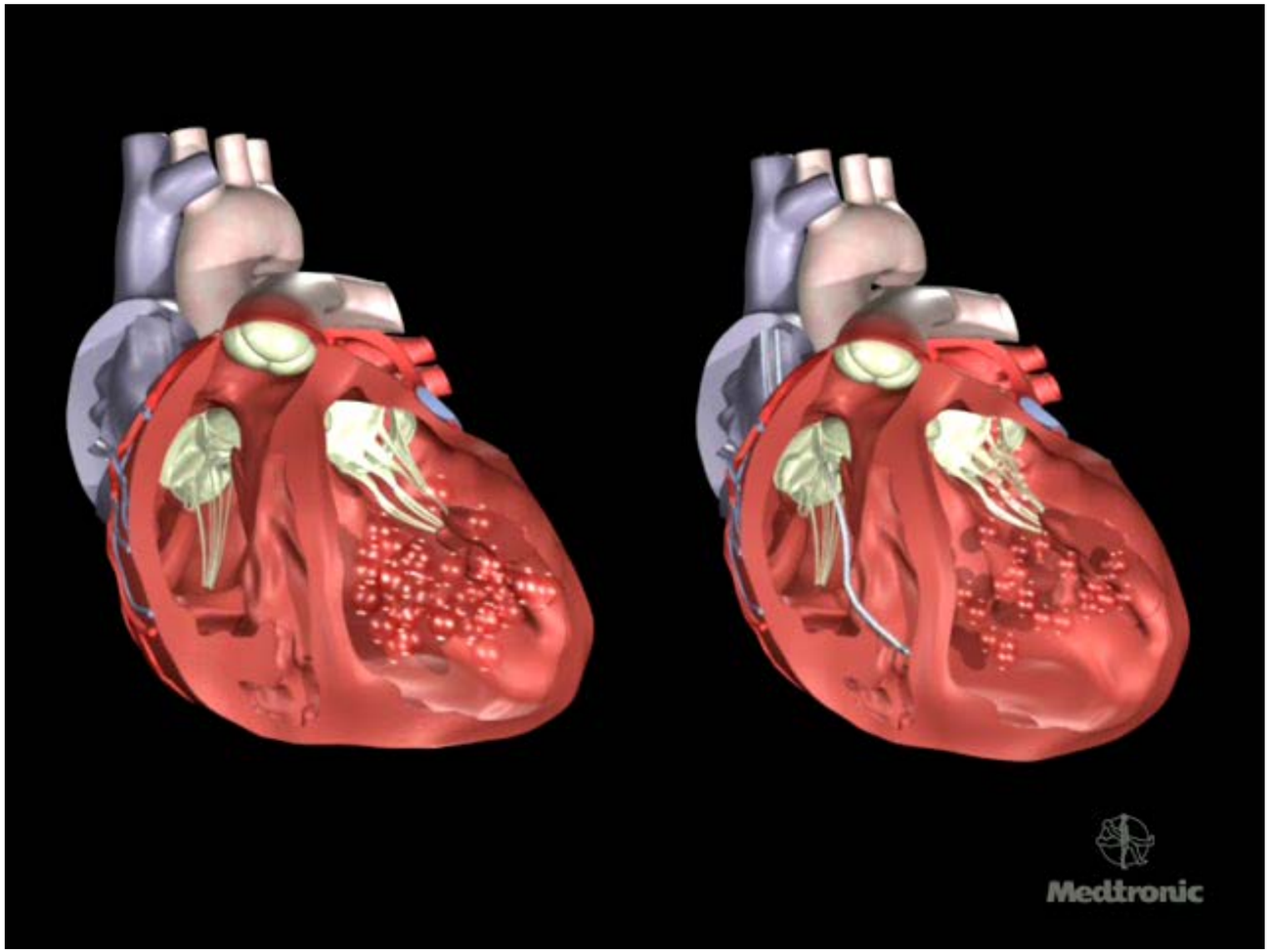
CRT impact



Desynchronized contraction
Systolic heart failure

Synchronized contraction
due to CRT delivery

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Tyrx

Procedure innovation

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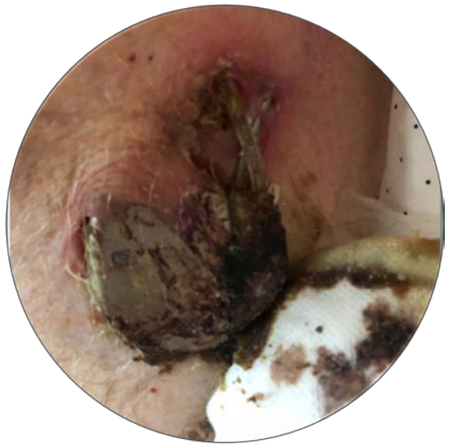
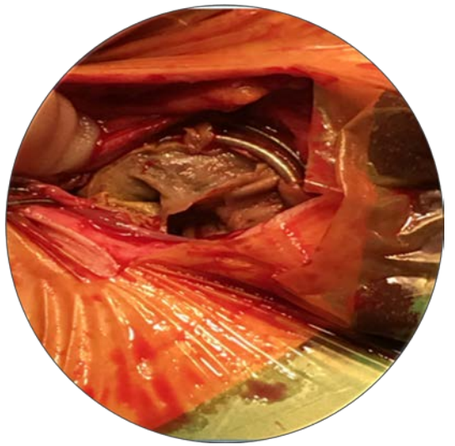
Managing CIED infection risk





>3x

mortality risk at 1 year

23-40

average length of patient hospital days

€21k-70k

average costs to treat an infection in EU

Managing CIED infection risk

Who would benefit?

Patients with

- generator replacement
- System upgrade
- Revision
- Initial CRT-D
- Hemodialysis or peritoneal dialysis
- Immunosupressive agents
- Recent infection

Managing CIED infection risk

How can we minimize the risk for those patients?

What

TYRX is an absorbable antibacterial envelope that helps reduce cardiac implantable electronic devices infections

How

Two antibiotics locally delivered that account for ~70% of all device infections

Patient Management

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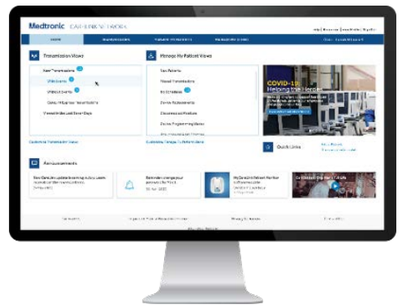
Medtronic Carelink

Remote Monitoring

Patients use a mobile app or a bedside monitor to send data from their device



Clinicians can access patient's data using CareLink™ clinician website

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The Carelink Network

Leading Remote Monitoring Service*

Faster Diagnosis

94%

Up to 94% reduction in time to review[5-8]

Reduction in Visits

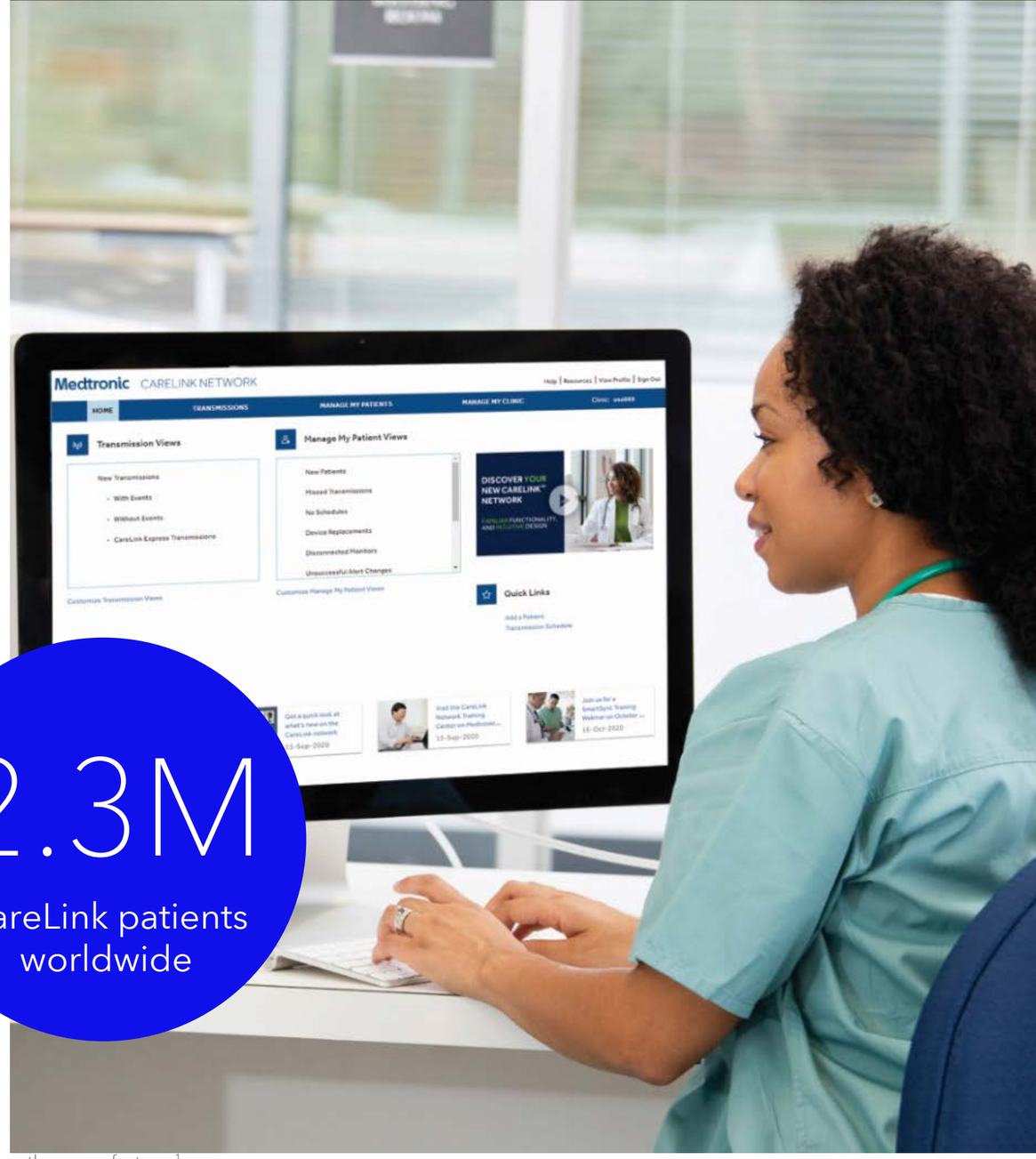
41%

Up to 35% in ED and urgent in-office visits[5], 41% in total visits[9]

Increased Patient Quality of Life

QoL

Favorable change in the patient quality of life observed[5]



2.3M

CareLink patients worldwide

*Significantly more respondents associate Medtronic with remote monitoring capability overall, and with each of the specific aspects, than any other manufacturer[1]

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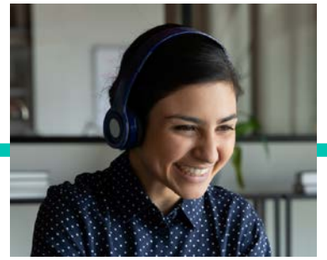
Patient Management Portfolio

In-Clinic Management

Medtronic Medtronic LINQ Medtronic

BeConnected



Patient & Clinic Services

Remote Monitoring

https://europe.medtronic.com/xd-en/healthcare-professionals/products/cardiac-rhythm/managing-your-patients.html

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Cardiac Rhythm Management

Key products

Brady

Azure™ XT MRI IPG

Attesta MRI IPG

Micra VR and Micra AV Transcatheter Pacing System

Tachy

Cobalt™ XT ICDs

Cobalt™ ICDs

Crome™ ICDs

Heart Failure

Cobalt™ XT CRT-D

Cobalt™ CRT-D

Crome™ CRT-D

Percepta™ , Serena™ , Solara ™ CRT-P

Patient Management

CareLink SmartSync™ Device Manager

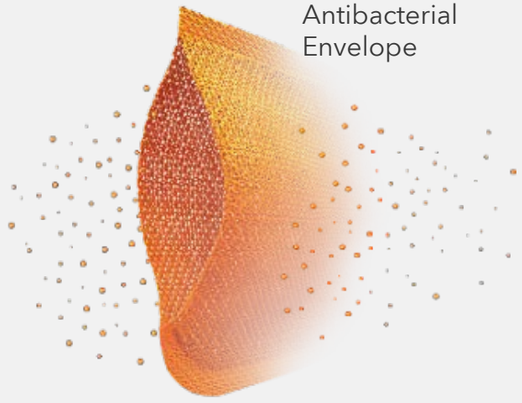
CareLink™ network

MyCareLink Heart™ Mobile App

MyCareLink Relay Home Communicator

Procedure Innovation

TYRX™ Absorbable Antibacterial Envelope



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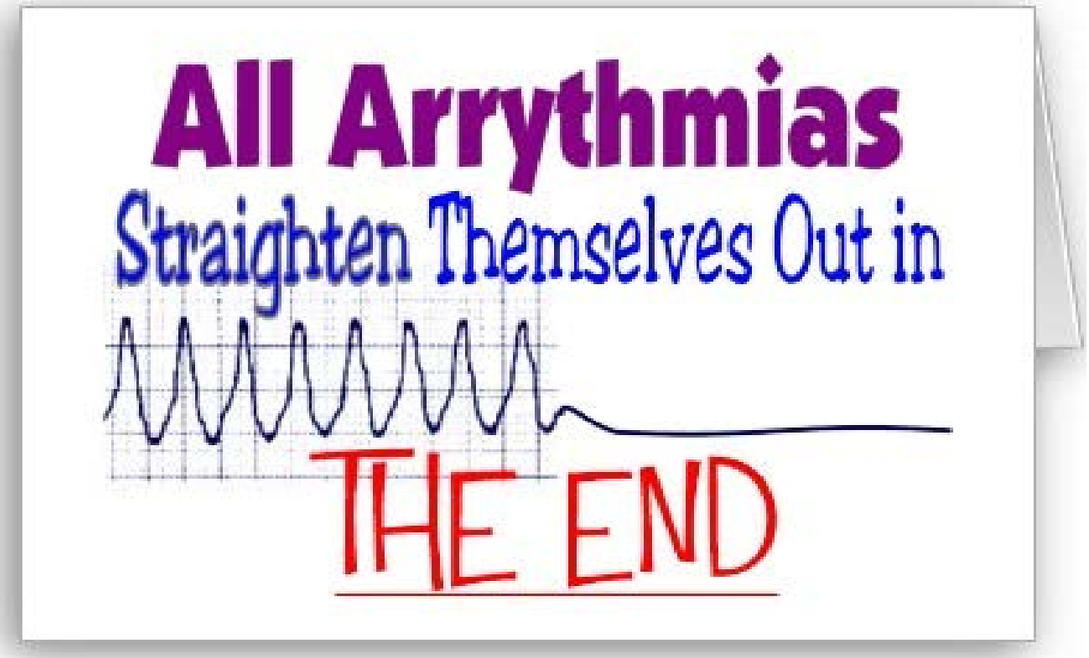
That’s it for today…
Questions?



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