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DEVICE THERAPY: HOW TO MEET THE CHALLENGES OVER THE NEXT 5-10 YEARS

Nick Linker

James Cook University Hospital, Middlesbrough

South Tees Hospitals NHS
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- Increasing demand / aging population
- New technologies
- Financial constraints
- Physiologist support

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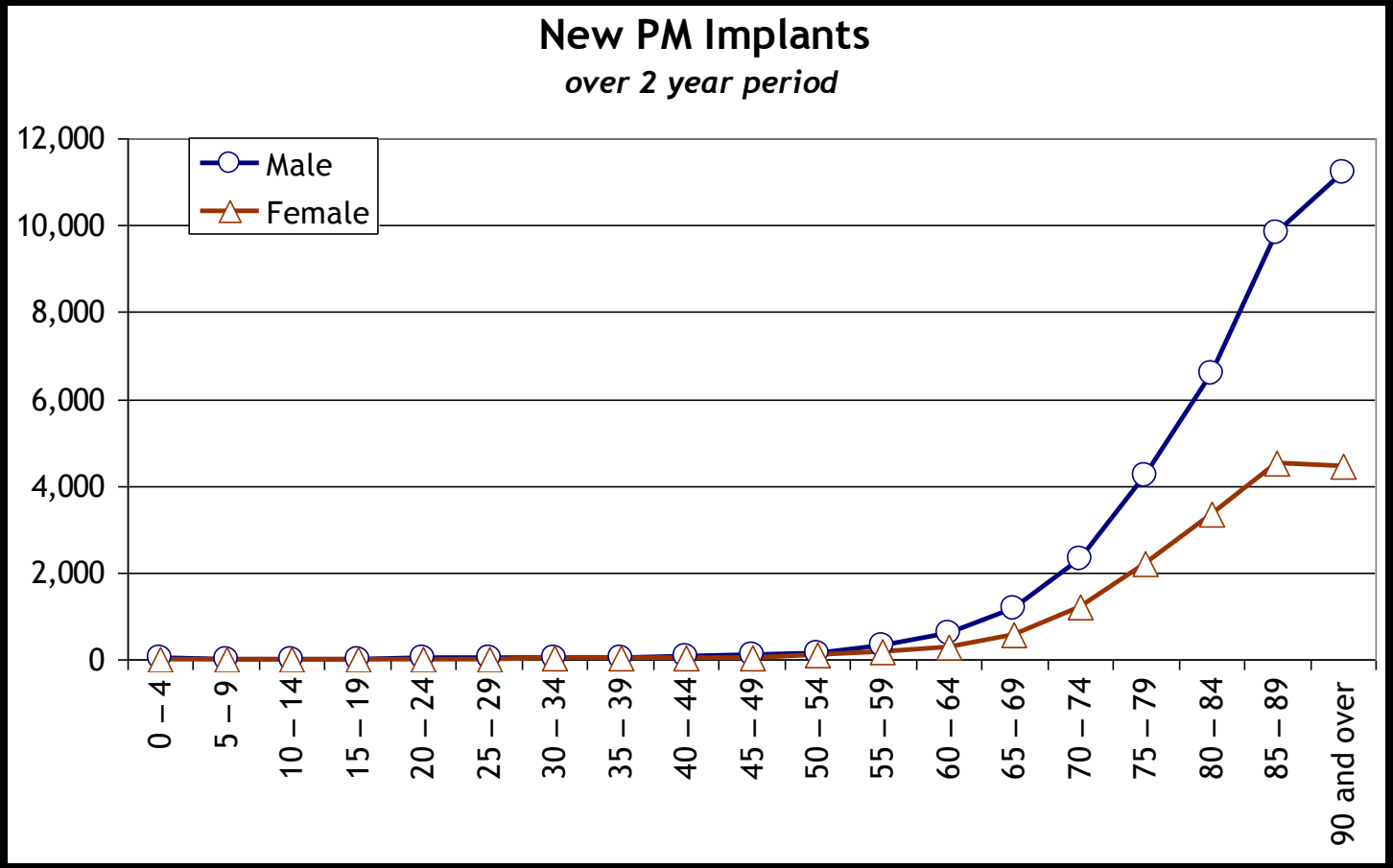
THE POPULATION 'NEED' FOR PACEMAKERS INCREASES EXPONENTIALLY WITH AGE



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AGING POPULATION

- Requirement for increasing numbers of pacemakers
- Average annual increase in new pacemaker implant rate in the UK from 2005-2016 was 4.8%
- Average annual increase required to maintain status quo due to aging population in the UK is 2.5%

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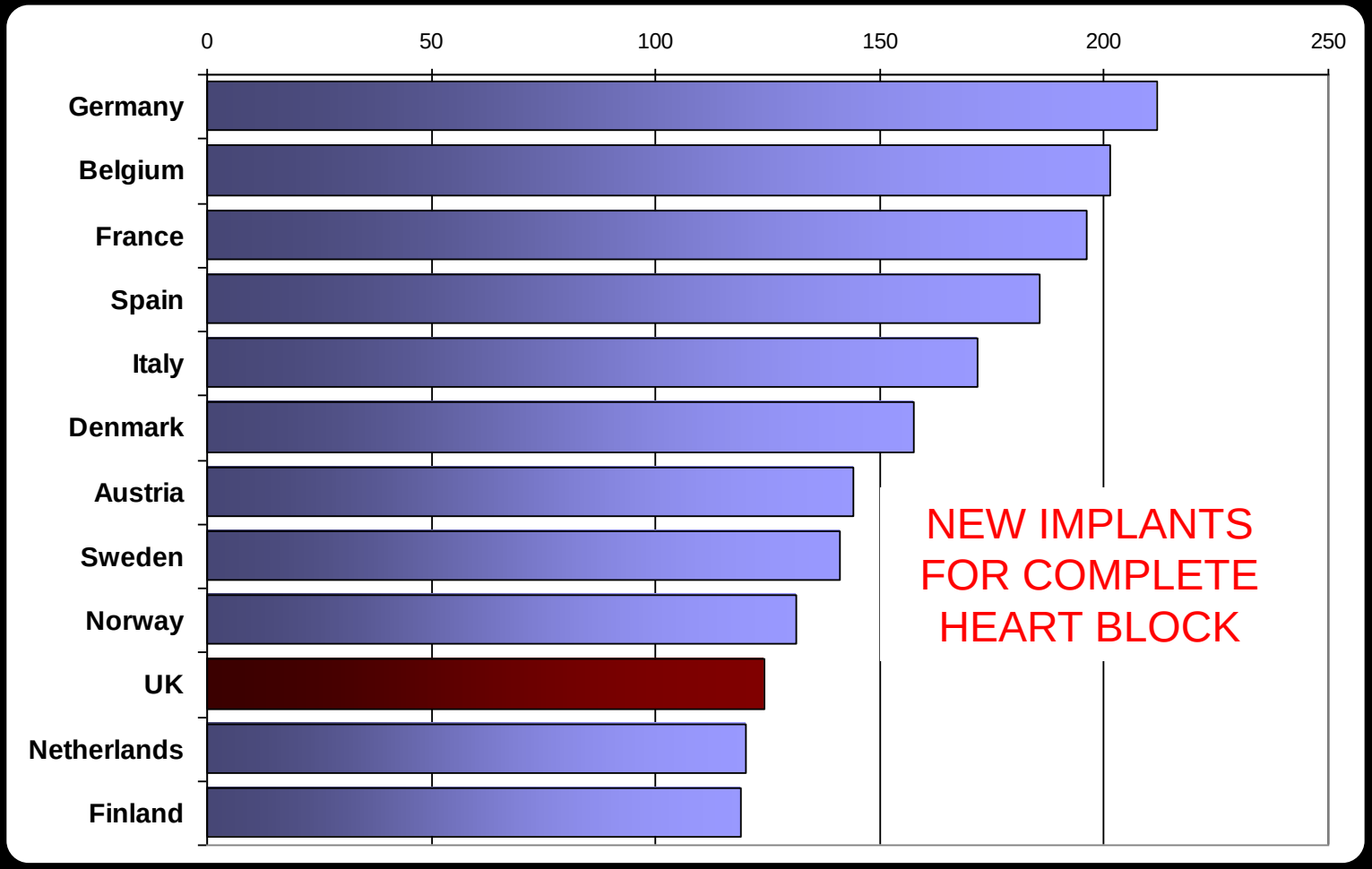
PACEMAKER IMPLANT RATES



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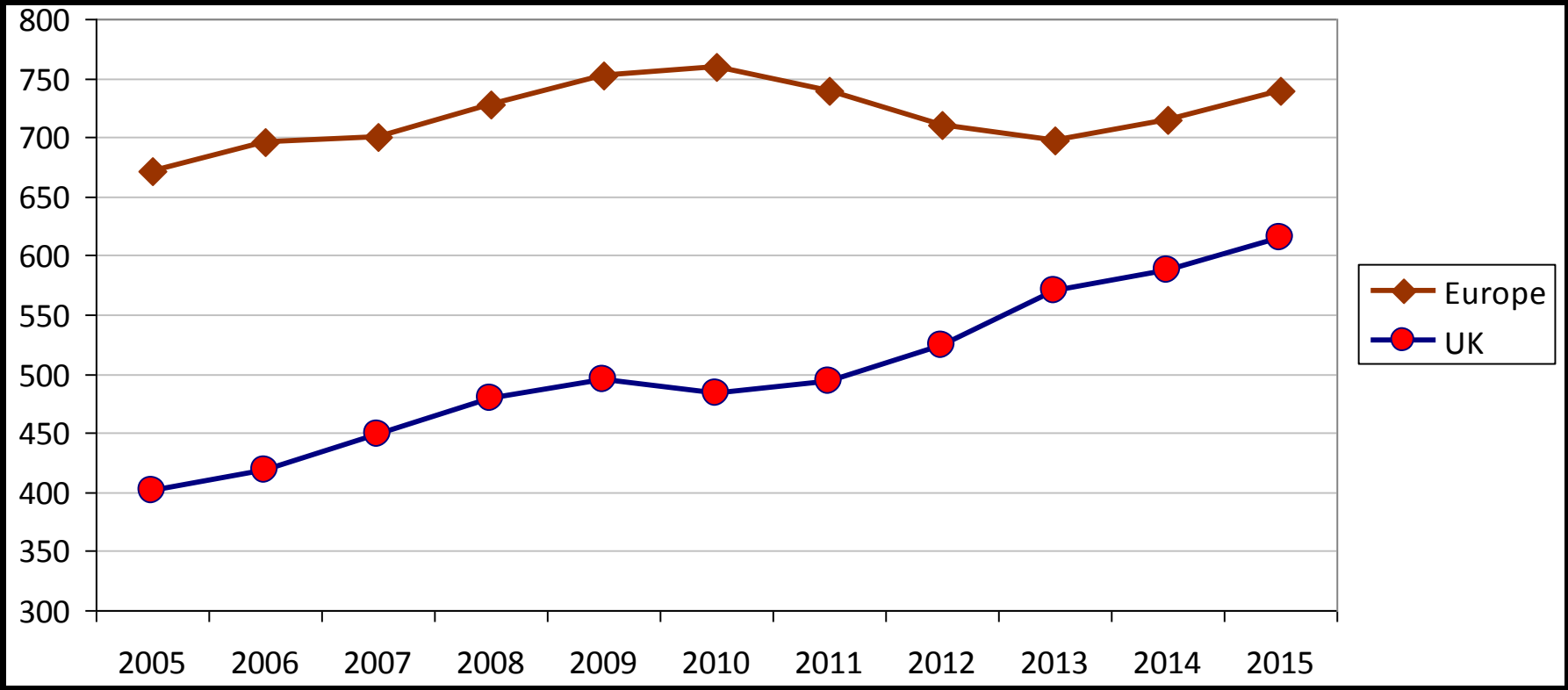
EUROPE AND UK NEW PACEMAKER IMPLANT RATES



- UK has 230 implanting centres – same as Belgium (population 11 million)
  - Germany has 1,000 implanting centres

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CONCLUSIONS OF 2014/15 NATIONAL CRM AUDIT

- The UK new pacemaker implant rate (594) is well below the Western European average (740)

- This has been consistently so for more than a decade. There are no clinical reasons why the need for pacemakers should be less in the UK

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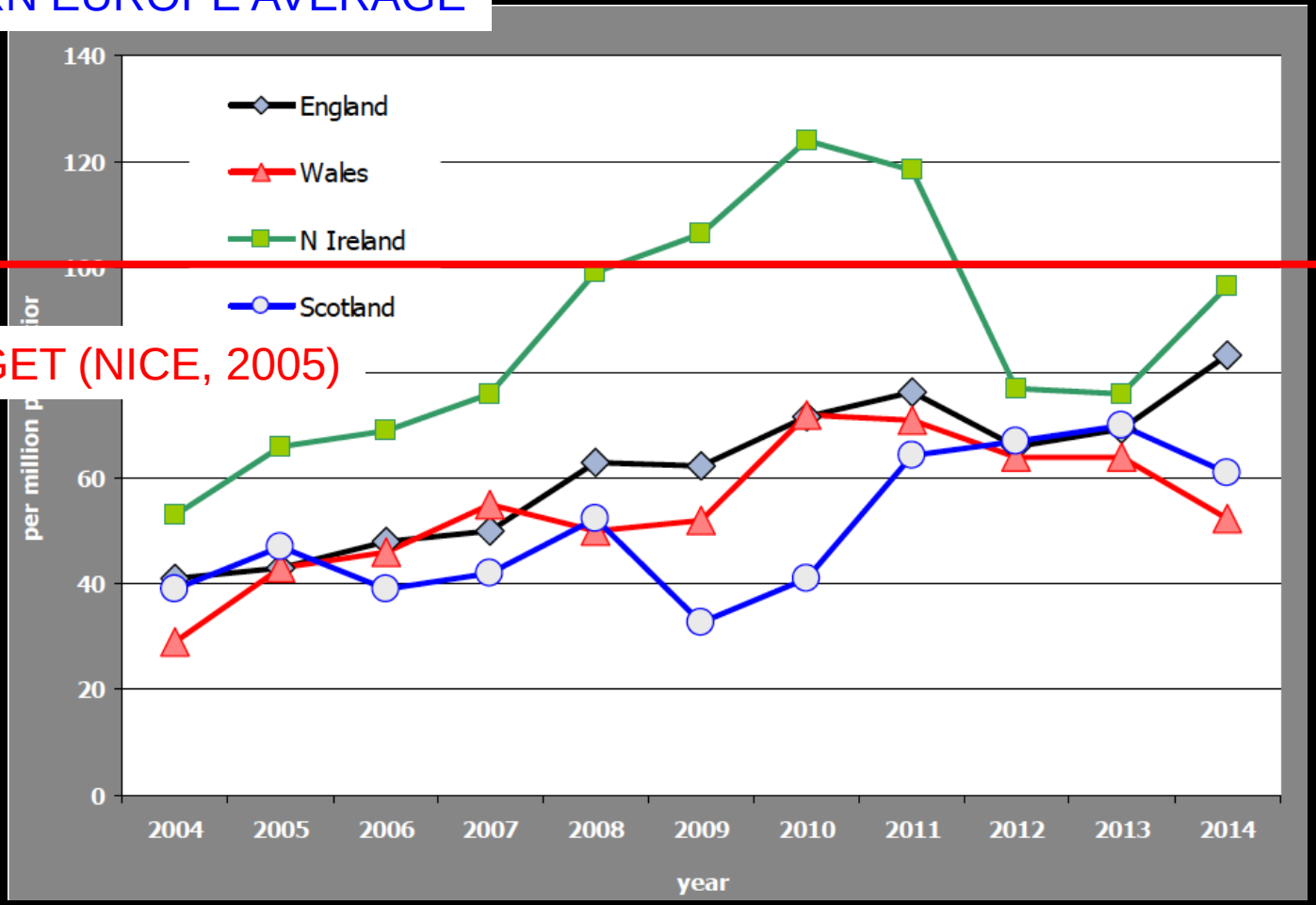
ICD IMPLANT RATES 2004-14

WESTERN EUROPE AVERAGE

UK TARGET (NICE, 2005)



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CONCLUSIONS OF 2014/15 NATIONAL CRM AUDIT

- The UK new ICD implant rate (83) is much lower than the Western European average (166)

- This rate has been falling further behind in recent years. There are no clinical reasons why the need for ICDs should be less in the UK

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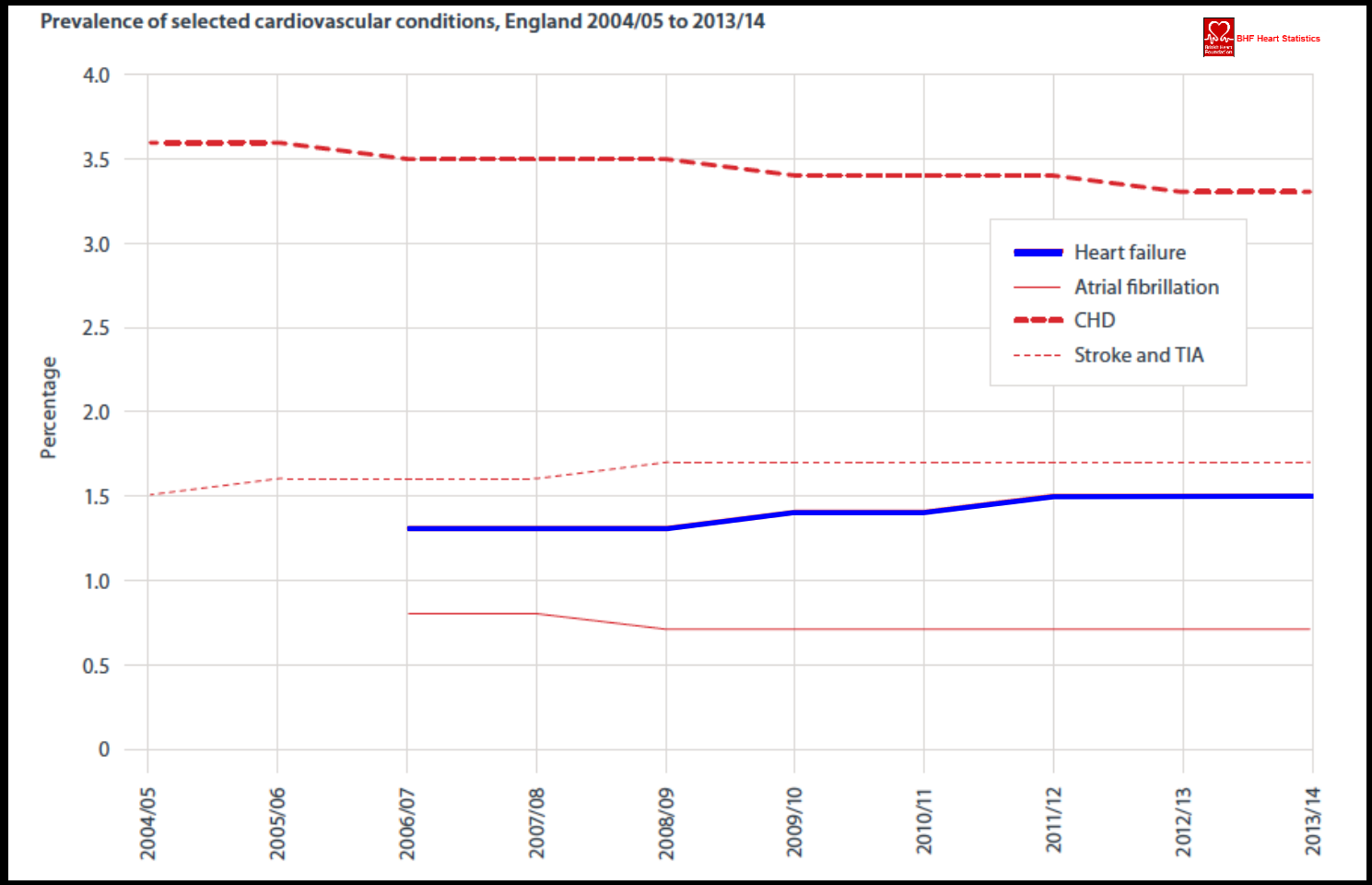
PREVALANCE OF HEART FAILURE



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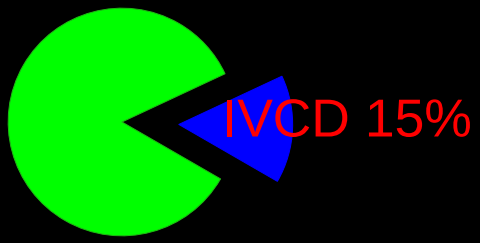
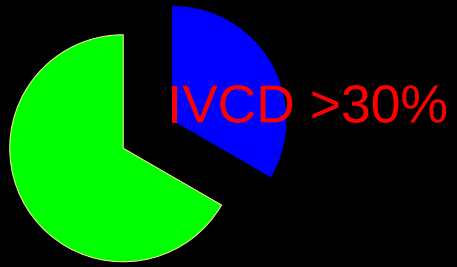
INCREASING DEMAND

- Around 900,000 people in the UK have heart failure (NICE, 2010)
  - 1.4% of population
  - 2015 approximately 1.5 million (1.5%)
- Approximately 73,000 new cases per year
- A significant proportion of heart failure patients may have clinically detrimental ventricular dyssynchrony

General HF Population



Moderate to Severe HF Population



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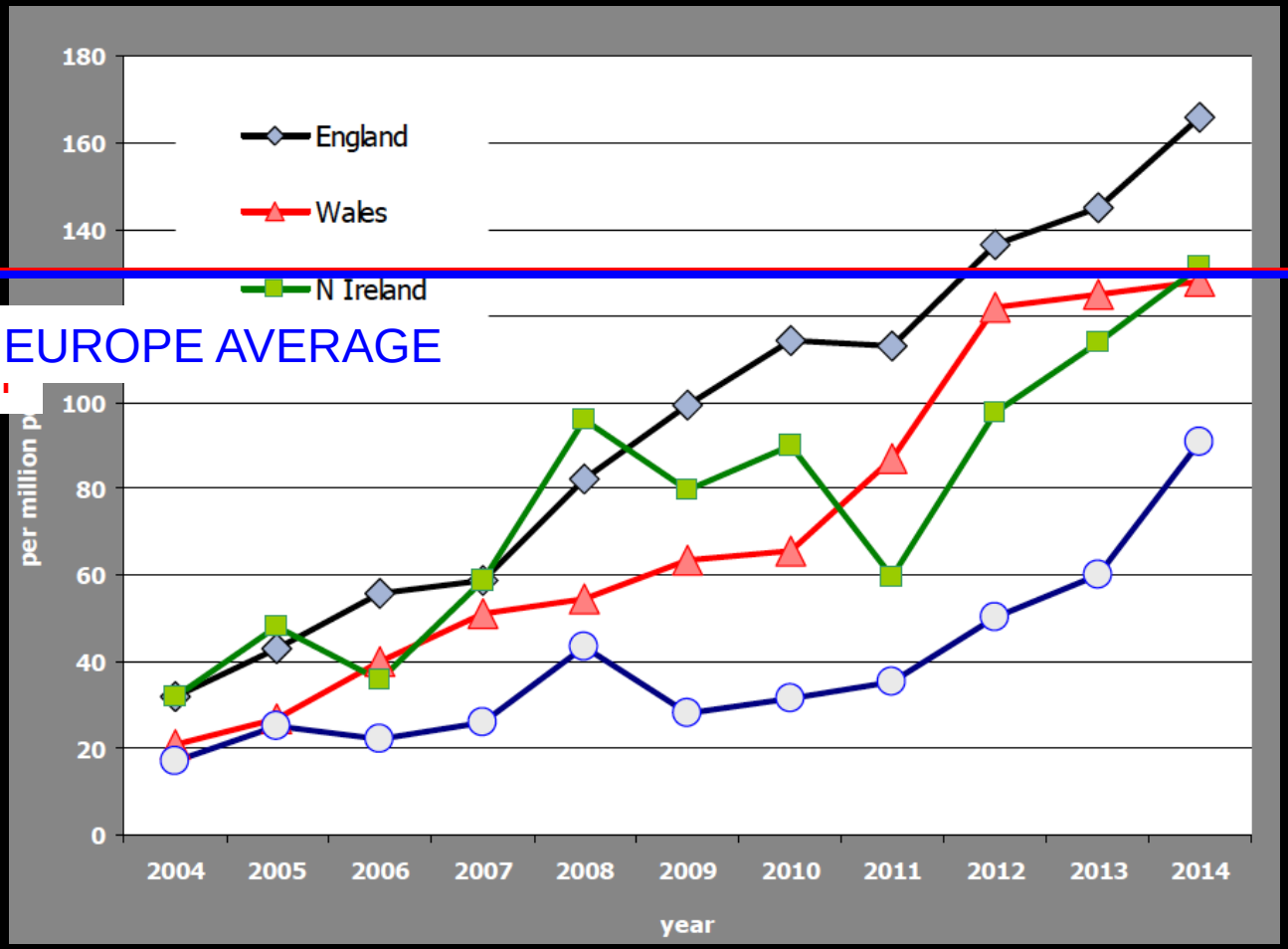
TOTAL CRT IMPLANT RATES 2004-14



WESTERN EUROPE AVERAGE

UK TARGET

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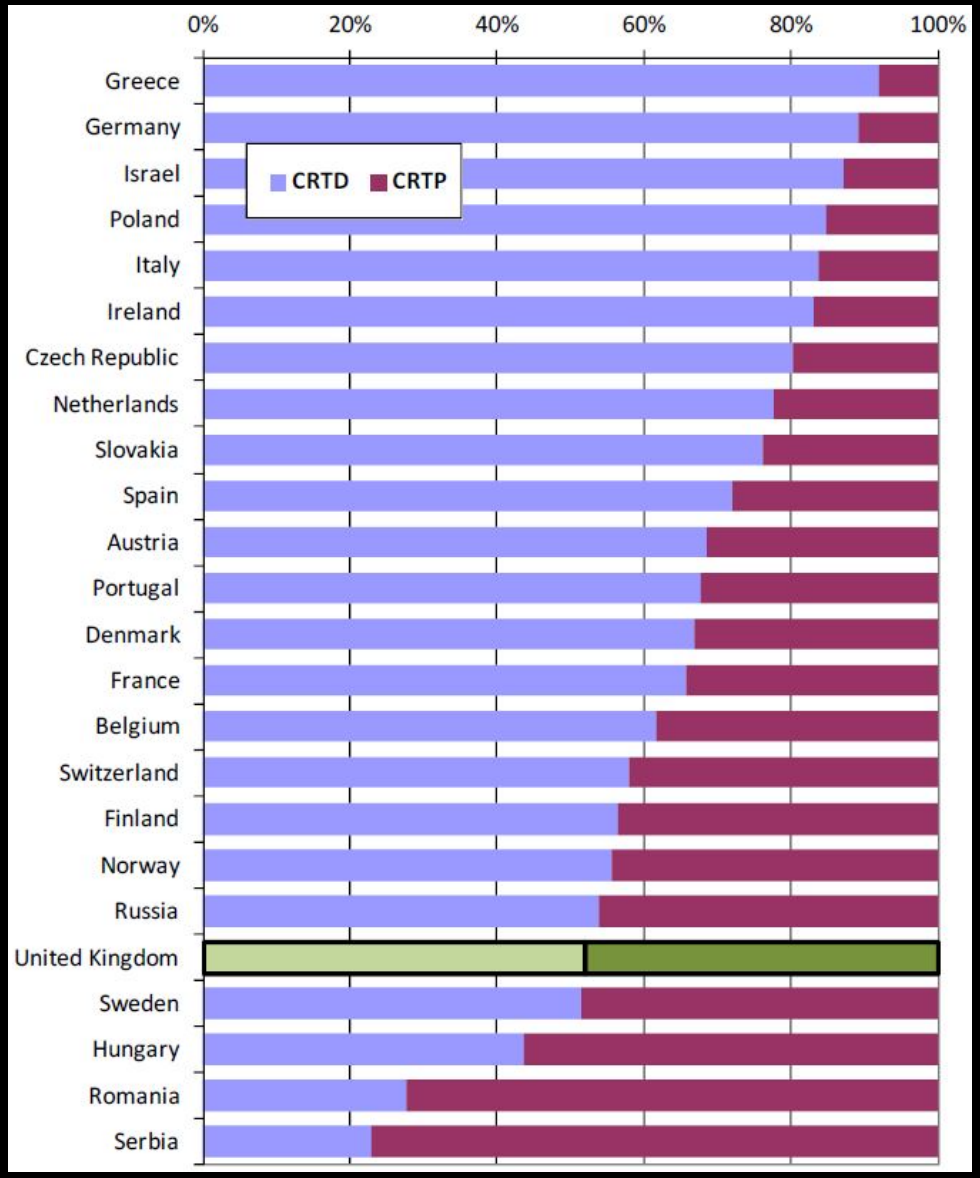
RATIO OF CRT-D TO CRT-P IMPLANTS (2012)



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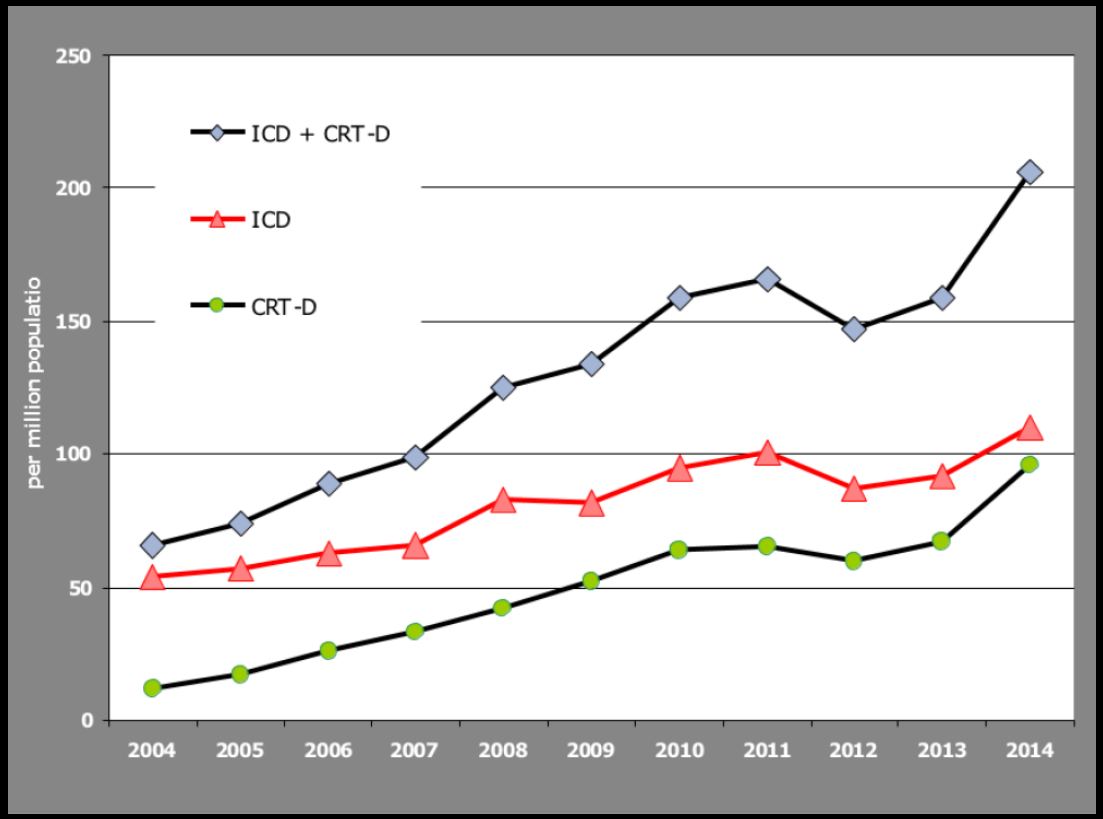
TOTAL HIGH ENERGY IMPLANT RATES 2004-14 (ENGLAND)

WESTERN EUROPE AVERAGE



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CONCLUSIONS OF 2014/15 NATIONAL CRM AUDIT

- The total rate of CRT therapy implantation in the UK is slightly above the European average
- This is mainly due to a higher than average implant rate of CRT-P devices
- The rate of implantation of all high energy devices (ICD + CRT-D) is around 70% of the European average

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“NEW” TECHNOLOGY?

LEADLESS DEVICES

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J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

Special Article

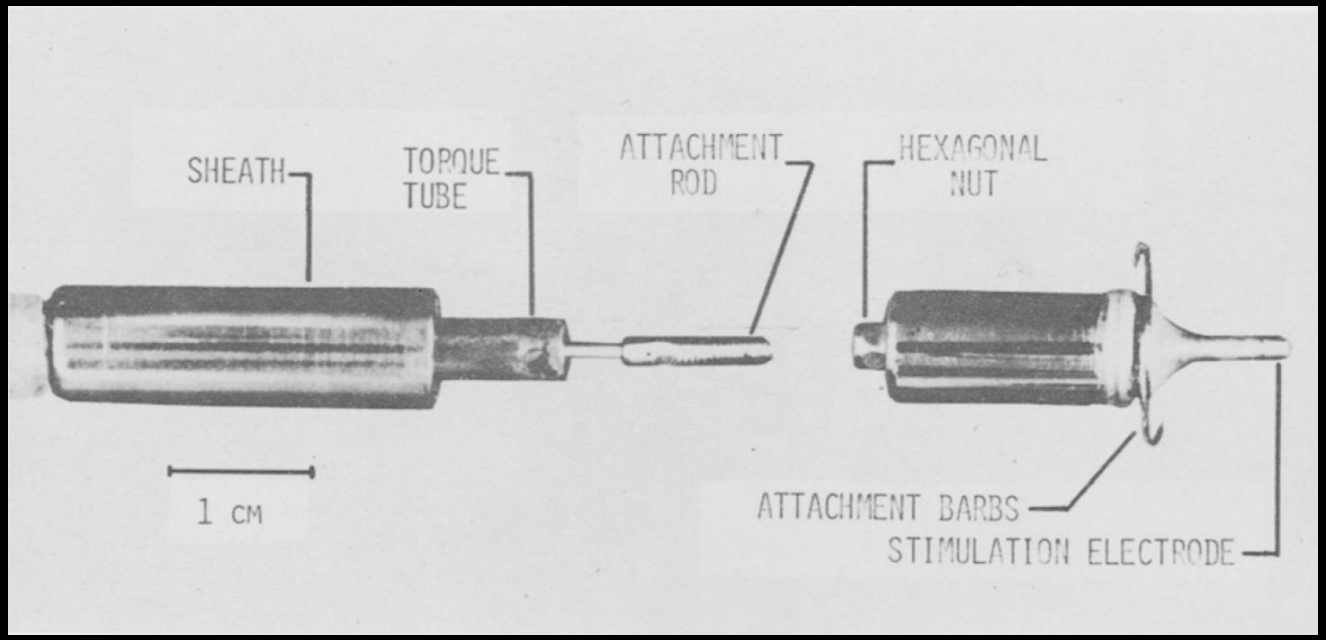
Totally Self-Contained Intracardiac Pacemaker*

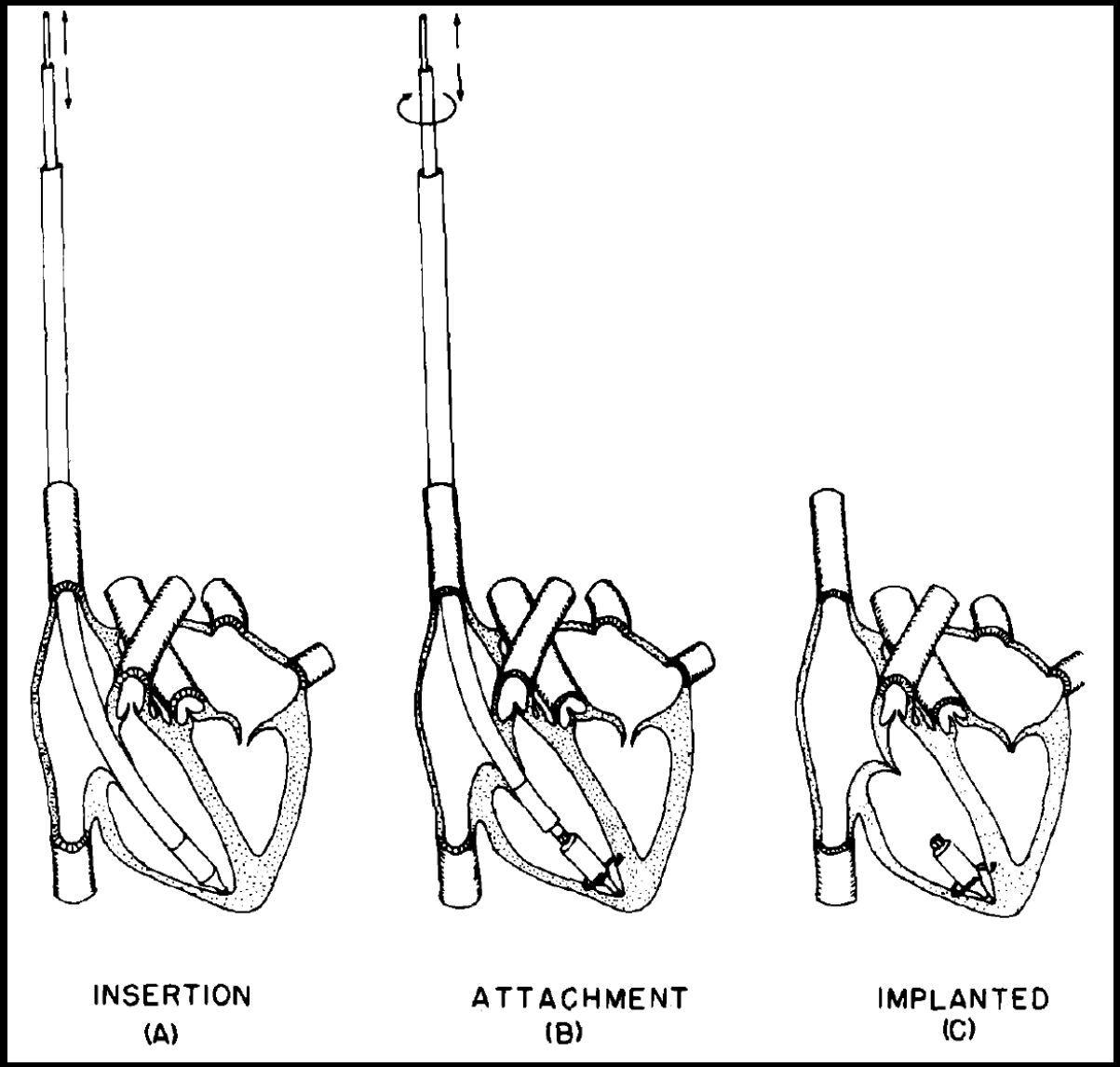
J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion. Since the IC pacemaker eliminates all leads, problems associated with the leads such as lead breakage or dislocation are also eliminated. Furthermore, since it is feasible

circuits have been improved substantially. In addition, the development of the endocardial catheter electrode has broadened the choice of operative procedures to include a larger portion of the patient population. Two major problems that still exist with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short life of the batteries that are presently used. In addition, there is a certain physical and psychological discomfort involved with having the relatively large pacemaker implanted under the skin[1].


SHEATH
TORQUE TUBE
ATTACHMENT ROD
HEXAGONAL NUT
1 CM
ATTACHMENT BARBS
STIMULATION ELECTRODE


INSERTION
(A)
ATTACHMENT
(B)
IMPLANTED
(C)

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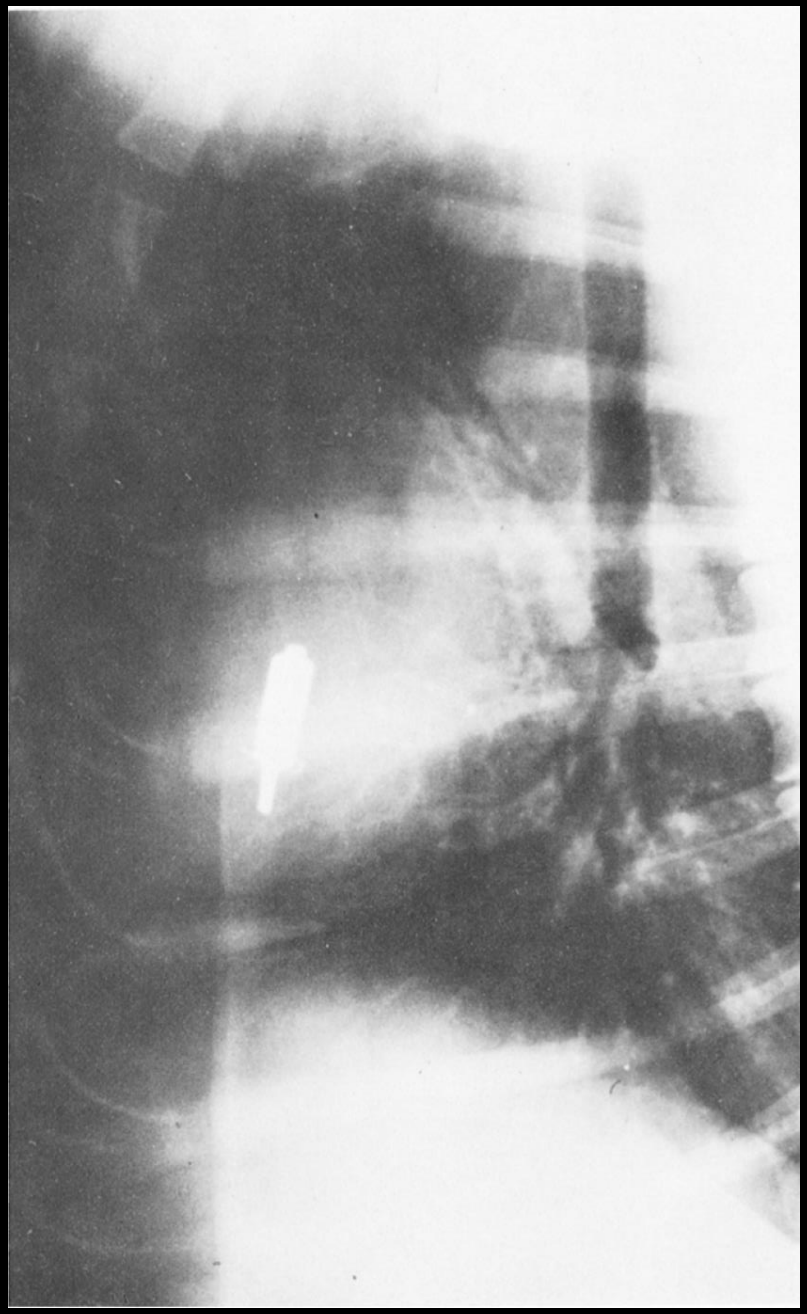

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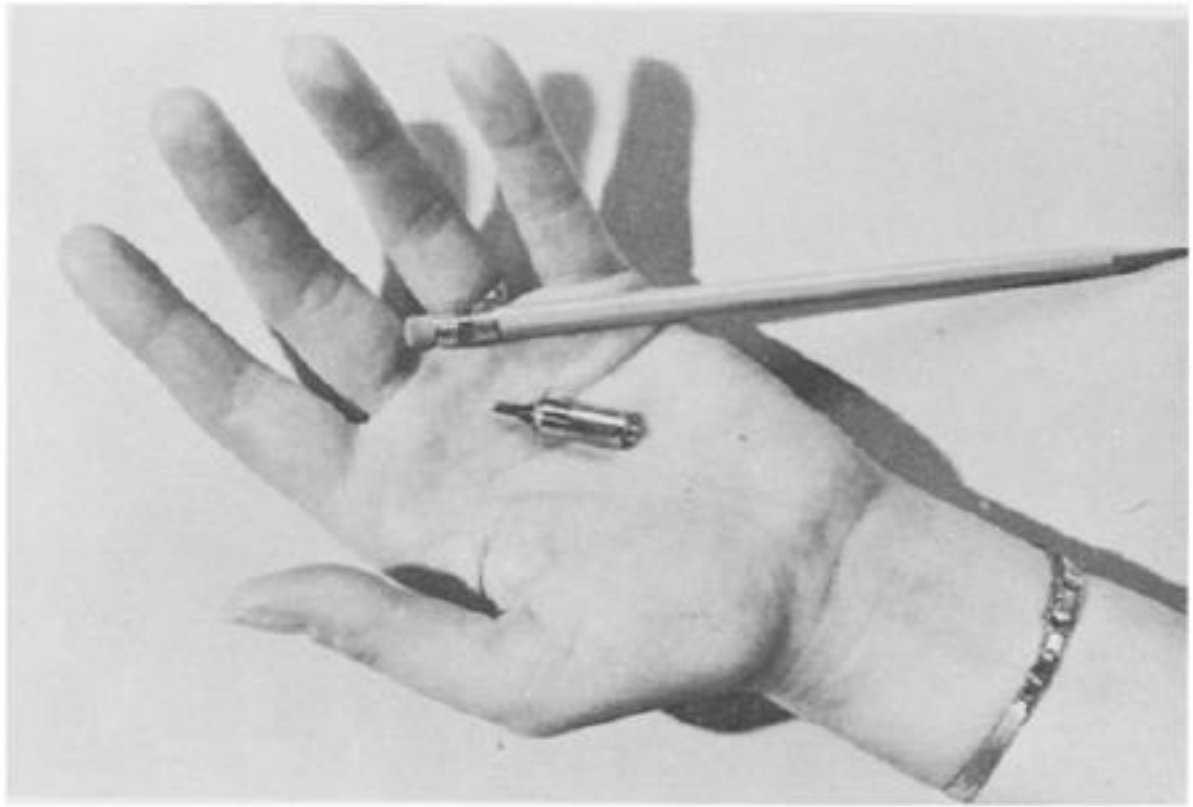

Fig. 8. Nuclear-powered intracardiac pacemaker.

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BACKGROUND

- First human implant in Czech Republic in 2013

Session: Featured Poster Session and Reception

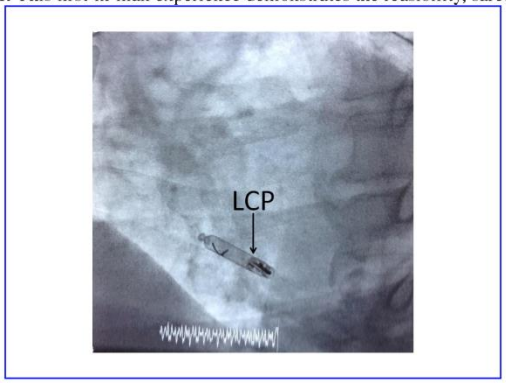
Wednesday, May 08, 2013, 6:00 PM - 7:30 PM

Presentation: PO01-49 - Percutaneous *In Vivo* Placement of a Novel Leadless Cardiac Pacer: A First-In-Man Report

Location: Exhibit Hall

Author(s): Vivek Y. Reddy, MD, Alex Khairkhahan, MS, David Ligon, MS, Marc A. Miller, MD and Petr Neuzil, MD. Mount Sinai School of Medicine, New York, NY, Nanostim, Sunnyvale, CA, Cardiovascular Center, Na Homolce Hospital, Prague, Czech Republic

Abstract: **Background:** A novel leadless cardiac pacemaker (LCP) has been developed to deliver pacing current to the ventricle. This percutaneously-delivered device is designed to be implanted at the RV apex and functions in a VVIR capacity with an estimated battery life ~8 years. We report on the acute feasibility and safety of *in vivo* implantation of the LCP in humans.
Methods: Percutaneous LCP implantation was performed with femoral venous access using an 18Fr sheath. The LCP (Nanostim, Inc) was implanted in the RV apex using a deflectable sheath under fluoroscopic guidance. Non-invasive assessment of pacing/sensing thresholds was determined at baseline and at 2 days post-implant.
Results: Three patients (ages 68-75 years, 2M/1F) with bradycardia indications for a VVI pacemaker and preserved LV ejection fraction underwent successful implantation of the LCP at the RV apex; in two patients, pacing/sensing was good at the first position; in the third, the LCP position was sub-optimal and was thus re-positioned 3 times. The mean procedure time was 52 min (range 20 - 75). At the time of implantation, the pacing threshold (at 0.4msec pulse duration) was 0.8 ± 0.6 V (range 0.5 - 1.5), the R-wave amplitude was 9.5 ± 1.8 mV (range 7.5 - 11), and the impedance 837 ± 226 Ohms (range 600 - 1050). These parameters improved just prior to hospital discharge on day 2: the pacing threshold (at 0.4msec) was 0.4 ± 0.3 V (range 0.25 - 0.75), the R-wave amplitude was 10.8 ± 2.0 mV (range 8.5 - 12), and the impedance 720 ± 44 Ohms (range 670 - 750).
Conclusion: This first-in-man experience demonstrates the feasibility, safety and early efficacy of a novel leadless cardiac pacemaker.



Disclosures: **V.Y. Reddy:** C - Equity Interests/Stock Options; **1**; Nanostim. **A. Khairkhahan:** K - Salary; **5**; Nanostim. **D. Ligon:** K - Salary; **5**; Nanostim. **M.A. Miller:** None. **P. Neuzil:** C - Equity Interests/Stock Options; **1**; Nanostim.

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Nanostim™

St. Jude Medical
More control. Less risk.

Micra™

Medtronic

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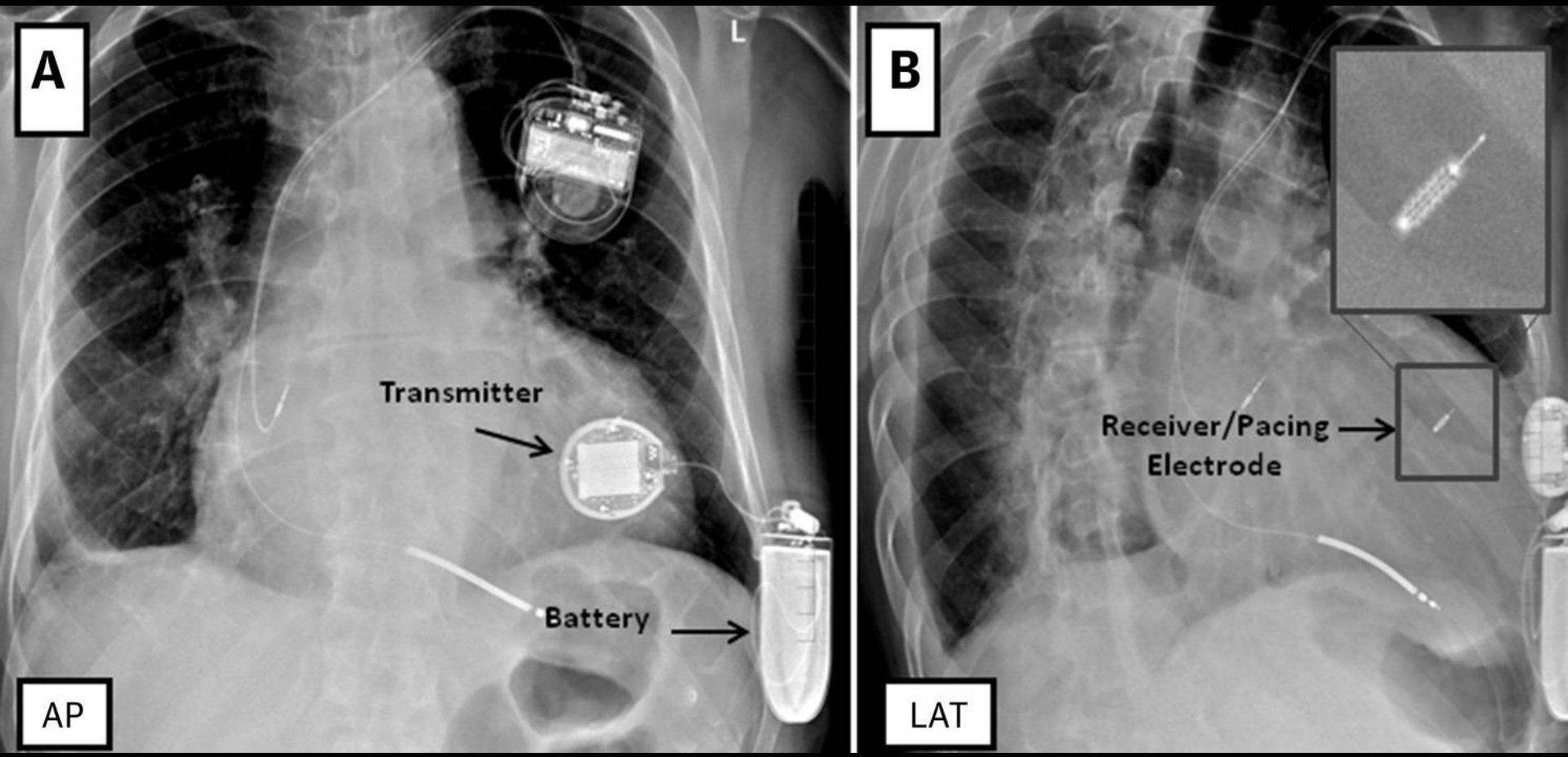
WiCS-LV STIMULATION



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CURRENT IMPLANTS

- Medtronic: 2,350 Micra implants
- St Jude Medical: 1,400 Nanostim implants
- EBR: 79 WiCS CRT implants

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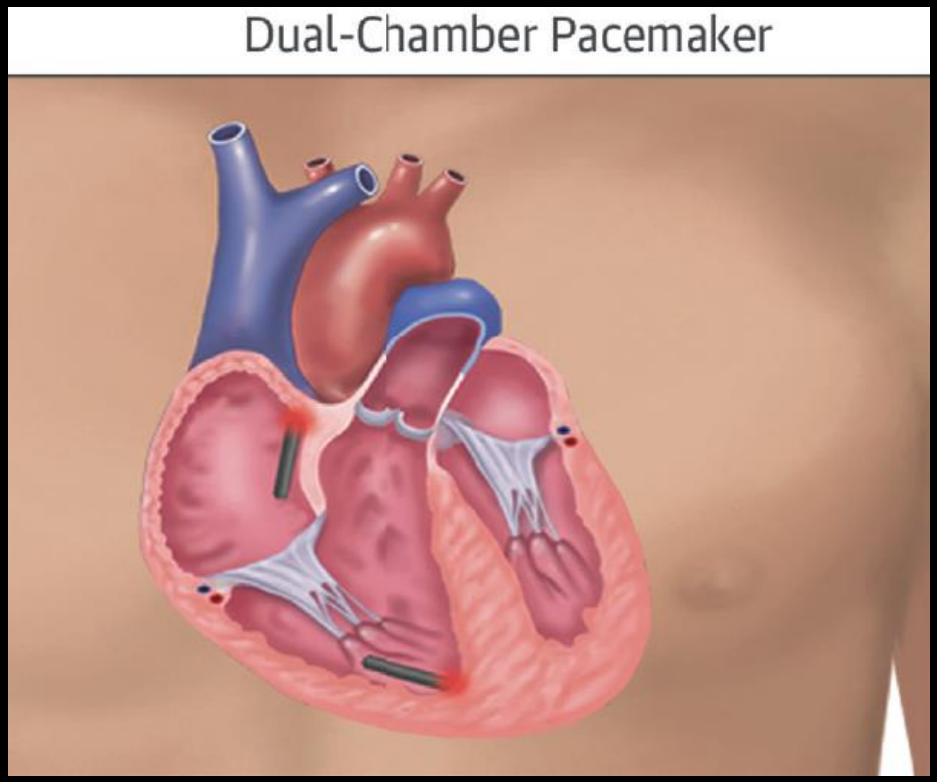
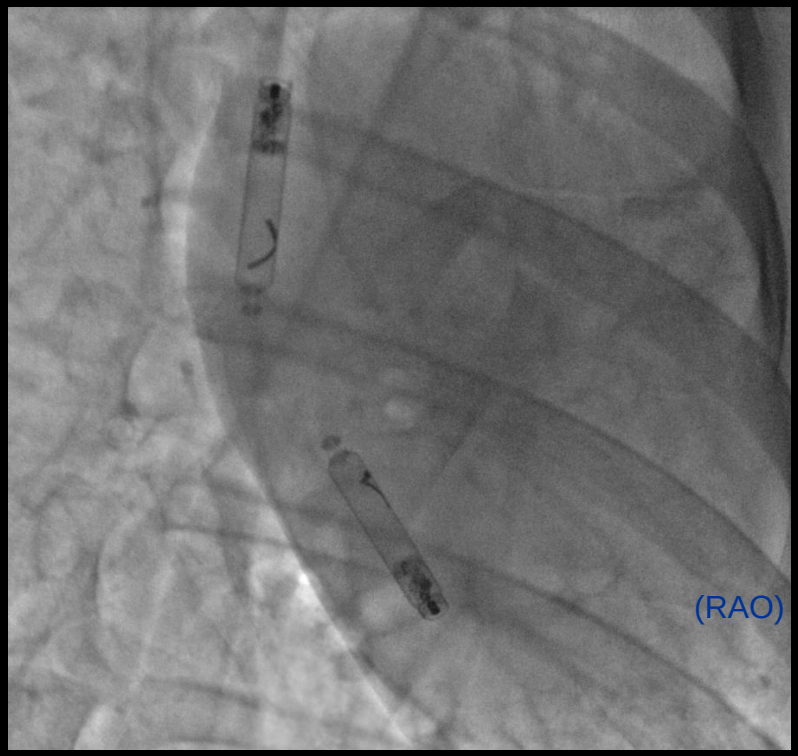
THE FUTURE?





Miller MA, et al. Leadless cardiac pacemakers: back to the future. *J Am Coll Cardiol* 2015; **66:** 1179-89

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THE FUTURE?

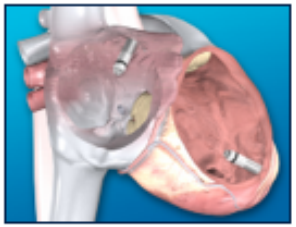
NEXT GEN MICRA: EXTENDING THERAPY TO MORE PATIENTS

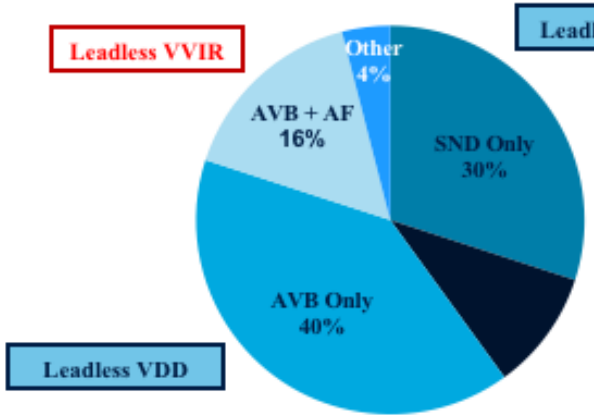
Micra VR

- World's smallest pacemaker
- Repositionable, tine-based fixation
- Simpler, faster, safer and cost-effective
- Approved for 1.5 & 3 T full-body MRI scans
- First transcatheter pacemaker approved in the U.S.
- Addresses 15-20% of Brady patients

Next Gen Micra

- Leverages Micra platform technologies with a modular approach where patients receive appropriate therapy with potential to upgrade as needed
- Novel proprietary technologies for cross-chamber sensing
- Potential for even greater complication reductions relative to transveneous DR
- Expands indications to reach ~90% of Brady patients





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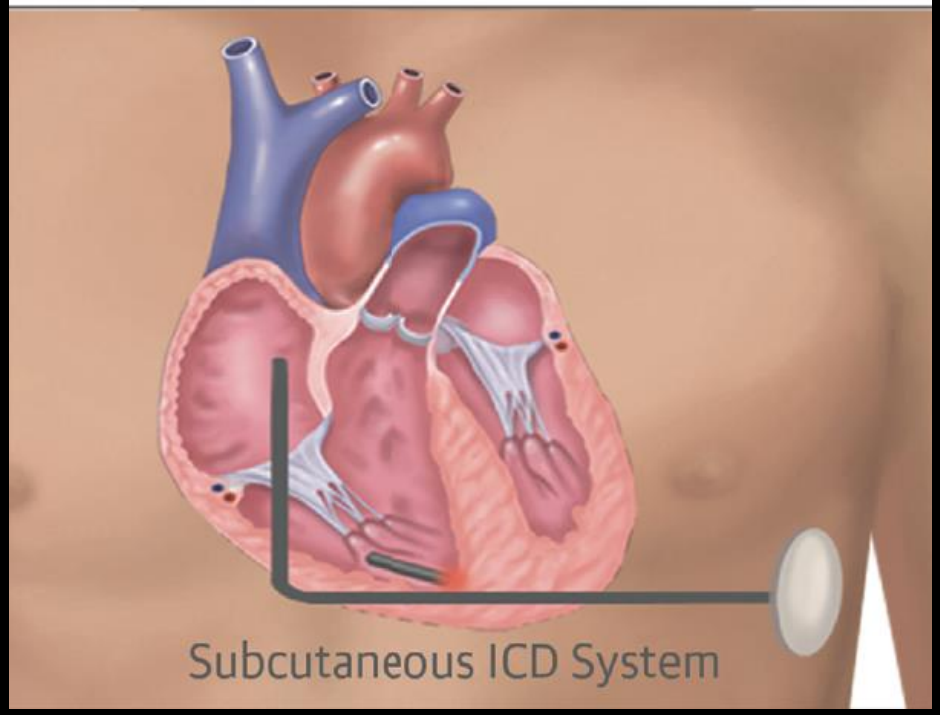
THE FUTURE?

EMBLEM™ S-ICD + Leadless Cardiac Pacemaker

Boston Scientific

Design Parameters	Design Goals
Patient Experience	Coordinate S-ICD with leadless pacemaker.
Quality Outcomes	Convert arrhythmias with ATP instead of a shock.
Operational Efficiency	Allow leadless pacemaker to be added any time after initial S-ICD implant with femoral access, instead of adding a transvenous system.
Financial Health	Give even more people access to the S-ICD by offering a combined S-ICD plus Leadless pacemaker system.

Subcutaneous ICD and Leadless Pacemaker



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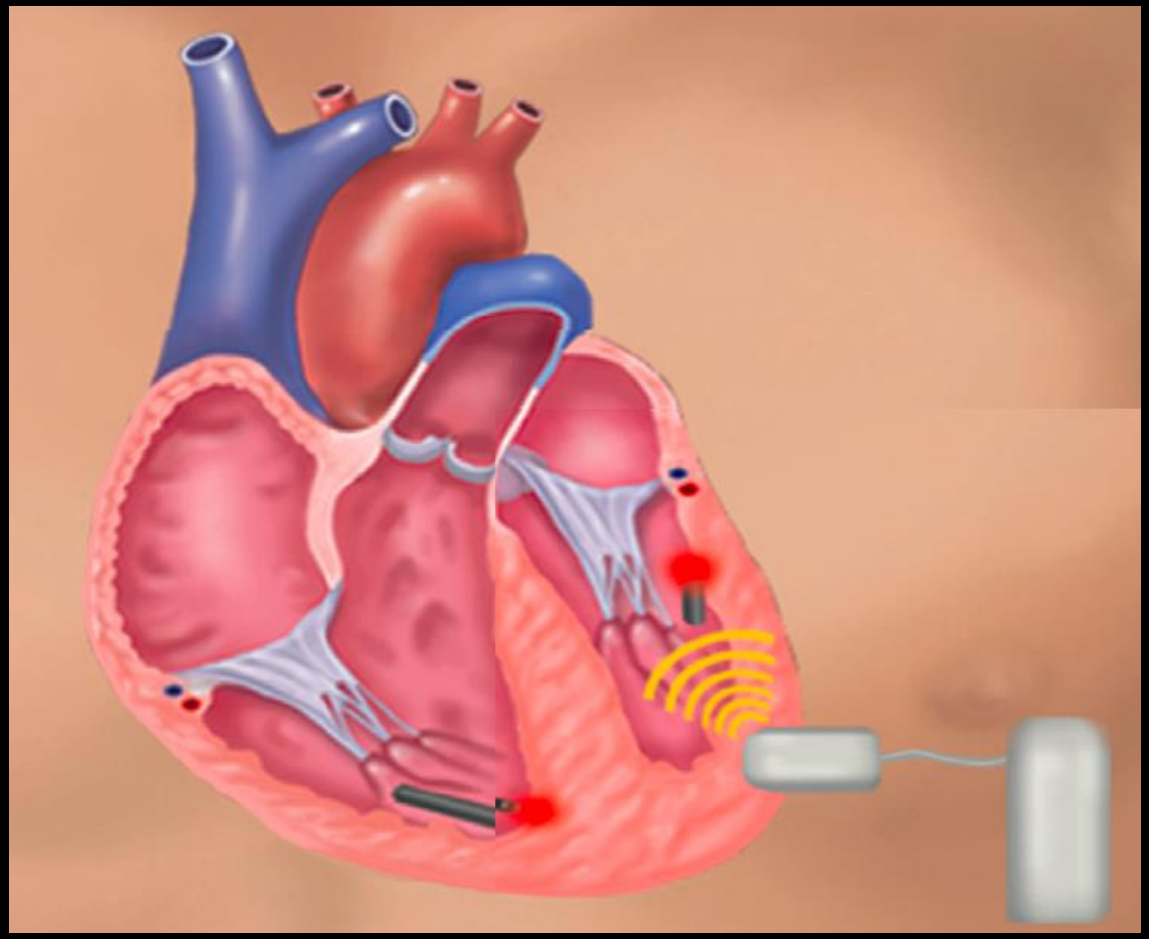
THE FUTURE?



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FINANCIAL CONSTRAINTS

- Tariff
- Excluded devices / pass through costs

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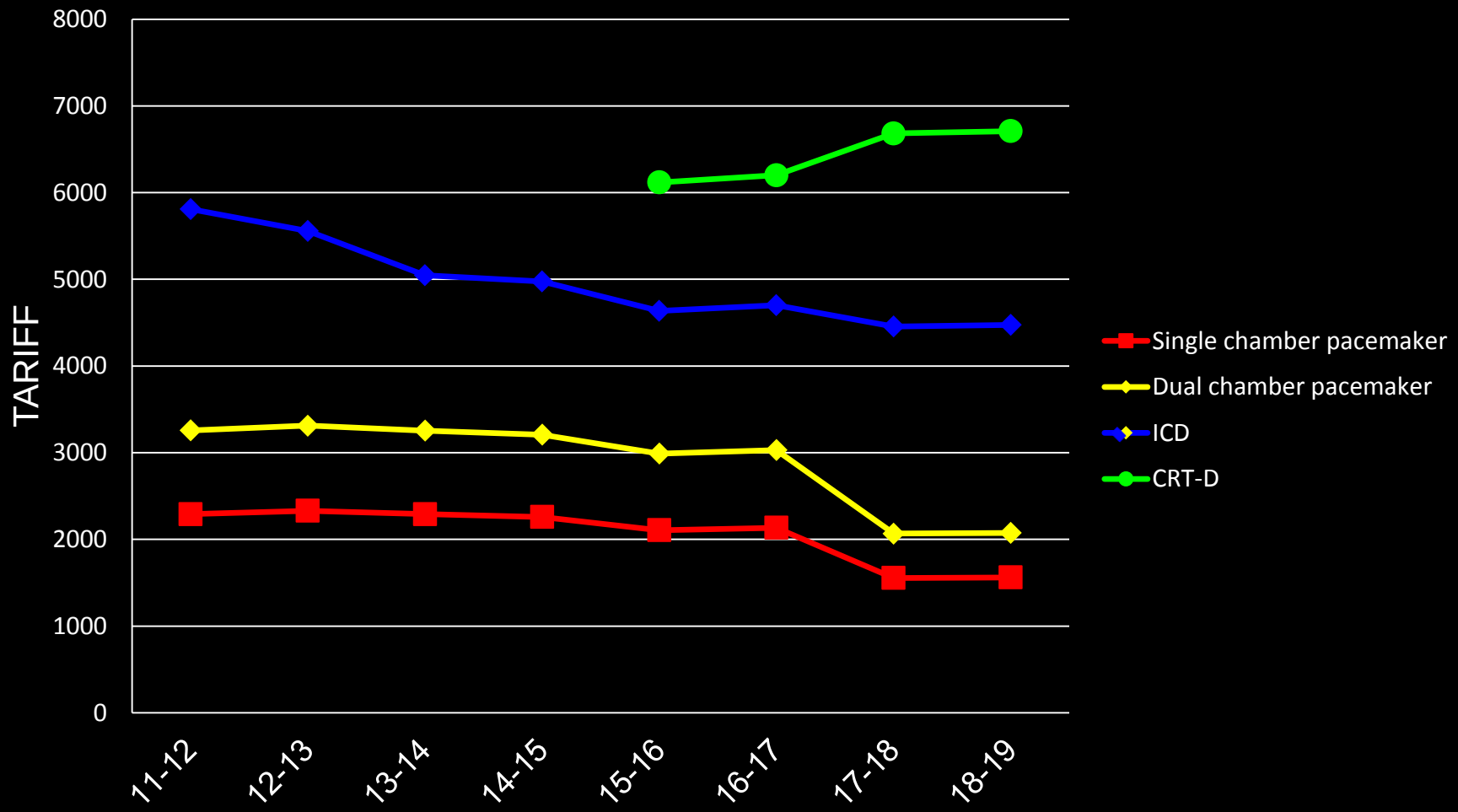
ELECTIVE TARIFF FOR CIEDs



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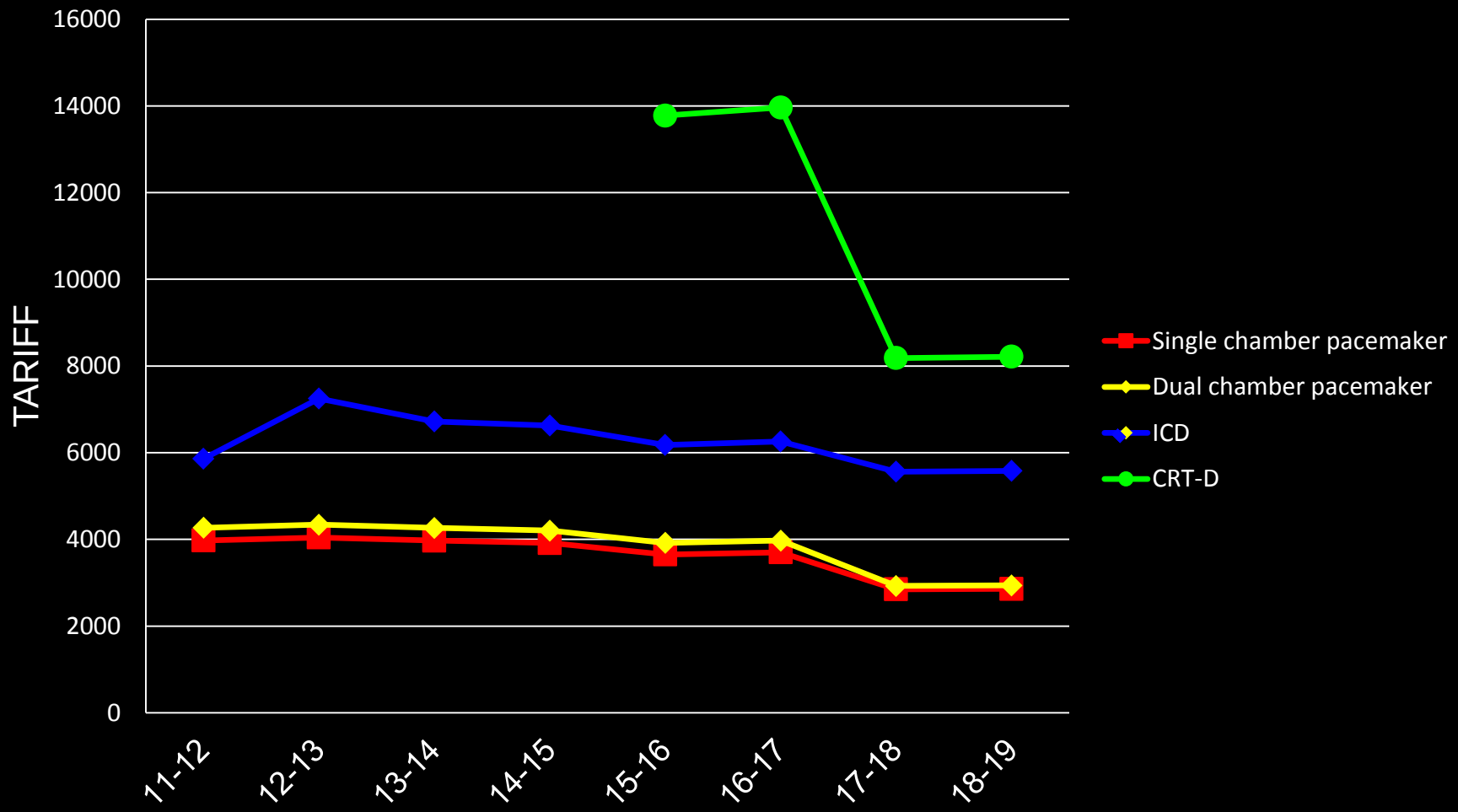
NON-ELECTIVE TARIFF FOR CIEDs



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COMPLEXITY & COMORBIDITY SCORE

HRG code	HRG name	Non-elective spell tariff (£)
EY01A	Implantation of Cardioverter Defibrillator with Cardiac Resynchronisation Therapy, with CC Score 9+	9,819
EY01B	Implantation of Cardioverter Defibrillator with Cardiac Resynchronisation Therapy, with CC Score 0-8	8,183
EY06E	Implantation of Dual Chamber Pacemaker with CC Score 0-2	2,067

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COMPLEXITY & COMORBIDITY SCORE

1601	EA_CC	ICD	Z941	Heart transplant status	1
1602	EA_CC	ICD	Z942	Lung transplant status	1
1603	EA_CC	ICD	Z943	Heart and lungs transplant status	1
1604	EA_CC	ICD	Z944	Liver transplant status	1
1605	EA_CC	ICD	Z945	Skin transplant status	1
1606	EA_CC	ICD	Z946	Bone transplant status	1
1607	EA_CC	ICD	Z947	Corneal transplant status	1
1608	EA_CC	ICD	Z948	Other transplanted organ and tissue status	1
1609	EA_CC	ICD	Z949	Transplanted organ and tissue status, unspecified	1
1610	EA_CC	ICD	Z991	Dependence on respirator	1
1611	EA_CC	ICD	Z992	Dependence on renal dialysis	1
1612	EA_CC	ICD	Z993	Dependence on wheelchair	1
1613	EA_CC	ICD	Z998	Dependence on other enabling machines and devices	1

Cardiac HRGs | EA CC codes & scores | EB CC codes and scores | +

Ready 147%

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EA_CC	ICD	E876	Hypokalaemia	2
EA_CC	ICD	F819	Developmental disorder of scholastic skills, unspecified	1
EA_CC	ICD	I252	Old myocardial infarction	1
EA_CC	ICD	I361	Nonrheumatic tricuspid (valve) insufficiency	2
EA_CC	ICD	I420	Dilated cardiomyopathy	1
EA_CC	ICD	I421	Obstructive hypertrophic cardiomyopathy	1
EA_CC	ICD	I440	Atrioventricular block, first degree	1
EA_CC	ICD	I441	Atrioventricular block, second degree	1
EA_CC	ICD	I442	Atrioventricular block, complete	1
EA_CC	ICD	I443	Other and unspecified atrioventricular block	1
EA_CC	ICD	I444	Left anterior fascicular block	1
EA_CC	ICD	I445	Left posterior fascicular block	1
EA_CC	ICD	I446	Other and unspecified fascicular block	1
EA_CC	ICD	I447	Left bundle-branch block, unspecified	1
EA_CC	ICD	I450	Right fascicular block	1
EA_CC	ICD	I451	Other and unspecified right bundle-branch block	1
EA_CC	ICD	I452	Bifascicular block	1
EA_CC	ICD	I453	Trifascicular block	1
EA_CC	ICD	I454	Nonspecific intraventricular block	1
EA_CC	ICD	I460	Cardiac arrest with successful resuscitation	2
EA_CC	ICD	I461	Sudden cardiac death, so described	1
EA_CC	ICD	I469	Cardiac arrest, unspecified	1
EA_CC	ICD	I471	Supraventricular tachycardia	1
EA_CC	ICD	I472	Ventricular tachycardia	2
EA_CC	ICD	I48X	Atrial fibrillation and flutter	1
EA_CC	ICD	I490	Ventricular fibrillation and flutter	1
EA_CC	ICD	I495	Sick sinus syndrome	1
EA_CC	ICD	I498	Other specified cardiac arrhythmias	1
EA_CC	ICD	I500	Congestive heart failure	2
EA_CC	ICD	I501	Left ventricular failure	2
EA_CC	ICD	I713	Abdominal aortic aneurysm, ruptured	1
EA_CC	ICD	I952	Hypotension due to drugs	2
EA_CC	ICD	K020	Caries limited to enamel	2
EA_CC	ICD	K021	Caries of dentine	2
EA_CC	ICD	K022	Caries of cementum	2
EA_CC	ICD	P059	Slow fetal growth, unspecified	1
EA_CC	ICD	R000	Tachycardia, unspecified	1
EA_CC	ICD	R001	Bradycardia, unspecified	1
EA_CC	ICD	R031	Nonspecific low blood-pressure reading	1
EA_CC	ICD	R32X	Unspecified urinary incontinence	2
EA_CC	ICD	R54X	Senility	2
EA_CC	ICD	T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified	1
EA_CC	ICD	Z500	Cardiac rehabilitation	1
EA_CC	ICD	Z515	Palliative care	2
EA_CC	ICD	Z602	Living alone	1

EA_CC	ICD	I48X	Atrial fibrillation and flutter
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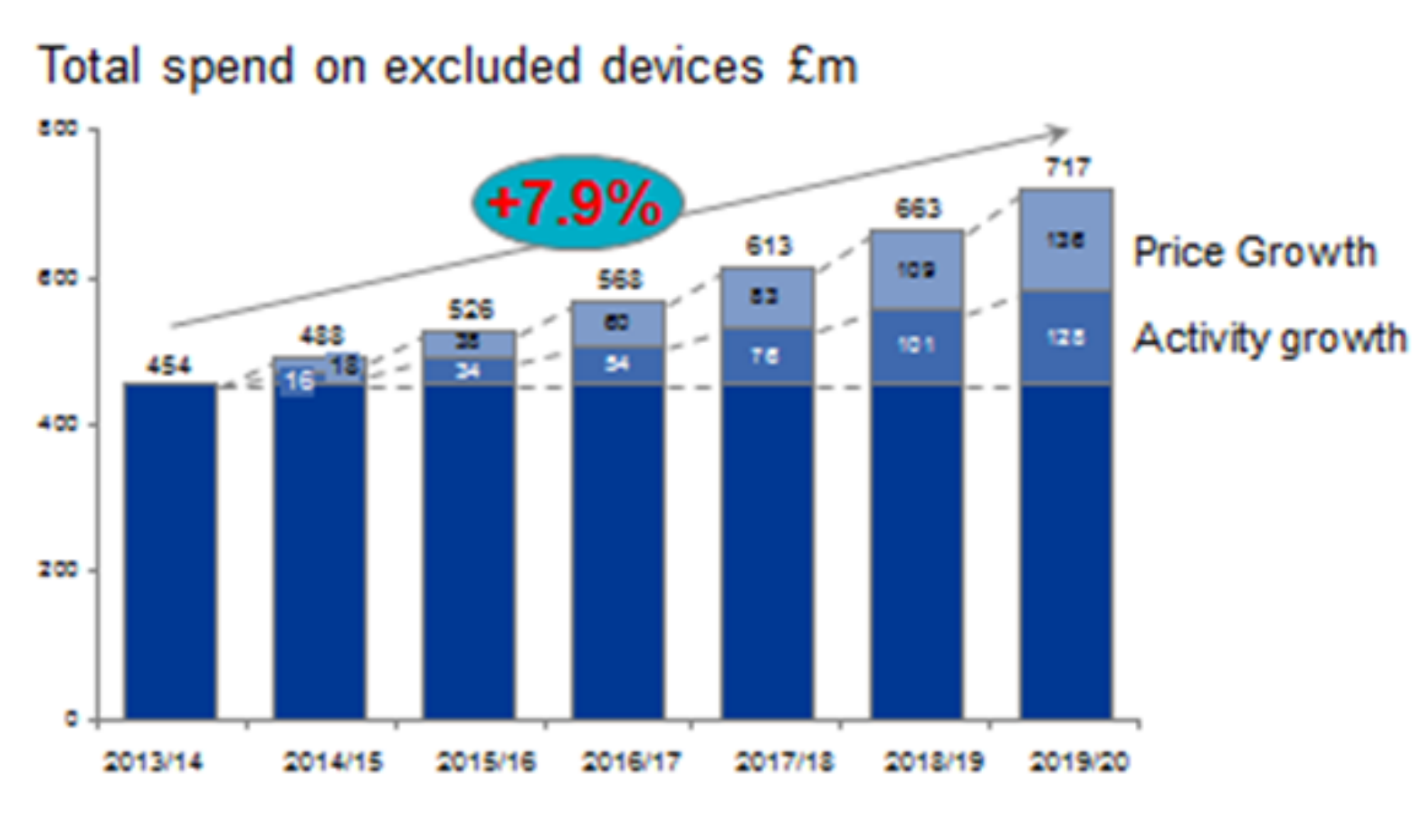
TARIFF EXCLUDED DEVICES HAVE GROWTH RATES THAT FAR EXCEED RESOURCE GROWTH



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EXCLUDED DEVICE COSTS

- Cardiology spend (ICDs & CRT-Ds) amounts to 26% i.e. £146m for 2016/17
- NHS England's plan is to offset the cost of one year's growth through aggregating national demand i.e. 8% of c.£500m = £40m
- This will not be achieved in 1 year, therefore the target is to save £60m in 2 years

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"ZERO COST" OPTION

- What is / is not included
- Restrict choice
- "The consistent adoption and spread of effective technologies (and decommissioning of ineffective technologies)"
- "Incentives to reduce unwarranted clinical variation in device usage"

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PHYSIOLOGIST WORKFORCE ISSUES

- Physiologists essential for device implant and follow up
  - Existing shortfall in workforce
    - Projected shortfall of 663 WTE physiologists by 2018
  - Decline in numbers entering the workforce
    - Projected retirement of 20% of the workforce by 2020
  - Increasing demand on cardiac physiology services
    - Seven day working
  - Variation in supply
    - Wide range of variation in numbers of physiologists

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PHYSIOLOGIST WORKFORCE ISSUES

- Potential solutions:
  - Increase the numbers entering STP programme
  - Encourage career progression and increase uptake of Accredited Specialist Scientific Practice
  - Employ individuals for targeted roles
  - Seek skilled operators from abroad

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CONCLUSIONS

- Still need to push for more device implants
- Financial issues around tariff and device costs
- Lack of physiologists

HRG code	HRG name	Outpatient procedure tariff (£)
EY12A	Implantation of Electrocardiography Loop Recorder with CC Score 3+	0
EY12B	Implantation of Electrocardiography Loop Recorder with CC Score 0-2	3,480

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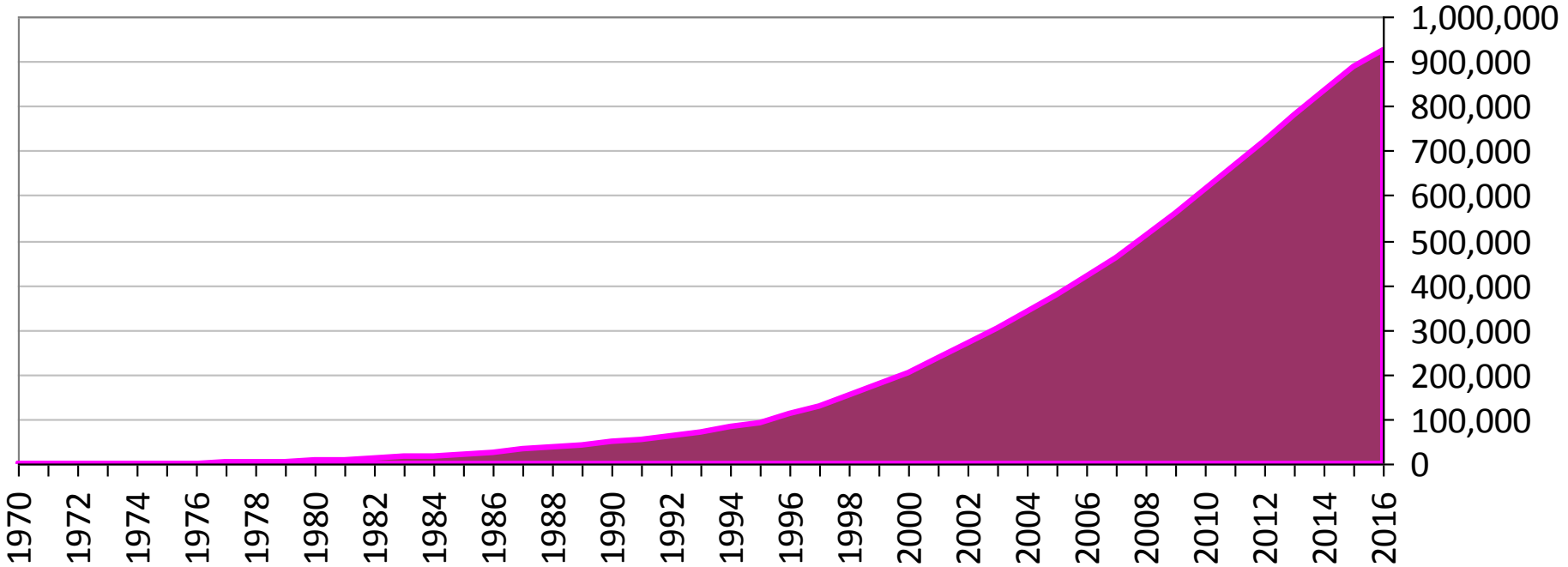
Total Device Implants in the UK



July 2016: **924,284** implants

Predicted date for millionth implant: **November 2017**

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ndation Trust