Leadless pacemaker,

Didier KLUG

CHRU Lille

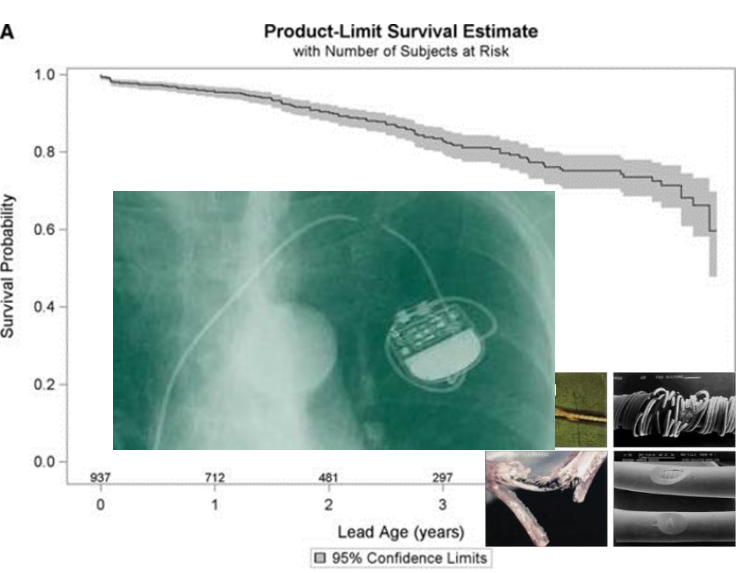
- Consulting for:
  - Medtronic
  - St jude
  - Boston
  - Livanova
  - Sanofi
  - Bayer

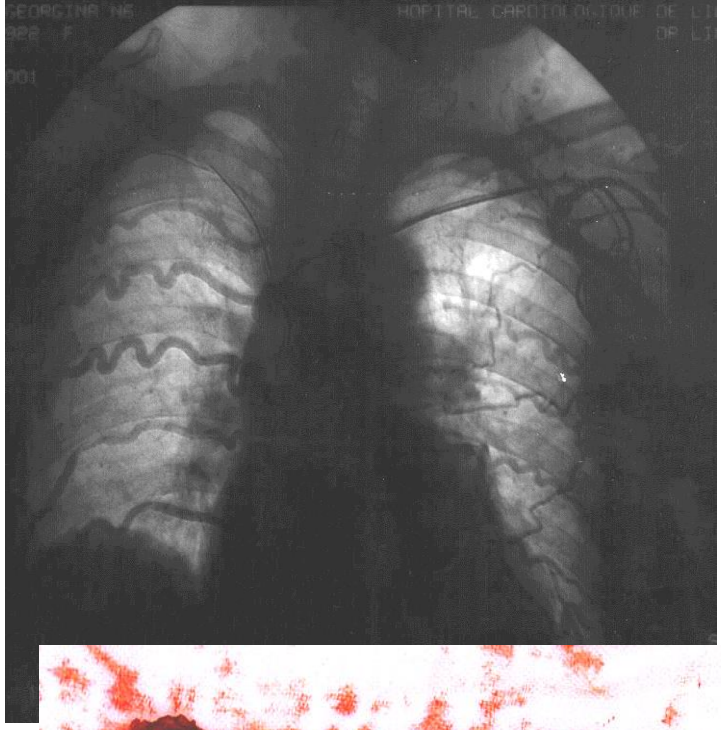
Implant Evolution

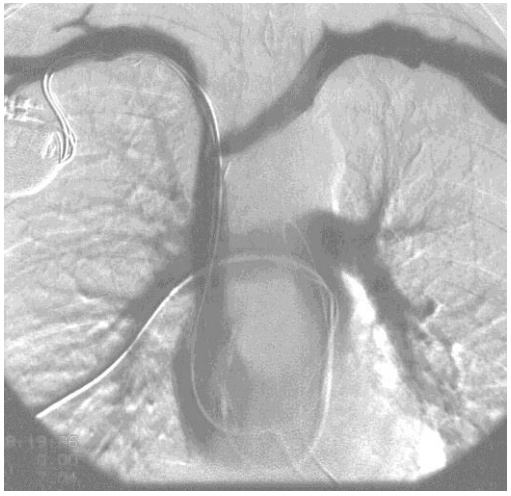
Pacemakers—Yesterday

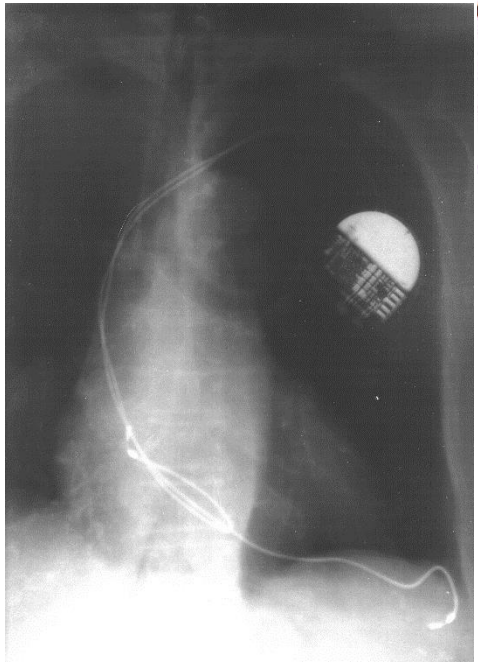
- First Implants in early 1960s
- Single Chamber, non programmable
- About 2 year longevity


WHY ??


A
Product-Limit Survival Estimate
with Number of Subjects at Risk
Survival Probability
1.0
0.8
0.6
0.4
0.2
0.0
937
712
481
297
0
1
2
3
Lead Age (years)
95% Confidence Limits








METRIC
INCHES
DEVON INDUSTRIES, INC.
1-800-DEVON P.O.

Complications of Pacemaker Leads

Danish Pacemaker Registry: Effect of Time

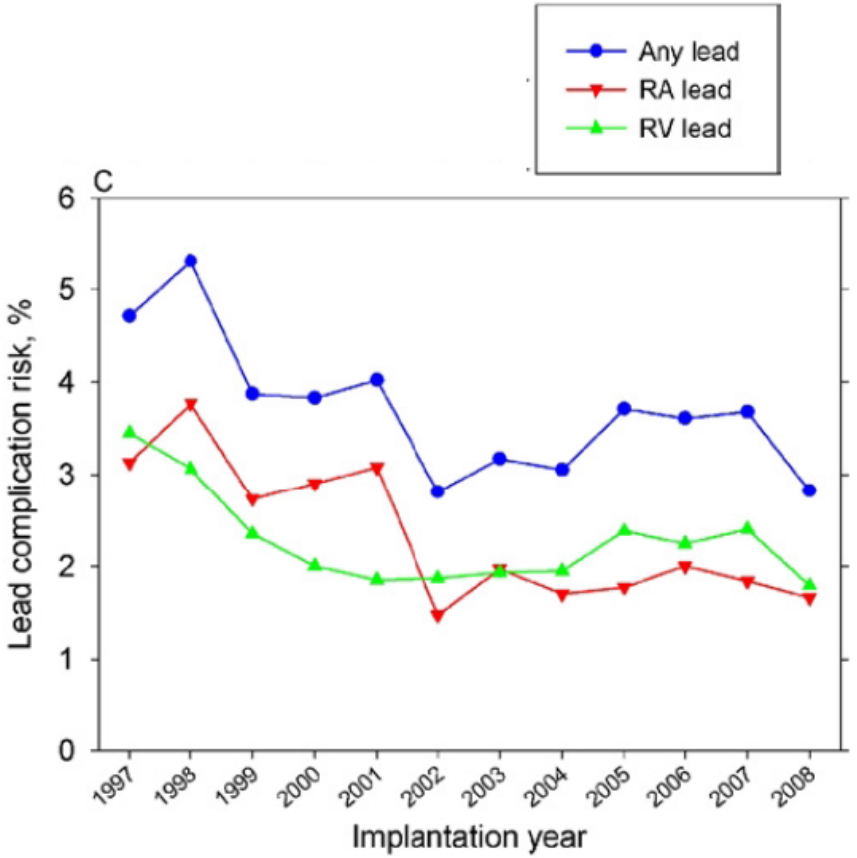


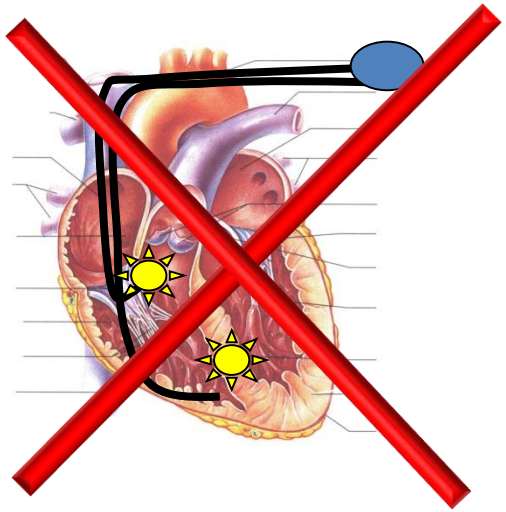
Table 2 Lead complication risks after device implantations: The Danish Pacemaker Register 1997–2008

	Total number	Lead complications	Risk (%)	95% CI
Lead type				
RA lead	21,024	472	2.3	2.0–2.5
RV lead	26,079	575	2.2	2.0–2.4
LV lead	884	38	4.3	3.1–5.9
Any lead	28,860	1,048	3.6	3.4–3.9

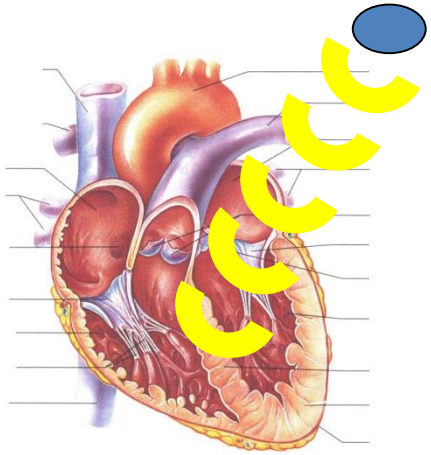
CI = confidence interval; LV = left ventricular; other abbreviations as in Table 1.

Kirkfeldt et al, *Heart Rhythm* 8:1622–1628 (2011)

HOW ??



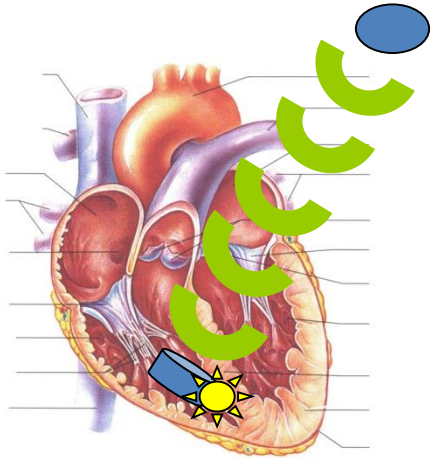
non contact cardiac pacing



« wireless cardiac stimulation »

-Ultrasons: WICS

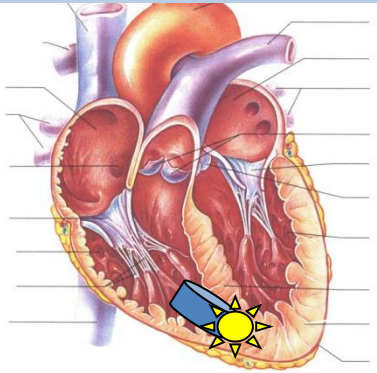
-Champ electromagnétique



stimulateur intracardiaque

-électronique: capsule intracardiaque

-biologique: cellules automatiques



Electrode reliée sans fil Champ magnétique

Leadless Pacing of the Heart Using Induction Technology: A Feasibility Study

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From the *West-German Heart Center, University Clinics Essen, Essen, Germany; and †Institute of Applied Physics, Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

Objectives: To develop a leadless pacemaker system based on induction technology and to investigate its feasibility and safety in the pig model.

Background: Despite tremendous technical advances during the last decades, cardiac pacing is still associated with a considerable rate of complications that can be primarily attributed to the leads.

Methods: The device consists of a transmitter unit implanted subcutaneously just above the heart and an endocardial receiver unit implanted in the apex of the right ventricle. The transmitter unit generates an alternating magnetic field that is converted into a voltage pulse by the receiver unit. In order to test feasibility, the receiver unit was attached to an electrophysiology catheter for signal recording and placed in the apex of the right ventricle of a pig. Subsequently, the receiver unit was implanted without external connection in the right ventricle.

Results: An alternating magnetic field of about 0.5 mT was generated by the transmitter unit in a distance of 3 cm. Voltage pulses with a duration of 0.4 ms and voltage amplitude of 0.6–1.0 V were generated. Using these pulse characteristics, a reliable stimulation of the heart could be achieved. A secure fixation of the receiver unit in the apex of the right ventricle could be obtained for the duration of this short-term study by using screw fixation.

Conclusions: This study shows that induction technology is feasible for cardiac pacing. Typical voltage pulses could be generated by which an effectively stimulation in vivo could be achieved. (PACE 2009; 32:177–183)

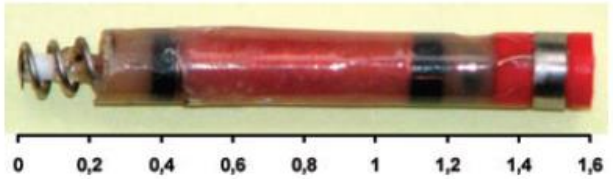


Figure 1. *The figure shows a screw-equipped receiver unit without external connection. In contrast to commercially available active-fixation leads, the screw of this sensor was electronically not active, but the sensor was also equipped with a high impedance head (cathode electrode hemispherical 1.3 mm², fractal Iridium-coated–anode iron 15.8 mm², 3 cm proximal). The high impedance heads were taken from commercially available pacemaker leads (Selox™ ST 60; Biotronik). Measuring unit: cm.*

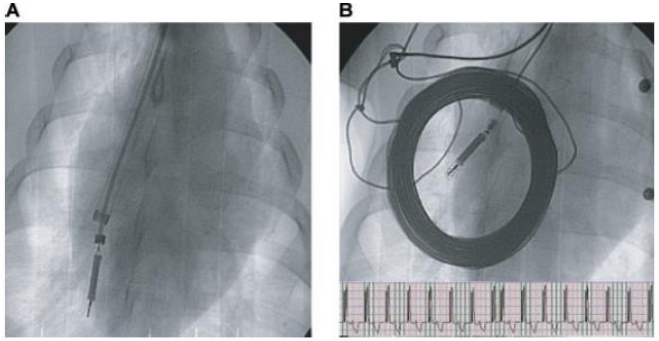
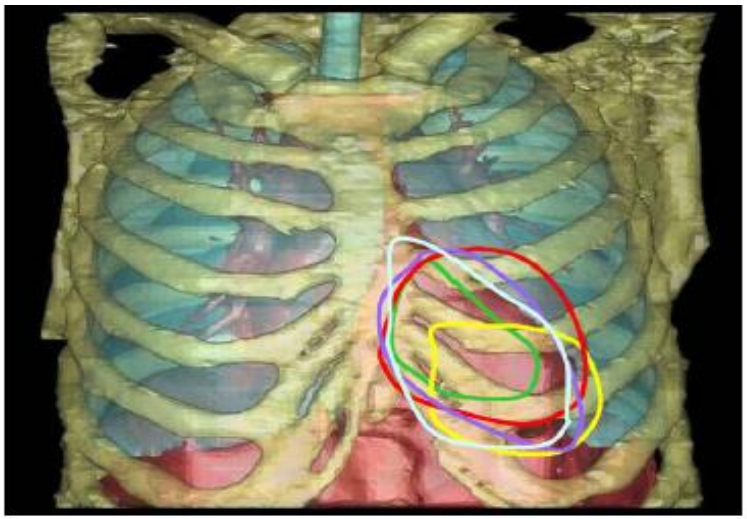
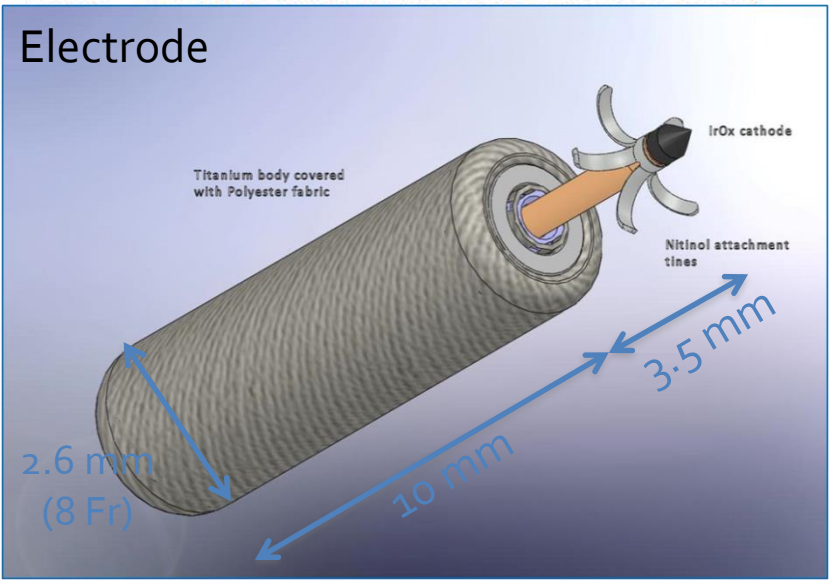


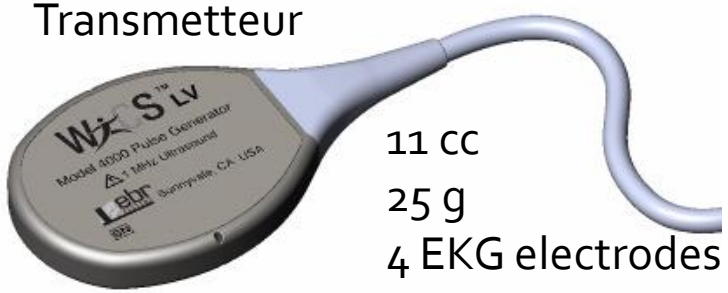
Figure 3. *(A) Receiver unit mounted on an EP catheter positioned in the right ventricle. Using this approach, the induced voltage pulse could be measured by the oscilloscope. (B) Top: Receiver unit without external connection in the right ventricle. The transmitter unit is placed on the outer thoracic wall directly beyond the receiver unit. Bottom: ECG tracing during wireless pacing.*

Electrode reliée sans fil Ultrasons



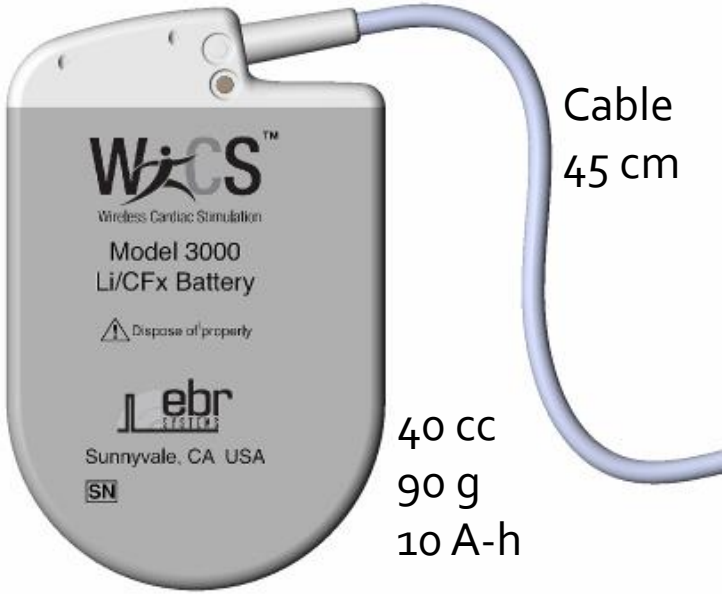


Transmetteur



11 cc
25 g
4 EKG electrodes

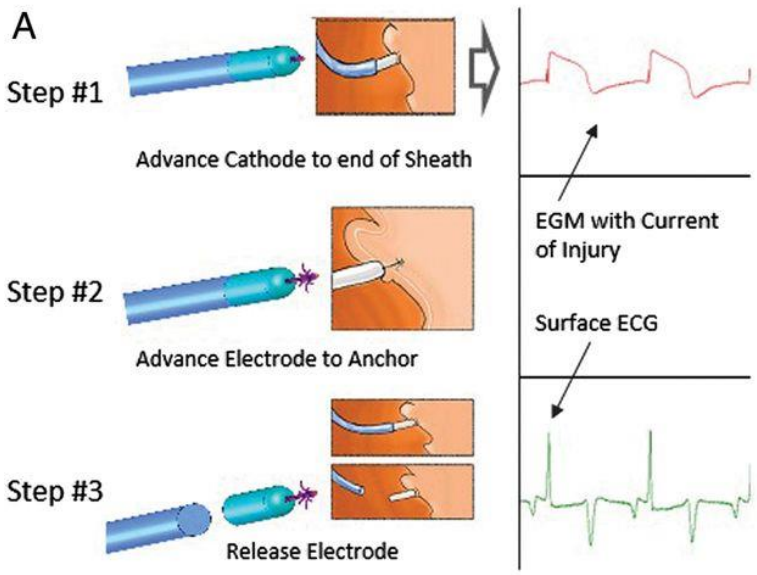
Batterie

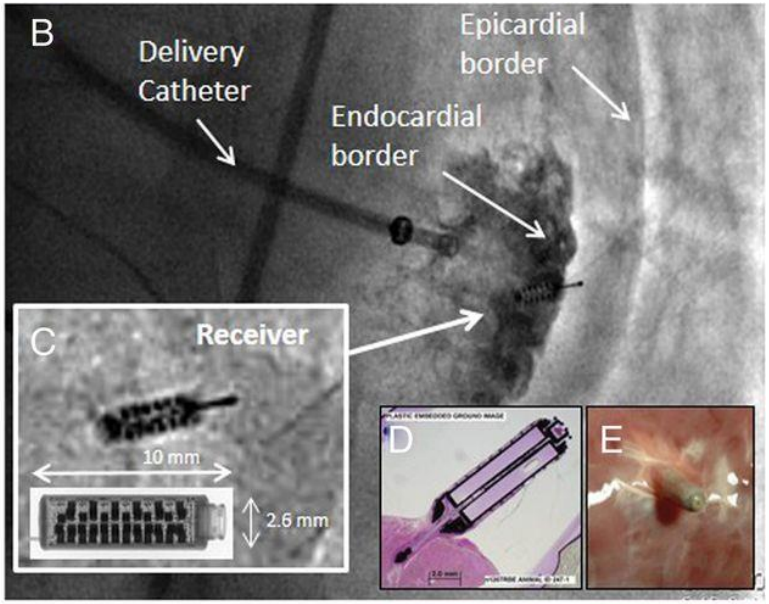


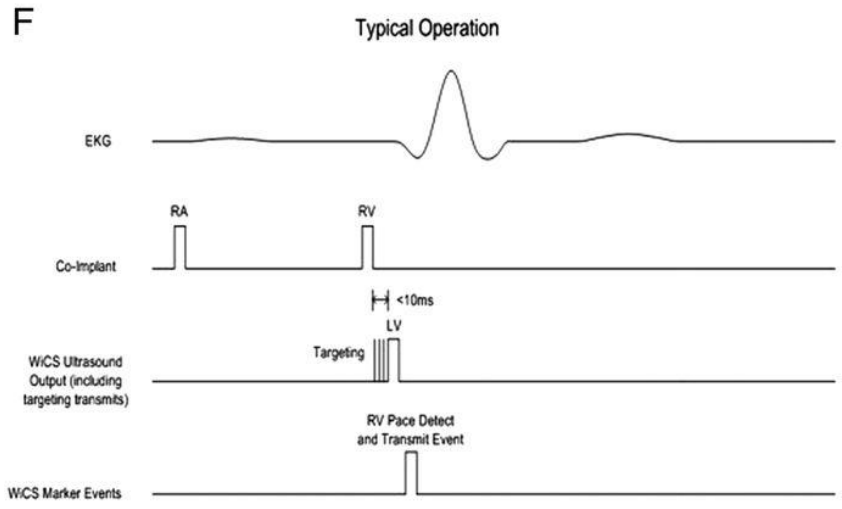
Cable
45 cm

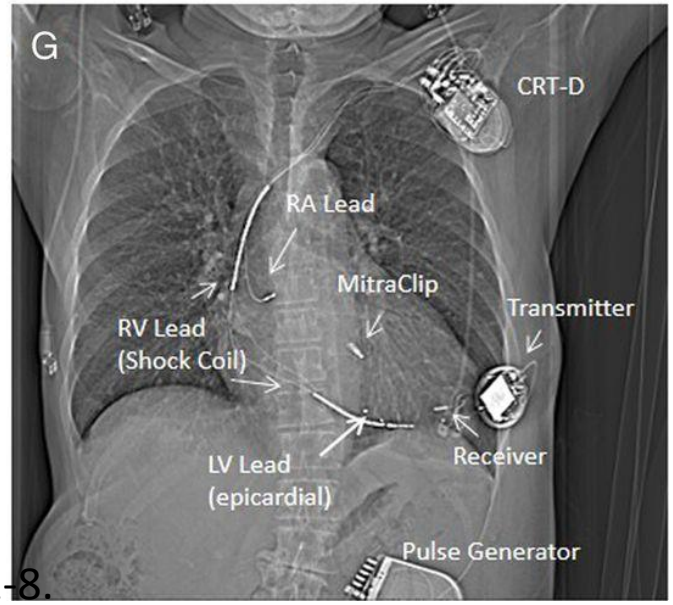
40 cc
90 g
10 A-h

WiSE-CRT



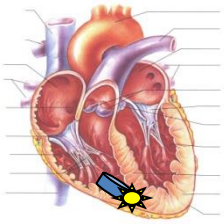






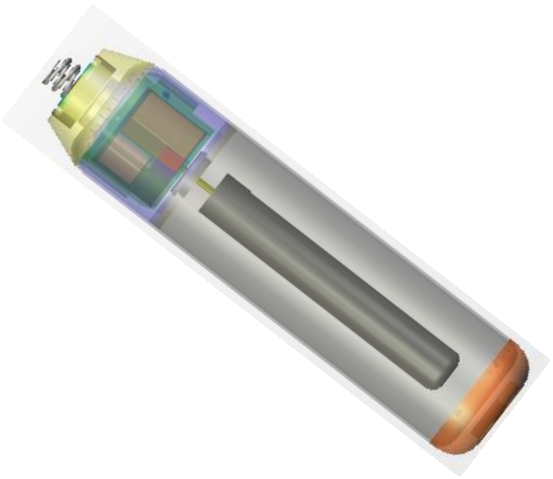
A. Auricchio et al. Europace. 2014 May;16(5):681-8.

Leadless PM

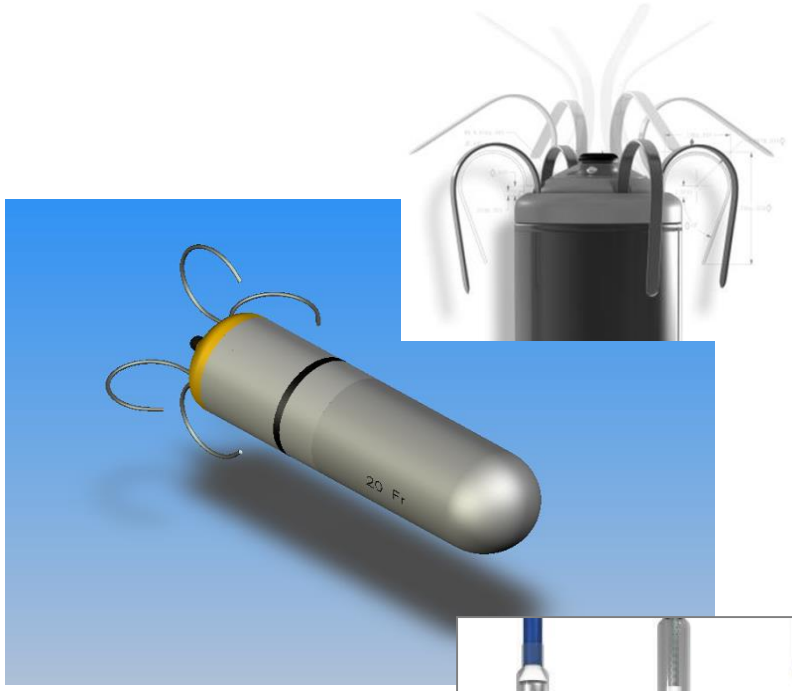


2 projects : Nanostim, Medtronic

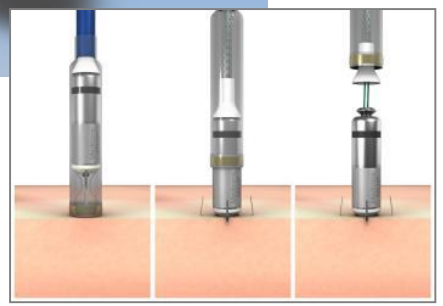
Many others .....



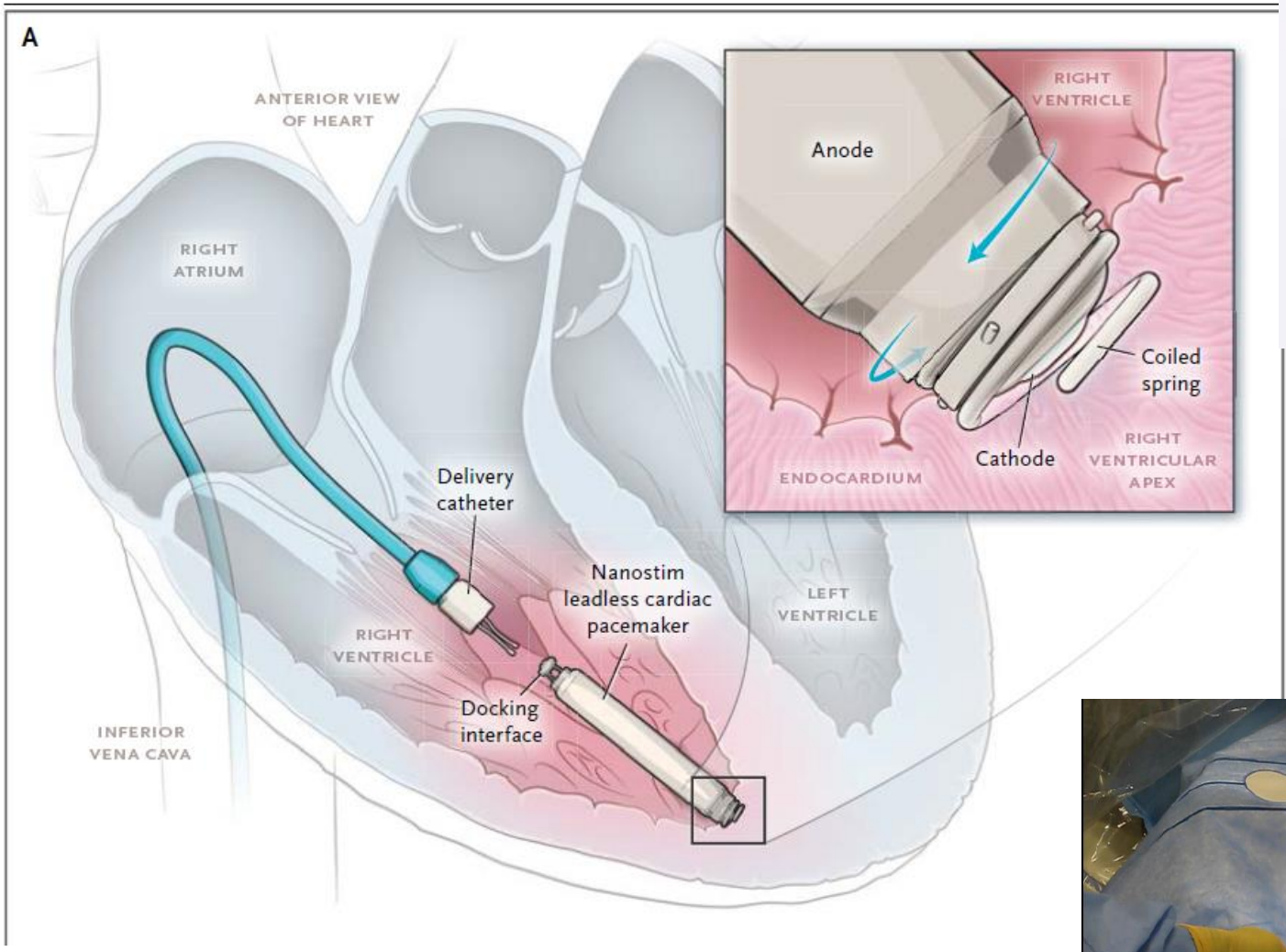
7 mm x 28 mm

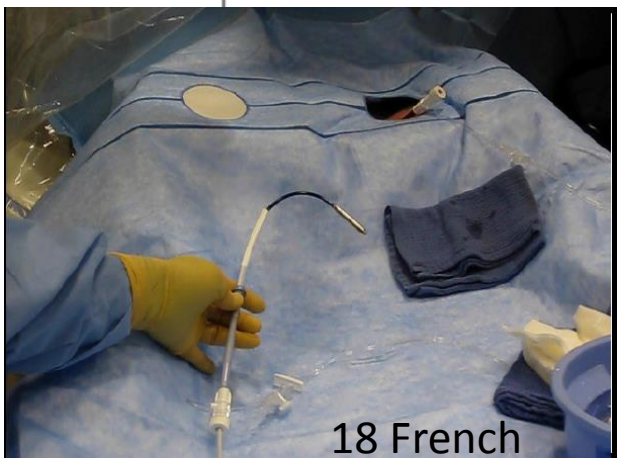


7 mm x 24 mm



Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker



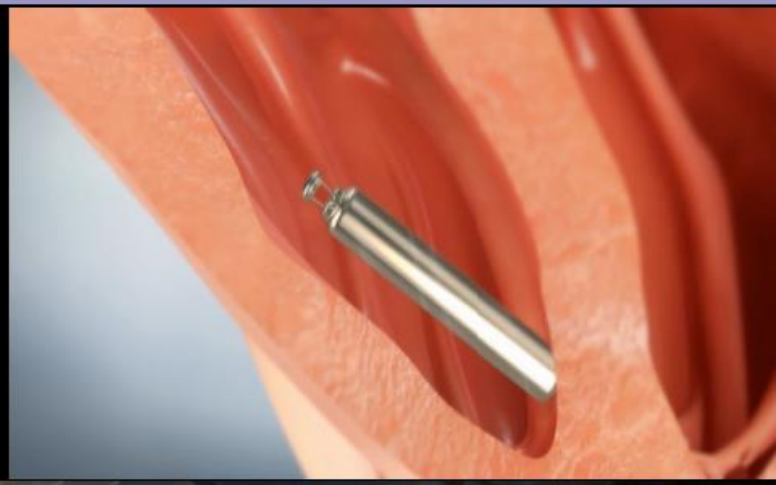


Vivek Y. Reddy et al. **N Engl J Med 2015;373:1125-35**

Today's Leadless Pacemaker System

The Nanostim Device

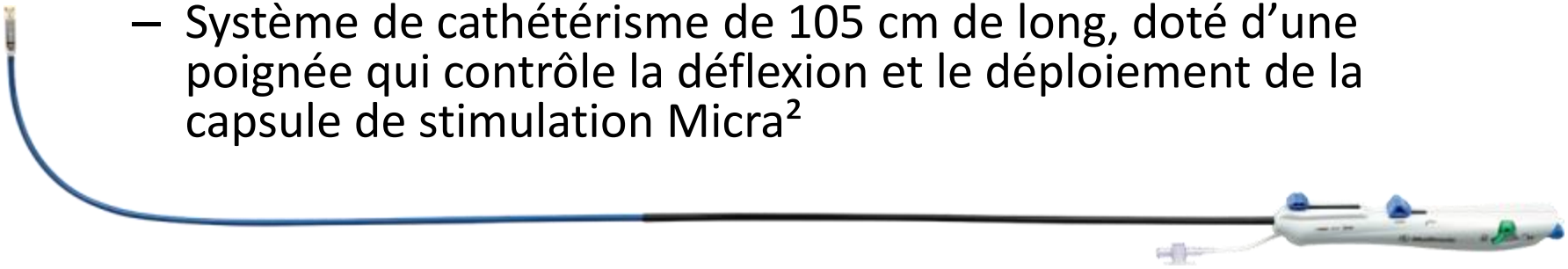
- **Percutaneous femoral vein delivery**
  - 18F introducer /steerable catheter
  - <30 minute skin-to-skin procedure
- **Self-contained device in ventricle**
  - No lead or surgical pocket
  - Inherently MRI compatible
- **Conventional Features**
  - -Temperature-Based Rate Response
  - >10-yr battery life
  - Hysteresis
  - Magnet Mode
- **Flexible replacement options**
  - Catheter-based retrieval
  - Place additional leadless pacemakers
  - Revert to conventional pacing lead



MOUNT SINAI SCHOOL OF MEDICINE

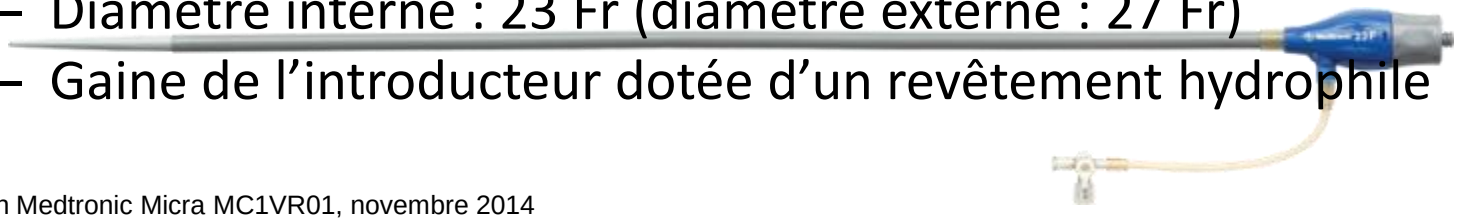
Cathéter d'introduction et introducteur[2]

- Cathéter d'introduction
  - Système de cathétérisme de 105 cm de long, doté d'une poignée qui contrôle la déflexion et le déploiement de la capsule de stimulation Micra[2]



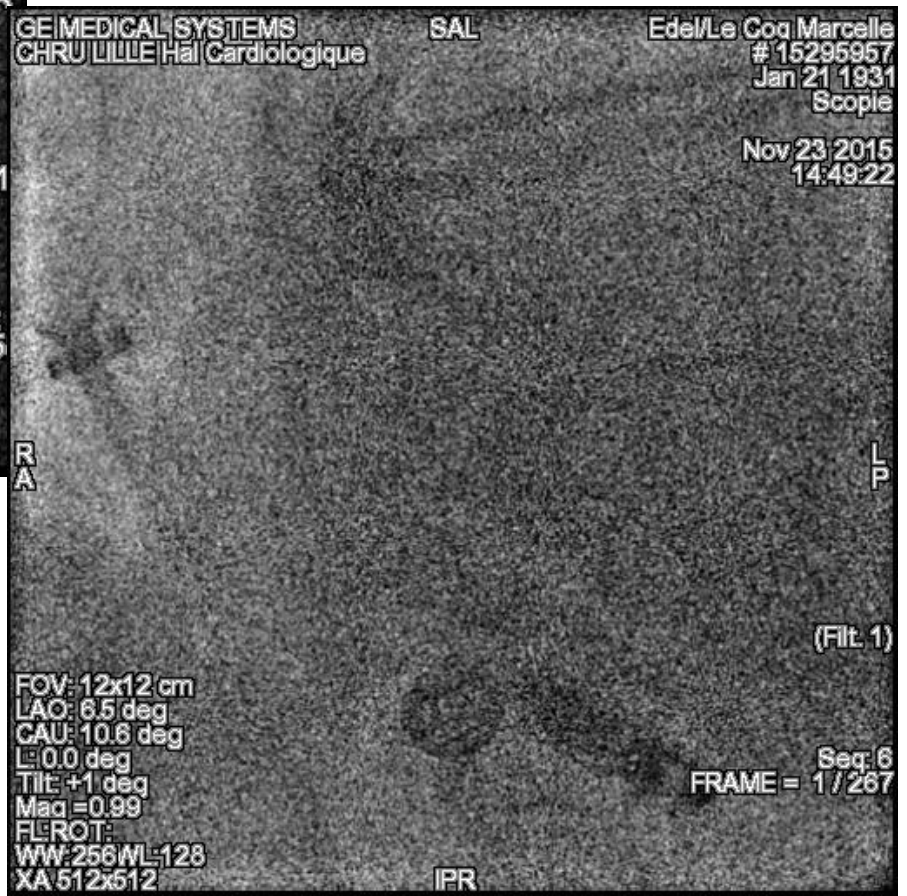
poignée

- Introducteur Micra
  - Longueur utile : 56 cm, avec effilement distal prolongé
  - Diamètre interne : 23 Fr (diamètre externe : 27 Fr)
  - Gaine de l'introducteur dotée d'un revêtement hydrophile



[2] Manuel médecin Medtronic Micra MC1VR01, novembre 2014


GE MEDICAL SYSTEMS
CHRU LILLE Hal Cardiologique
SP
Edel/Le Coq Marcelle
#15295957
Jan 21 1931
Scopie
Nov 23 2015
14:26:38
R
P
L
A
(Filt. 1
FOV: 30x30 cm
RAO: 28.1 deg
CRA: 1.1 deg
L: 0.0 deg
Tilt: +1 deg
Mag =0.99
FL:ROT:
WW:256 WL:128
XA 512x512
Seq:
FRAME = 1 / 25
IA

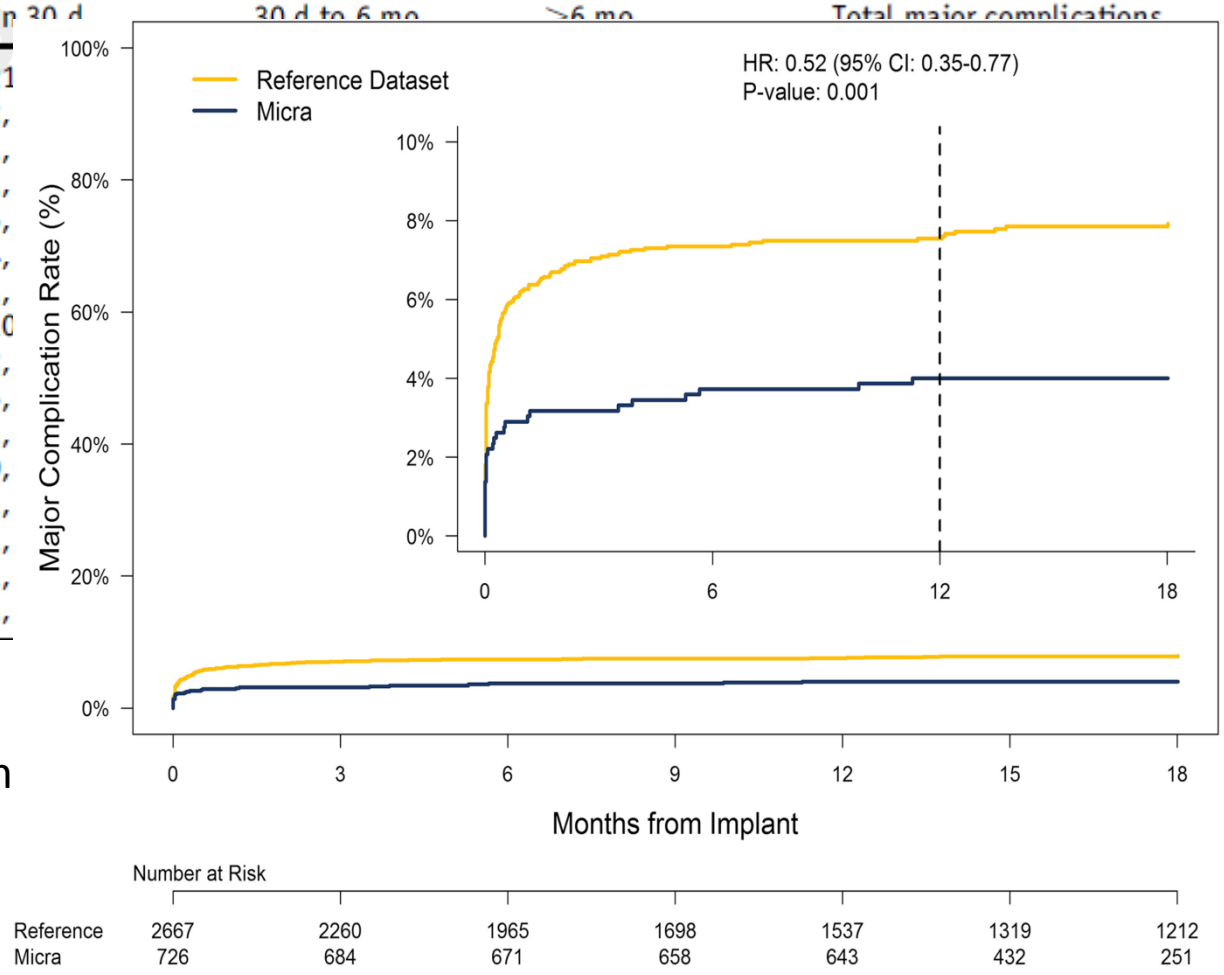

GE MEDICAL SYSTEMS
CHRU LILLE Hal Cardiologique
SAL
Edel/Le Coq Marcelle
15295957
Jan 21 1931
Scopie
Nov 23 2015
14:49:22
R
A
L
P
(Filt. 1)
FOV: 12x12 cm
LAO: 6.5 deg
CAU: 10.6 deg
L: 0.0 deg
Tilt: +1 deg
Mag =0.99
FL:ROT:
WW:256 WL:128
XA 512x512
Seq: 6
FRAME = 1 / 267
IPR


IT WORKS
!

Long-term performance of a transcatheter pacing system: 12-Month results from theMicra Transcatheter Pacing Study

Table 1 Major complications (patients with an attempted Micra implant; N = 726)

Adverse event key term	No. of events (No. of subjects, %) Within 30 d	30 d to 6 mo	>6 mo	Total major complications
Total major complications	24 (21			
Embolism and thrombosis	2 (2,			
Deep vein thrombosis	1 (1,			
Pulmonary embolism	1 (1,			
Events at groin puncture site	5 (5,			
Arteriovenous fistula	4 (4,			
Vascular pseudoaneurysm	1 (1,			
Cardiac effusion/perforation	10 (10			
Pacing issues: elevated thresholds	2 (2,			
Other	5 (5,			
Acute myocardial infarction	1 (1,			
Cardiac failure	0 (0,			
Metabolic acidosis	1 (1,			
Pacemaker syndrome	1 (1,			
Presyncope	1 (1,			
Syncope	1 (1,			



32 major complications:

-18 with prolonged hospitalization

-17 with new hospitalization

-5 with system revision

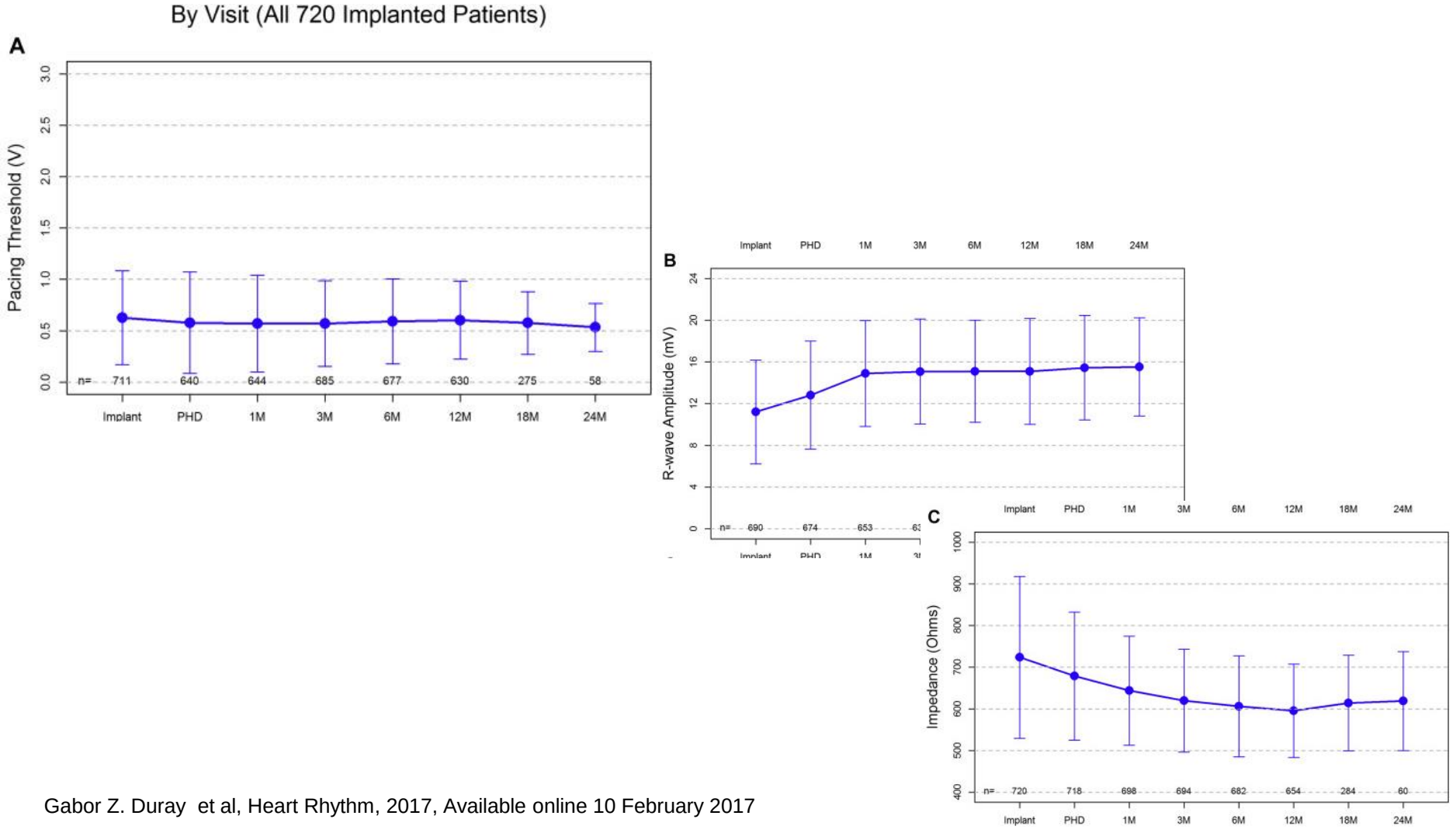
-2 with loss of device function

Gabor Z. Duray et al, Heart Rhythm, 2017, Available online 10 February 2017

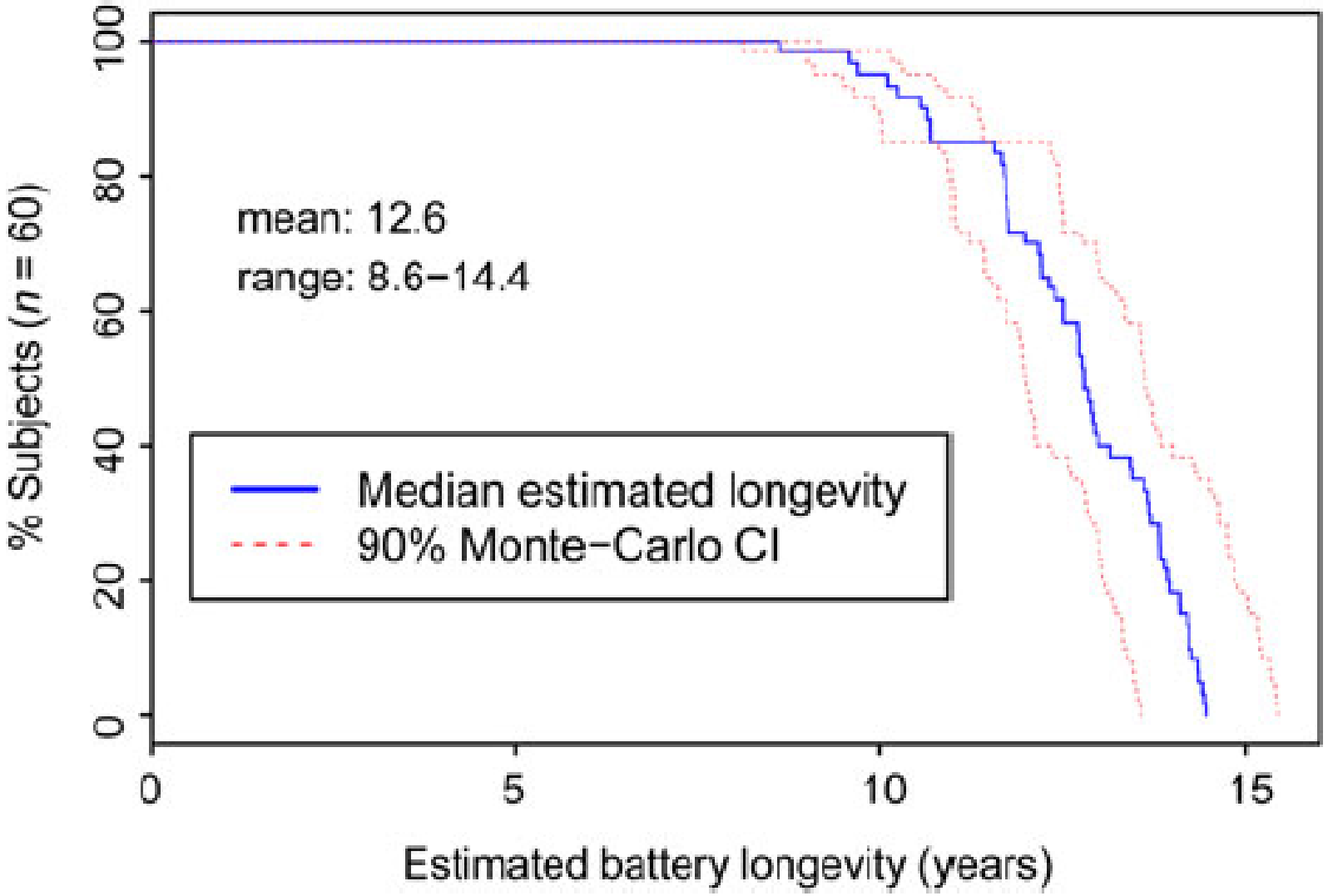
- 94 implanters in 20 centers
- 94 implanters with a good formation and training !!!!!!!!!!
- A new work

Long-term performance of a transcatheter pacing system: 12-Month results from theMicra Transcatheter Pacing Study

- 726 pts attempted Micra implant by 94 physicians, 720 patients (**99.2%**) were successfully implanted



Gabor Z. Duray et al, Heart Rhythm, 2017, Available online 10 February 2017


% Subjects (n = 60)
100
80
60
40
20
0
mean: 12.6
range: 8.6–14.4
Median estimated longevity
90% Monte-Carlo CI
0
5
10
15
Estimated battery longevity (years)

Opportunité de redéfinir l'expérience patient

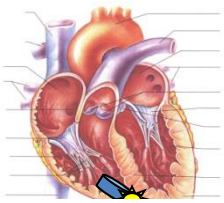
- Possibilité d'augmenter la satisfaction du patient :
  - Vis-à-vis du stimulateur
  - Pas de cicatrice
  - Pas de bosse
  - Pas de rappel visible ou physique
  - Procédure mini-invasive
  - Potentiellement moins de restrictions des activités post-implantation

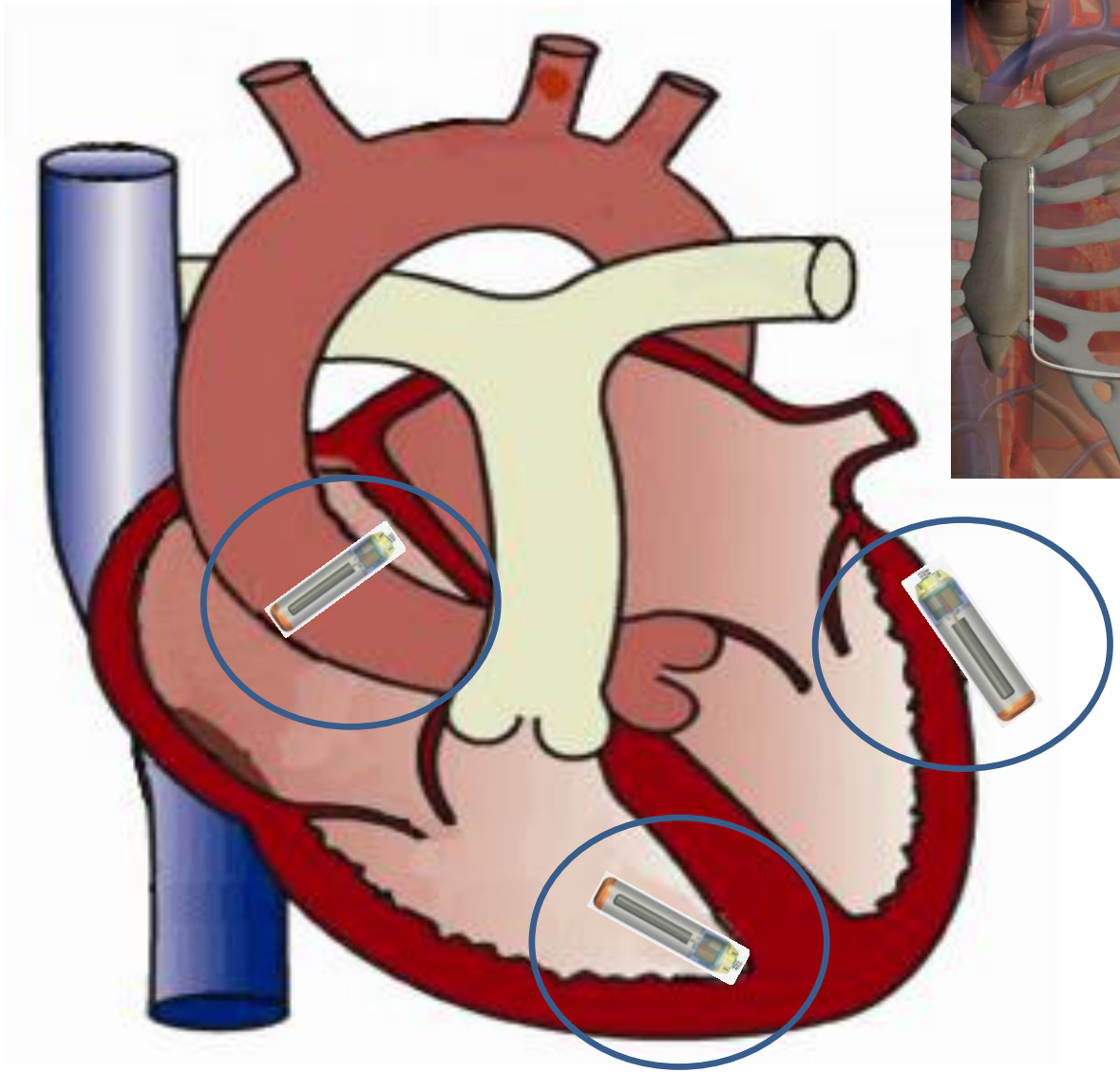
- VVI pacemaker
- How will we manage end of life batteries after 10-15 years ?
- How manage burial in France ?

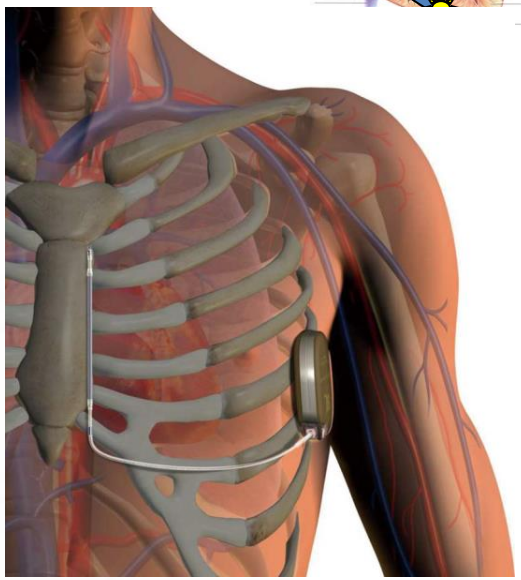
WHO IS THE GOOD

INDICATION ?

Leadless pacing







Moins il y en a plus c’est cher !!!!

Mais

C’est mieux …… Non ?

La stimulation est efficace…….voire meilleur
Mais pour combien de temps
Risque infectieux …incertain
Plus cher qu’un vieux système
Pour qui ?