

# Cardiac Rhythm Management for enthusiasts

October 2022

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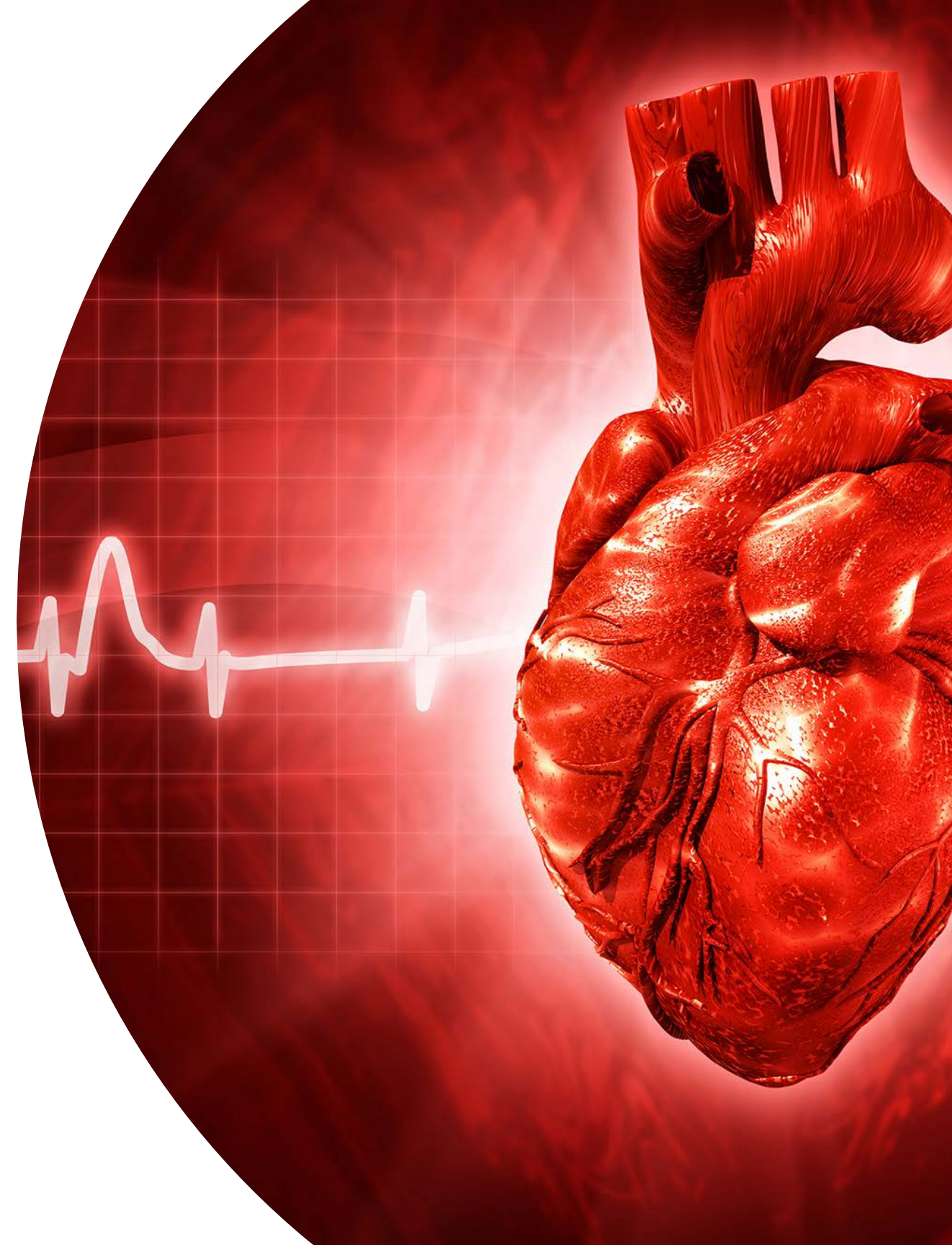


**Medtronic**

Engineering the extraordinary

# Rhythm disorders

... and CRM therapies



# Who does NOT belong to the group?

A.



B.



C.



D.



E.

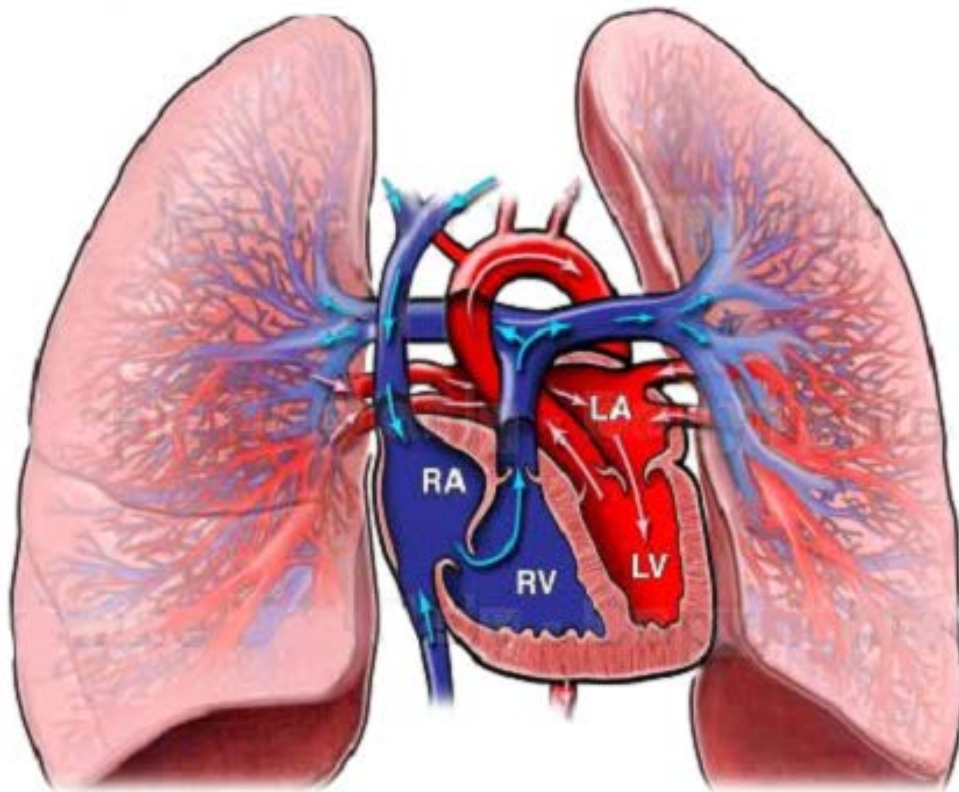
F.



Babec

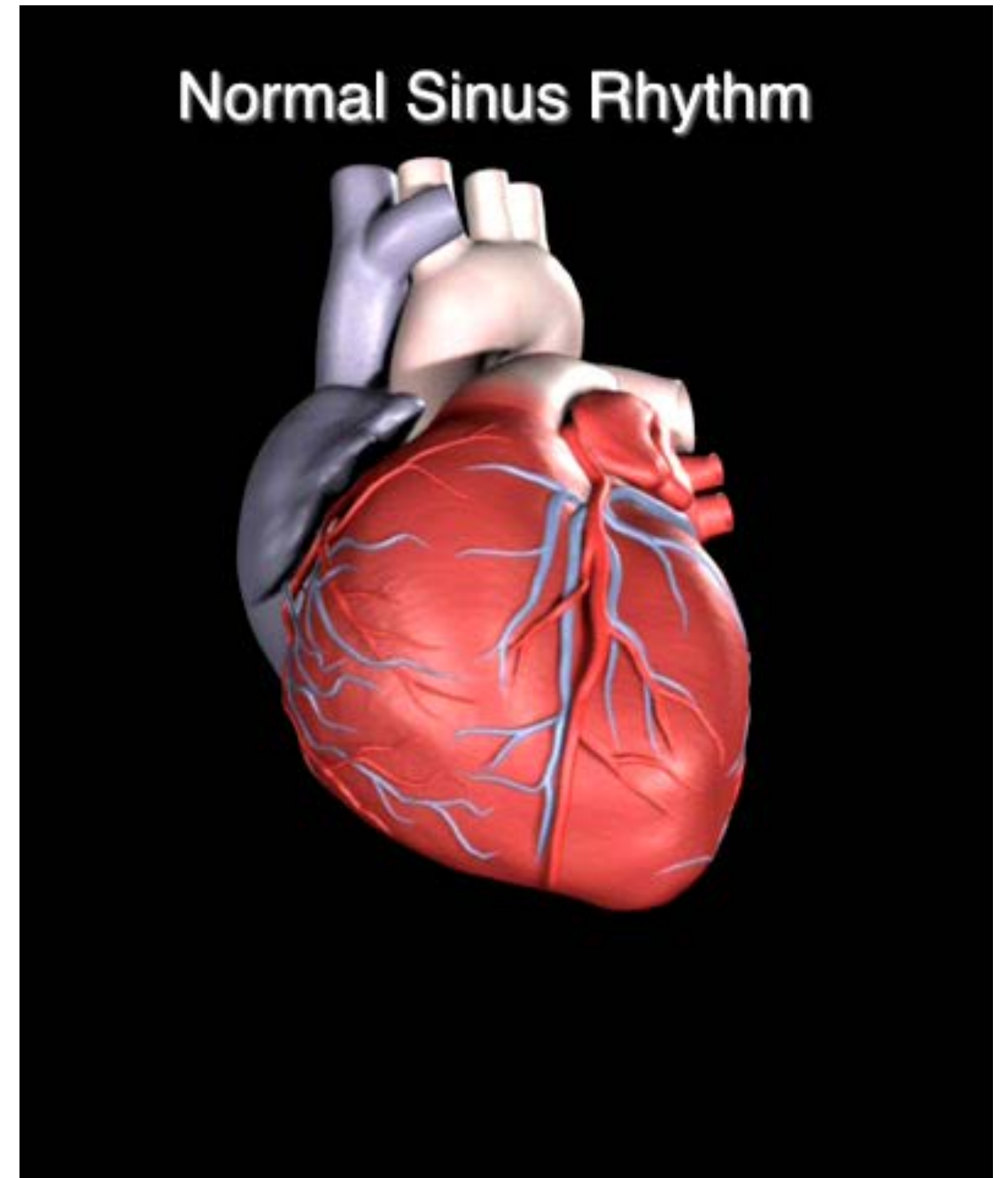
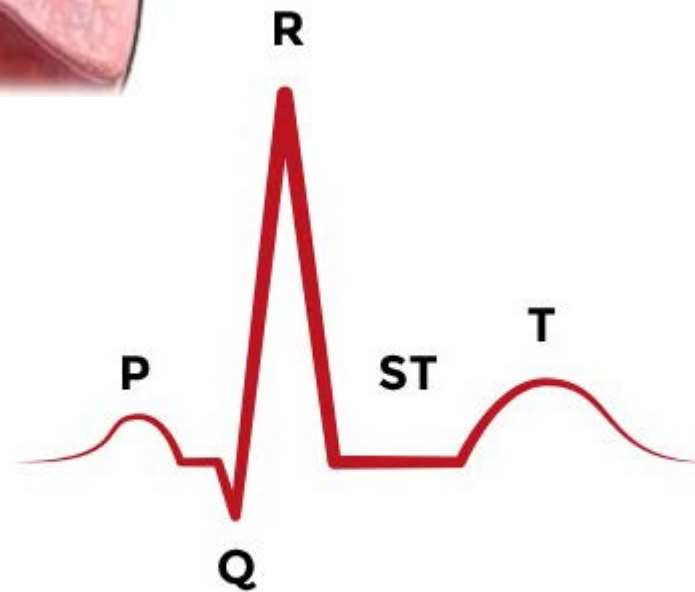


# Heart is a pump

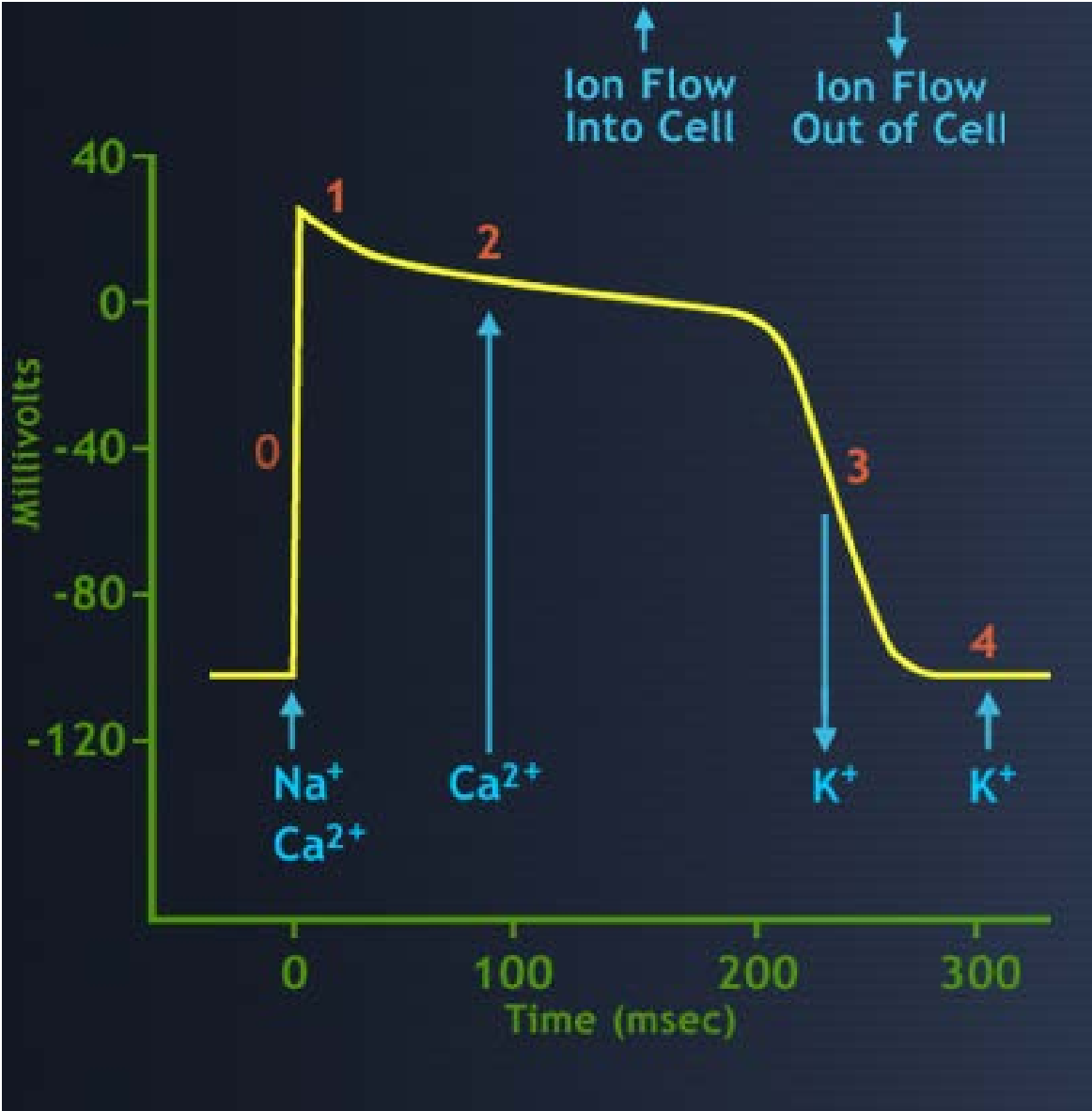
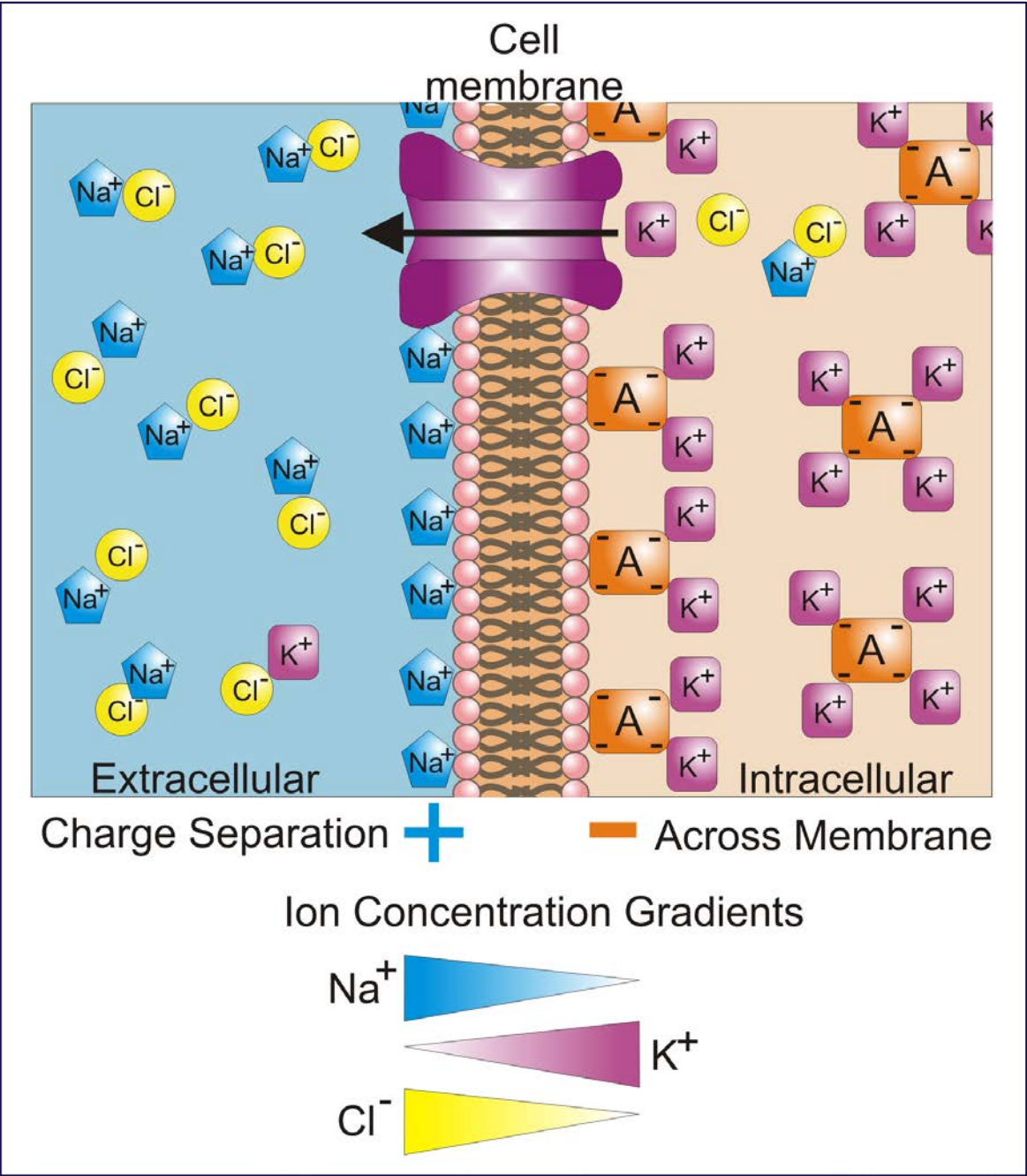


RA = Right Atrium  
RV = Right Ventricle

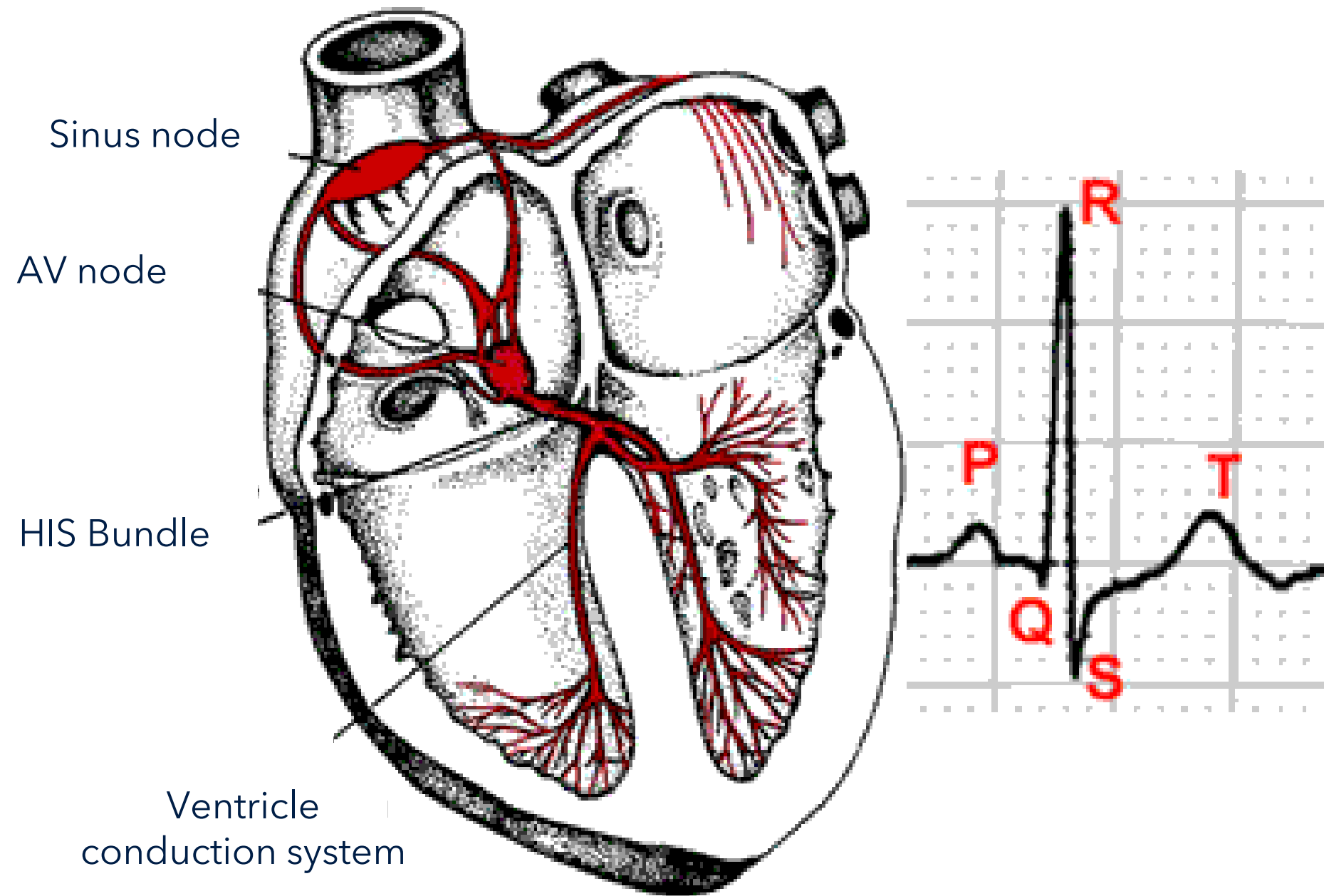
LA = Left Atrium  
LV = Left Ventricle



# Heart muscle cell - action potential

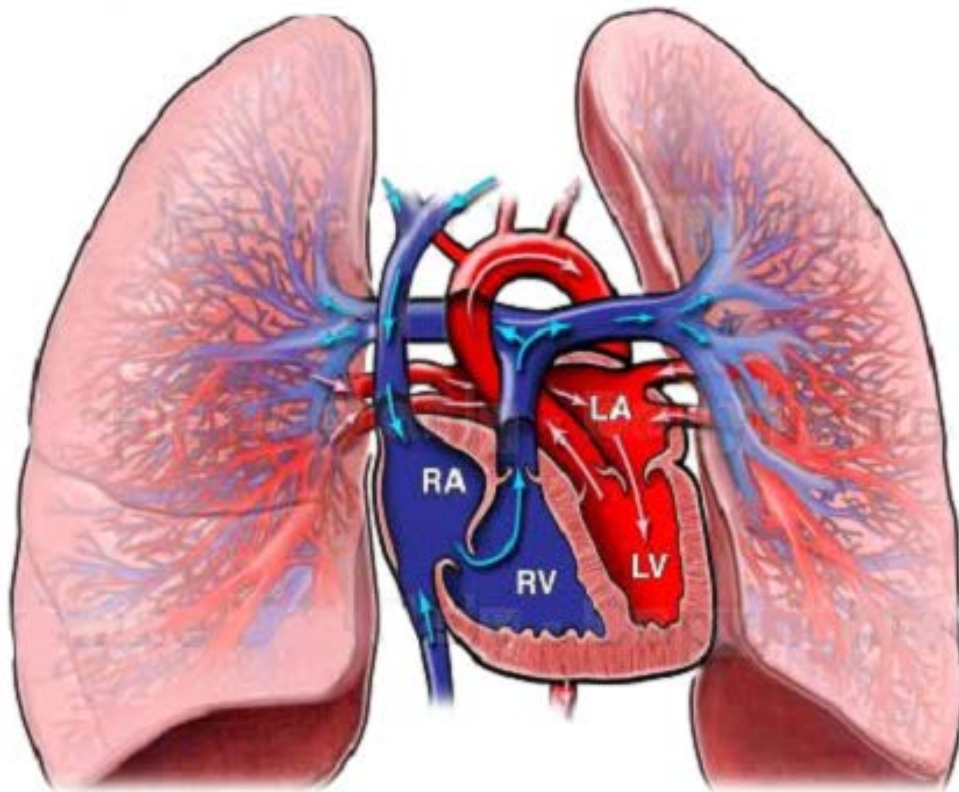


# Heart conduction system



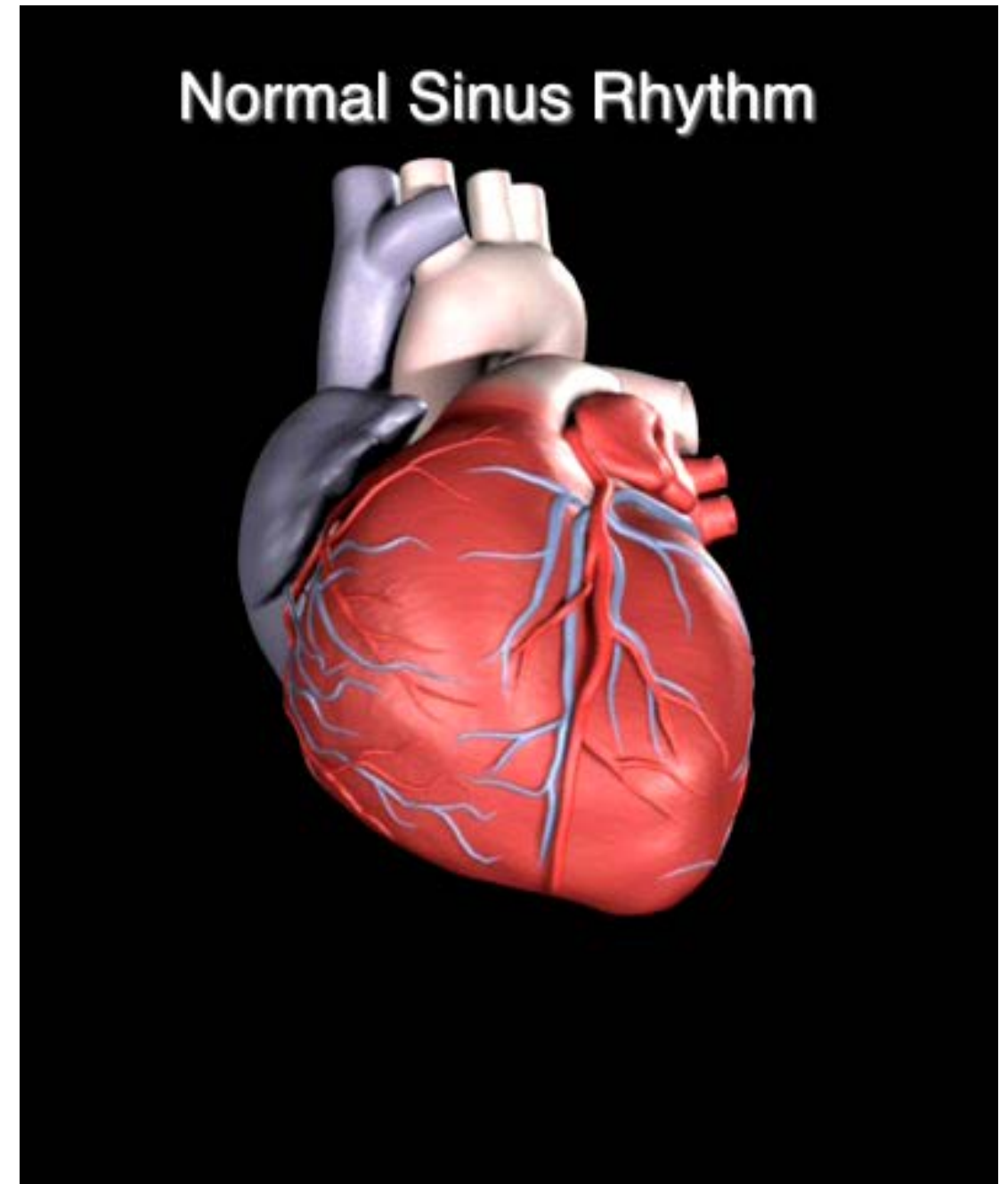
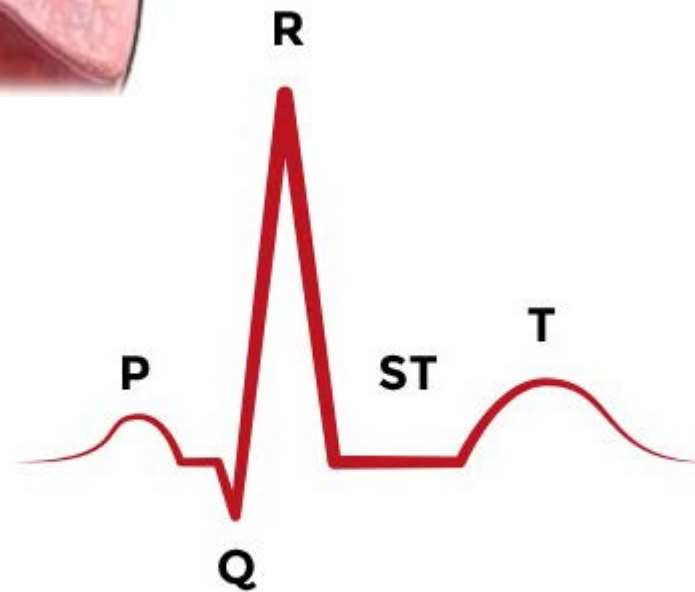


# Heart is a pump



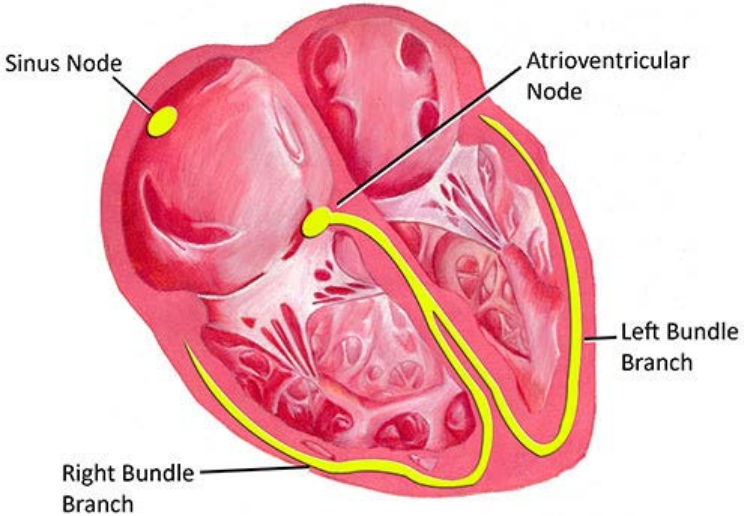
RA = Right Atrium  
RV = Right Ventricle

LA = Left Atrium  
LV = Left Ventricle



# 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.

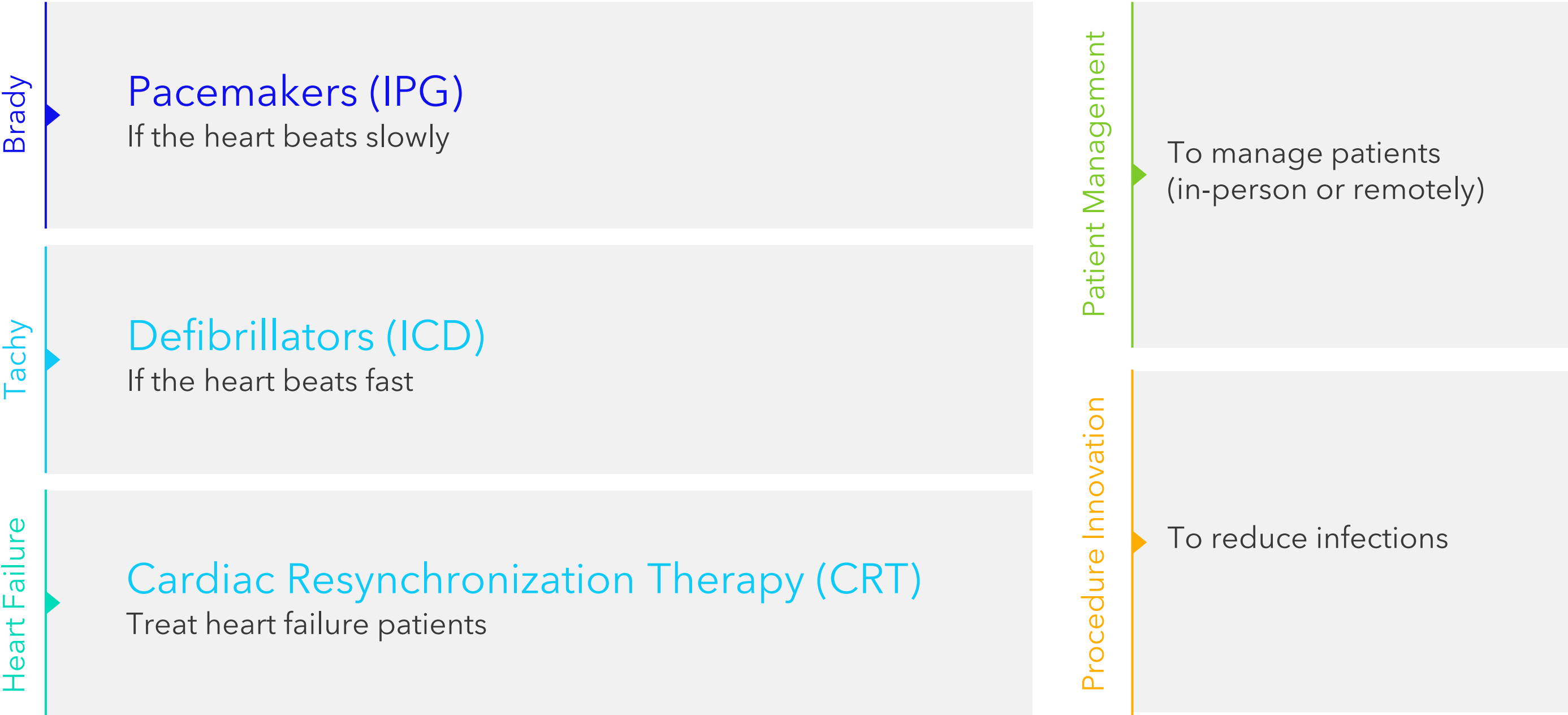
AF Mgmt Algorithms

**Medtronic**



# Cardiac Rhythm Management

## Focus areas



# Cardiac Rhythm Management

## Key products

Brady	<p>Pacemakers (IPG)</p> <p>If the heart beats slowly</p>
Tachy	<p>Defibrillators (ICD)</p> <p>If the heart beats fast</p>
Heart Failure	<p>Cardiac Resynchronization Therapy (CRT)</p> <p>Treat heart failure patients</p>

Patient Management	<p>To manage patients (in-person or remotely)</p>
Procedure Innovation	<p>To reduce infections</p>



# Pacemakers

Brady

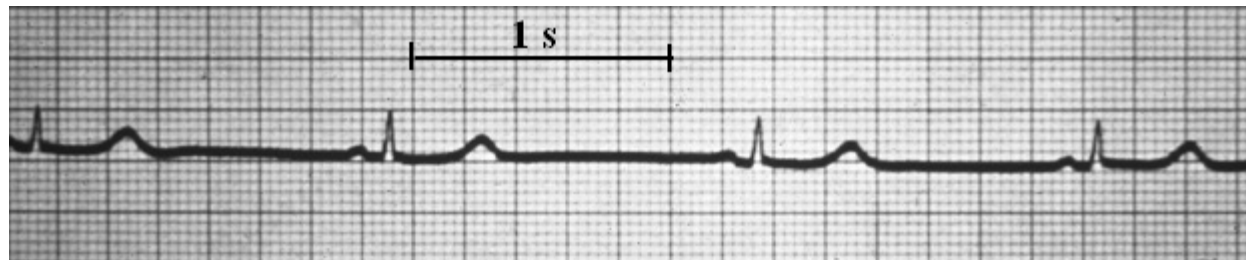
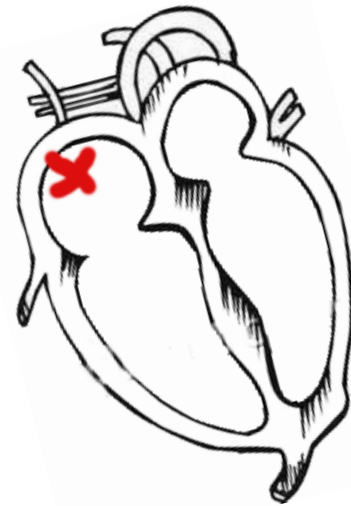


# Slow rhythms

## Synus Bradicardia

Regular heart contractions

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

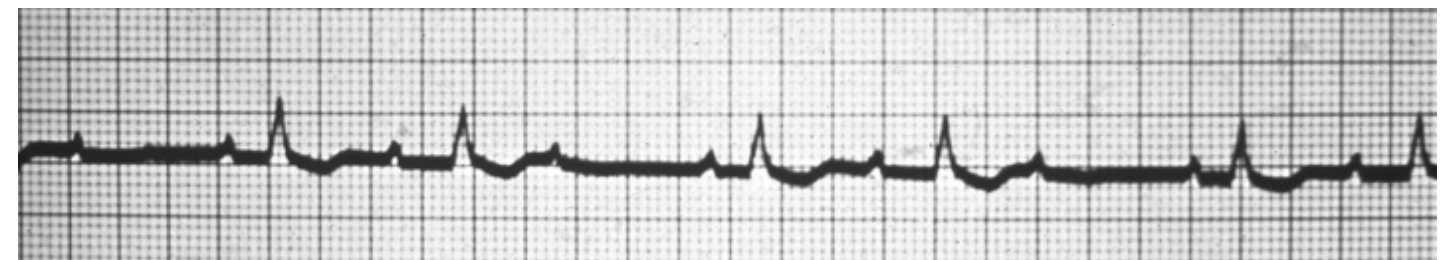
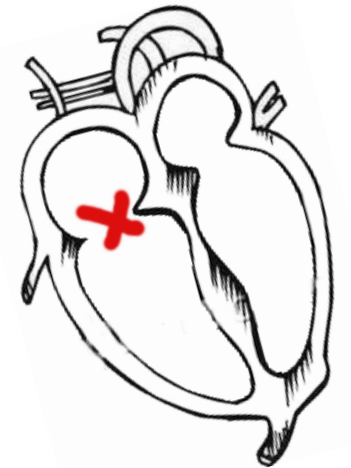


## AV Block

Conduction disorders between atria and ventricles

Atria contract normally

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



# 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.

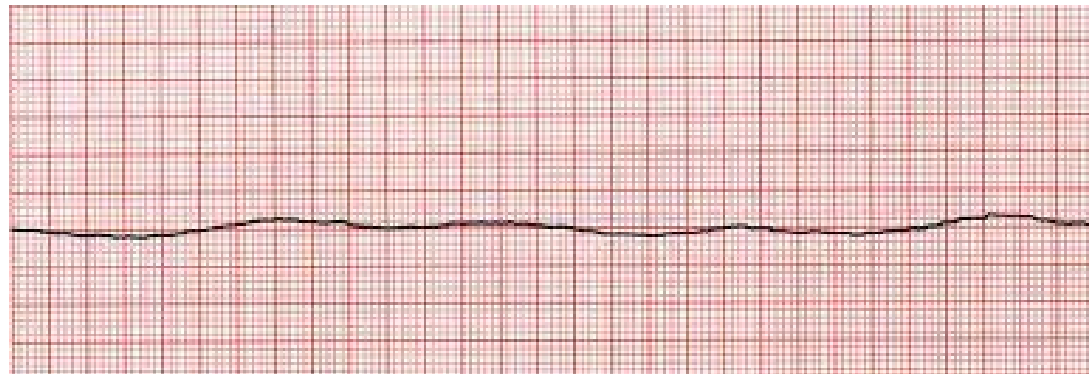


Pacemaker therapy can be

## Life saving

In case there's no intrinsic activity

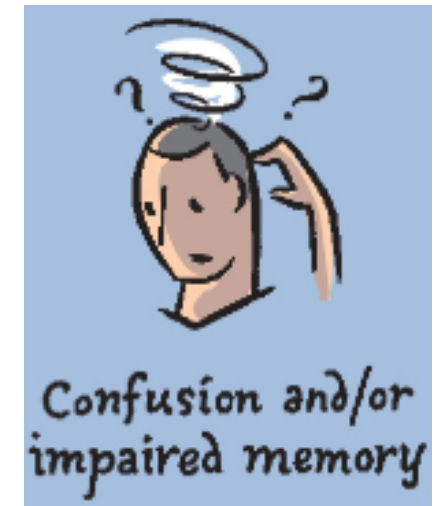
Resulting in asystole



## Improving quality of life

Some intrinsic activity exists

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

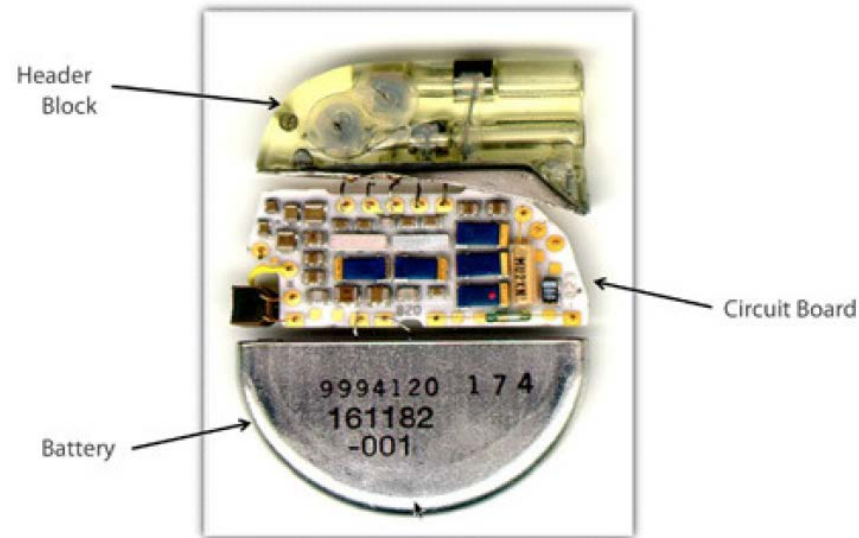




# Implantable Pacemaker Circuit

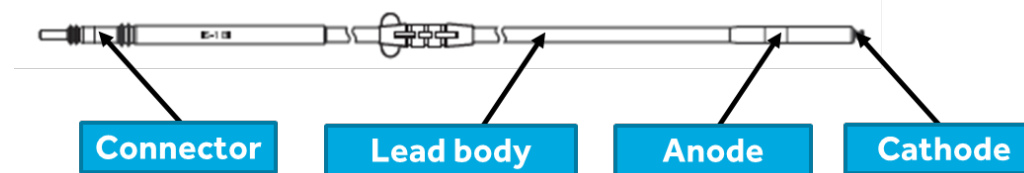
## Implantable pulse generator (IPG)

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

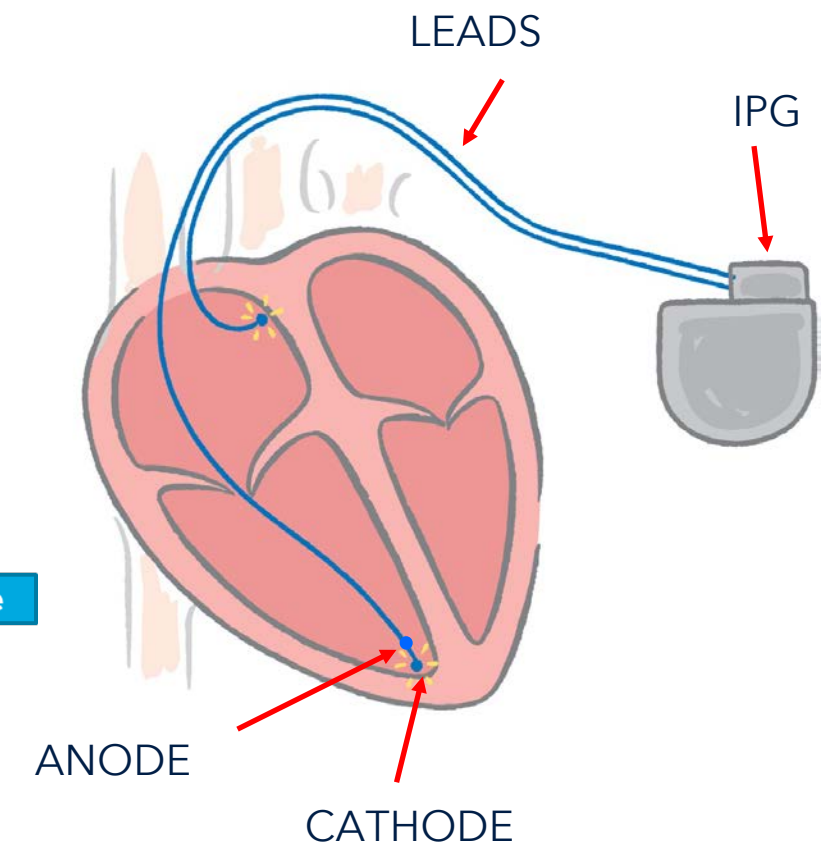


## Leads (wires)

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



## Body tissue

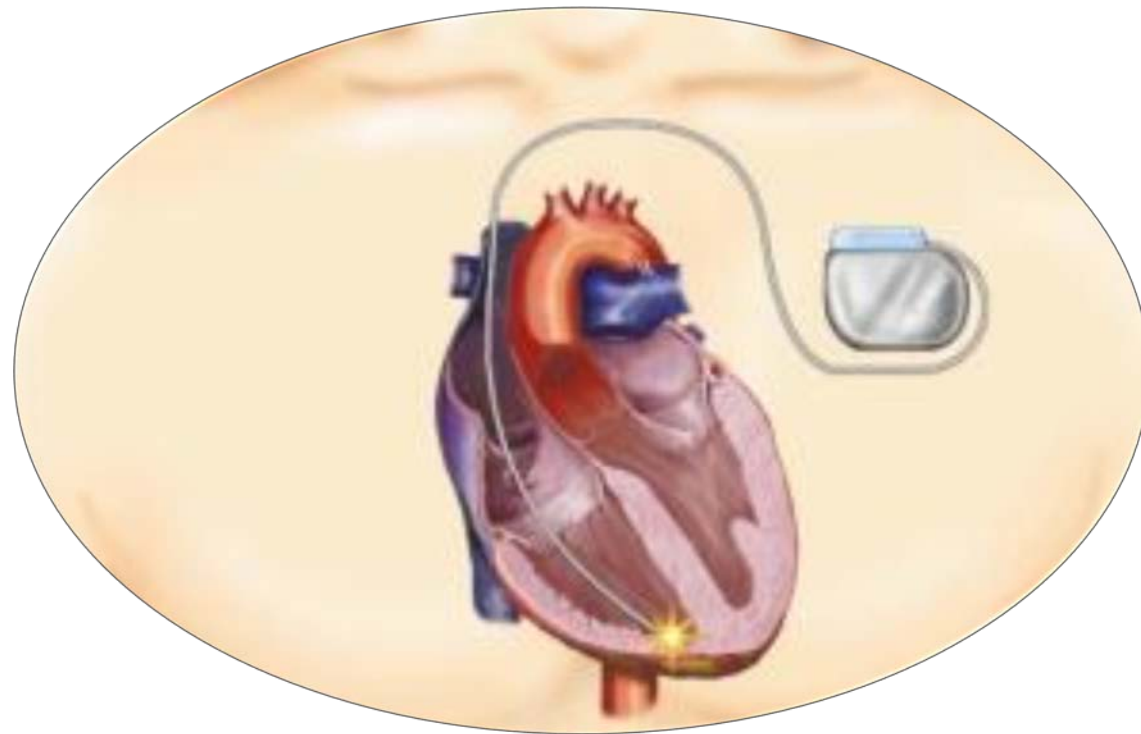


# Pacemaker systems

## Basic classification

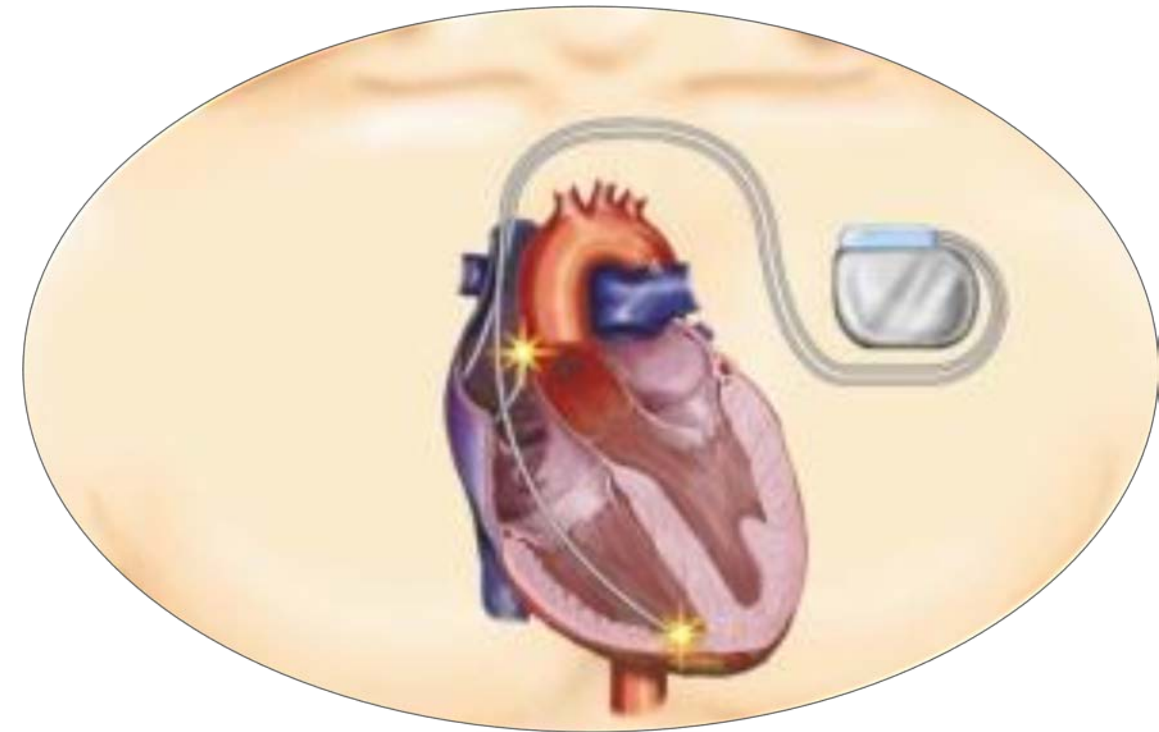
### Single chamber

- Implanted one lead only
- Usually in the right ventricle



### Dual chamber

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



# Pacemaker

## What it does?

Constantly **checks** the intrinsic **rhythm** of the patient and in case of need via the lead(s) **it delivers a small electrical pulse** that stimulates the heart muscle and results in contraction

**Collects** lots of **data** about the device performance as well as about the status of patient's heart rhythm and some other statistics

Such data are possible to be displayed via **programmer** when the patient comes for the follow-up and/or can be transmitted remotely to the CareLink system (Patient management network for **remote follow-up**)

### Medtronic programmer / device manager



2090 CareLink Programmer

SmartSync Device Manager

### Medtronic patient monitors for remote transmissions



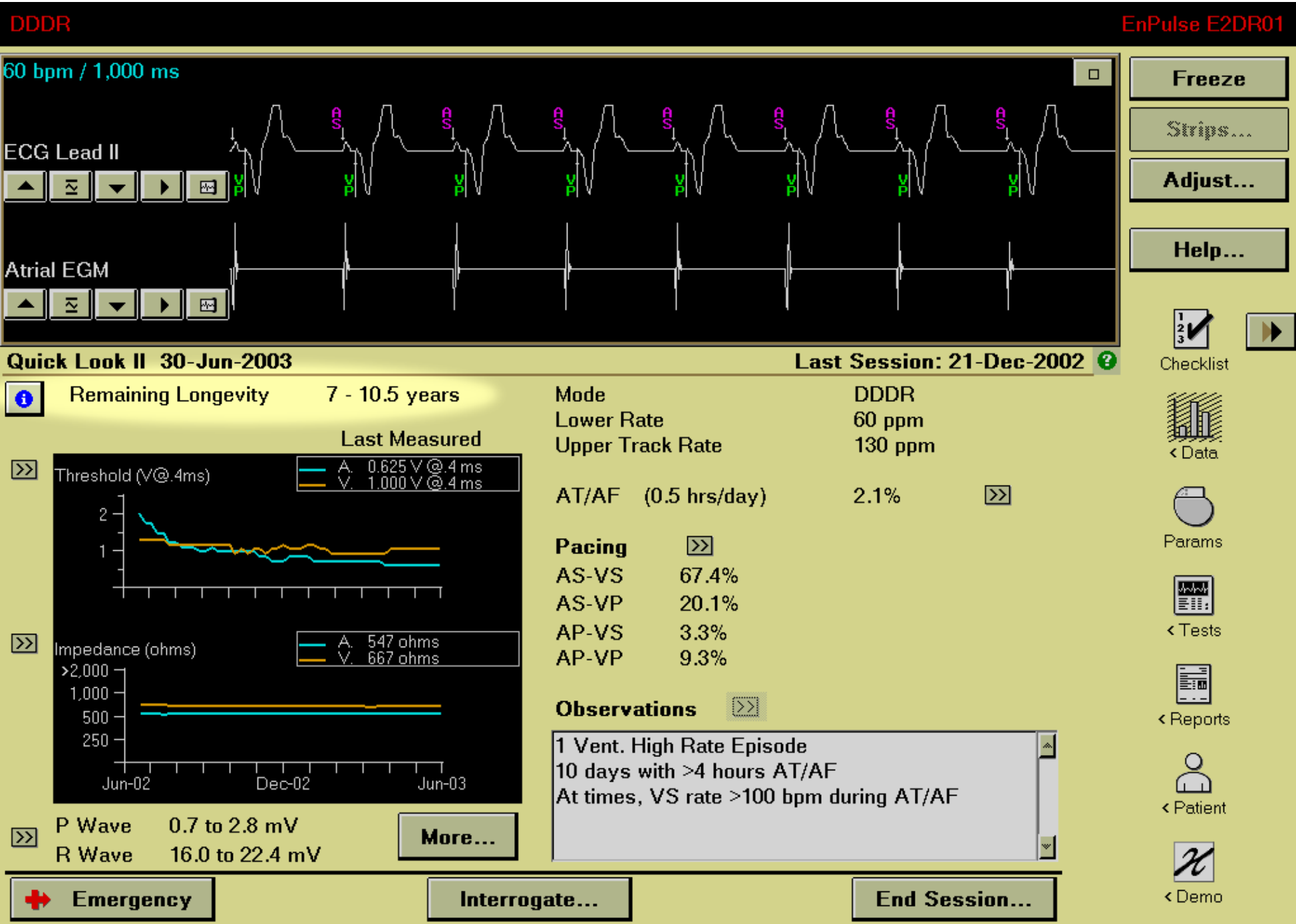
MyCareLink monitor

MyCareLink Smart monitor  
MCL Smart mobile App

MCL Heart mobile App



# Programmer screen

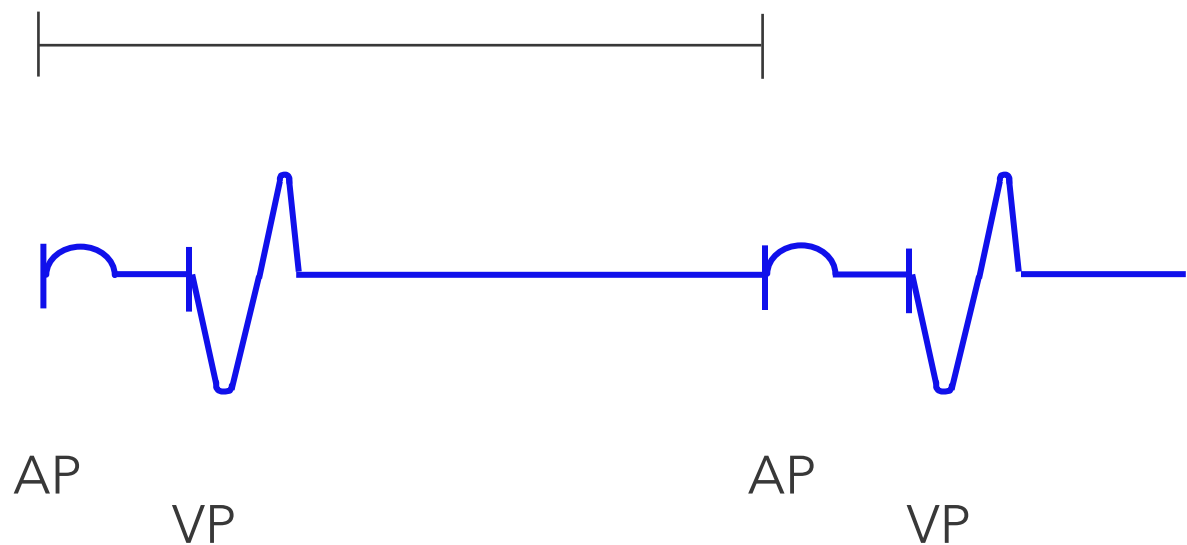


# Lower rate and rate response

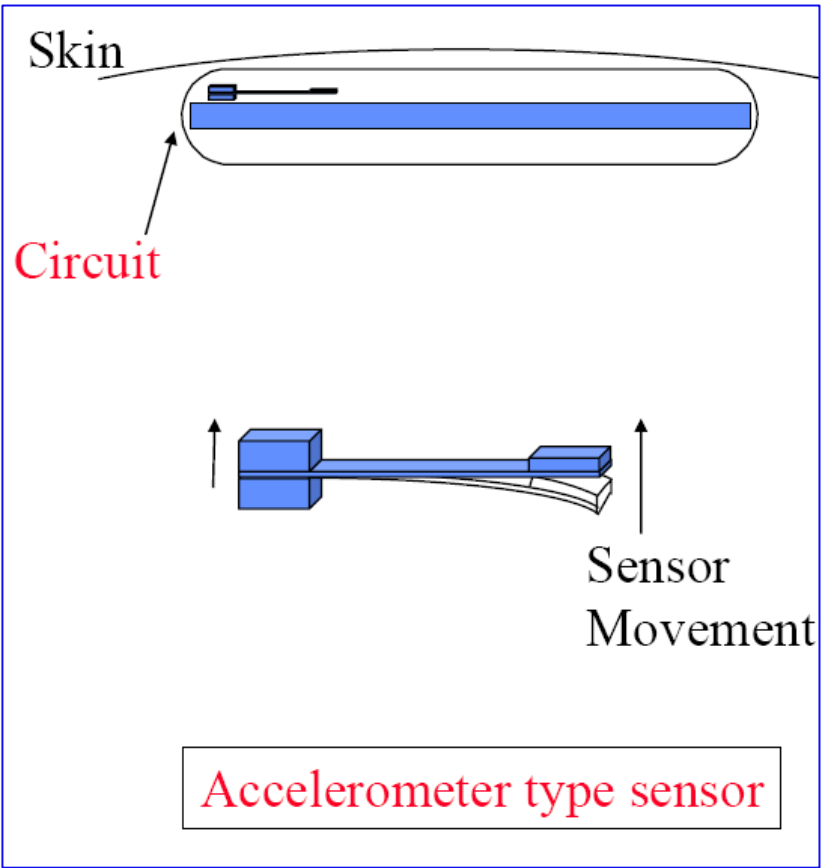
The lowest rate the pacemaker will pace in the absence of intrinsic events

DDD(R) 60

Lower Rate Interval



Rate response - accelerometer



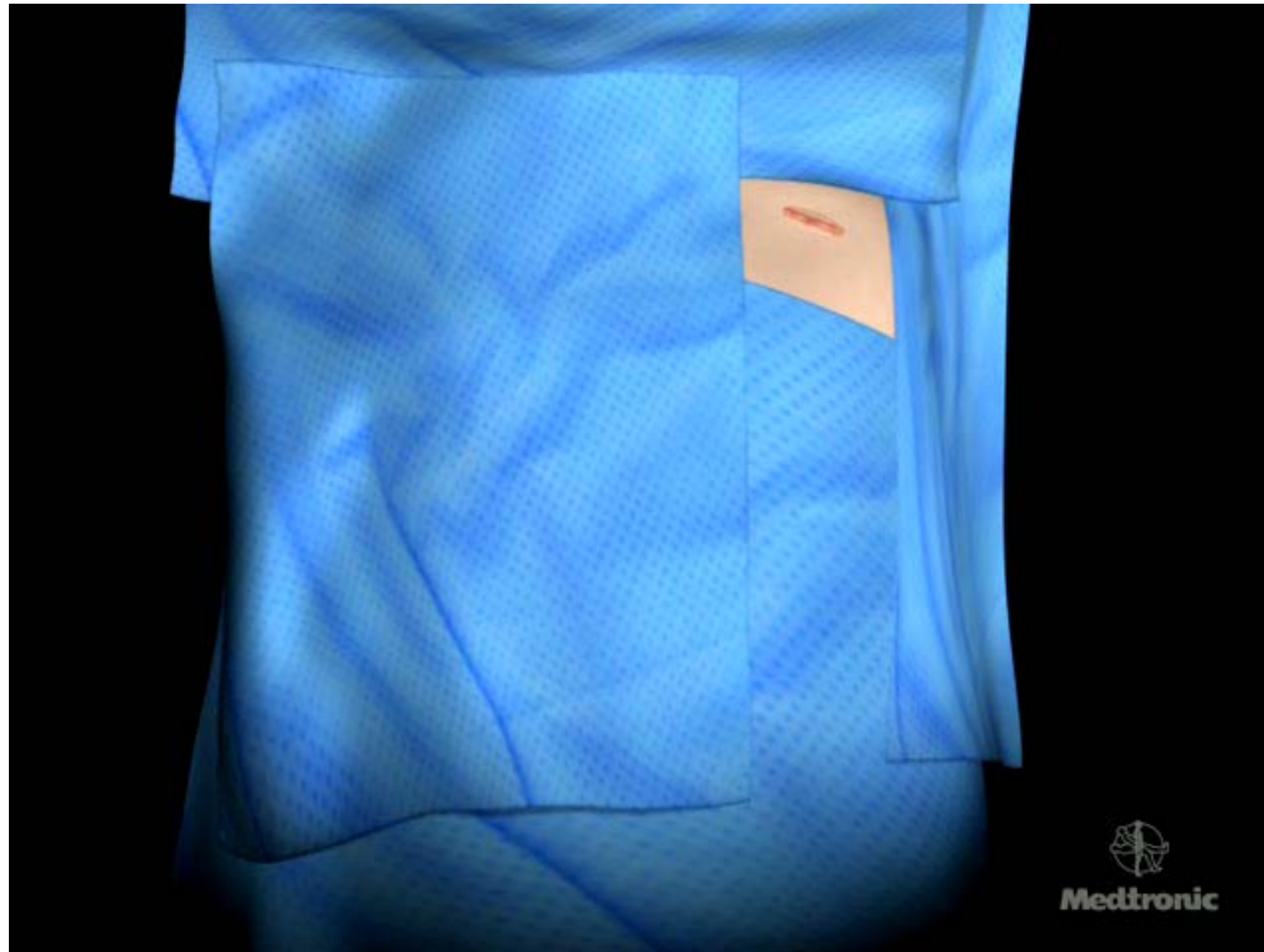
# History of pacemakers





# Pacemaker implant

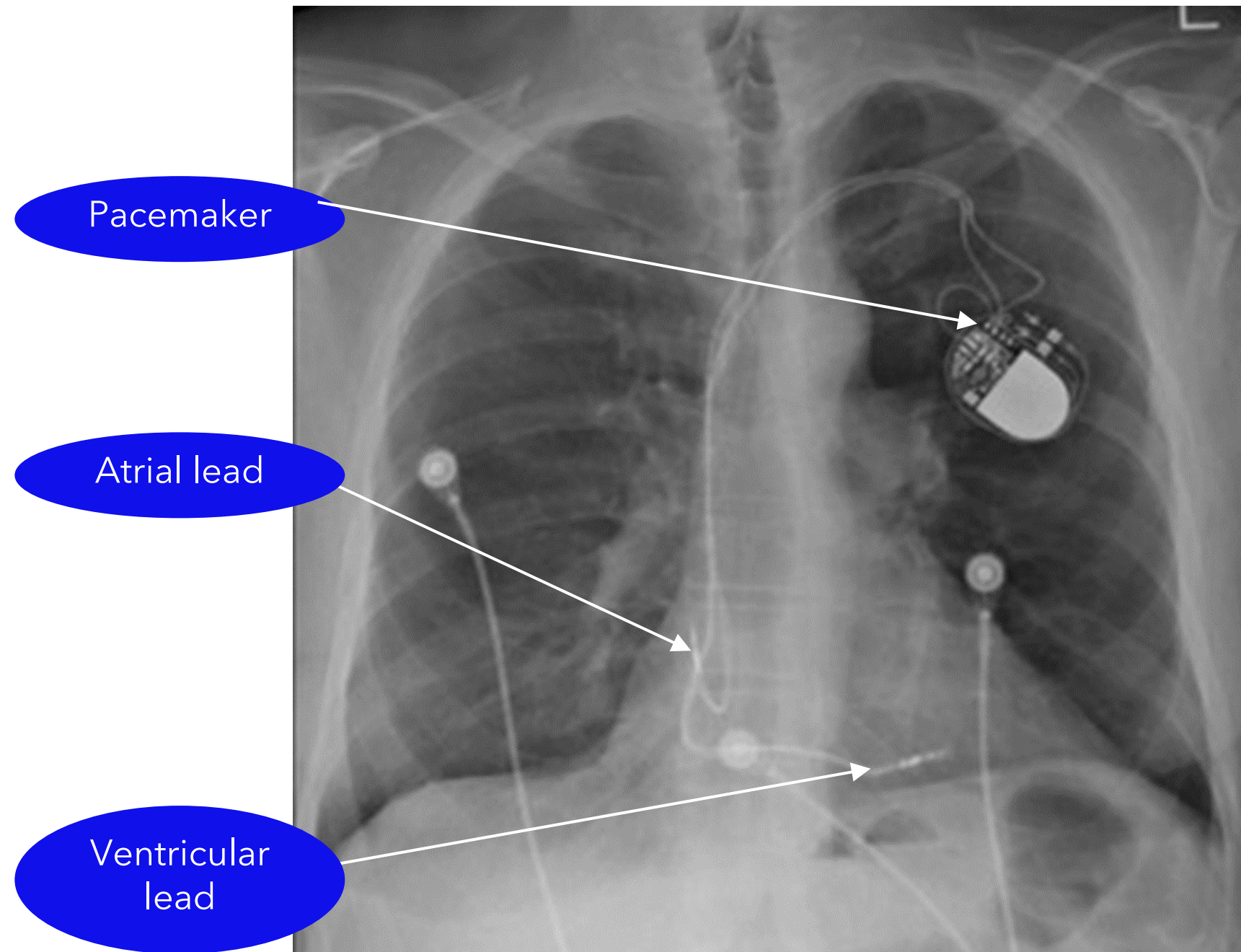
Procedure video



**Medtronic**

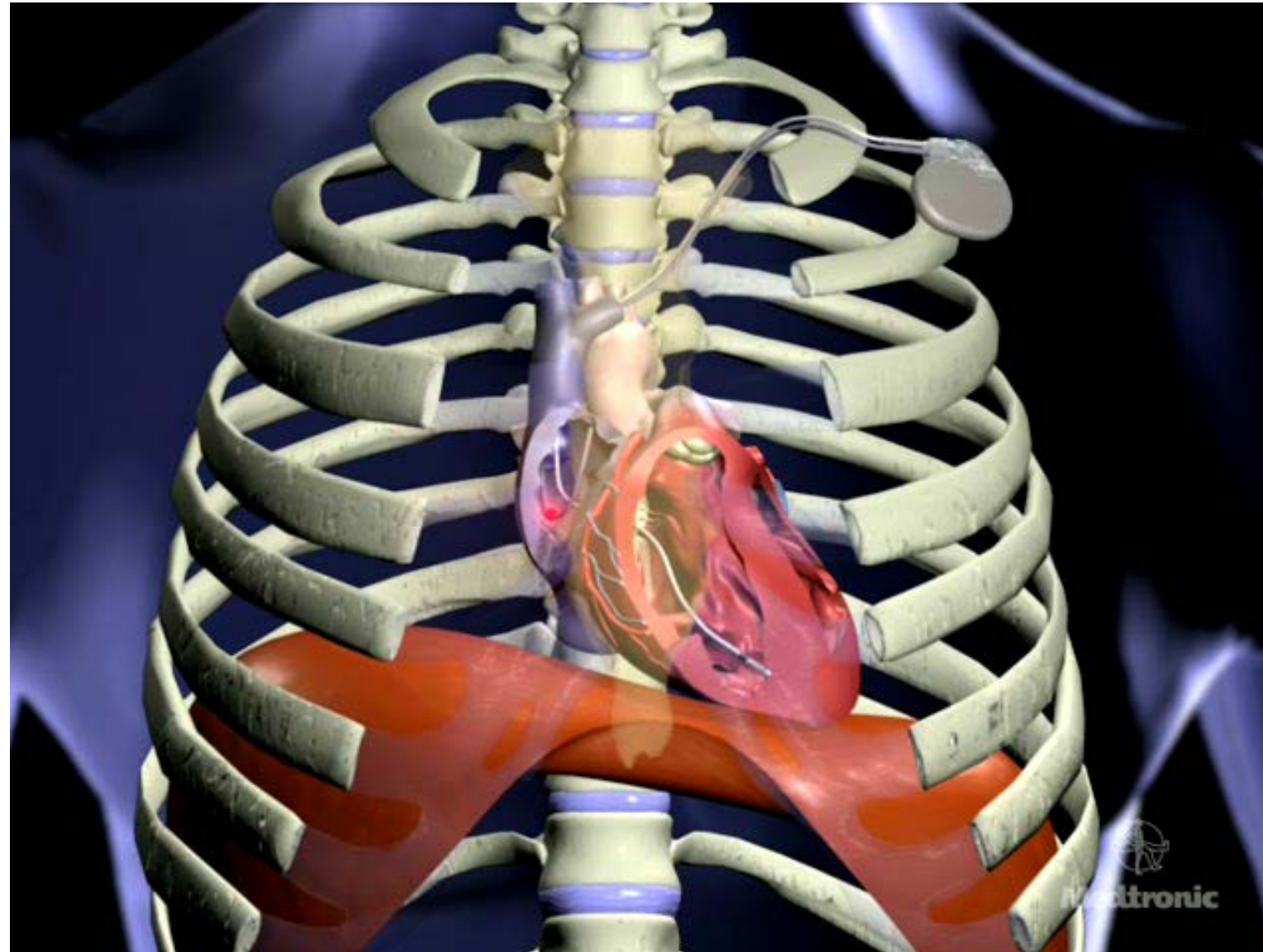
# Pacemaker implant

X-ray check



# Stimulated heart

Dual chamber pacing system video



**Medtronic**



# Pacing leads

Low voltage leads

## Passive

Fixated by silicone tines in the heart tissue



ventricle



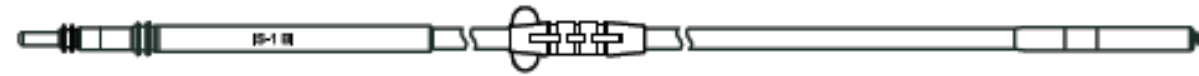
atrium

## Active

Fixated with (retractable) helix into the heart muscle



atrium and ventricle



### Typical lead lengths:

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



# THANK YOU FOR 20 YEARS OF TRUST



CapSureFix Novus MRI™  
SureScan™ 5076 lead

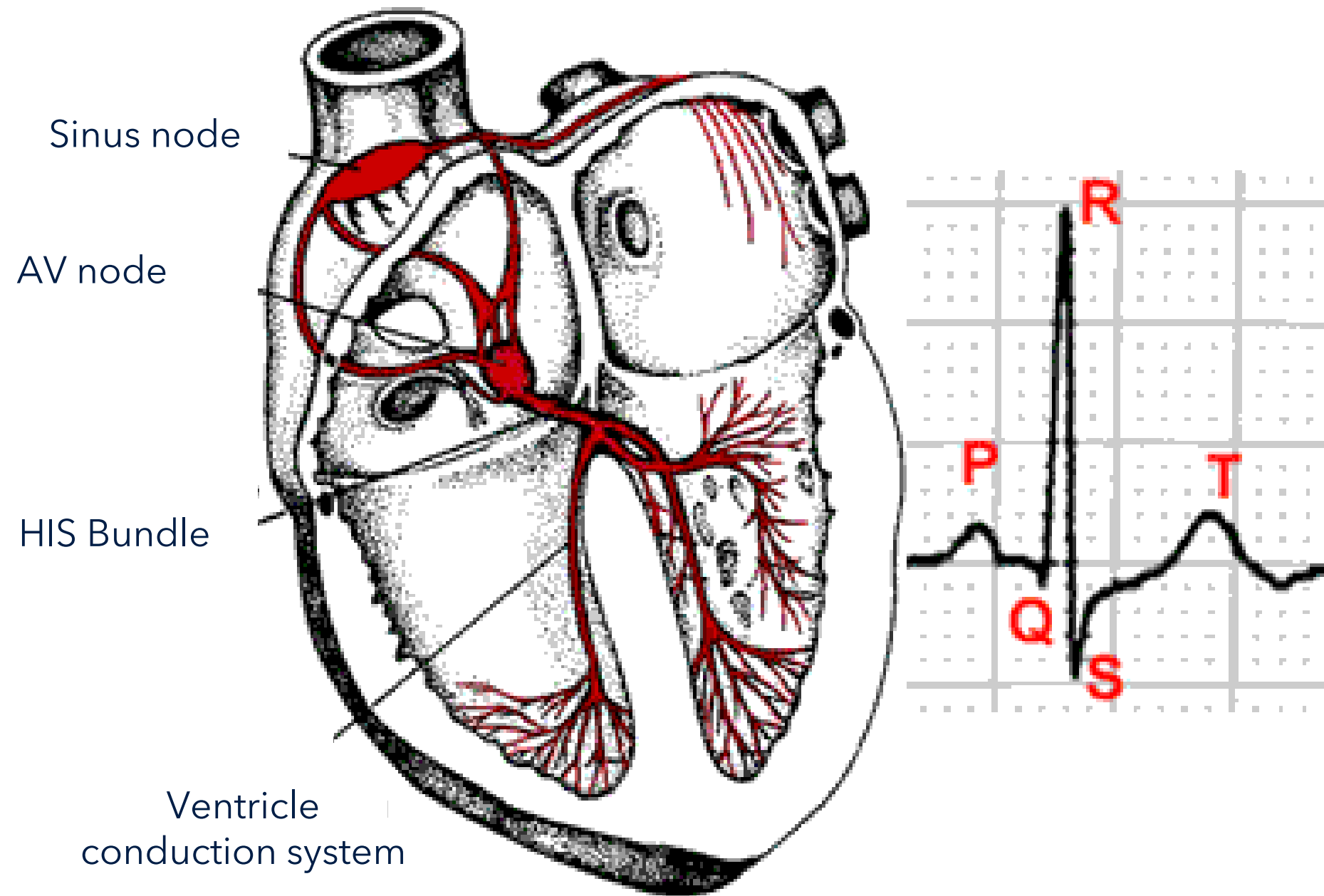
Sprint Quattro Secure™

More than  
**6.8 million** CapSure Fix Novus  
and **1.6 million** Sprint Quattro  
implanted since 2000<sup>1,2</sup>

1. Menard C. CapSureFix Novus 5076 global sales. February 2021. Medtronic data on file.

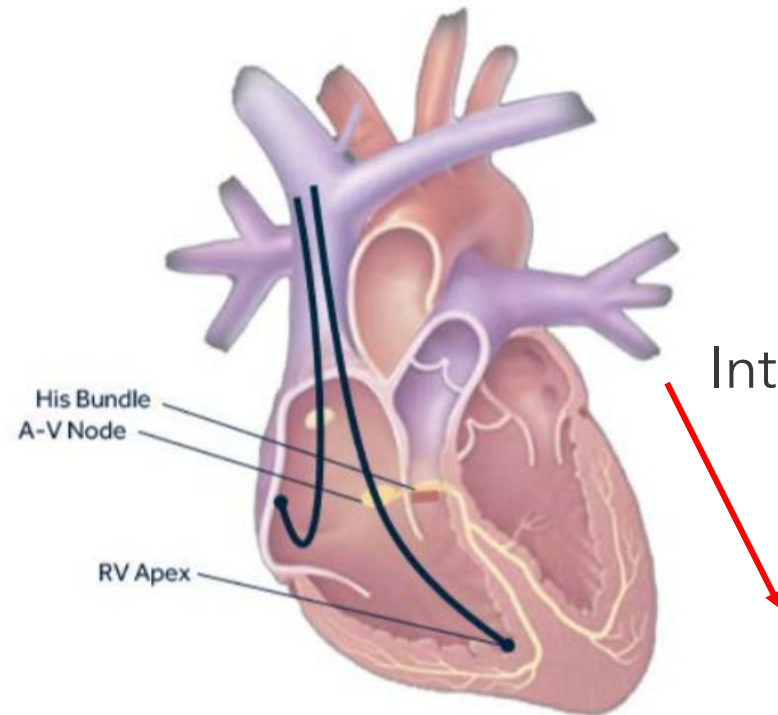
2. Heveling N. Sprint Quattro 6935, 6935M, 6946M, 6947, 6947M global sales. February 2021. Medtronic Data on file

# Heart conduction system



# Why His Bundle Pacing?

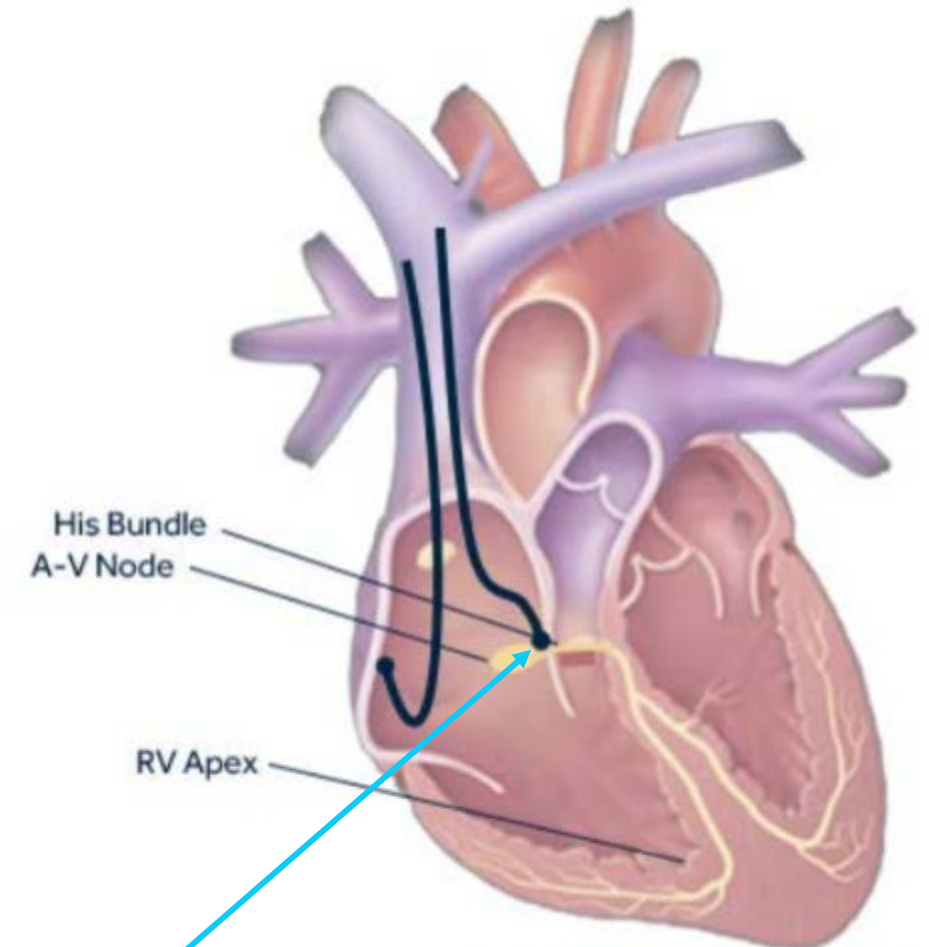
Long-term RV apical pacing creates a non-physiologic activation pattern and may lead to worsened systolic and diastolic function in a subset of patients



**Ventricular Lead at  
Right Ventricular Apex**

Intrinsic signal travels  
this way

So ventricular lead placed higher  
would be "more physiologic"



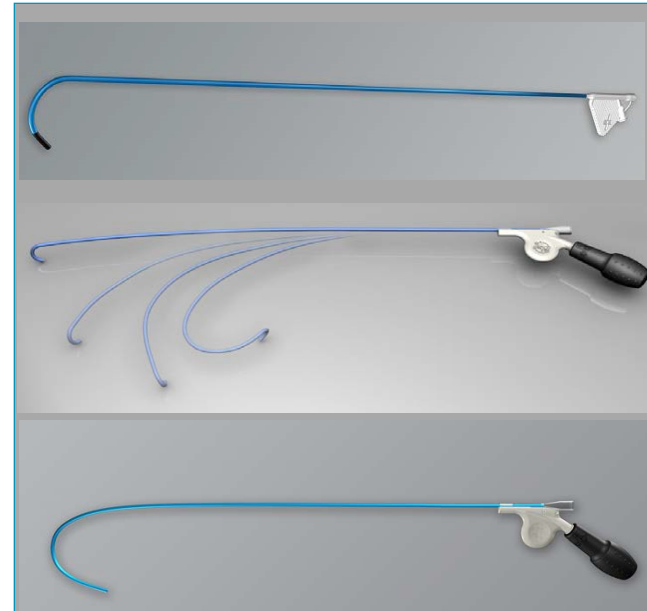
**Ventricular Lead at  
His Bundle†**

# Medtronic HBP Portfolio

## Delivery Systems

Options for variances in anatomy

- C315
- SelectSite™ C304-HIS
- SelectSite™ C304



## Pacing Lead

Only CE approved lead for His-bundle pacing

- 3830 SelectSecure™



## Pacemakers

Options in sensitivity settings and longevity

- Azure™
- Astra™
- Attest™ L

## Pacing System Analyzer

For visual analysis of small amplitude components

- CareLink SmartSync™ with EGM high gain feature

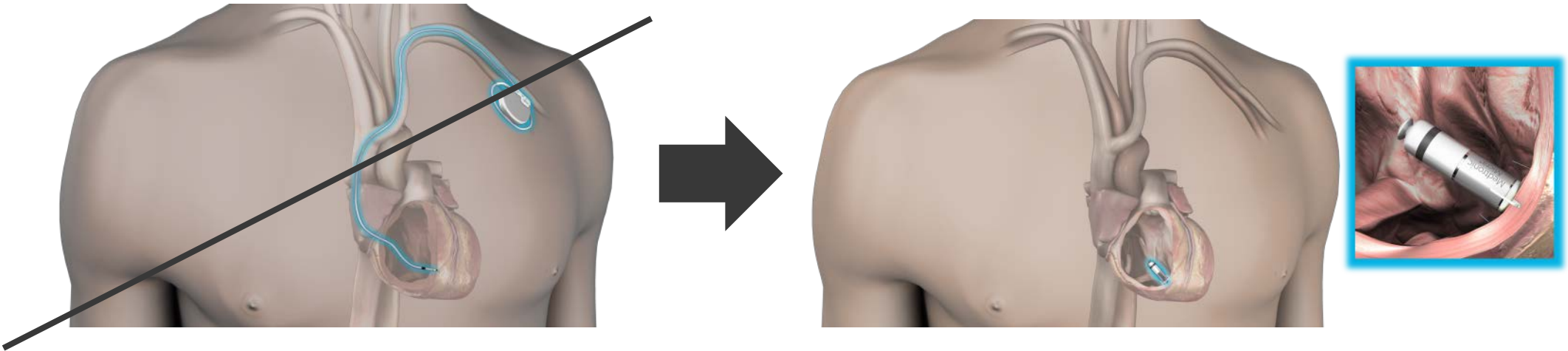
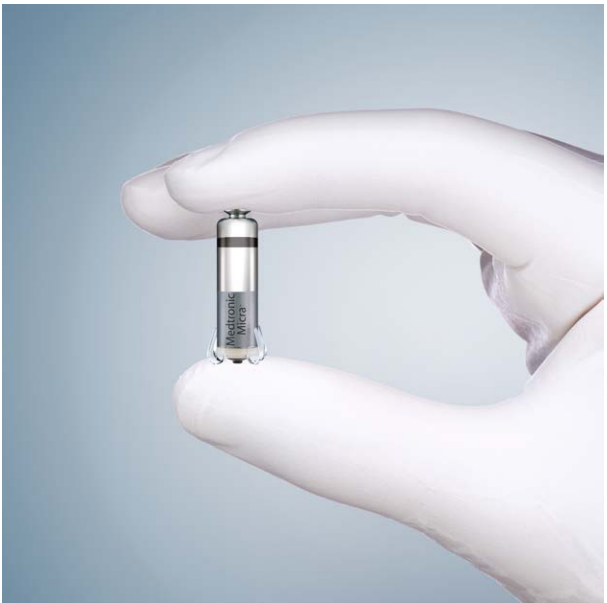




# Micra

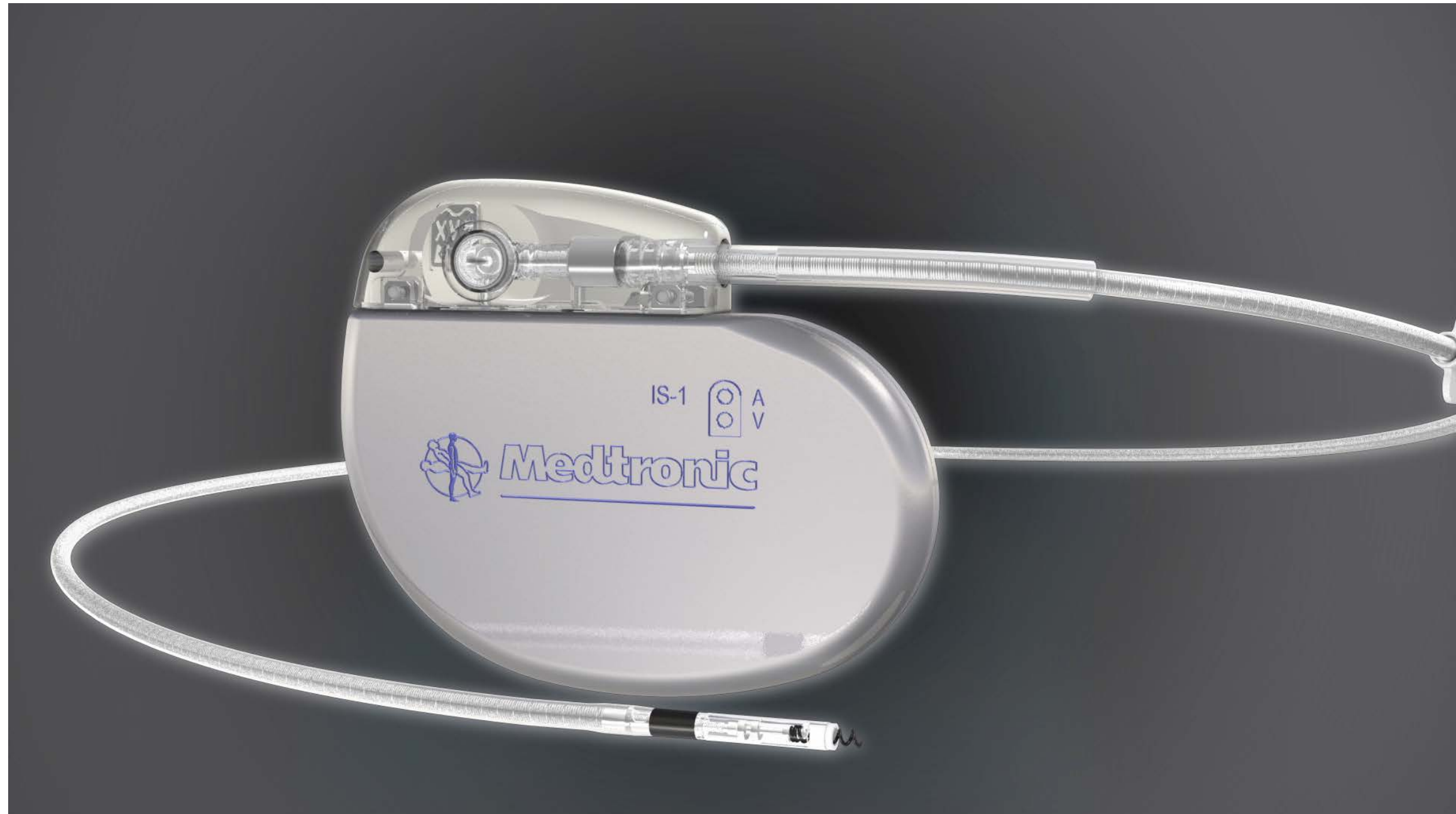
## Transcatheter Pacing System (“Leadless”)

Parameter	Micra
Pacing Mode	VVIR
Mass	2.0 g
Cathode Surface Area	2.5 mm <sup>5</sup>
Anode Surface Area	22 mm <sup>5</sup>
Volume	0.8 cc



# Micra

## Transcatheter Pacing System ("Leadless")

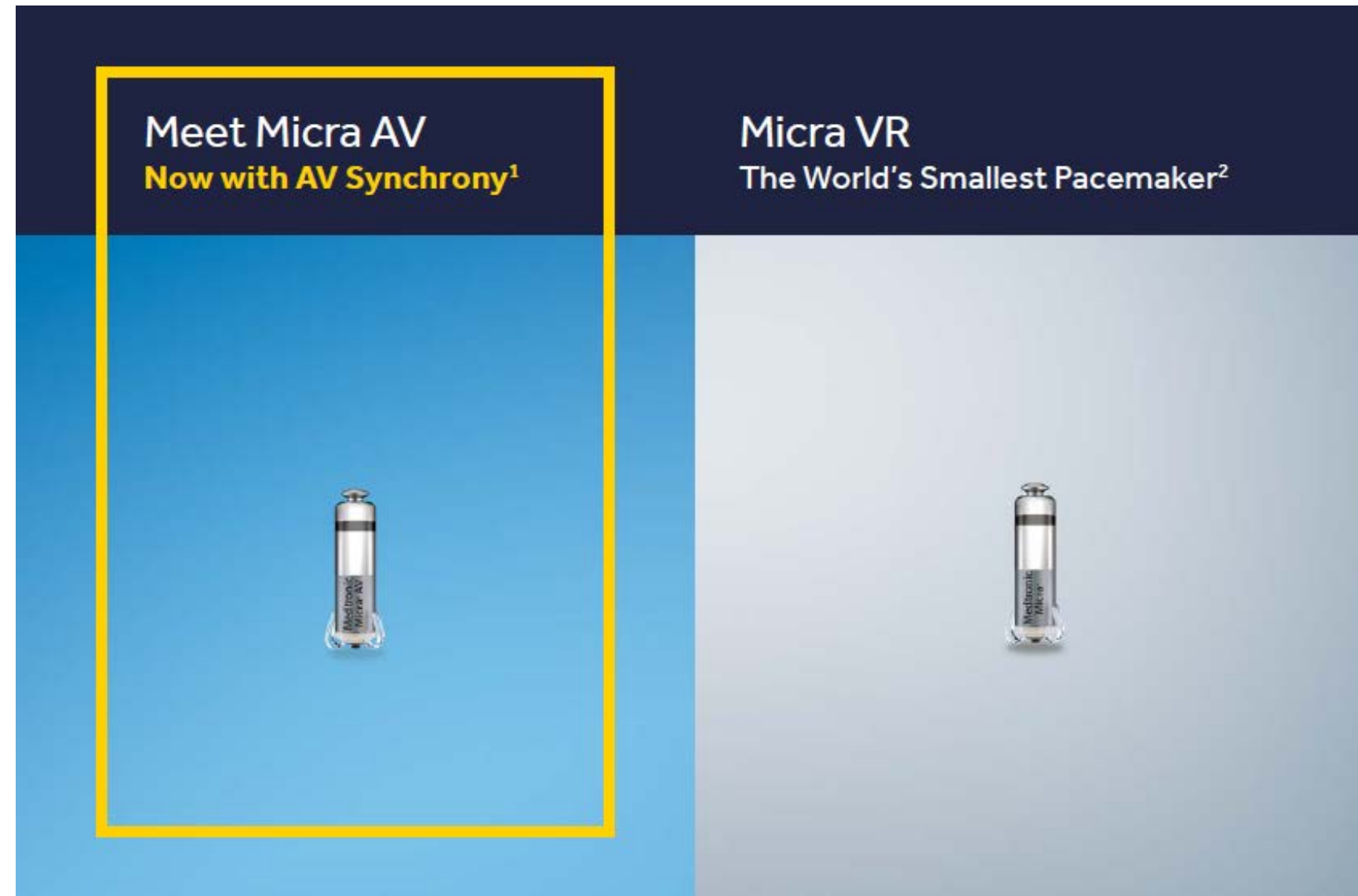
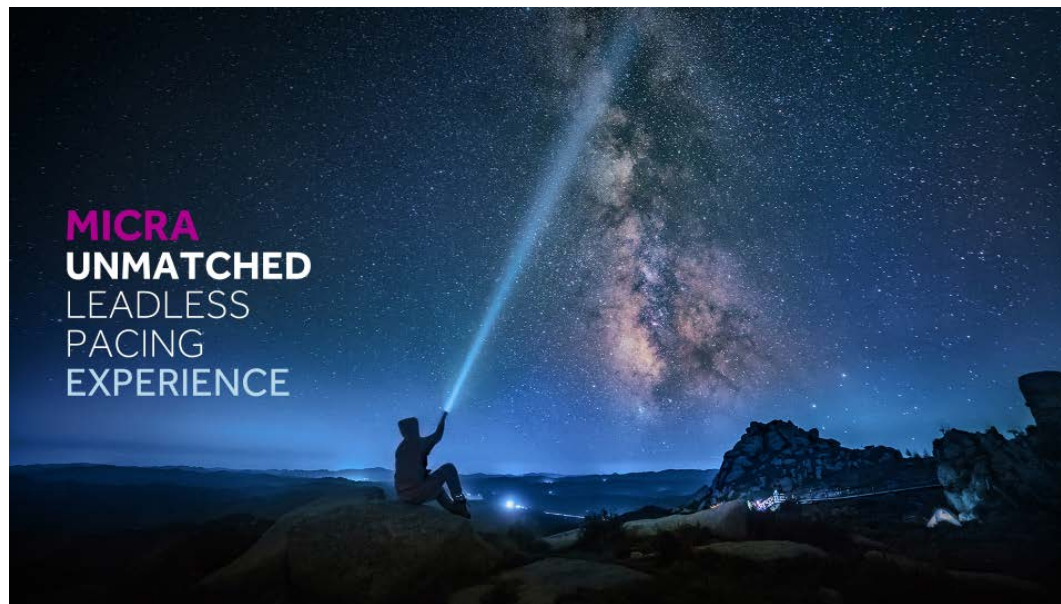


**Medtronic**

# Micra

## Now offering two leadless pacing options

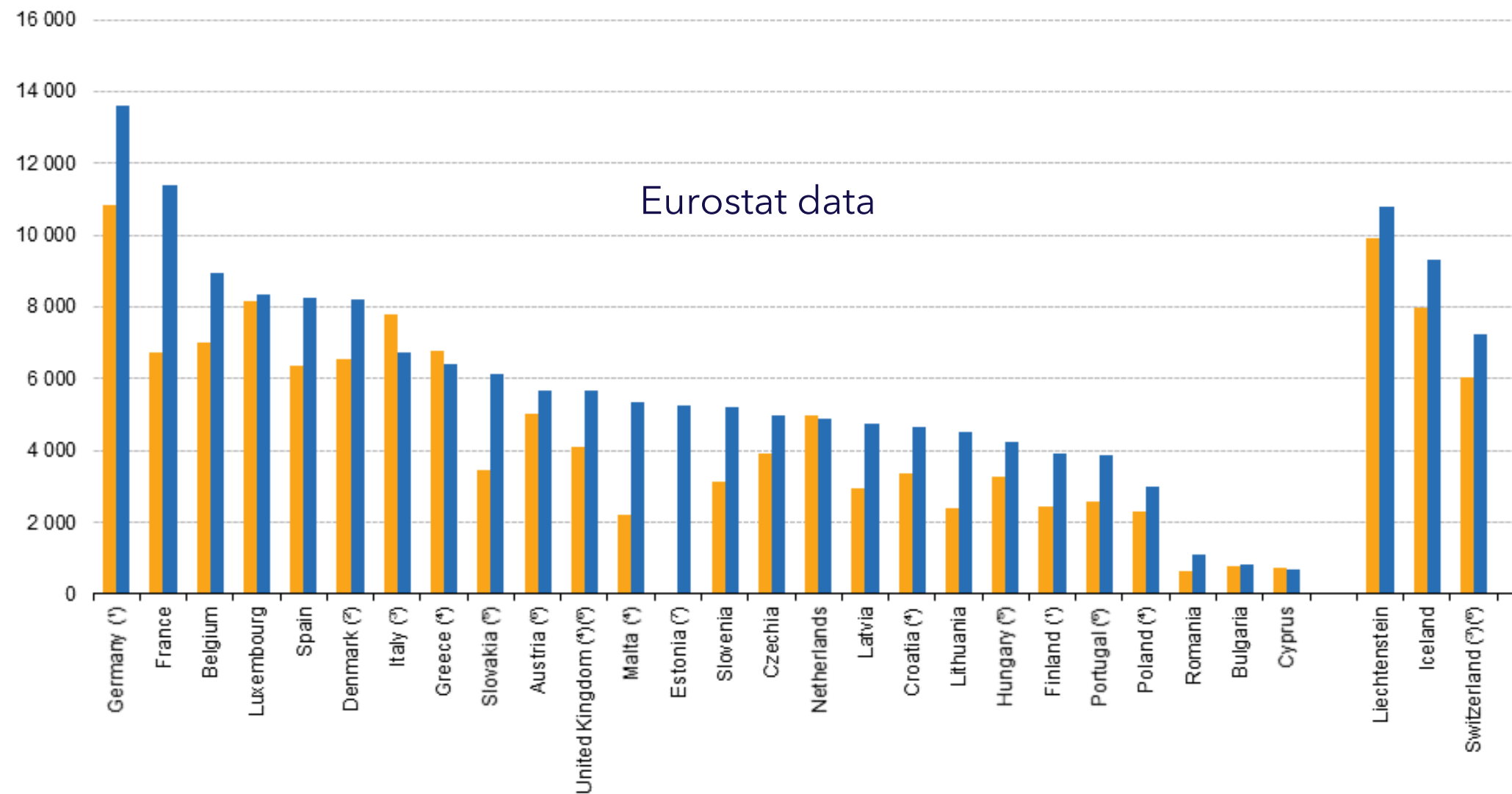
- The world's smallest pacemaker
  - **93% smaller** vs traditional pacemakers<sup>1</sup>
- 99% implant success rate<sup>2,3</sup>
- 63% reductions in major complications<sup>2</sup>
- Leadless pacing option now for 45% of pacing population<sup>4</sup>



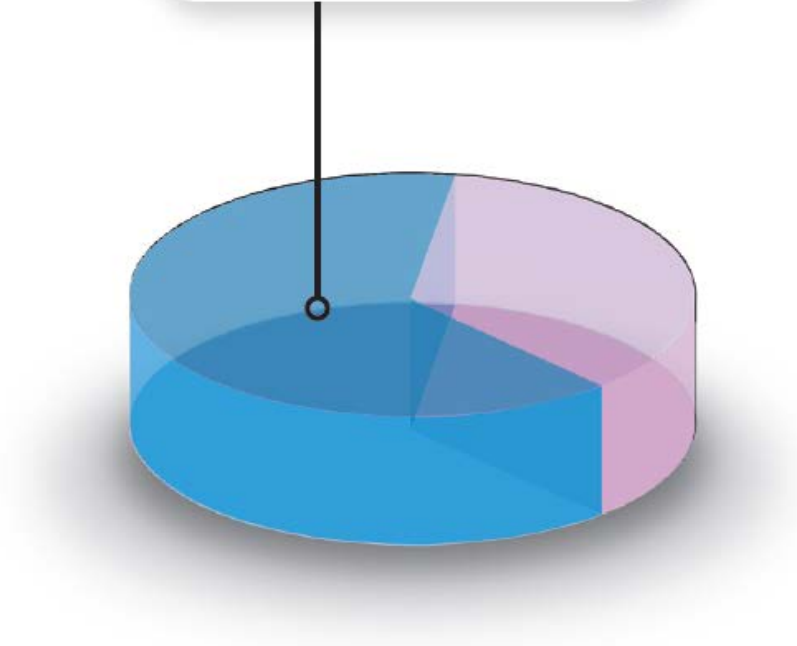
<sup>1</sup> Williams E, Whiting J. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic data on file; <sup>2</sup> El-Chami MF, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. Heart Rhythm. 2018; <sup>3</sup> Reynolds D, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med. 2016; <sup>4</sup> Lewis D, Whiting J. Bradycardia Indication Breakdown. January 2020. Medtronic data on file.

# MRI Procedures are increasing

Use of imaging equipment — number of magnetic resonance imaging (MRI) scans, 2011 and 2016  
(per 100 000 inhabitants)



50-75% of patients with an implantable cardiac device will need an MRI scan over the lifetime of their device<sup>2</sup>





# 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



**Medtronic**

# 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



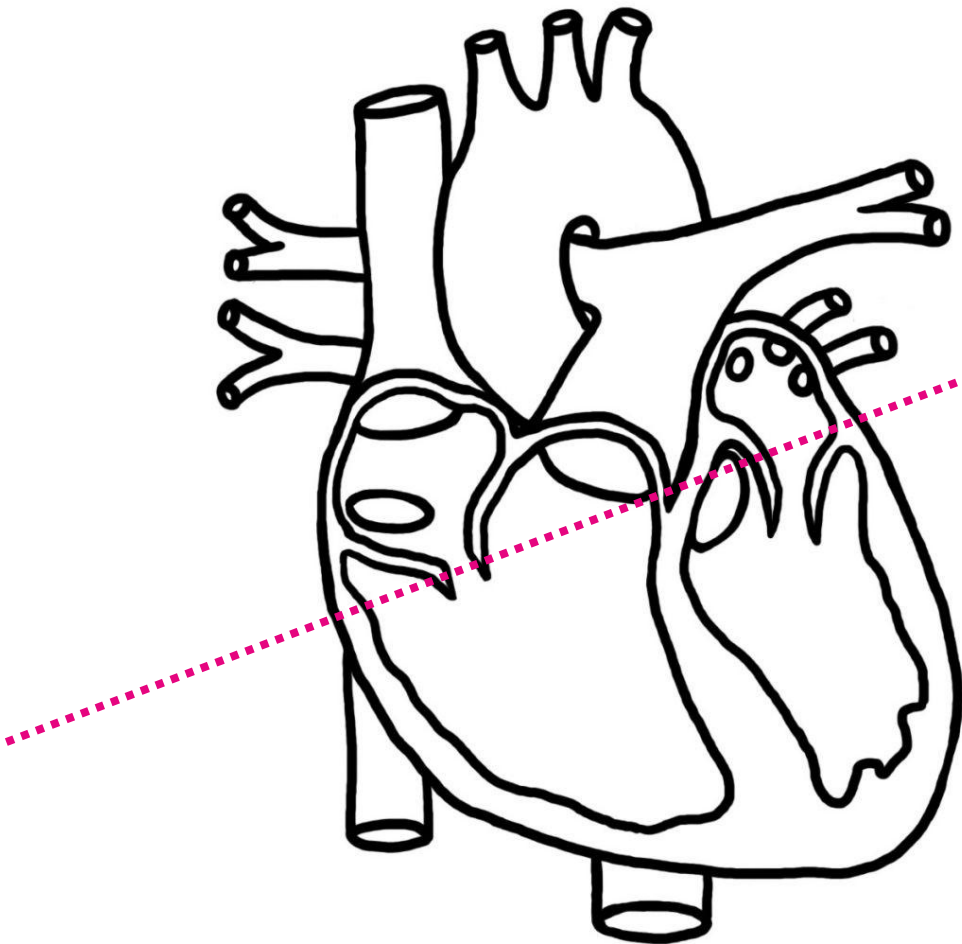
# Defibrillators

Tachy

# Classification of tachyarrhythmias

SVT  
Supraventricular tachycardia

from above  
the ventricles  
fast heart rate

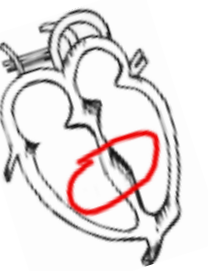


VT  
Ventricular tachycardia

VF  
Ventricular fibrillation



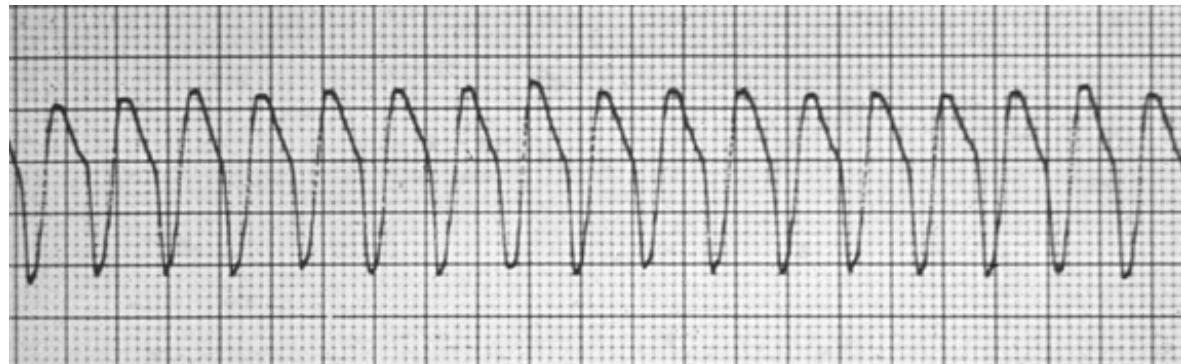
# Ventricular arrhythmias



## VT

### Ventricular tachycardia

- Fast
- 150-250 bpm
- Regular



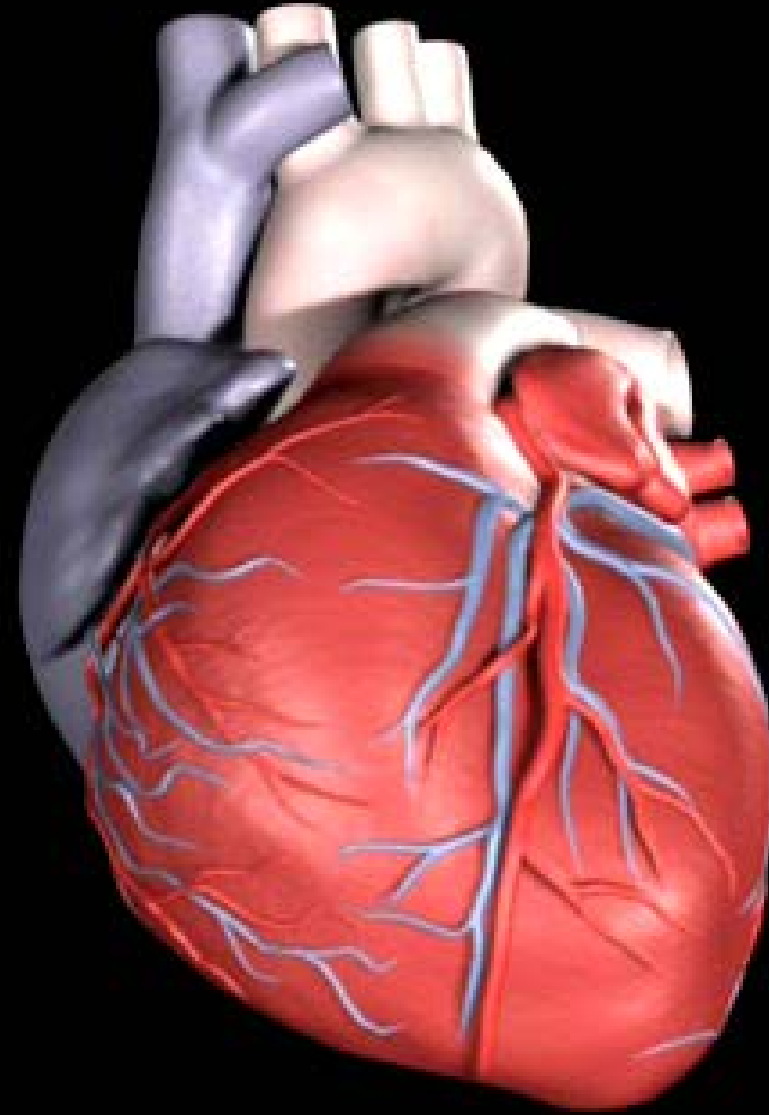
## VF

### Ventricular fibrillation

- Very fast
- >200 bpm
- Irregular



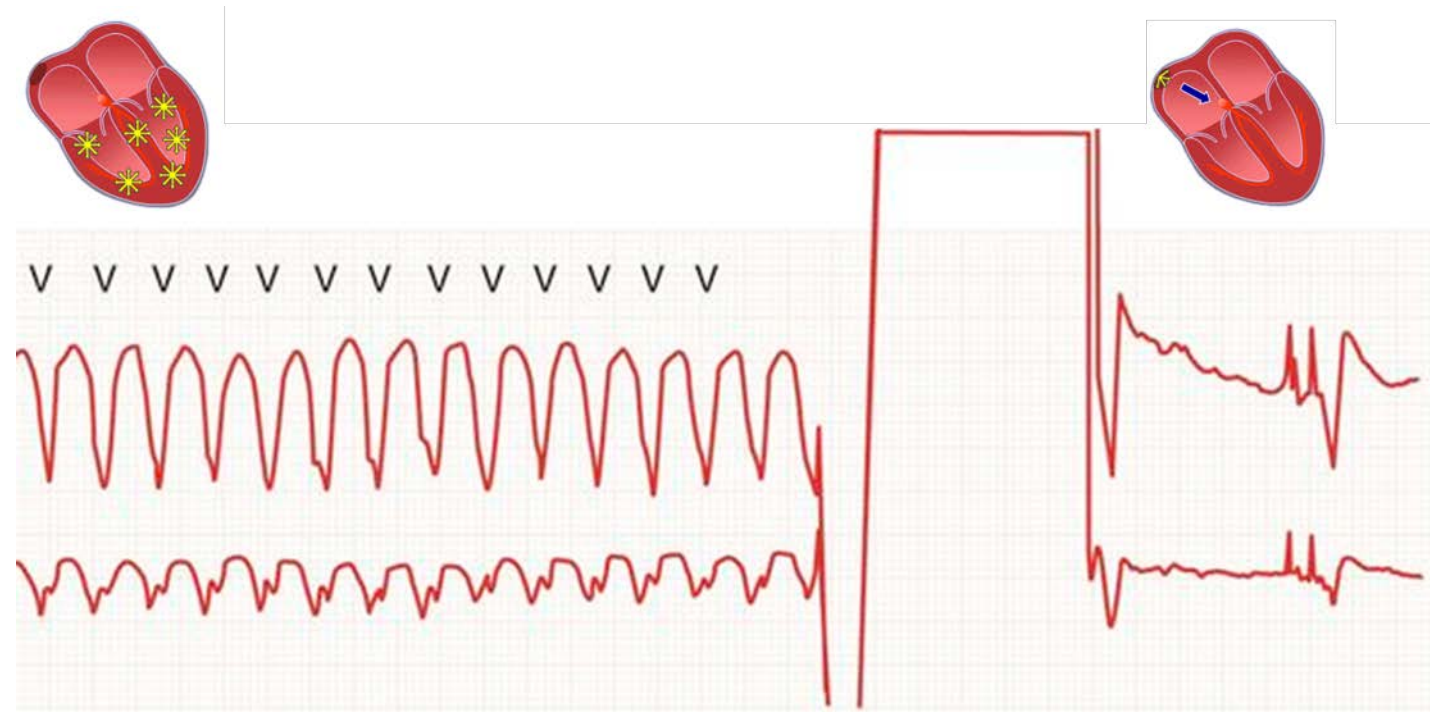
# Ventricular Fibrillation (VF)



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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**



# 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





# Sudden Cardiac Arrest vs. Heart Attack



## SUDDEN CARDIAC ARREST (SCA)

An electrical problem

A diagram of a heart with several white starburst shapes on the coronary arteries, representing an electrical malfunction.

**CAUSE:** Electrical malfunction of the heart that causes the heart to stop beating.

**RISK FACTORS:** Previous heart attack, heart failure, abnormal heart rhythm, low ejection fraction (EF , 35%), family history of SCA, coronary artery disease.

**SYMPTOMS:** Generally no symptoms, may experience racing heartbeat, lightheadedness, dizziness, fainting.

## HEART ATTACK

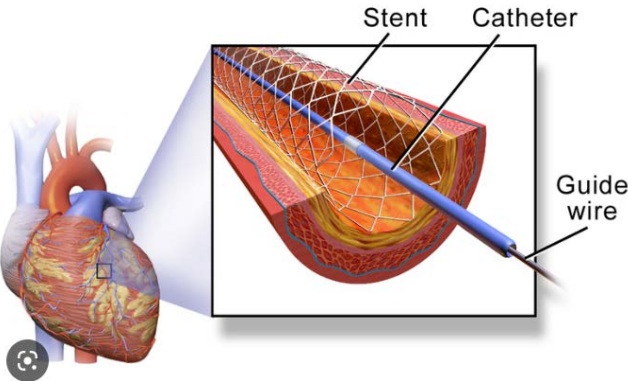
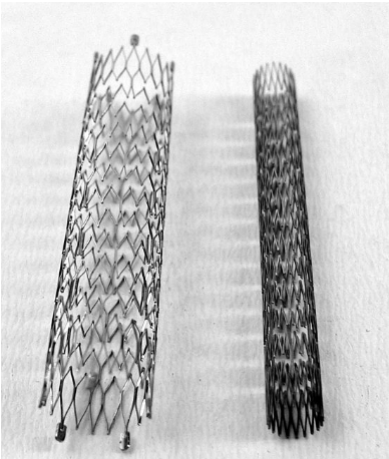
A circulation or plumbing problem

A diagram of a heart with a red blockage in one of the coronary arteries. A circular inset provides a magnified view of the blockage.

**CAUSE:** Blockage in a vessel that supplied blood to the heart muscle, which may permanently damage part of the heart.

**RISK FACTORS:** High cholesterol, high blood pressure, obesity, smoking, family history of heart attack, diabetes, coronary artery disease.

**SYMPTOMS:** May be accompanied by pressure in the chest, pain radiation to the arm, shortness of breath, sweating, nausea. Women may have different symptoms such as pain or discomfort in the back, neck, jaw, or stomach.

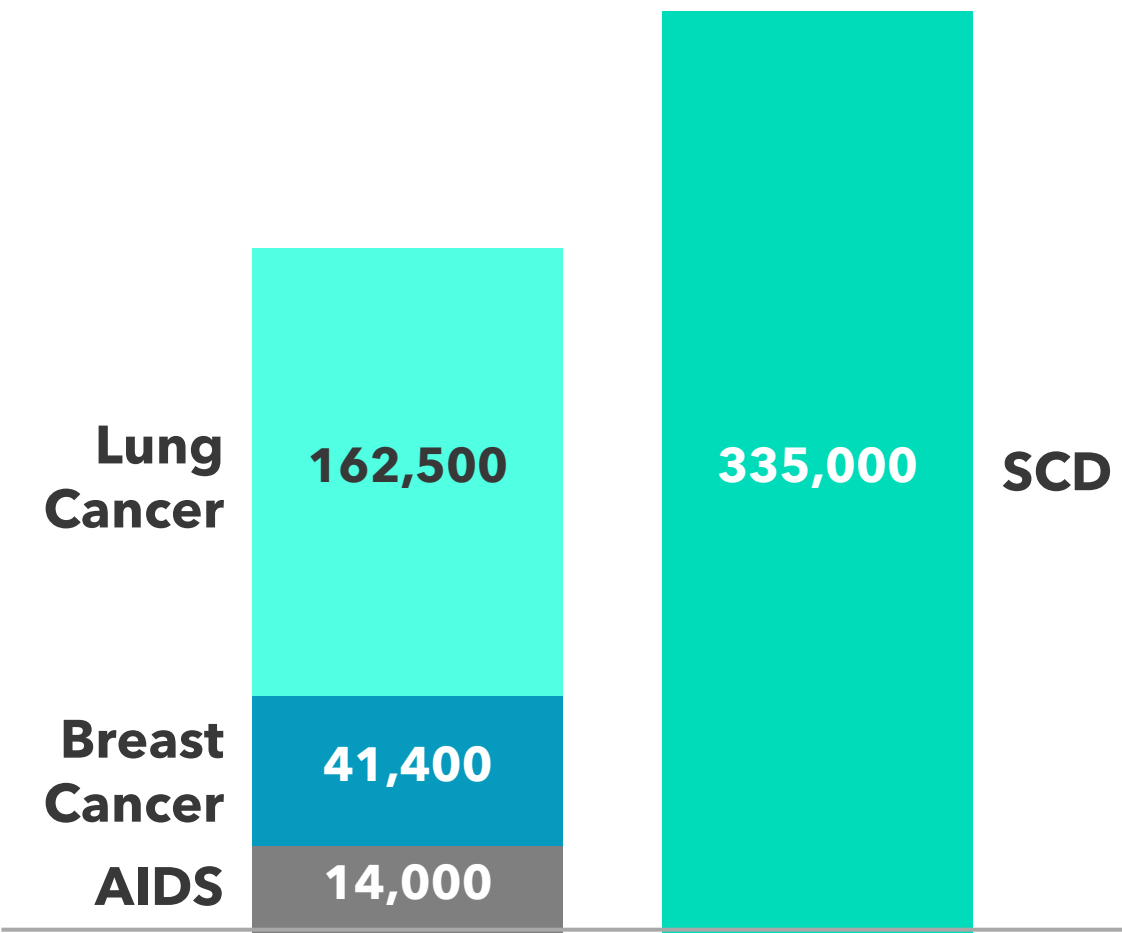


Stent photo source. Wikipedia



# Sudden cardiac arrest / death

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



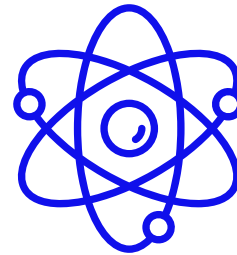
# Sudden cardiac arrest / death

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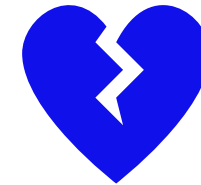
80%

due to VF or fast VT



40%

happens when alone



<5%

survival



# 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?

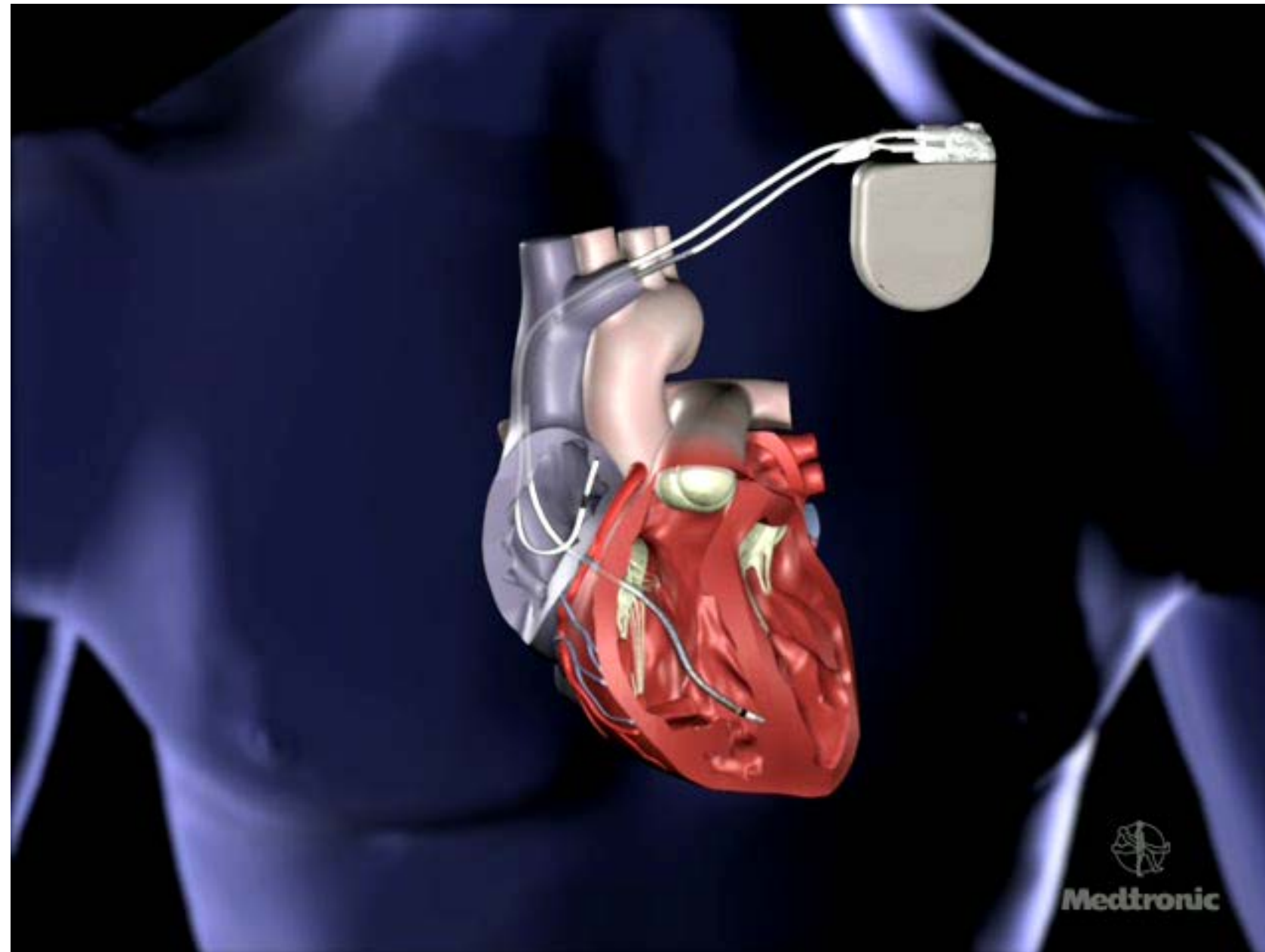
Constantly checks the patient's rhythm and **works the same as a pacemaker**

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

- Antitachycardia Pacing (ATP)
- Defibrillation shock

# How ICD works

## Defibrillation shock



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



Because IT HURTS!





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

# 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



# 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**.



Did you know?  
...the following on Medtronic



10

years of SmartShock technology



20+

years of studying shock reduction



14

prospective clinical trials



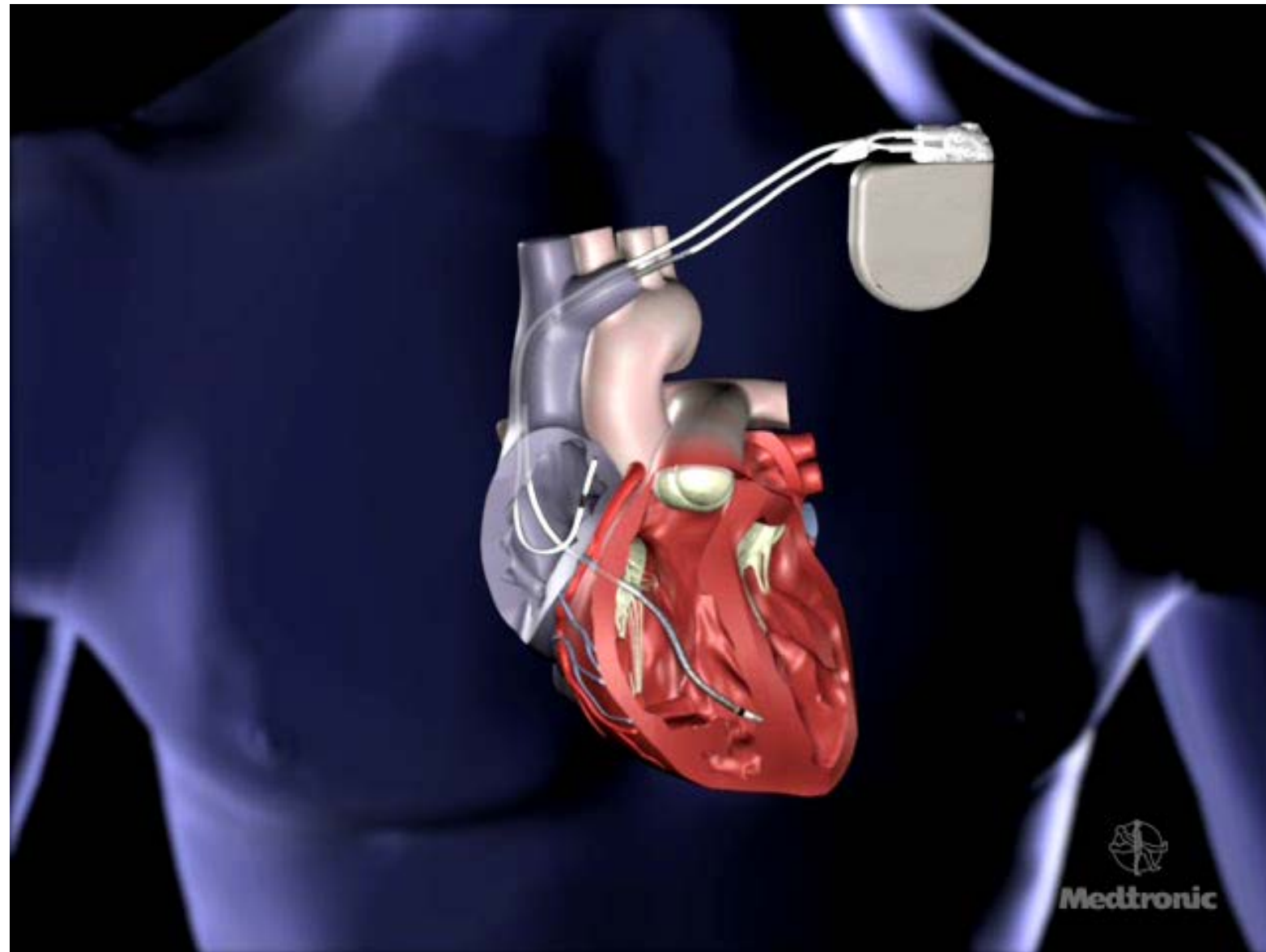
>15k

patients enrolled



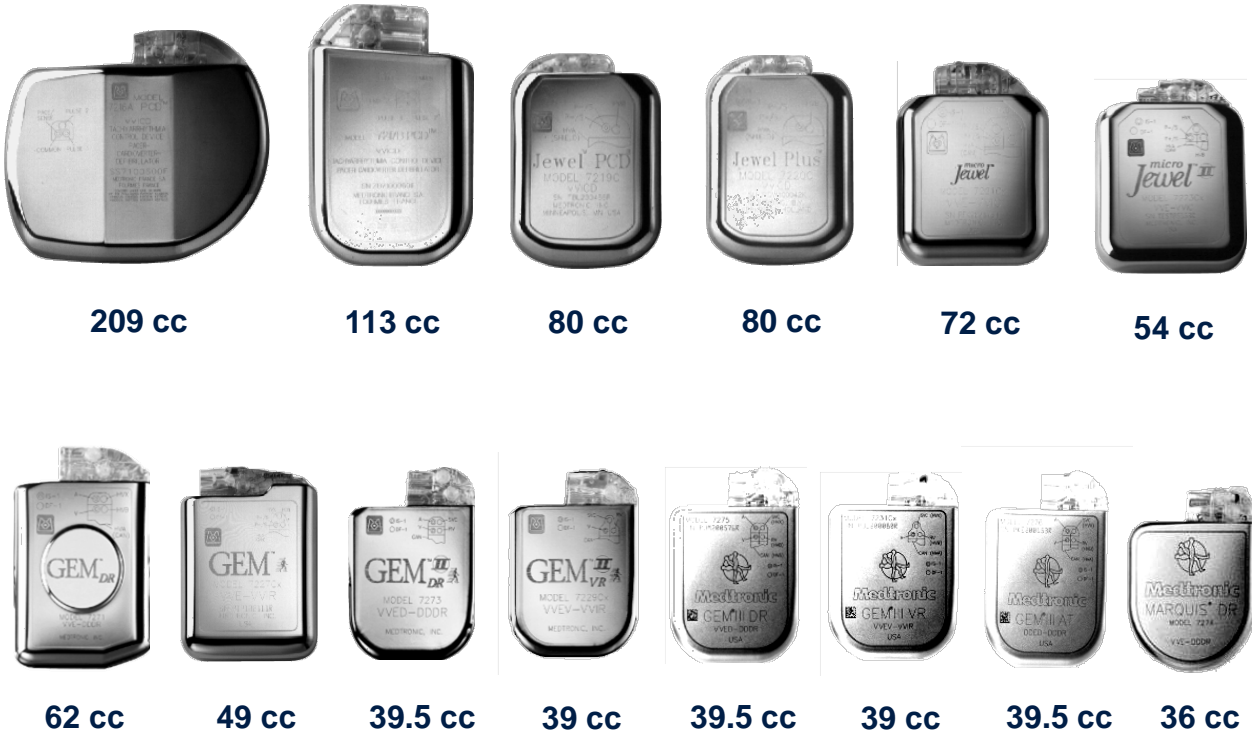
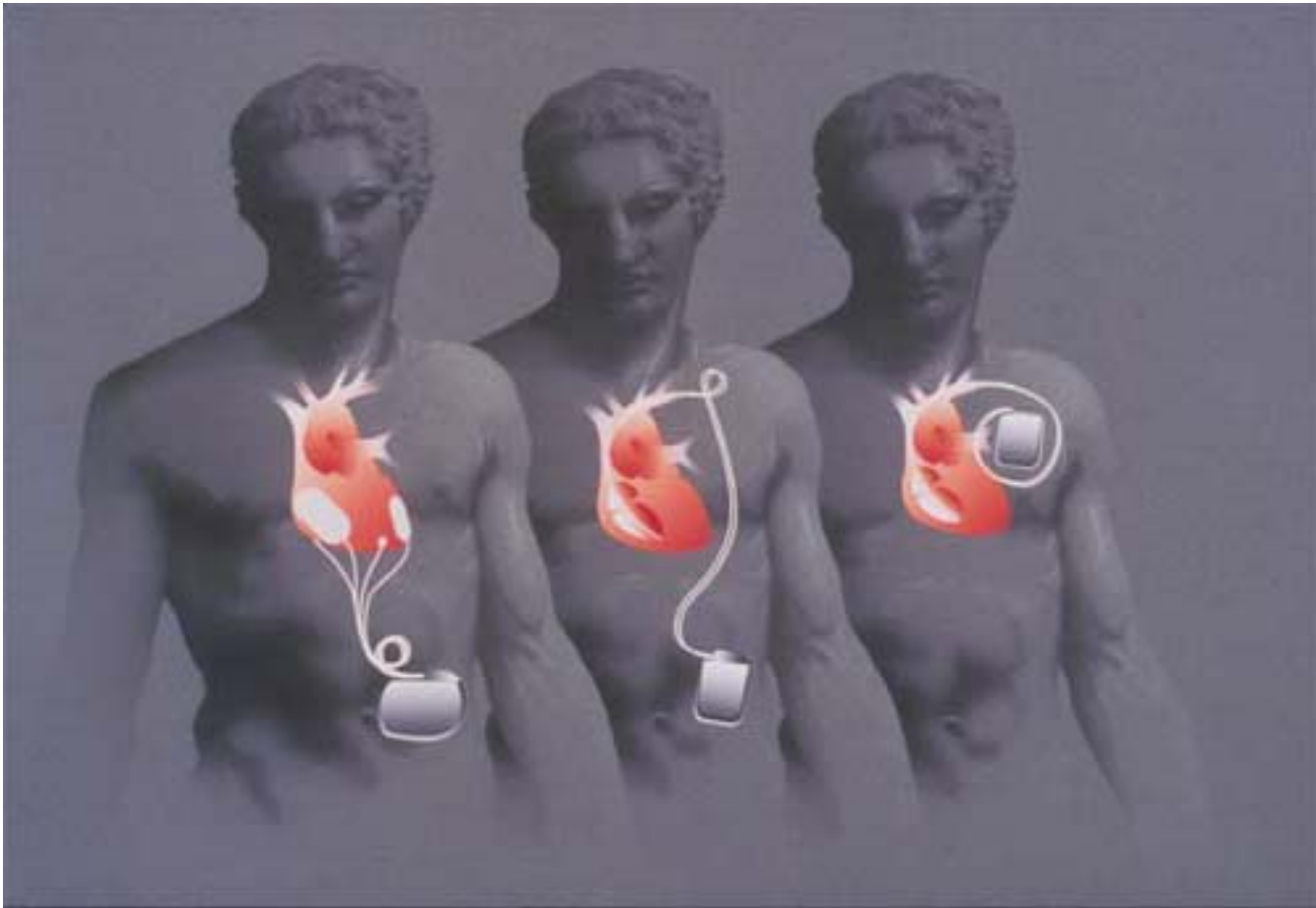
# Painless therapy

Antitachicardia pacing (ATP)



**Medtronic**

# ICD Evolution

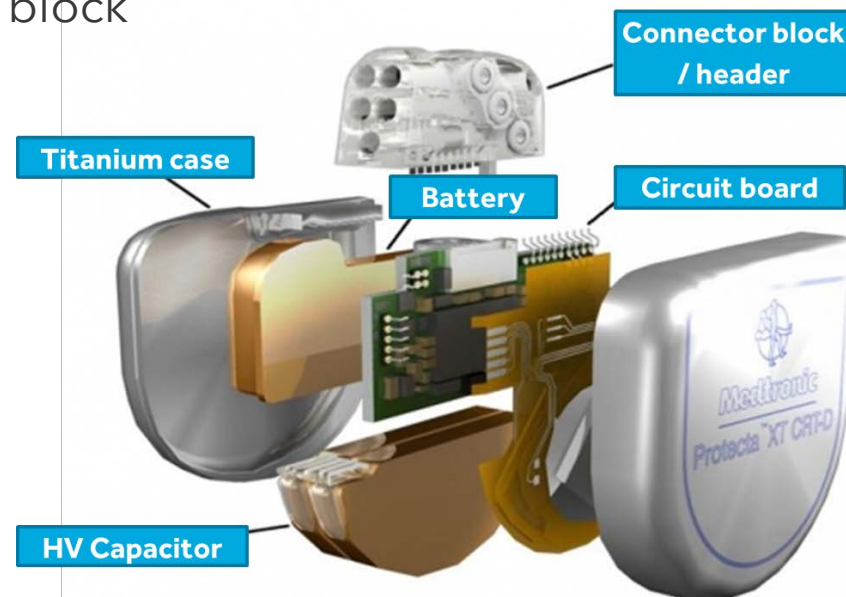


# ICD system components

## ICD

Implantable cardioverter-defibrillator

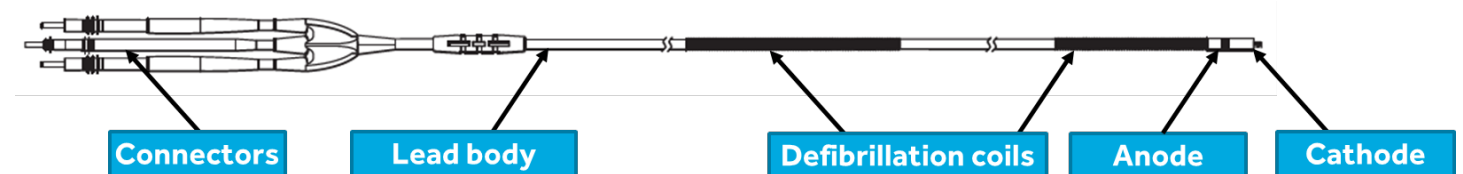
- Battery (lithium silver vanadium oxide)
- Electrical circuitry
- Microprocessor and memory
- HV Capacitor
- Connector block



## Lead

Lead

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

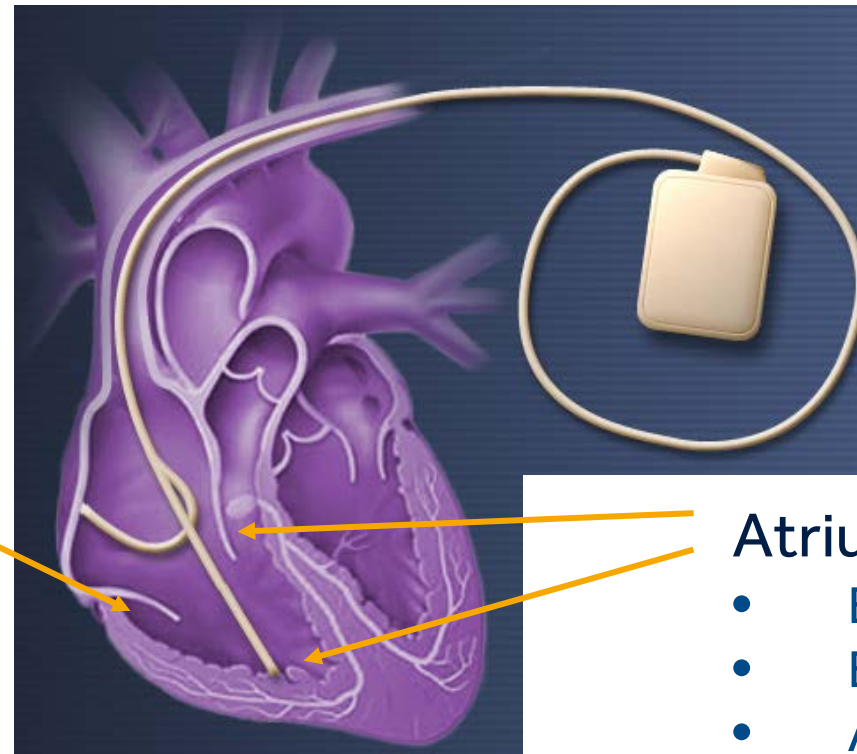


# ICD system

## How it works

### Ventricle

- VT prevention
- Cardioversion
- Defibrillation



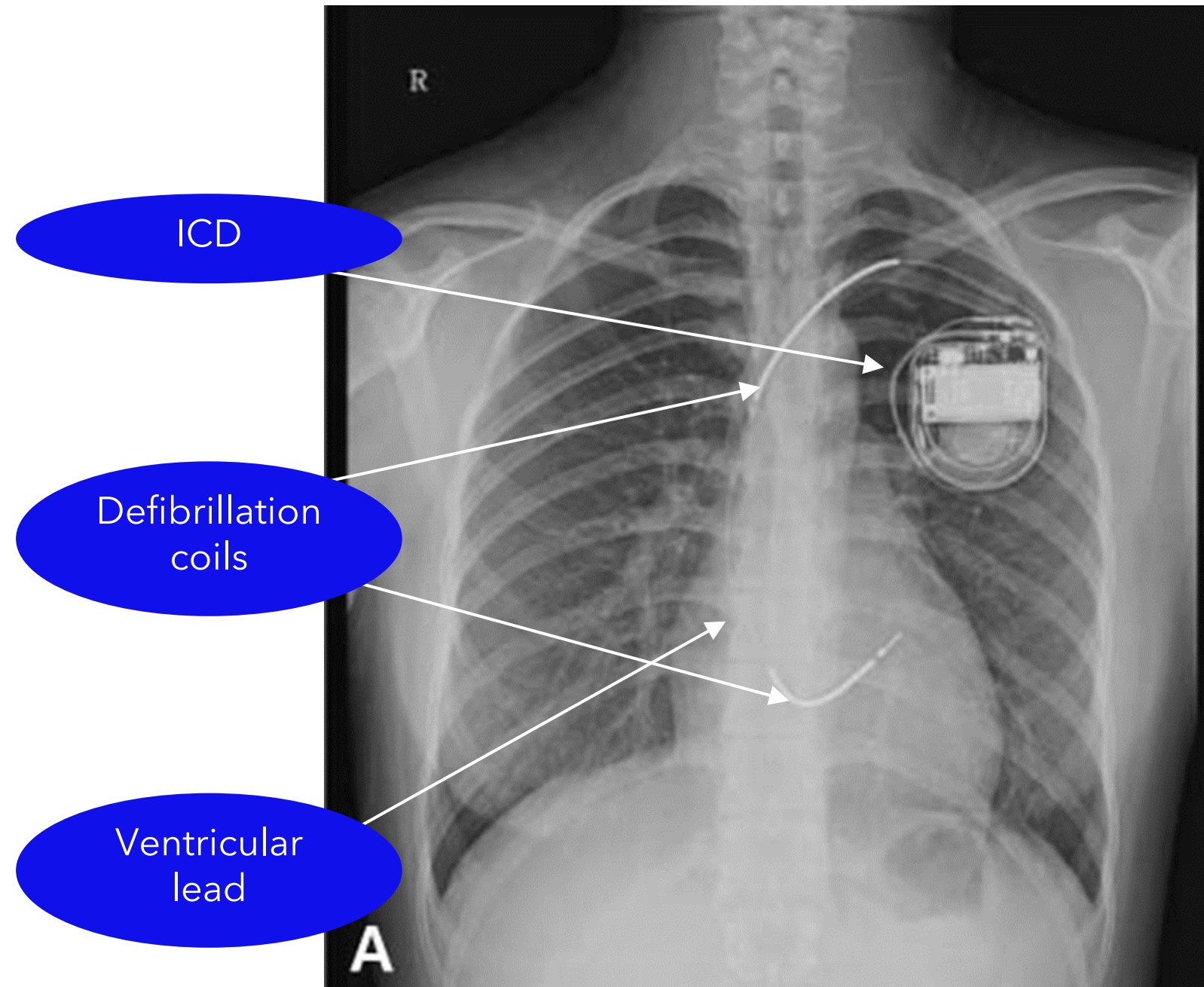
### Atrium & Ventricle

- Bradycardia sensing
- Bradycardia pacing
- Antitachycardia pacing



# ICD implant

X-ray check



# 'Standard' (endocardial) leads categorization

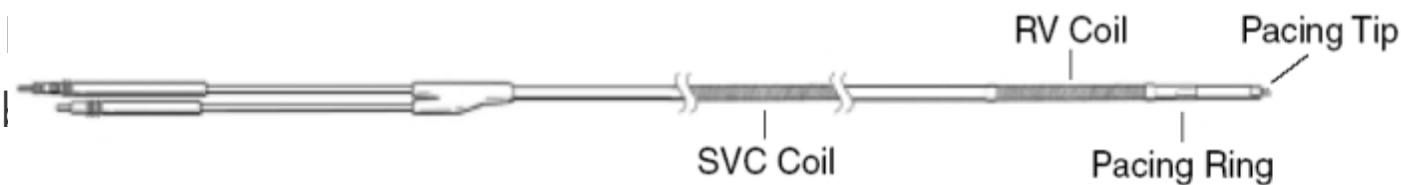
can be made according to:

## Fixation Mechanism



## Number of Shocking Coils

- Singl
- Doubl



## Connector Type

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



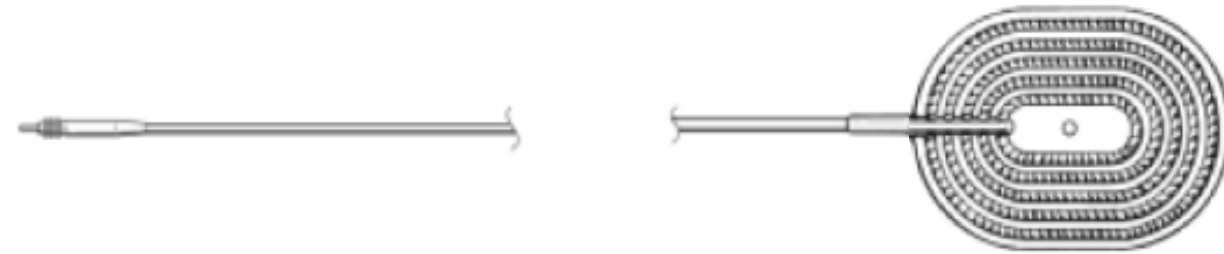
**Medtronic**

# 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





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





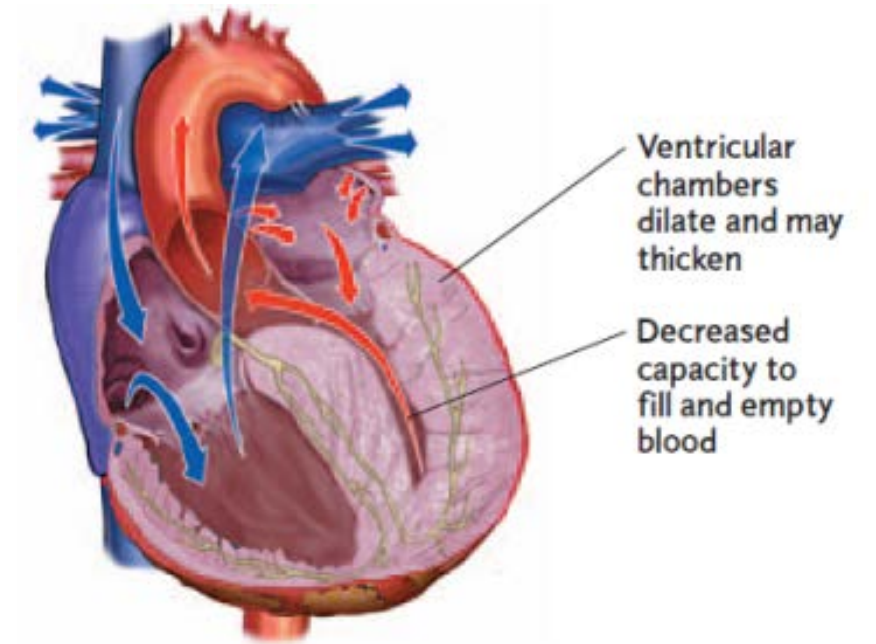
# Cardiac Resynchronization Therapy

Heart Failure

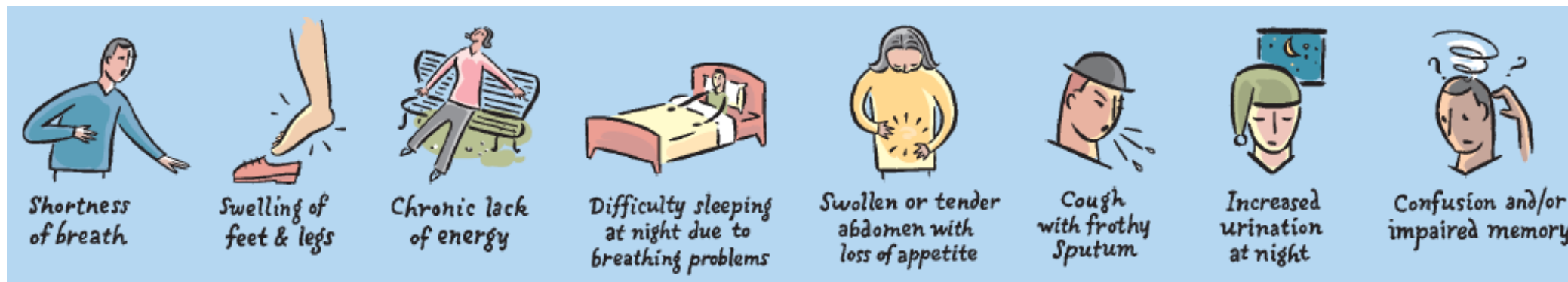
# Chronic Heart Failure (CHF)

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:



# HF Classification

## Symptoms<sup>1</sup>

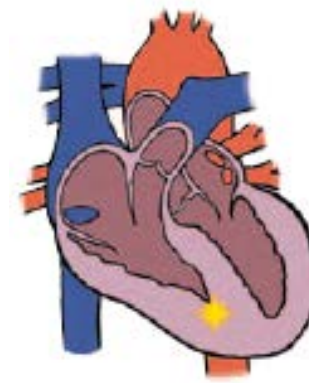
**NYHA Class** = New York Heart Association Classification



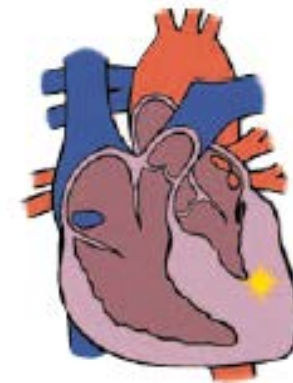
1. The Criteria Committee of the NYHA .Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256

# 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

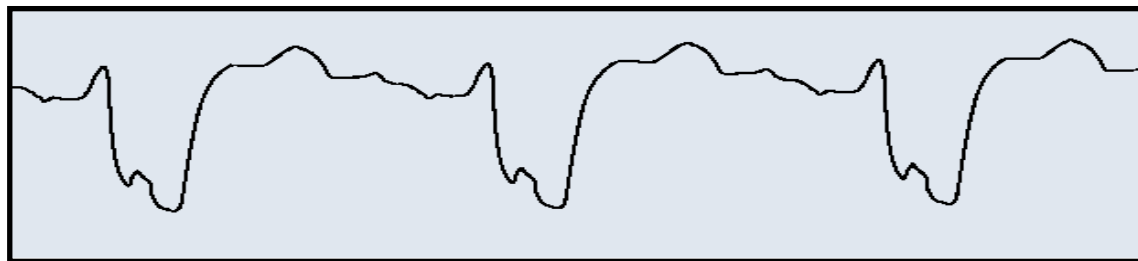
For Mild to Severe HF Patients  
with low ejection fraction ( $EF \leq 35\%$ )  
and ventricular dyssynchrony  
(long QRS)



# Ventricular dyssynchrony & CRT

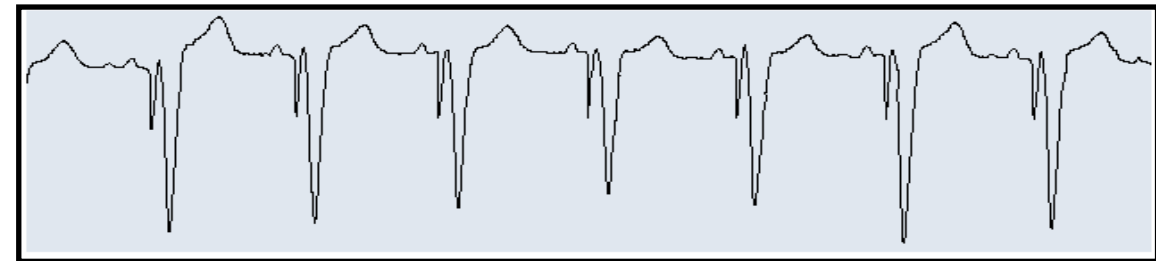
## Ventricular Dyssynchrony<sup>1</sup>

- Electrical
- Structural
- Mechanical



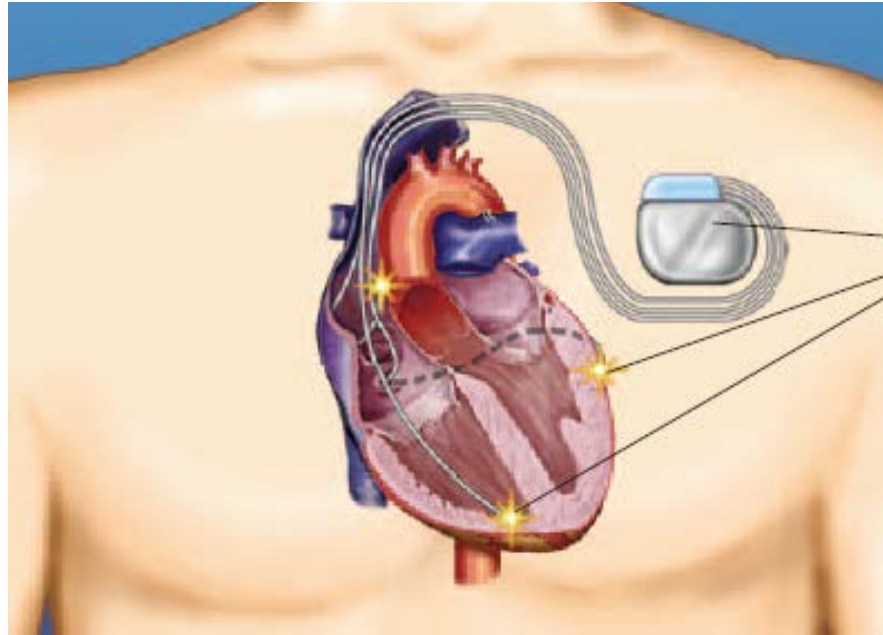
## CRT

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

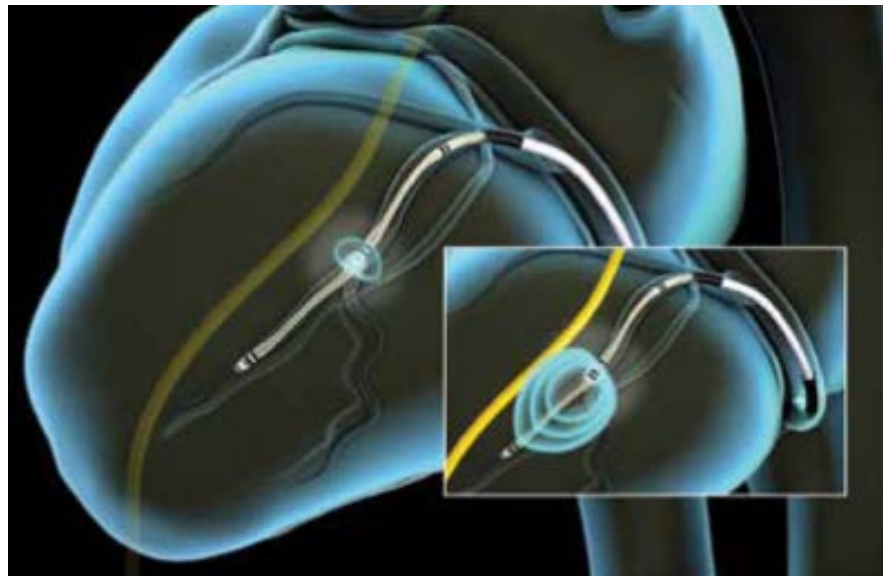


1. Tavazzi L. Eur Heart J 2000;21(15):1211-1214

# Cardiac Resynchronization Therapy



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

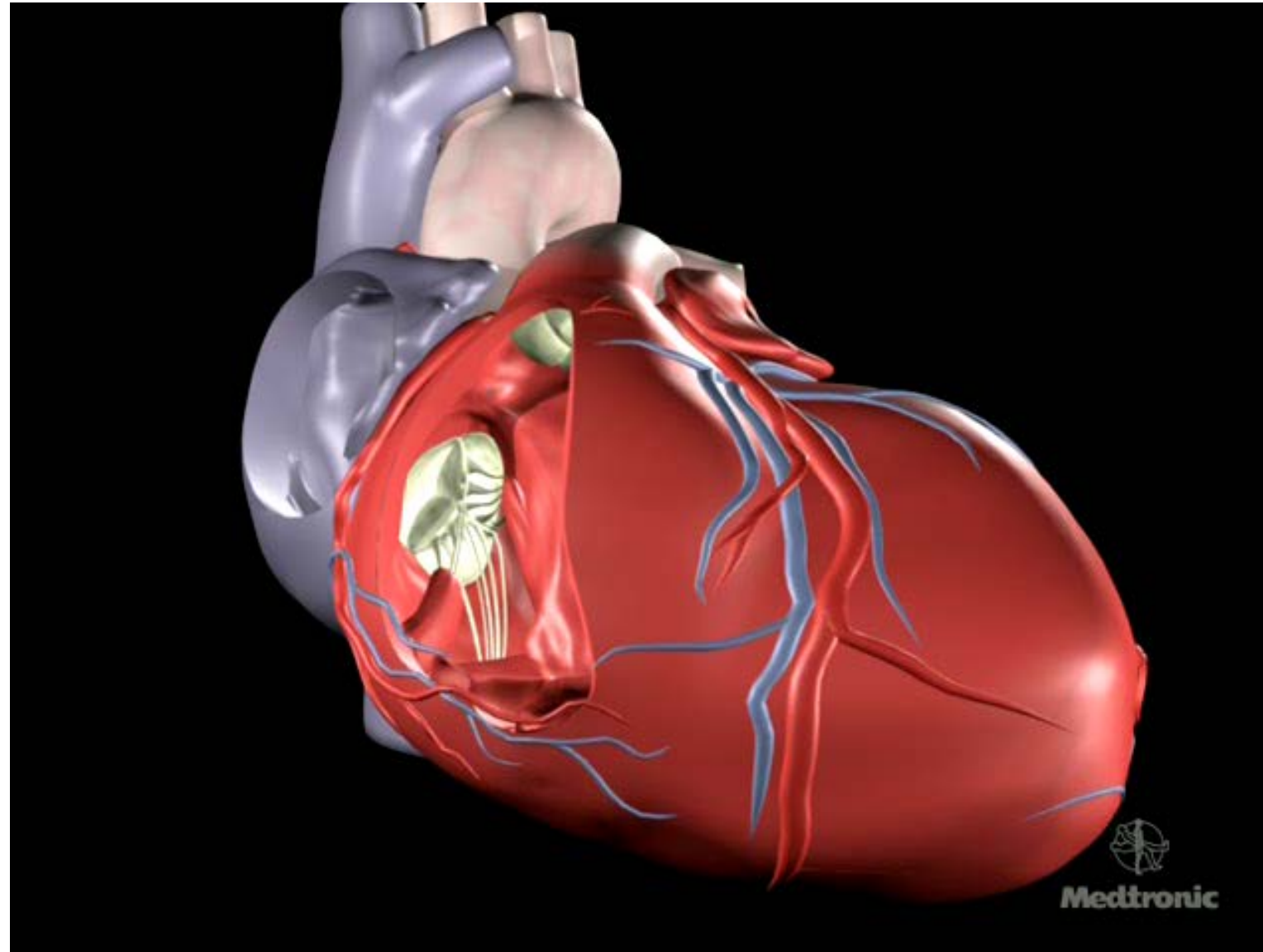


## Potential Benefits of the Therapy:

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

# CRT implant procedure

More complex than IPG/ICD



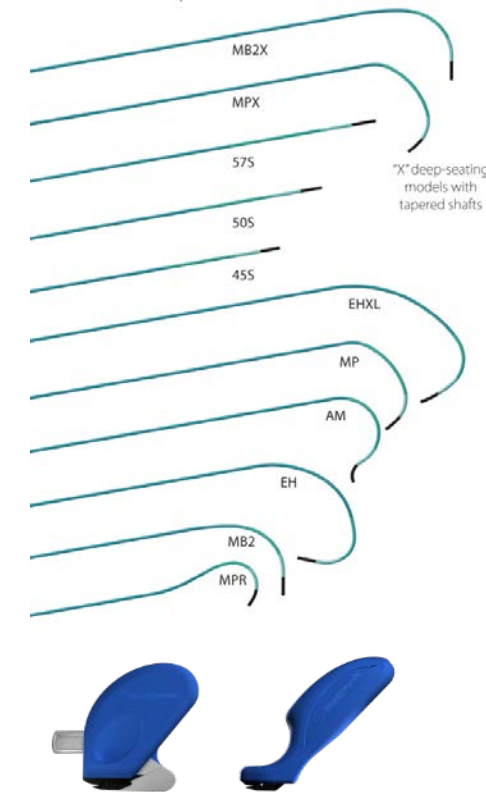
# CRT implant procedure

## 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, ...



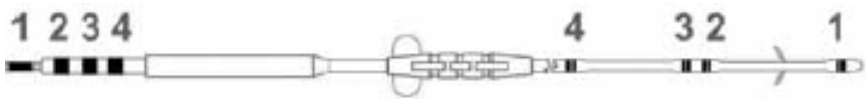


# Left heart leads

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)

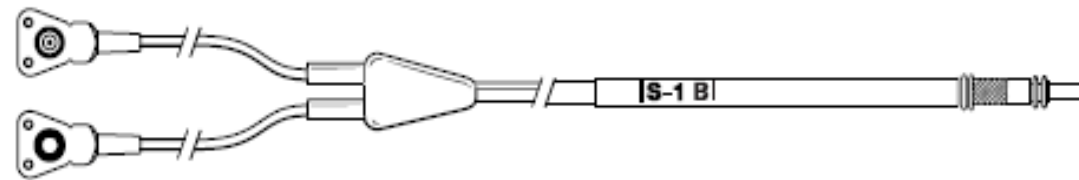


Family	Attain Ability		Attain Performa				Attain Stability	
Model #	4196	4396	4296	4598	4398	4298	4796	4798
Connector	IS-1	IS-1	IS-1	IS-4	IS-4	IS-4	IS-1	IS-4

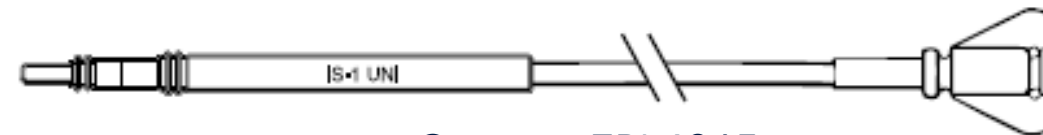
# Epicardial pacing leads

~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

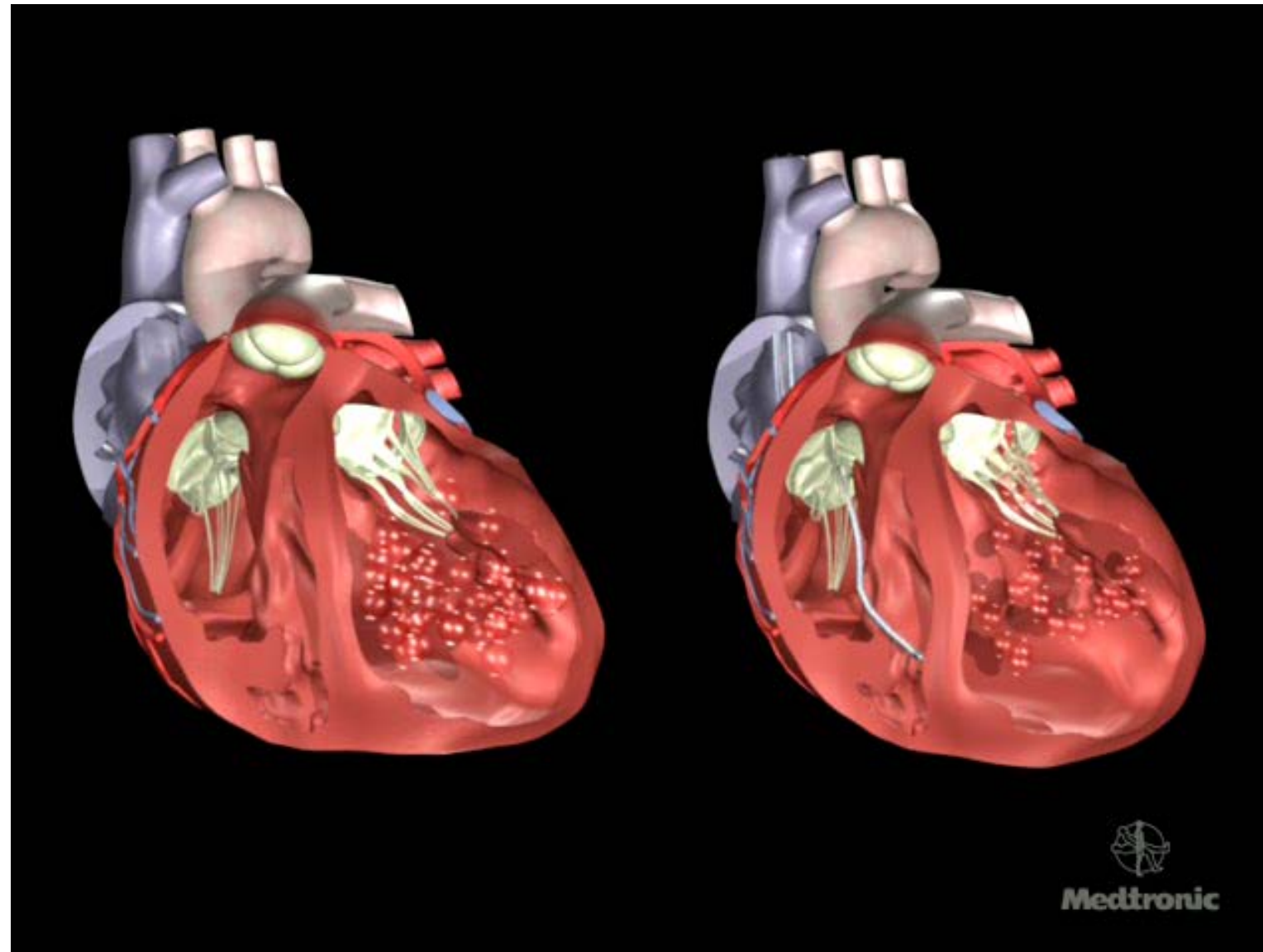


Capsure EPI 4968



Capsure EPI 4965

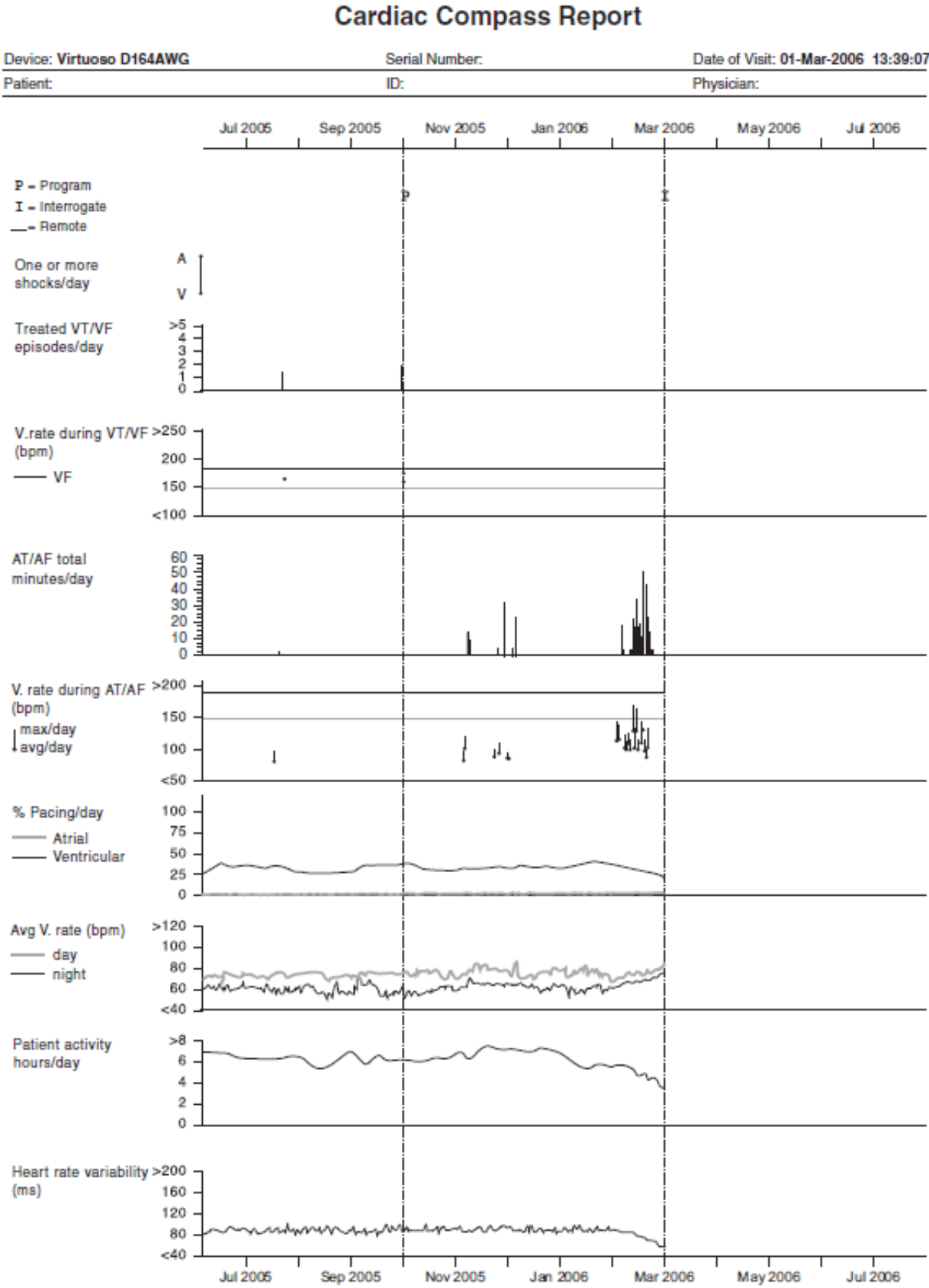
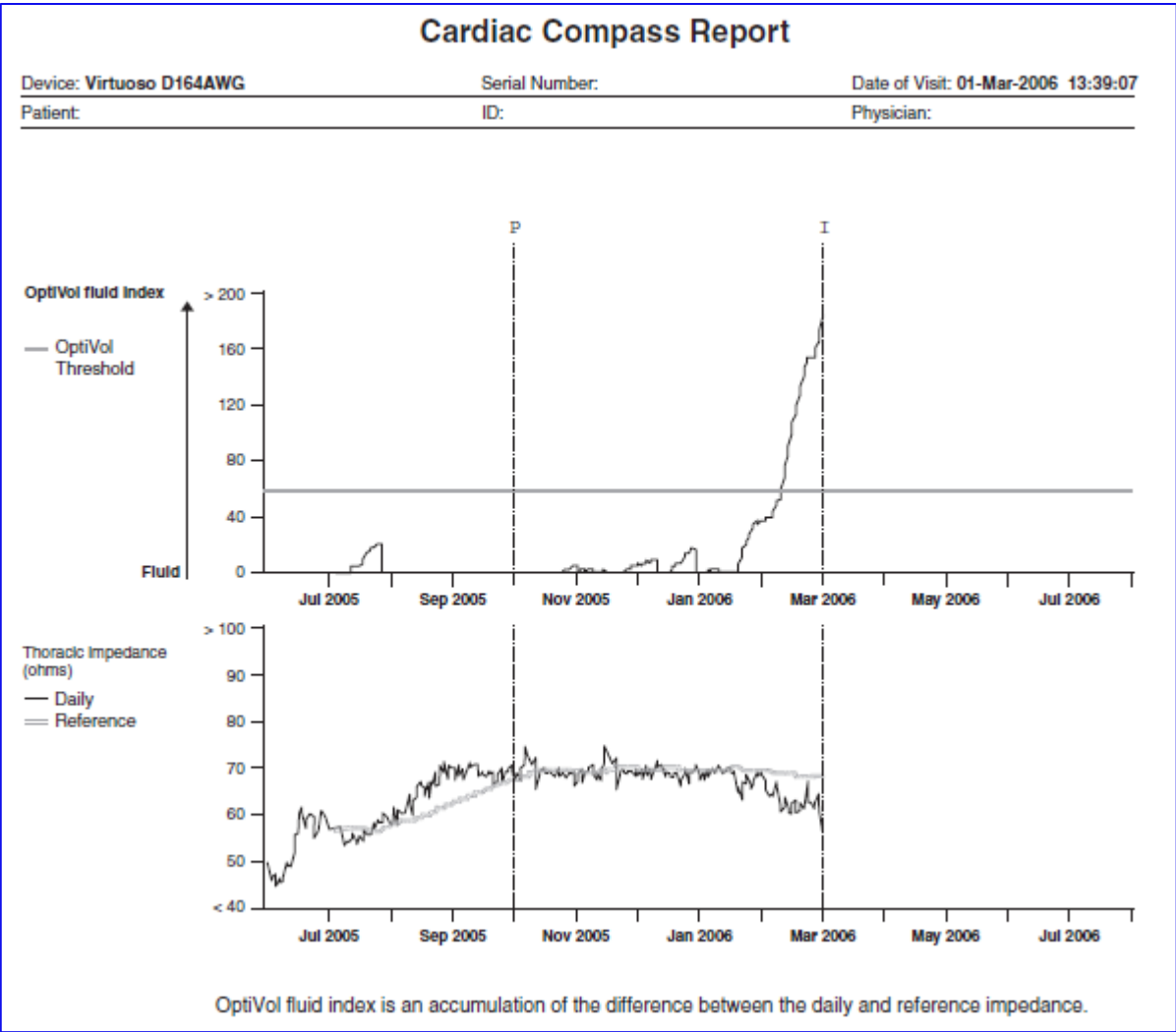
# CRT impact



Desynchronized contraction  
Systolic heart failure

Synchronized contraction  
due to CRT delivery

# Diagnostics



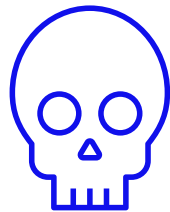
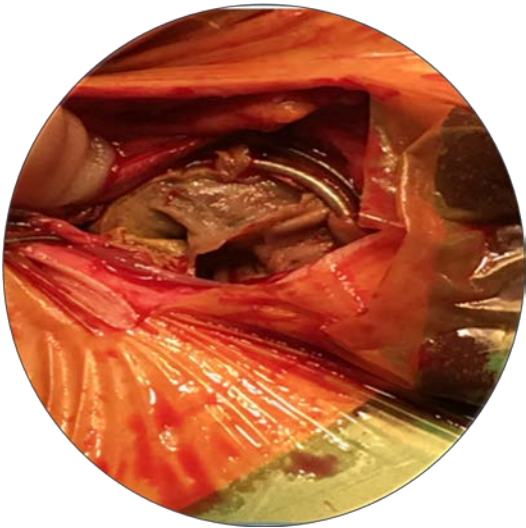


# Tyrx

Procedure innovation



# Managing CIED infection risk



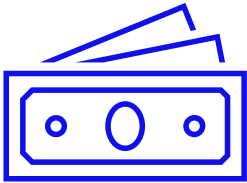
>3x

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
- Immunosuppressive 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

# 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



# The Carelink Network

## Leading Remote Monitoring Service\*

Faster  
Diagnosis

94%

Up to 94% reduction  
in time to review<sup>5-8</sup>

Reduction  
in Visits

41%

Up to 35% in ED  
and urgent in-office visits<sup>5</sup>, 41%  
in total visits<sup>9</sup>

Increased Patient  
Quality of Life

QoL

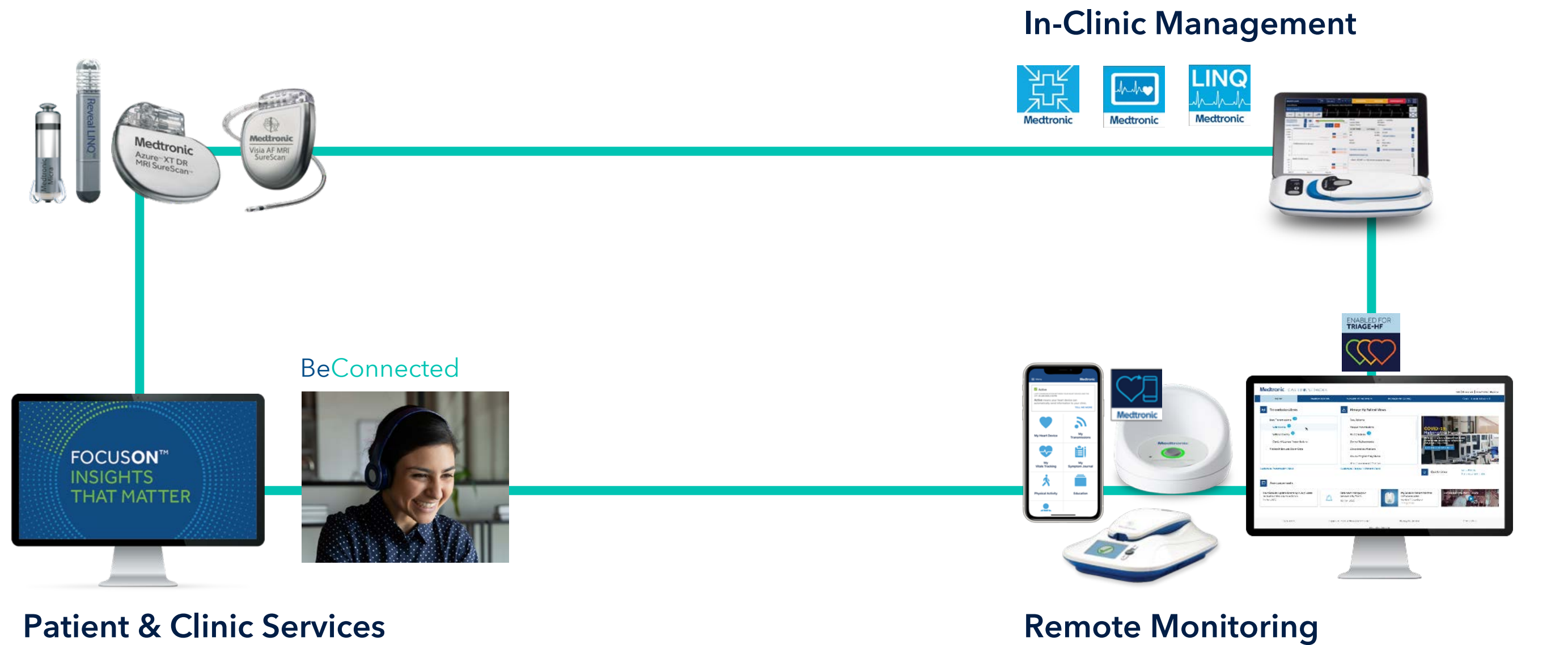
Favorable change in the patient  
quality of life observed<sup>5</sup>

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<sup>1</sup>

# Patient Management Portfolio



# 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

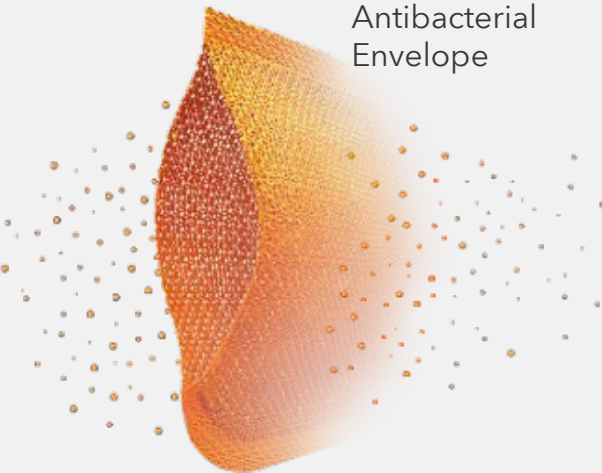


MyCareLink Heart™  
Mobile App  
MyCareLink Relay  
Home Communicator



Procedure Innovation

TYRX™ Absorbable  
Antibacterial  
Envelope



That's it for today...  
Questions?



**All Arrhythmias**  
Straighten Themselves Out in  
  
THE END