

What's New In Implants



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The Future

- New Battery Technology
 - Solar Powered pacemakers
 - Nuclear powered pacemakers
- Injectable pacemaker
- OPPM – orally taken pacemaker
 - No follow up necessary!

Load of Bollox!!

- Solar Powered pacemaker



Load Of Bollox cont'd (well.... almost!!)

- Nuclear powered pacemaker



Load of Bollox cont'd

- OADD



The Real Talk

- Leadless pacemakers
- MRI safe pacemakers
- Leadless pacemakers
- Remote FU
- New Sensors for CHF
- New automatic optimisation techniques
- Connectors

MRI Conditional

Traditional Thinking



WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist **BEFORE** entering the MR system room. **The MR system magnet is ALWAYS on.**

MR and Implantable Devices



Hazards of using MRI with Current Pacemakers and Defibrillators

Combined Field Effects

- Alteration of device function due to EMI
- Mechanical forces (vibration)
- Electronic reset of device

Variables Affecting Magnitude of Risks

- Length/position of pacing leads
- Patient and device position within machine
- Patient factors / medical history
- MRI scan duration
- Blood flow at lead/tissue interface
- Strength of RF field
- Target anatomy of scan
- Type of imaging MRI sequence
- Pacemaker and Lead Design

Do We Need MR Conditional Systems?

The likelihood of MRI indication doubles >65 years¹

MRI is indicated in 17 percent of all patients with pacemakers within 12 months of device placement²

Every six minutes in Europe, a patient is denied an MRI due to an implantable cardiac device

1. Magnetic Resonance Imaging (MRI) Equipment – A Global Strategic Business Report, Global Industry Analysts, Inc., San Jose, CA. 2002

2. Sakakibara et al., Jpn Heart J 1999

Why MR Safe Leads?

Rapidly expanding indications for MR scans

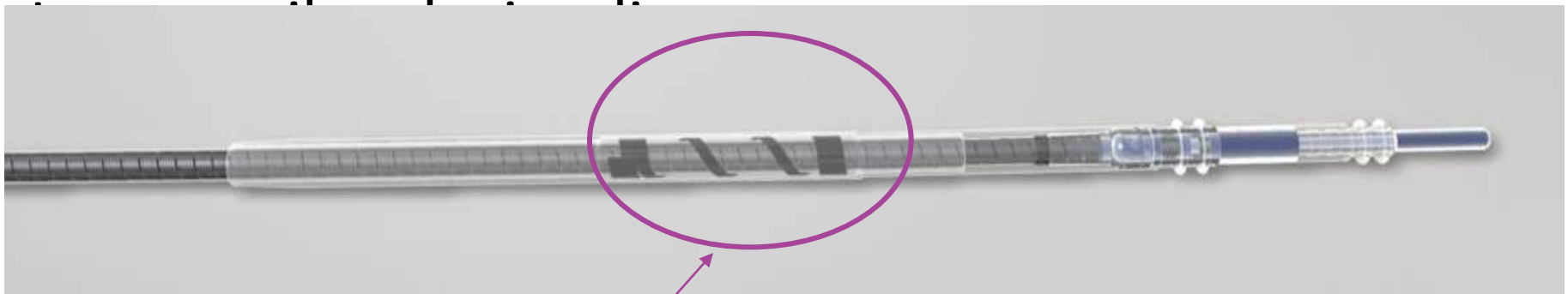
- neurological
- spine and joint
- soft tissue tumours
- hepatobiliary

Staging of Ca prostate is fast growing indication in UK

5086MRI Lead Design

Materials identical to 5076 lead

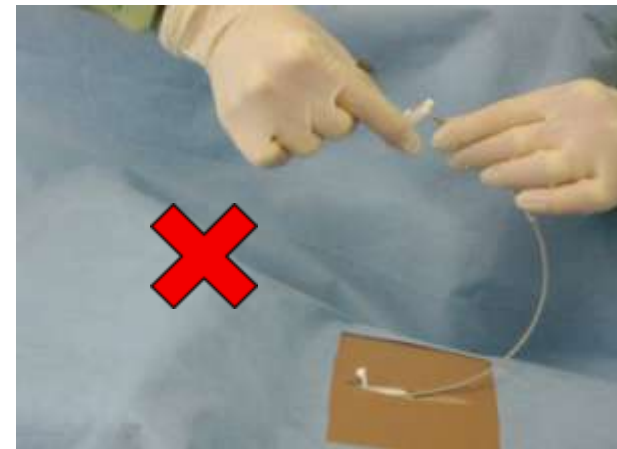
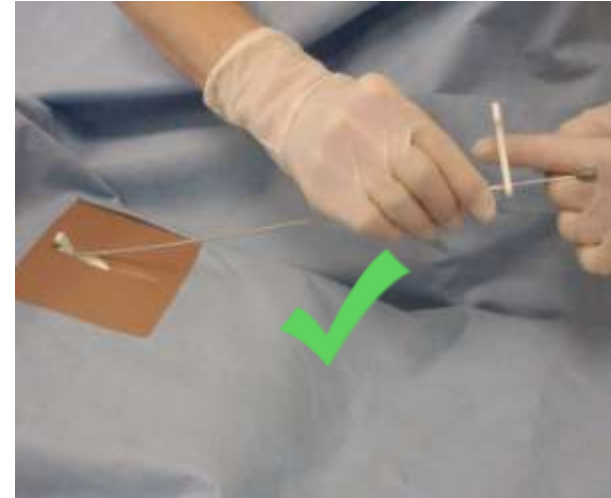
Reducing from 4 filar to 2 filar
increases inductance and reduces
heating



Unique radio-opaque MRI symbol

5086MRI Lead Handling

Stiffer than standard pacing leads
Screw deployment different

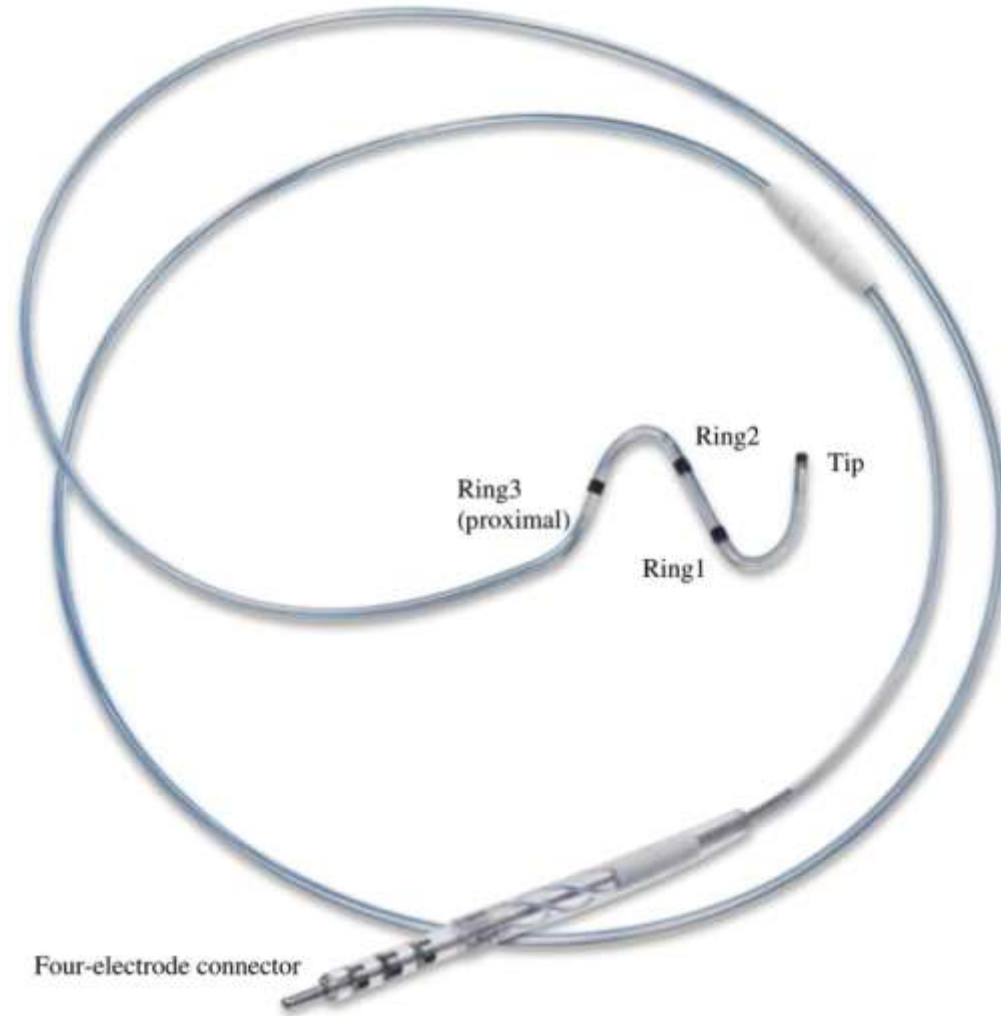


Pacing Complications – MR v Standard Leads

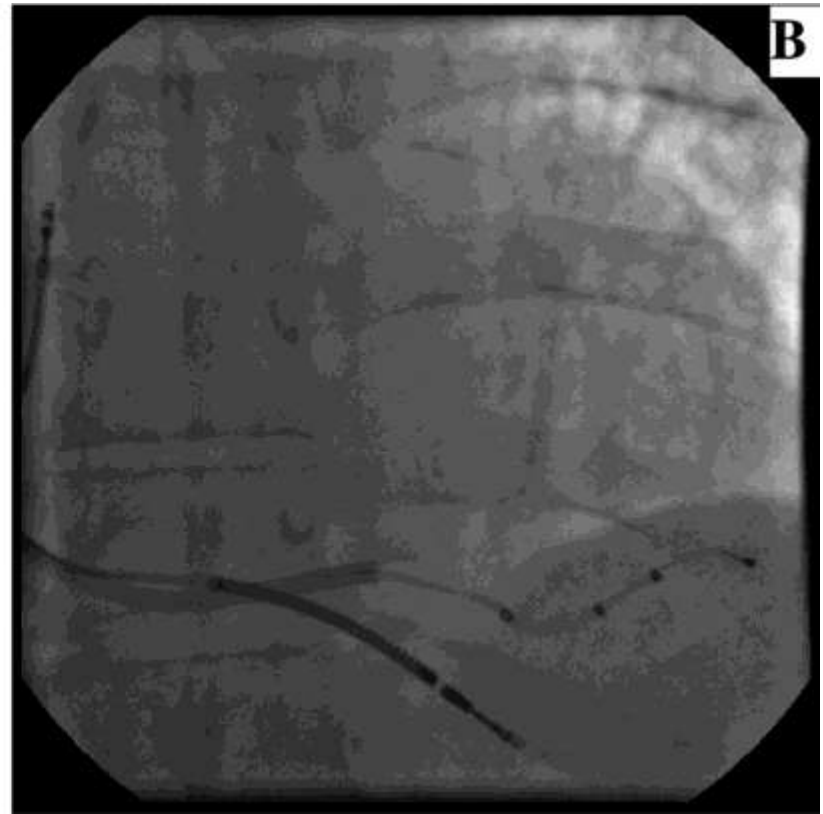
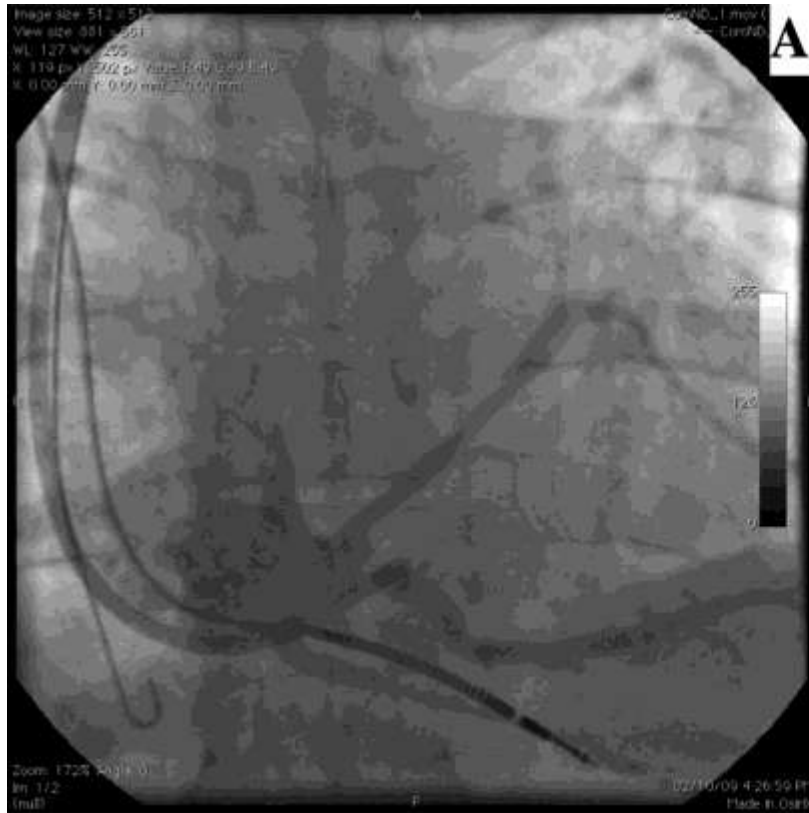
	MRI Conditional	Conventional	p
Number	156	147	NA
Mean Age	66.5	73.3	<0.01
Mean screening time (mins)	8.64	8.05	0.42
Lead displacements	5 (3.2%)	4 (2.7%)	0.80
Perforations	1 (0.6%)	0 (0%)	0.33

CRT

Quadripolar LV Lead



Quadripolar LV Lead



ILR's

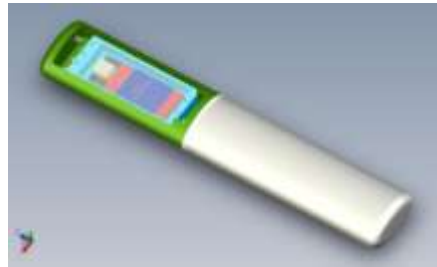
“Injectable” Loop Recorder

Insertable Reveal[®]
XT



9 cc

Injectable Reveal



1.0 cc

Injectable Reveal

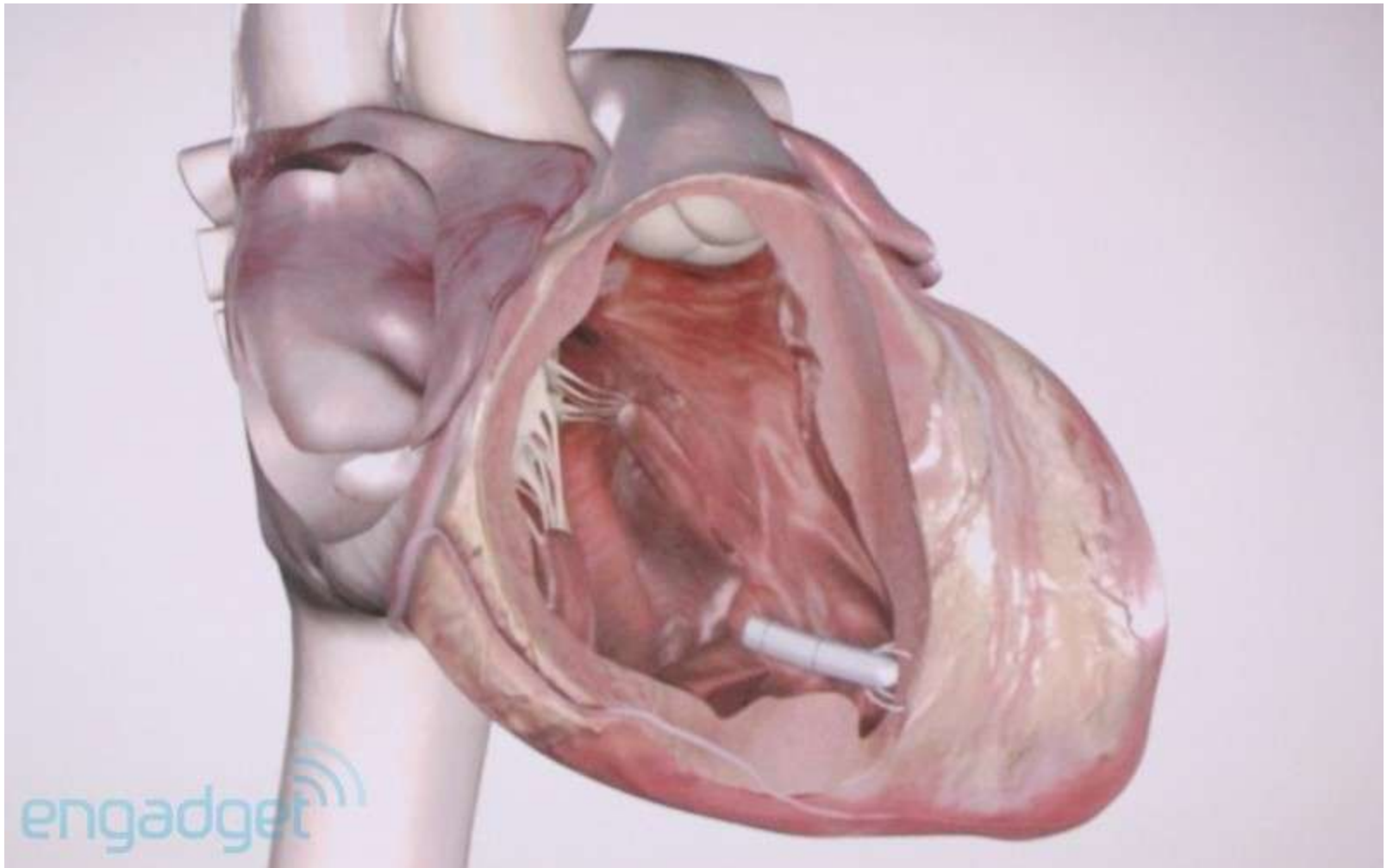


0.5 cc

Percutaneous Leadless Pacer



Percutaneous Leadless Pacer



Percutaneous Leadless Pacer

Miniaturisation + percutaneous delivery =
Less-invasive, easier-to-use and more cost effective therapies

Leadless pacer

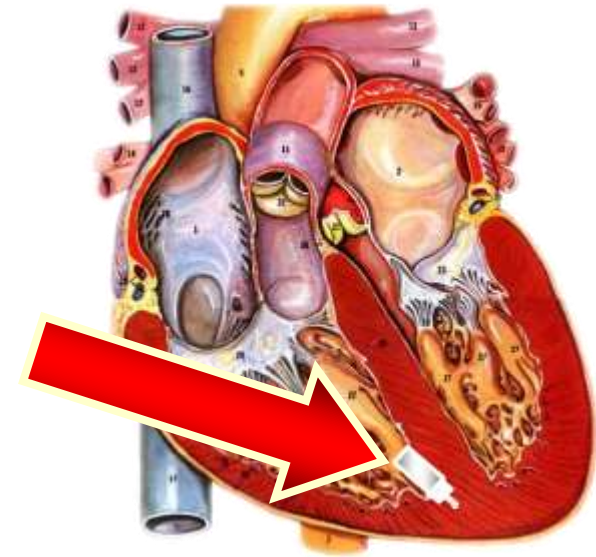


Catheter Delivery





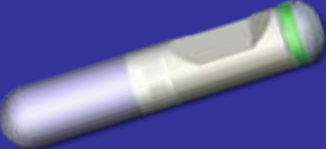
- <1 cc
- < 24mm length
- < 20Fr diameter
- Active fixation
- 7 year longevity (100% VVI paced)
- Output Amplitude: nom 2.0V; max 5.0V
- Basic device and arrhythmia diagnostics

Leadless pacer in
catheter



Leadless pacer in
place

Next Generation CRT and ICD Technologies

 <p>Next Generation CRT</p>	<ul style="list-style-type: none">• Adaptive CRT• Dynamic A-V/V-V optimization• OptiVol 2.0• Revolutionary physiological shape. Reduced size.
 <p>Multipolar Lead</p>	<ul style="list-style-type: none">• Addresses phrenic nerve stimulation• Improves haemodynamics
 <p>HF Management</p>	<ul style="list-style-type: none">• New sensor technologies for enhanced management of heart failure patients

CareLink Mobile Application

Same data. New access.

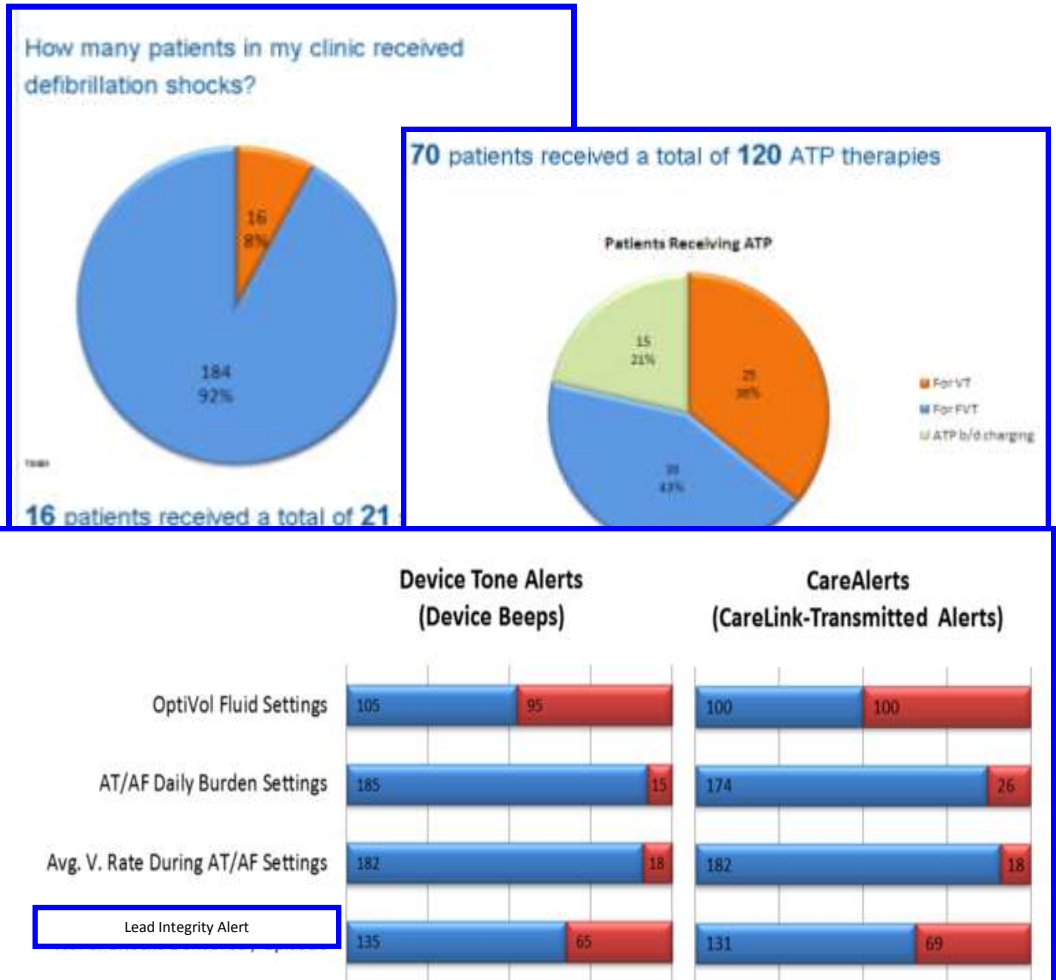
- Direct mobile access to reports on the CareLink[®] Network
- Review Medtronic CareAlert[®] Transmissions or any last transmission anytime, anywhere so you can triage clinical events and take action



New Tools to Organise Remote Monitoring Data

How many patients in your clinic...

- ...received shocks last year?
- ...were treated painlessly with ATP during the last three months?
- ...have the Lead Integrity Alert...OFF or not installed?



The SonR system design

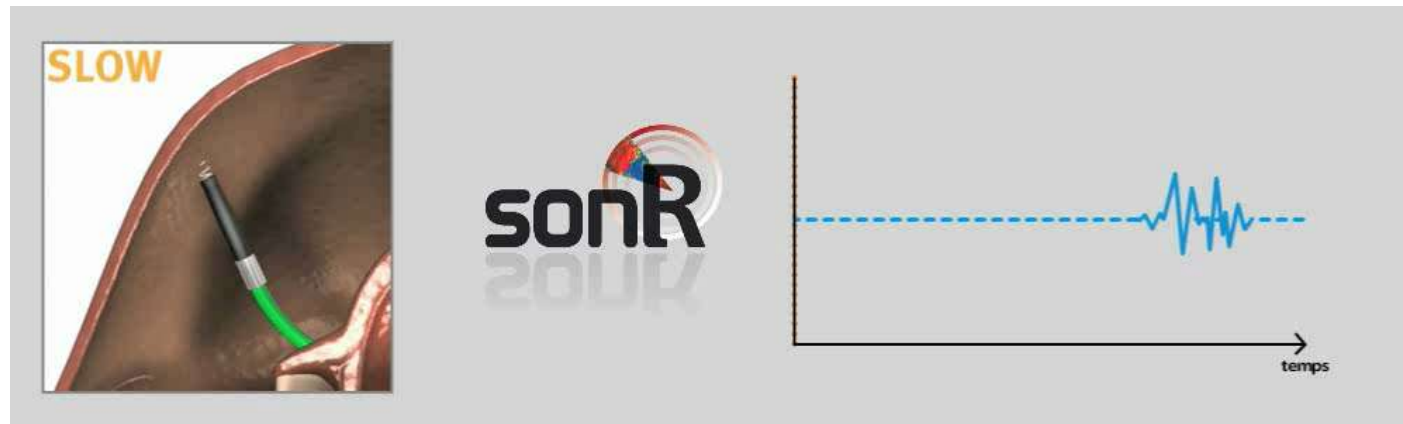
- The SonR sensor is designed to pick-up cardiac muscle vibrations without any soft deformable part in contact with blood
- Electronics encapsulated in a sealed titanium can:
 - resistant to mechanical stress
 - insensitive to fibrosis development



New Technique for CRT optimisation

The SonR signal properties

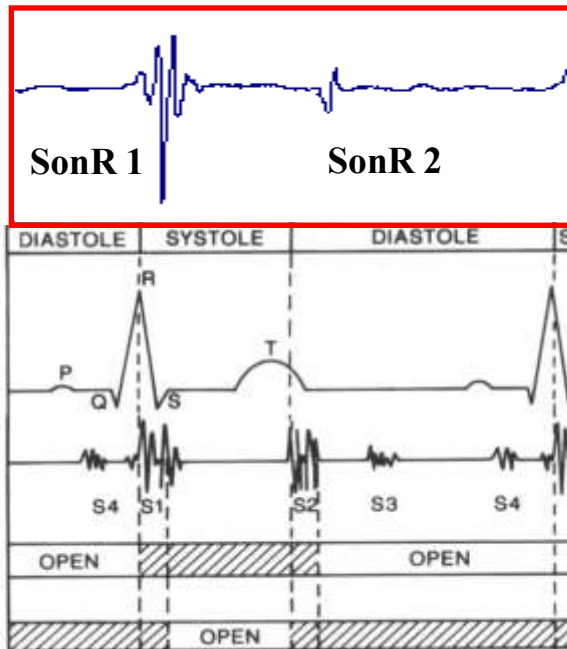
- SonR picks-up vibrations in a specific range of frequencies
 - SonR is recording infra-sounds in the range 10-70Hz (non audible components)
 - Atrial contractions are in a lower frequency band (max 5 Hz or 300bpm)
 - External sounds are filtered by the chest and do not alter SonR signal



SonR picks-up vibrations that reflect global contractility, and not just local cardiac wall movements

The SonR signal properties

- The SonR signal occurs at the same time in the cardiac cycle as the well-known heart sounds.
 - SonR1 and the 1st heart sound (S1) are generated by reverberation with the sudden block of reverse blood flow as the mitral valve closes
 - SonR2 and the 2nd heart sound (S2) correspond to the closing of the aortic valve



ECG
Heart sounds
Mitral Valve
Aortic Valve





New Sensors For CHF

Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

*William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelagaru, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay S Yadav, for the CHAMPION Trial Study Group**

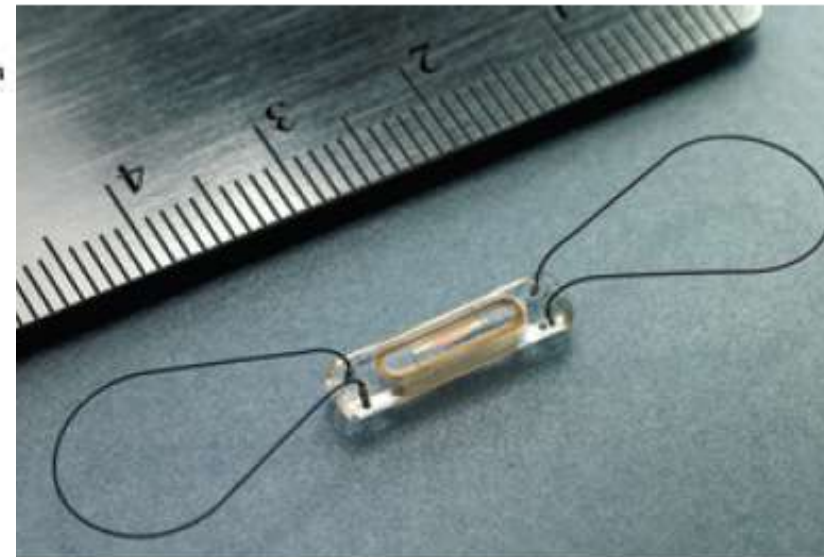
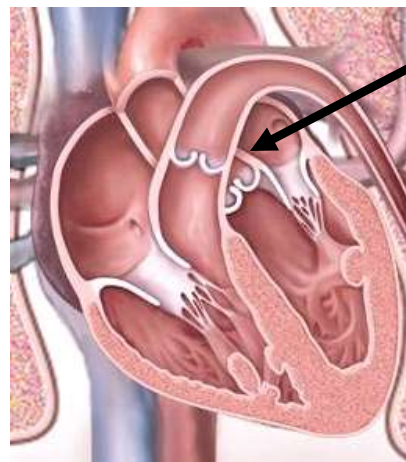


Figure 1 | The CardioMEMS[®] (Atlanta, GA, SA) continuous-waveform sensor. Courtesy of CardioMEMS, Inc.

Targeting Pressures Can Reduce Hospitalizations: HOMEOSTASIS Trial

The HOMEOSTASIS feasibility registry evaluated the effects of physician-directed, patient self-management of left atrial pressure (LAP) in Class III and Class IV HF patients



LAP Sensor

LAP was monitored using an investigational device by St. Jude Medical

Ritzema J, et al. Circulation, 2010.

CAUTION: Investigational Device, Limited by Federal (or United States) Law to Investigational Use

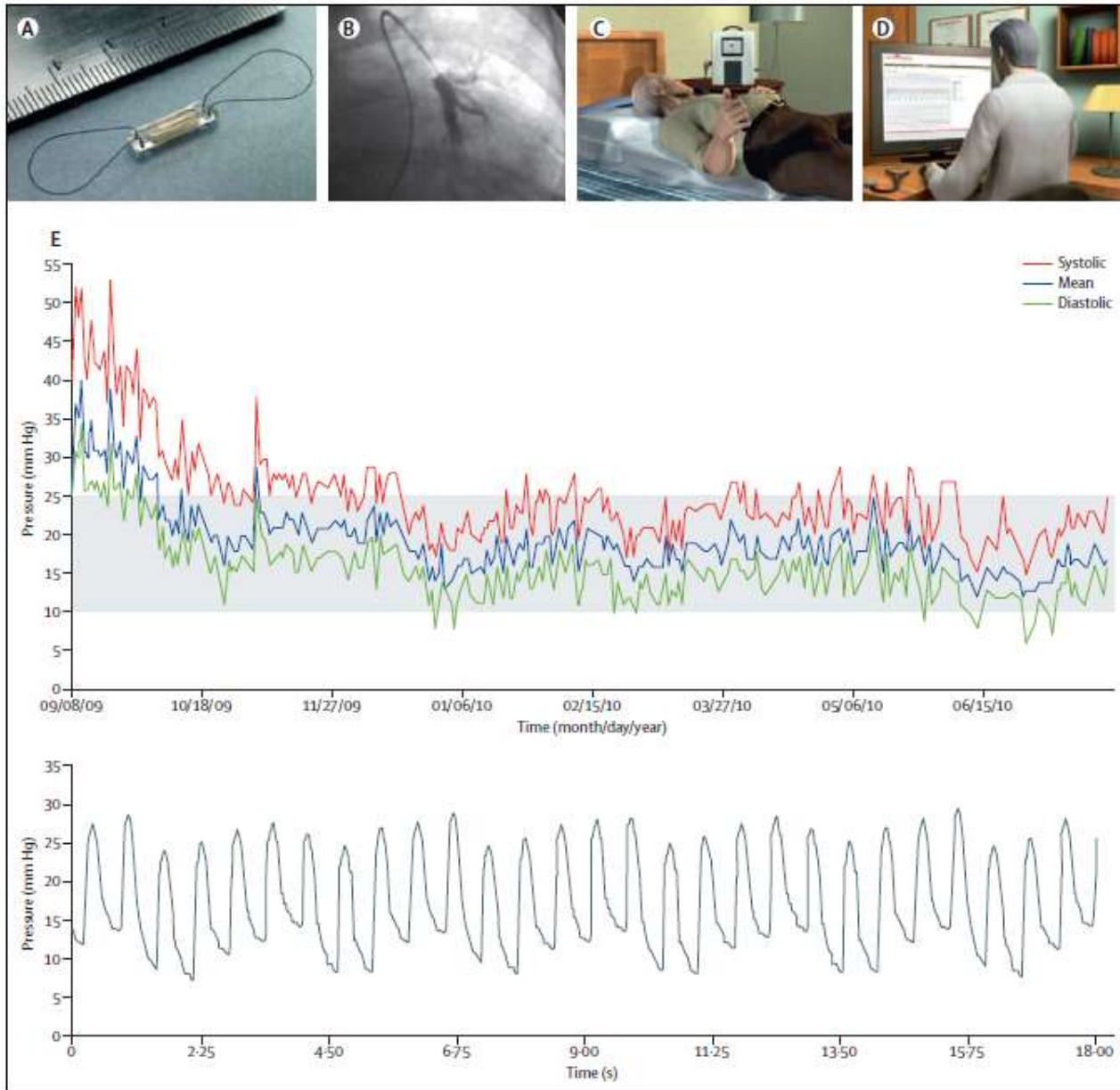
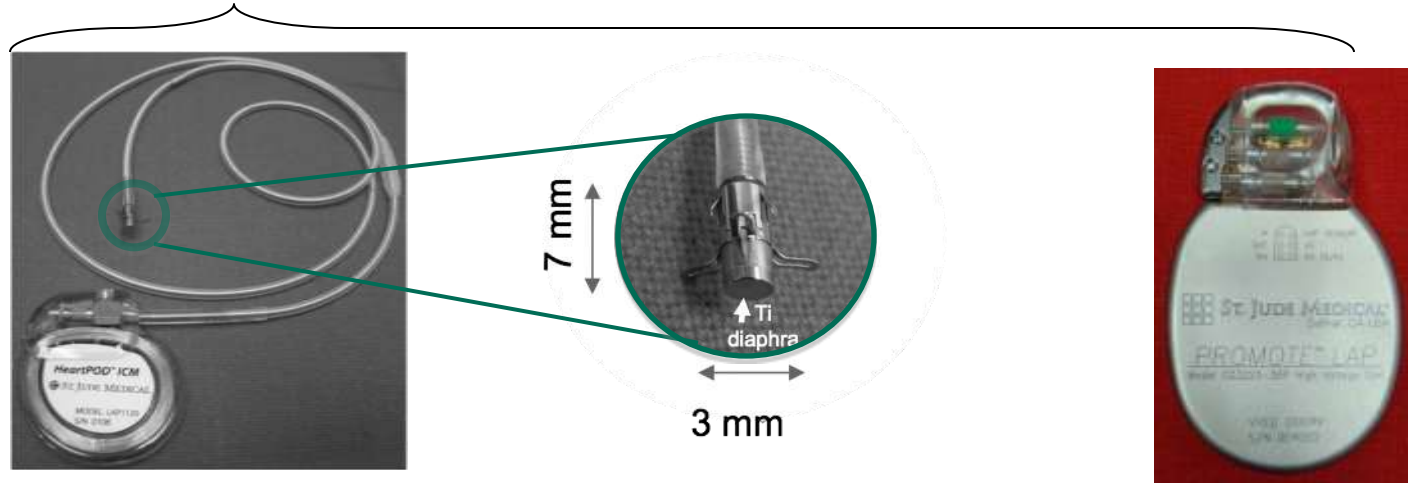


Figure 1: Implantable haemodynamic monitoring system

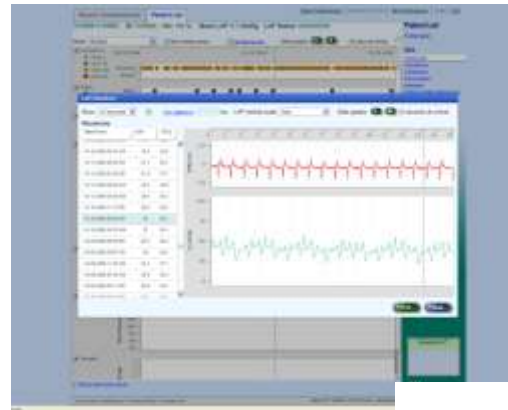
(A) CardioMEMS sensor or transmitter. (B) Transcatheter is implanted into a distal branch of the descending pulmonary artery. (C) Patient is instructed to take daily pressure readings from home using the home electronics. (D) Information transmitted from the monitoring system to the database is immediately available to the investigators for review. (E) Transmitted information consists of pressure trend information and individual pulmonary artery pressure waveforms.

LAP Sensor and System (current version)

LAP Sensor



→
Patient Advisor
Module (PAM) -
External
Measurement
System



←
Patient Database

*See appendix for information on implant techniques

DynamicRX™ guided HF therapy

Hemodynamic-based, Physician-Directed, Patient-Self Management of HF

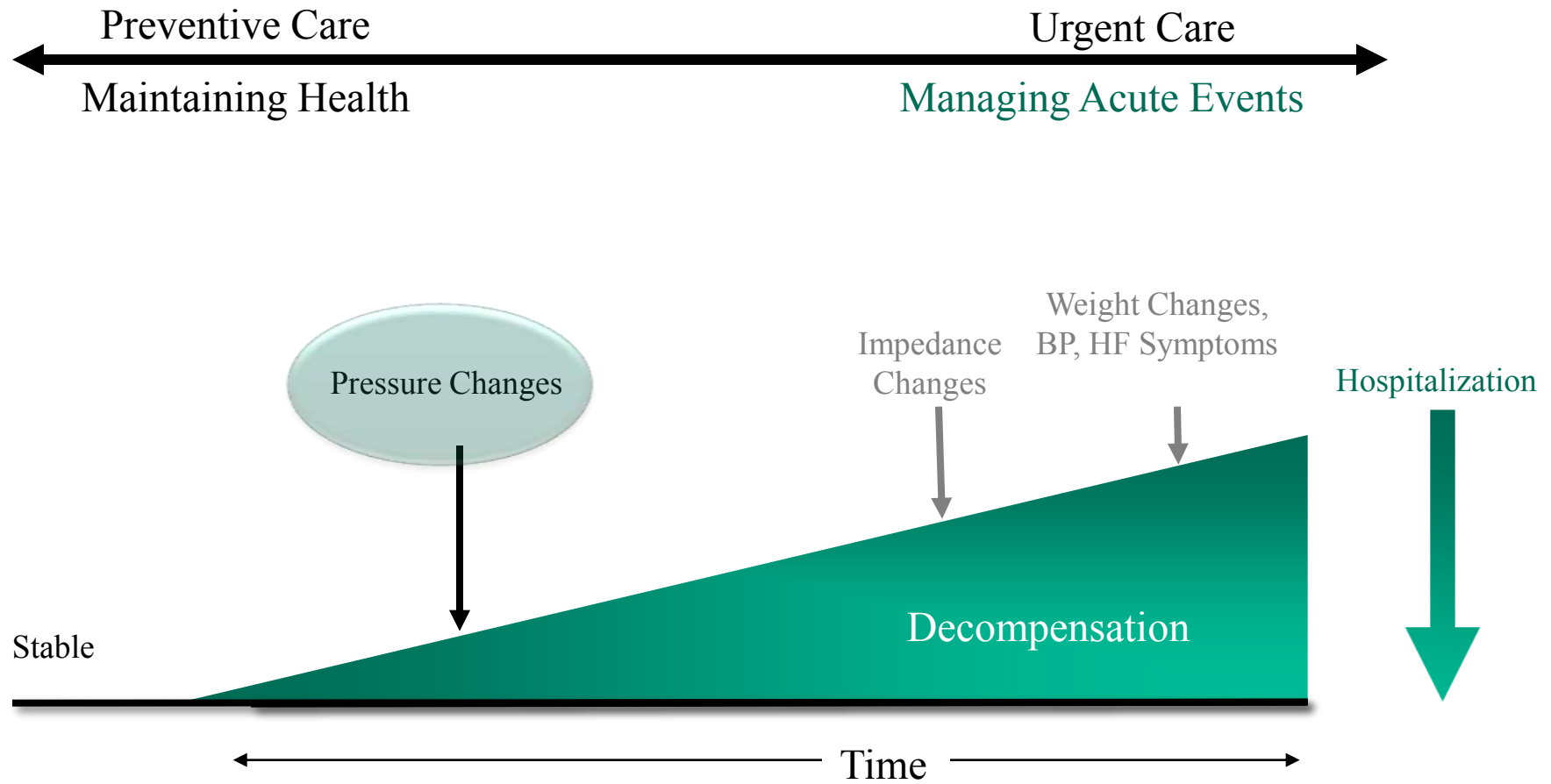
Physician formulates DynamicRX™ guided HF therapy based on patient history and hemodynamic (LAP) data

Patient reads daily LAP



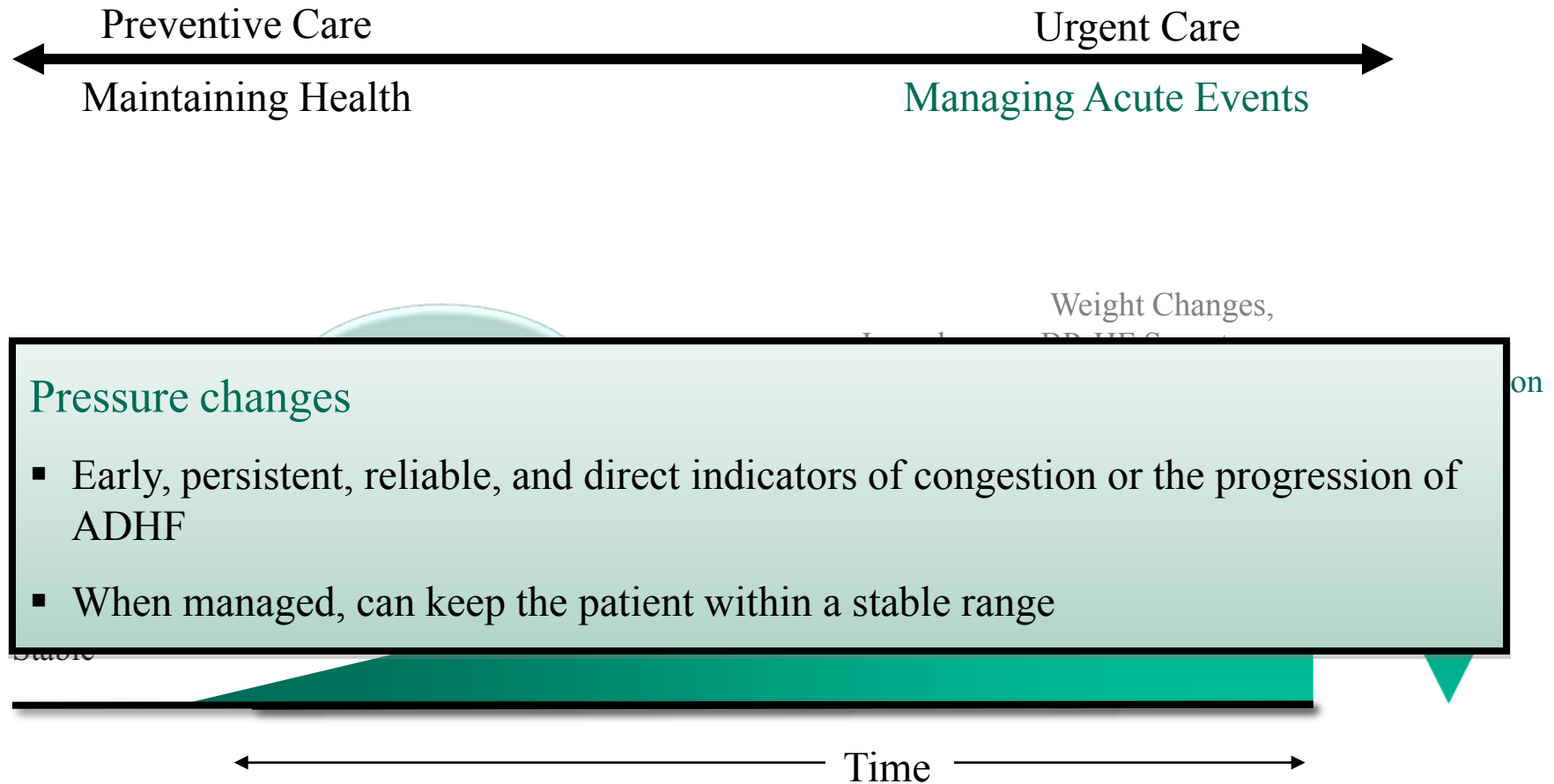
→ DynamicRX™ guided HF therapy: A system that allows patients to adjust their HF medications daily, as directed by their physician. Physicians will manage pressures to target pressure ranges.

Summary: Managing Pressures to Maintain Health and Manage Acute Events



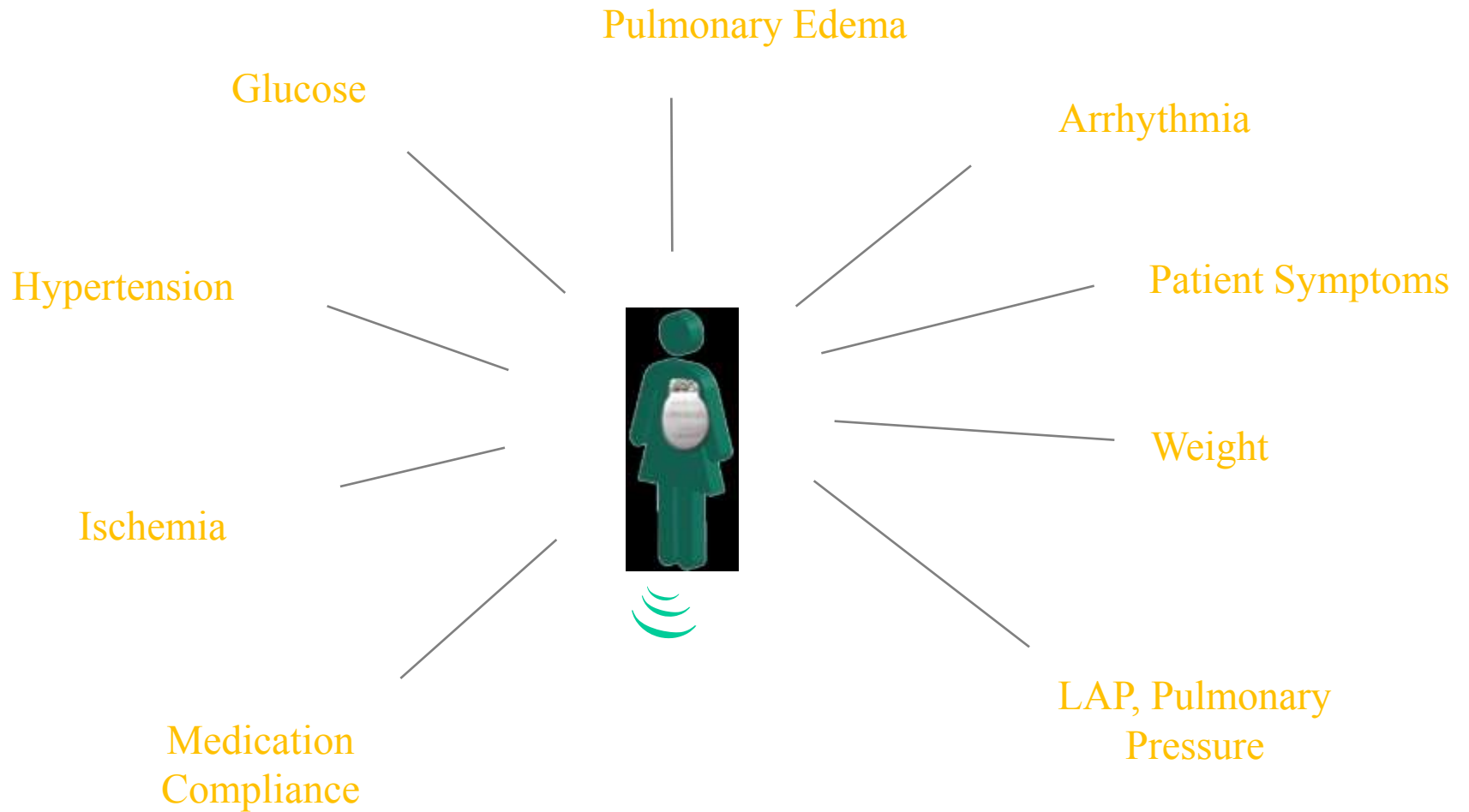
* Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

Summary: Managing Pressures to Maintain Health and Manage Acute Events



* Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

(FUTURE)



Connectors

DF4

Header Attributes

- The new St. Jude Medical DF4 connector replaces one IS-1 and two DF-1 connectors
 - The remaining IS-1 connectors on the CRT-D and dual chamber devices will use a single setscrew just like the pacemakers
 - CRT-D = three setscrews instead of eight
 - Dual chamber = two setscrews instead of six
 - Single chamber = one setscrew instead of four

DF4 Key Message (*Device*)

– *Simplicity*

- Streamlined design decreases chance of lead-to-port mismatch
- Simplified procedure improves patient comfort due to less traumatic tunneling

– *Speed*

- Fewer connections and set screws lessen complexity and shorten implantation times



Today's Promote® RF CRT-D Header (8 setscrews)

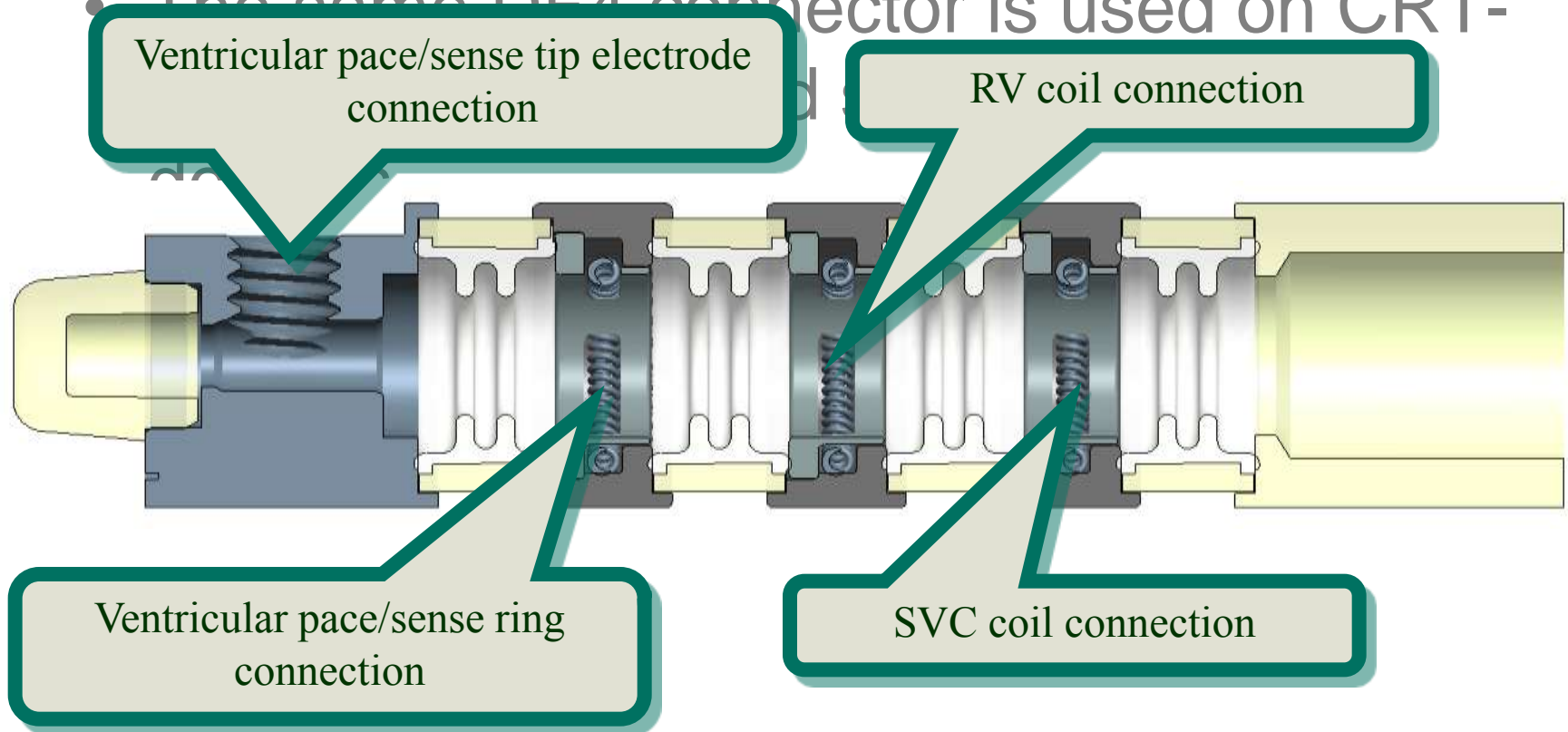


New DF4 Header for CRT-D Devices (3 setscrews)



The St. Jude Medical DF4 Connector

- The same DF4 connector is used on CRT-



The St. Jude Medical DF4 Connector

- Due to removal of trifurcation, DF4 lead lengths will be 52, 58 and 65 cm
 - Previous leads are 60, 65 and 75 cm

DF-1/IS-1 Lead (cm)	DF4 Lead (cm)
60	52
65	58
75	65



Thank You
(especially to all those
still in the bar at 3am!)

Questions?