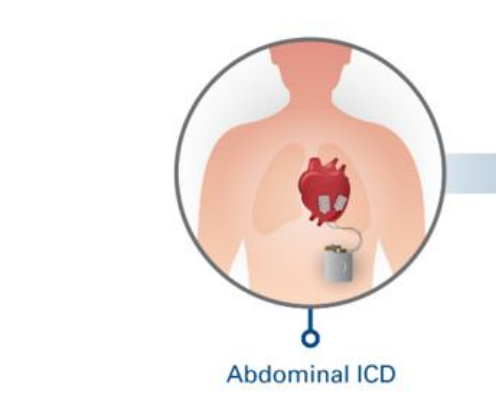
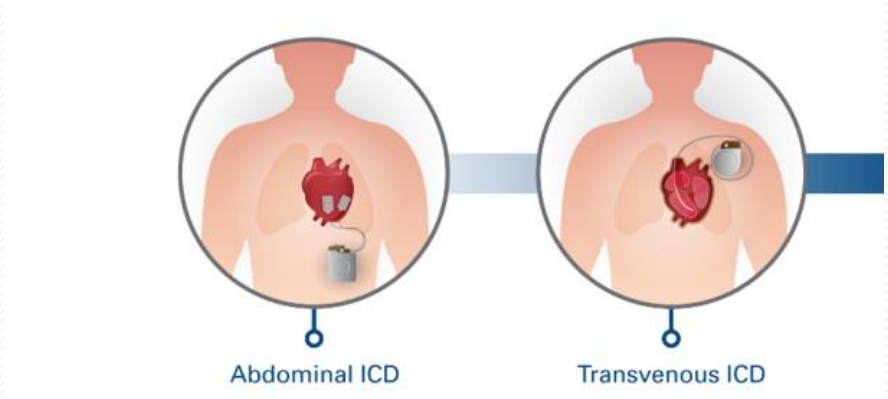
Εξελίξεις στην αντιμετώπιση των αρρυθμιών

Θεμιστοκλής Μαούνης
Ωνάσειο ΚΧΚ

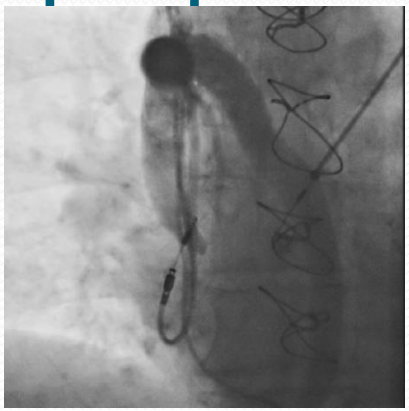
13.11.2015 Αθήνα

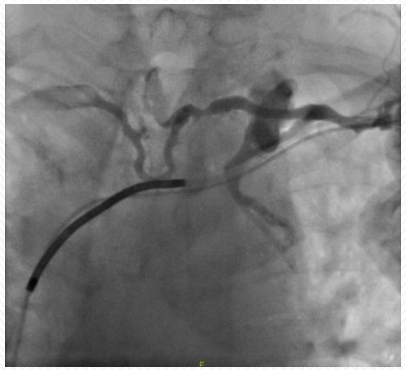

Abdominal ICD

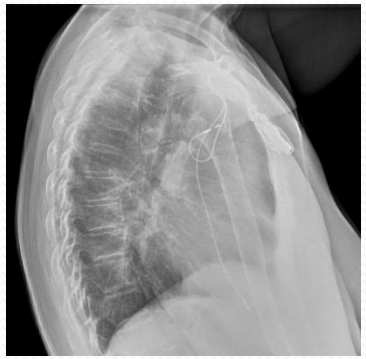

Abdominal ICD
Transvenous ICD

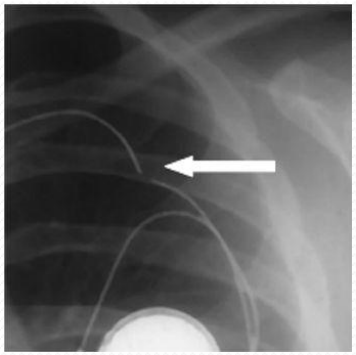
Προβλήματα με ενδοφλέβια ηλεκτρόδια

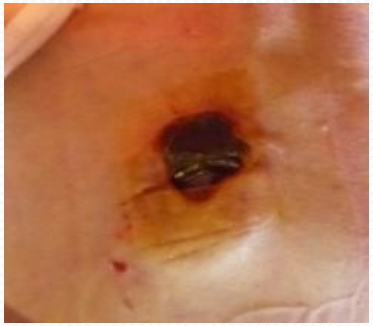
- Απόφραξη φλεβών αδυναμία πρόσβασης
- Θρόμβωση μεγάλων φλεβών, θρομβοεμβολικά, απόφραξή τους
- Μετακίνηση ηλεκτροδίου
- Θραύση ηλεκτροδίου
- Πνευμοθώρακας, αιμοθώρακας, αιμοπερικάρδιο
- Λοιμώξεις
- Νοσηρότητα –θνησιμότητα αφαίρεσης ηλεκτροδίων
- Επιβίωση ηλεκτροδίων με καλή λειτουργία: 1 έτος 91-99%, 5 έτη 85-96%, 8 έτη 60-72%

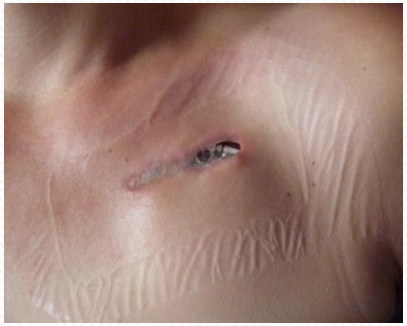


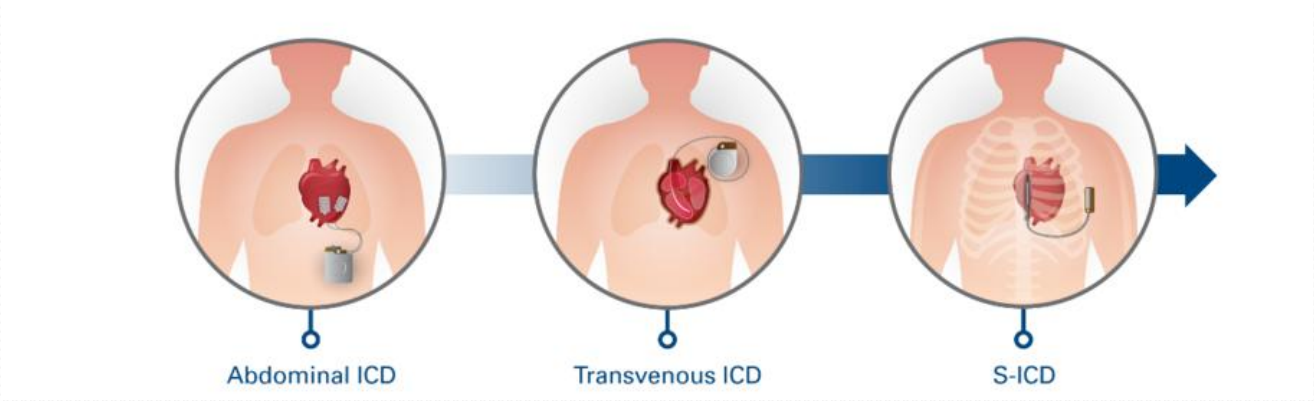




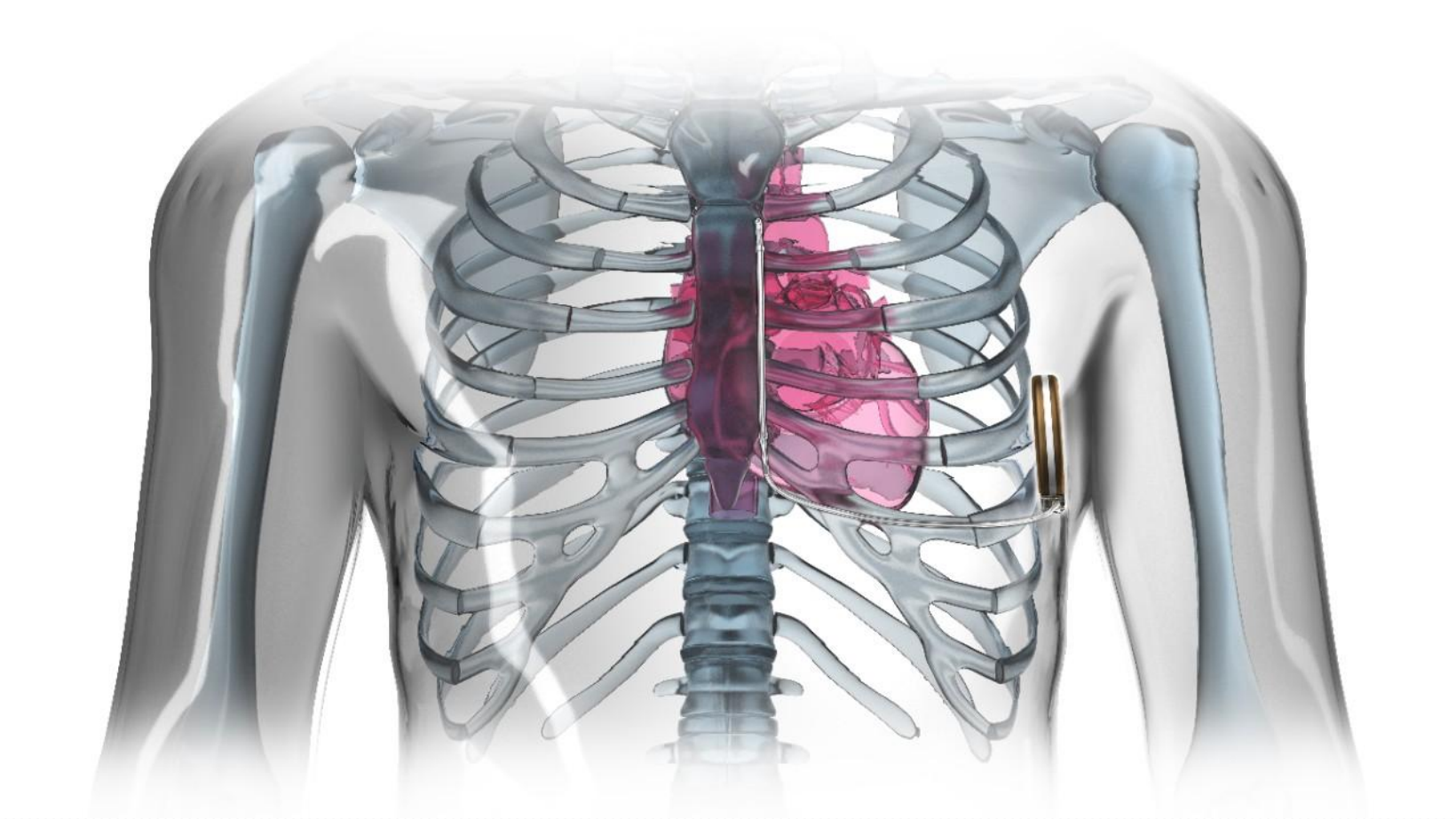


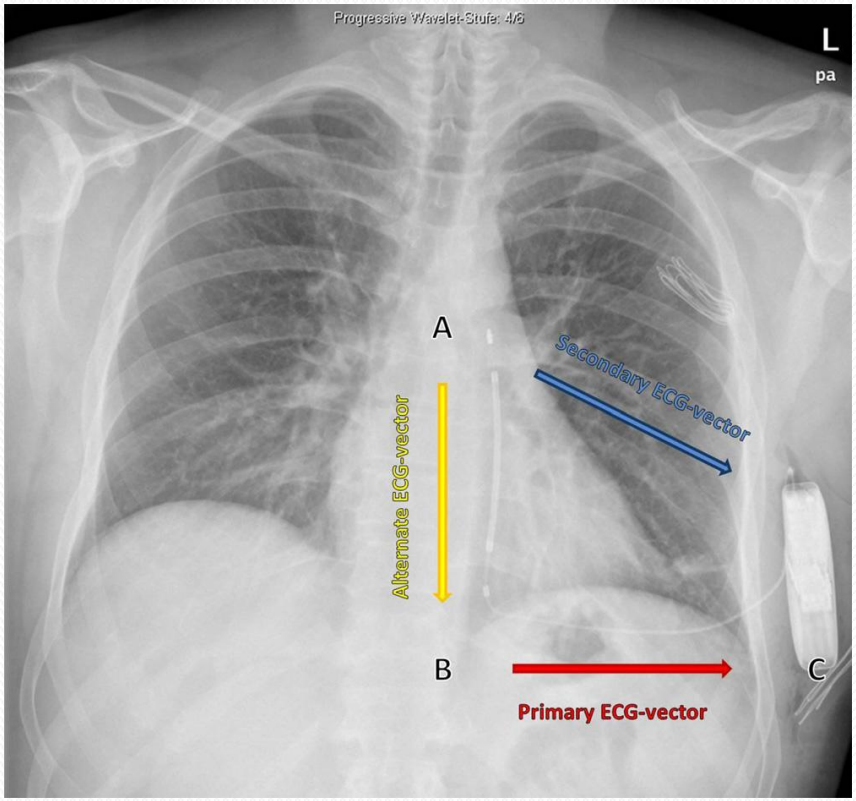


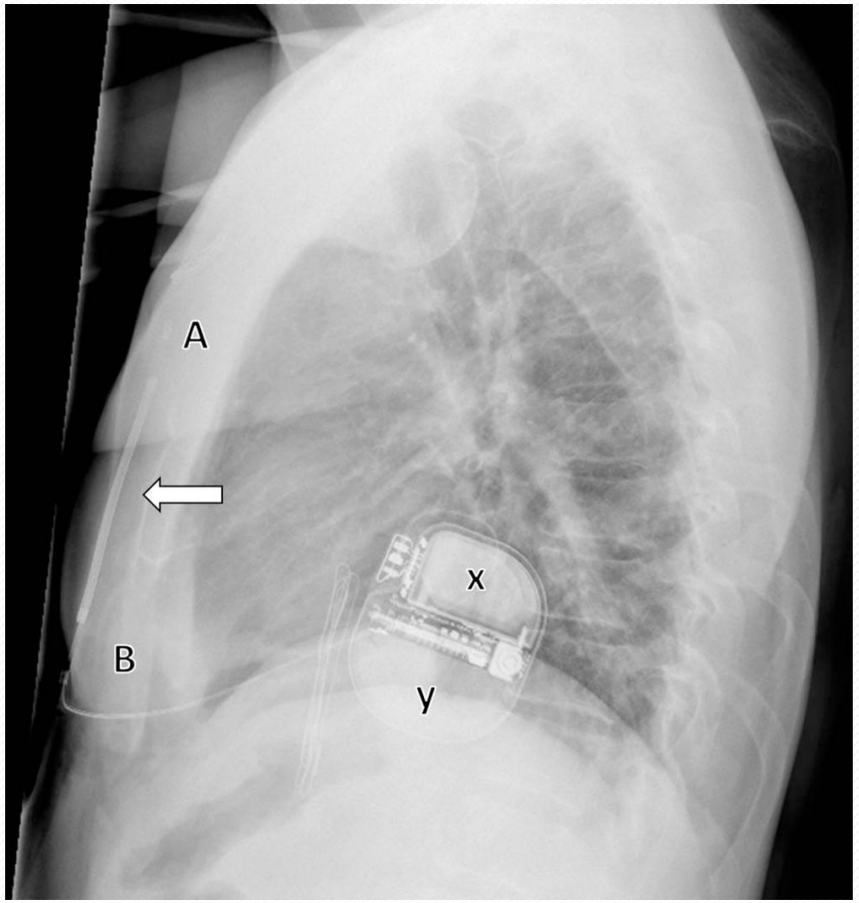


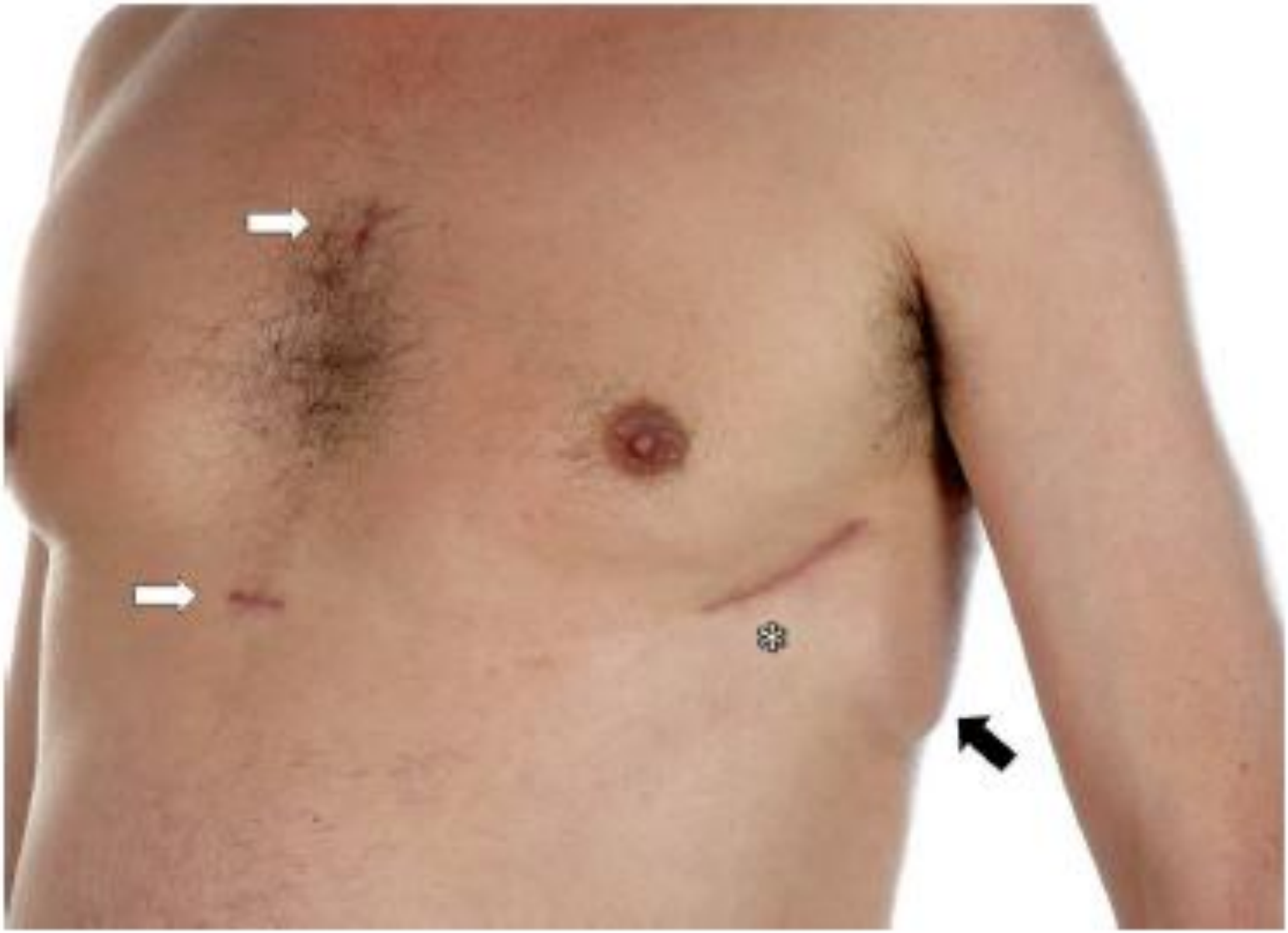

Abdominal ICD
Transvenous ICD
S-ICD

SQ defibrillator

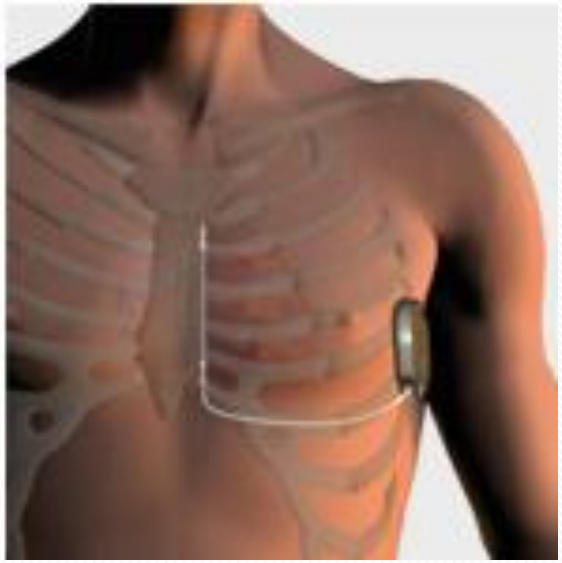


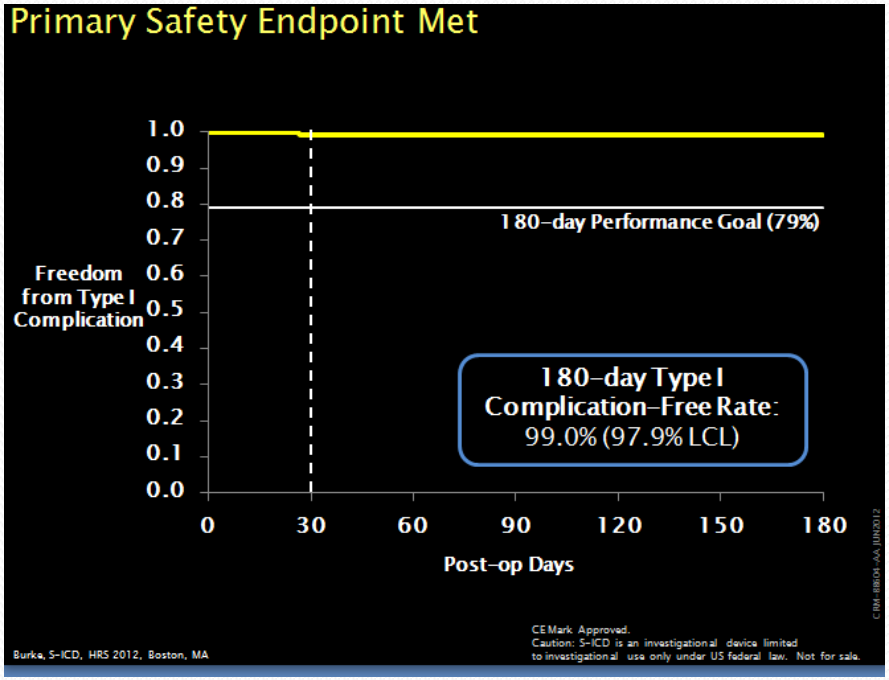

Progressive Wavelet-Stufe: 4/6
L
pa
A
Secondary ECG-vector
Alternate ECG-vector
B
C
Primary ECG-vector


A
x
B
y



S-ICD




Primary Safety Endpoint Met
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Freedom from Type I Complication
180-day Performance Goal (79%)
180-day Type I Complication-Free Rate: 99.0% (97.9% LCL)
0
30
60
90
120
150
180
Post-op Days
Burke, S-ICD, HRS 2012, Boston, MA
CE Mark Approved.
Caution: S-ICD is an investigational device limited to investigational use only under US federal law. Not for sale.

Μελέτες S-ICD

Table 1. Overview of different subcutaneous implantable cardioverter defibrillator trials

Author	Patients, number	Age, years	Primary/secondary indication	Ischemic cardiomyopathy	Dilated cardiomyopathy	Other indications	Follow-up, months	Adequate episodes	Inappropriate episodes
Bardy *et al.* [10] (2010)	55	56 ± 13	43/12	37	10	9	10 ± 1	12 (3 patients)	0
Dabiri *et al.* [18] (2011)	31	53 ± 16	21/10	18	4	9	10	11 (4 patients)	5
Jarman *et al.* [17] (2012)	16	20		-	-	16		8 (3 patients)	10 (25%)
Aydin *et al.* [26] (2012)	40	42 ± 15	17/23	9	9	22	8 ± 6	21 (4 patients)	4 (5%)
Köbe *et al.* (2013) [25]	69	45 ± 16	41/28	11	25	34	7 ± 5	23 (3 patients)	3 (5%)
Olde Nordkamp *et al.* [24] (2012)	118	50	71/47	45	22	52	18 ± 7	45 (8 patients)	33 (13%)
Lambiase *et al.* [14] (2014)	472	49	282/167	166	43	236	18	93 (33 patients)	73 (7%)

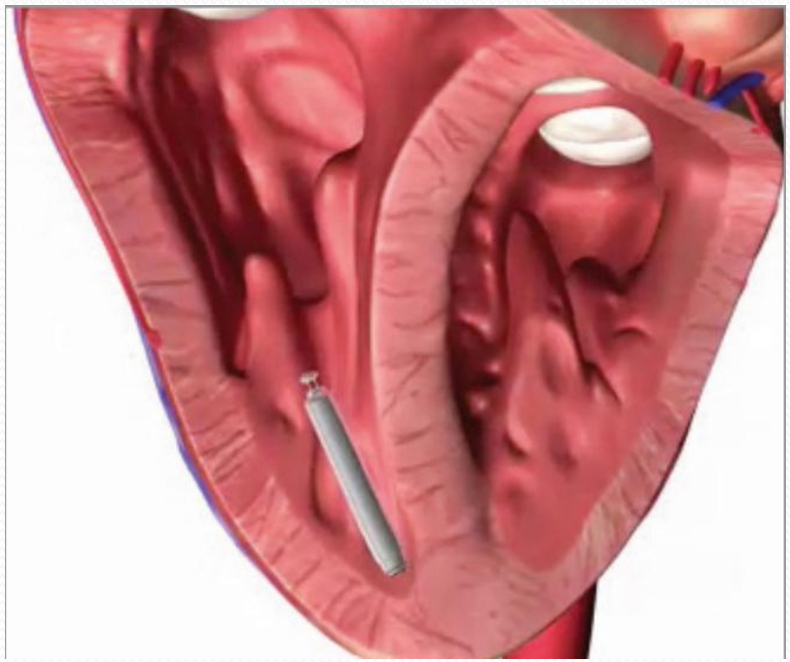
EFFORTLESS Registry Lambiase EHJ 2014

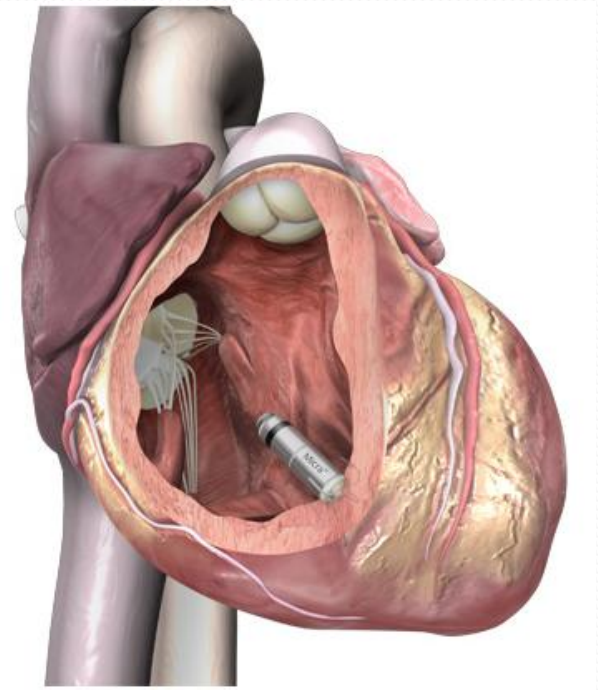
- 472 ασθενείς S-ICD
- 558 ημέρες παρακολούθησης
- Ανάταξη με πρώτο σοκ 88%, ως το 5ο 100%
- Επιπλοκές με ανάγκη παρέμβασης 6.4%
- Απρόσφορα σοκ 7%

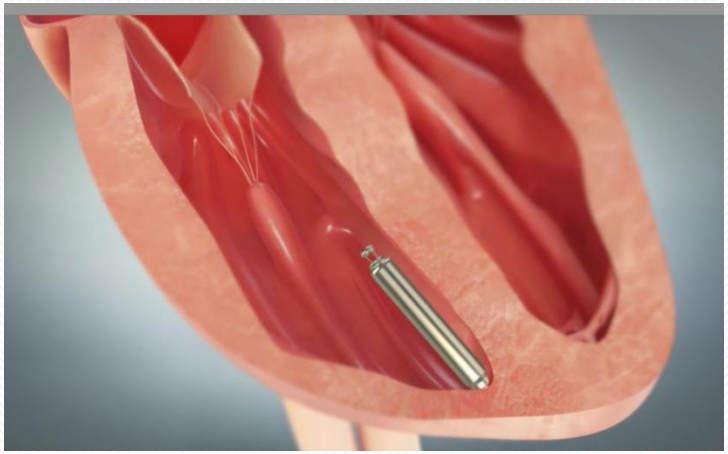
Μειονεκτήματα SICD

- Ψηλότερος ουδός απινίδωσης
- Μεγεθος
- Ζωή μπαταρίας
- Έλλειψη RV βηματοδότησης (ATP,backup), RA,LV
- Προβλήματα αίσθησης-υπεραίσθηση T
- Λοιμώξεις (≈4%)
- ΚΟΣΤΟΣ

ΒΗΜΑΤΟΔΟΤΗΣ ΧΩΡΙΣ ΗΛΕΚΤΡΟΔΙΑ



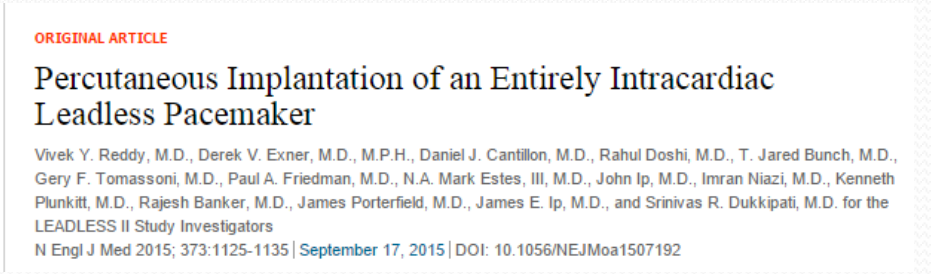





SJM
Nanostim
S1DLCP

LEADLESS II

- Επιτυχής εμφύτευση σε 95.8%(504/526 ασθενείς)
- 6.7% (20 ασθενείς) μείζονες επιπλοκές
- Χαμηλός και σταθερός ουδός βηματοδότησης και αίσθησης στους 6 μήνες 90%



ORIGINAL ARTICLE

Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D. for the LEADLESS II Study Investigators

N Engl J Med 2015; 373:1125-1135 | September 17, 2015 | DOI: 10.1056/NEJMoa1507192

MICRA Transcatheter Pacing Study Group

- Επιτυχής εμφύτευση σε 99.2%(719/725 ασθενείς)
- 4% (28 ασθενείς) μείζονες επιπλοκές
- Χαμηλός και σταθερός ουδός βηματοδότησης στους 6 μήνες 98.3%

ORIGINAL ARTICLE ONLINE FIRST

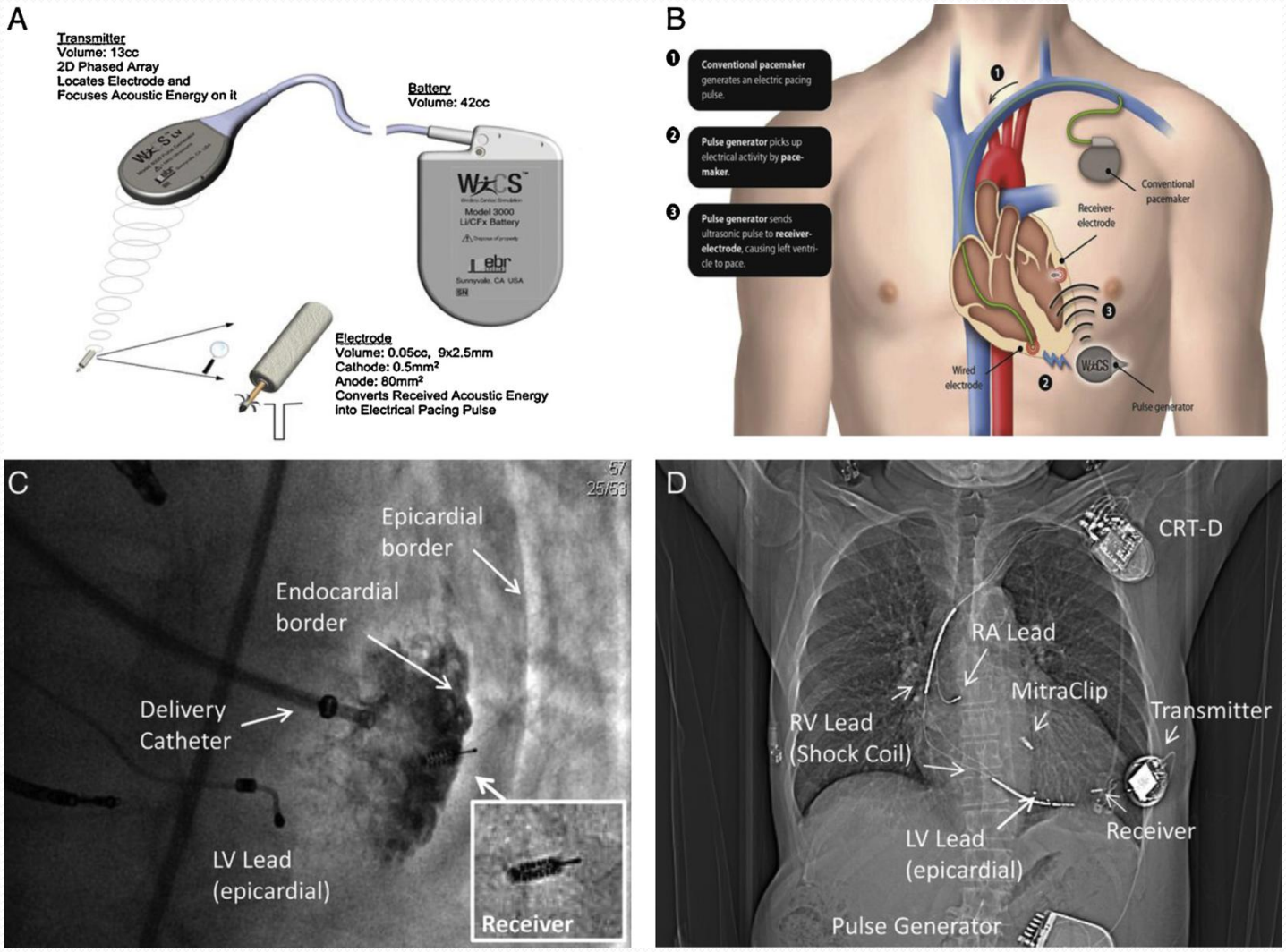
MEETING OF THE AMERICAN HEART ASSOCIATION

A Leadless Transcatheter Pacemaker

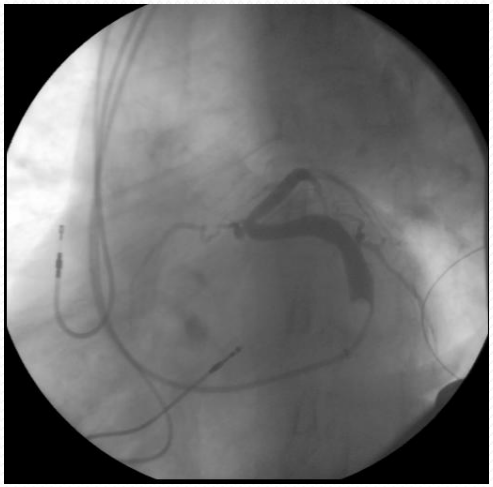
November 9, 2015 | D. Reynolds and Others
(DOI: 10.1056/NEJMoa1511643)

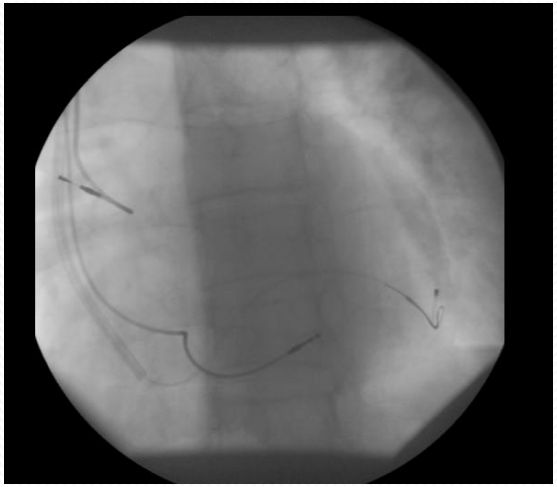
A series of 725 patients underwent attempted implantation of a leadless transcatheter pacemaker. At 6 months, 96.0% of patients had no major device-related complications, and 98.3% had a low and stable pacing capture threshold.

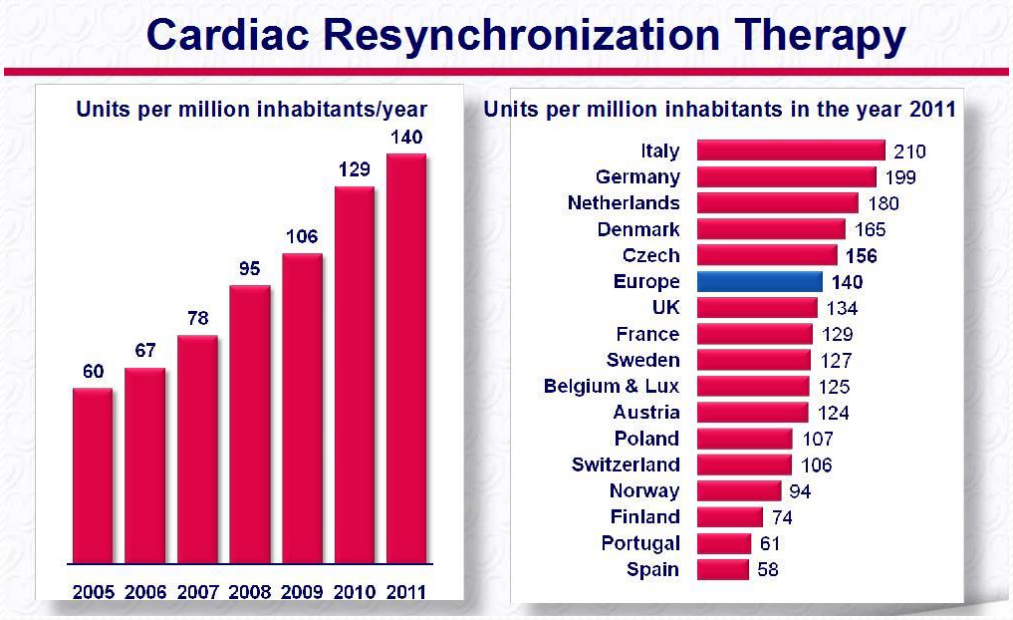
Wireless Cardiac Stimulation System



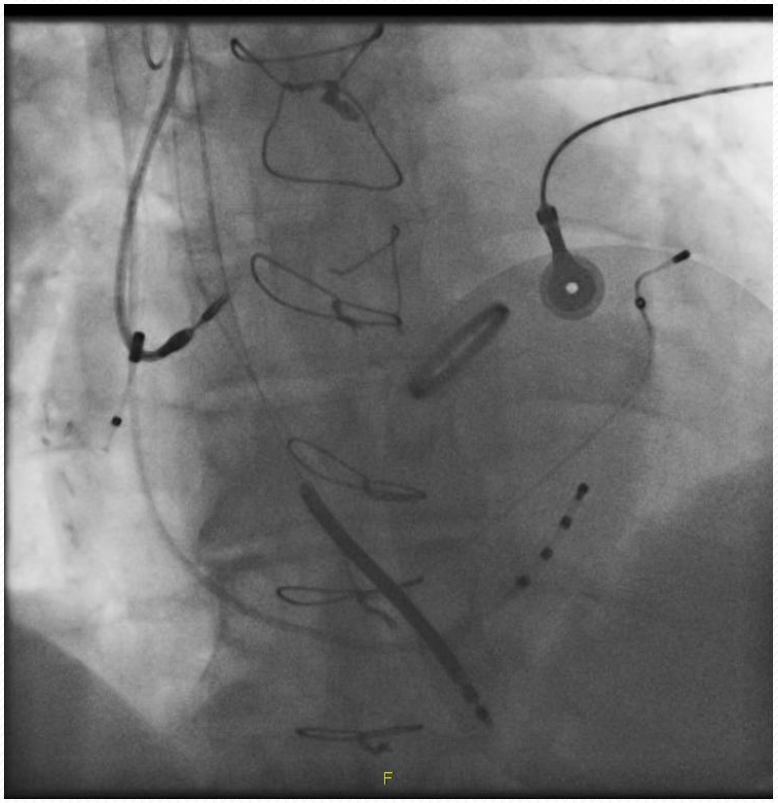
ΘΕΡΑΠΕΙΑ ΕΠΑΝΑΣΥΓΧΡΟΝΙΣΜΟΥ

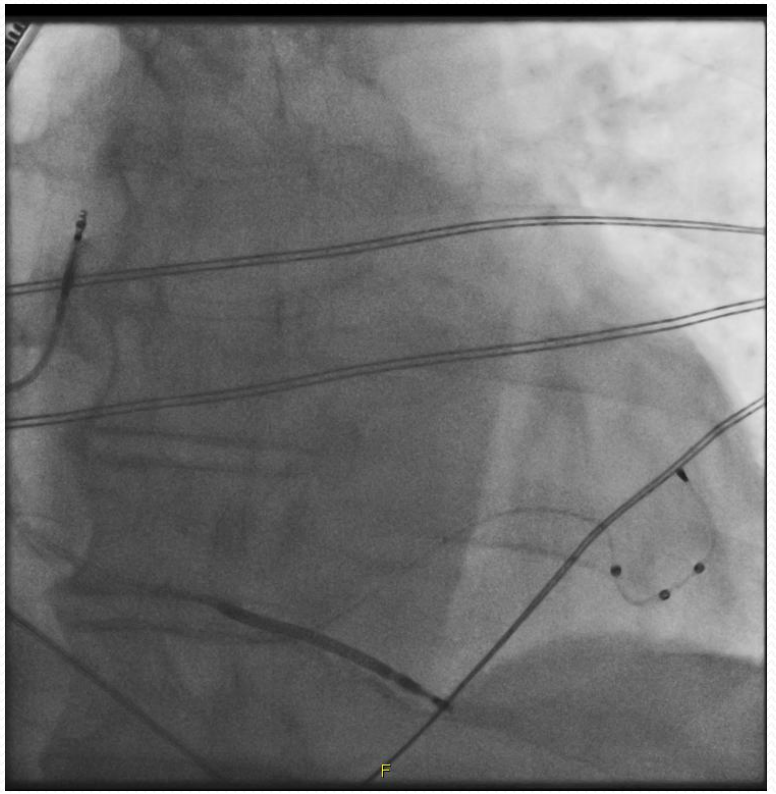




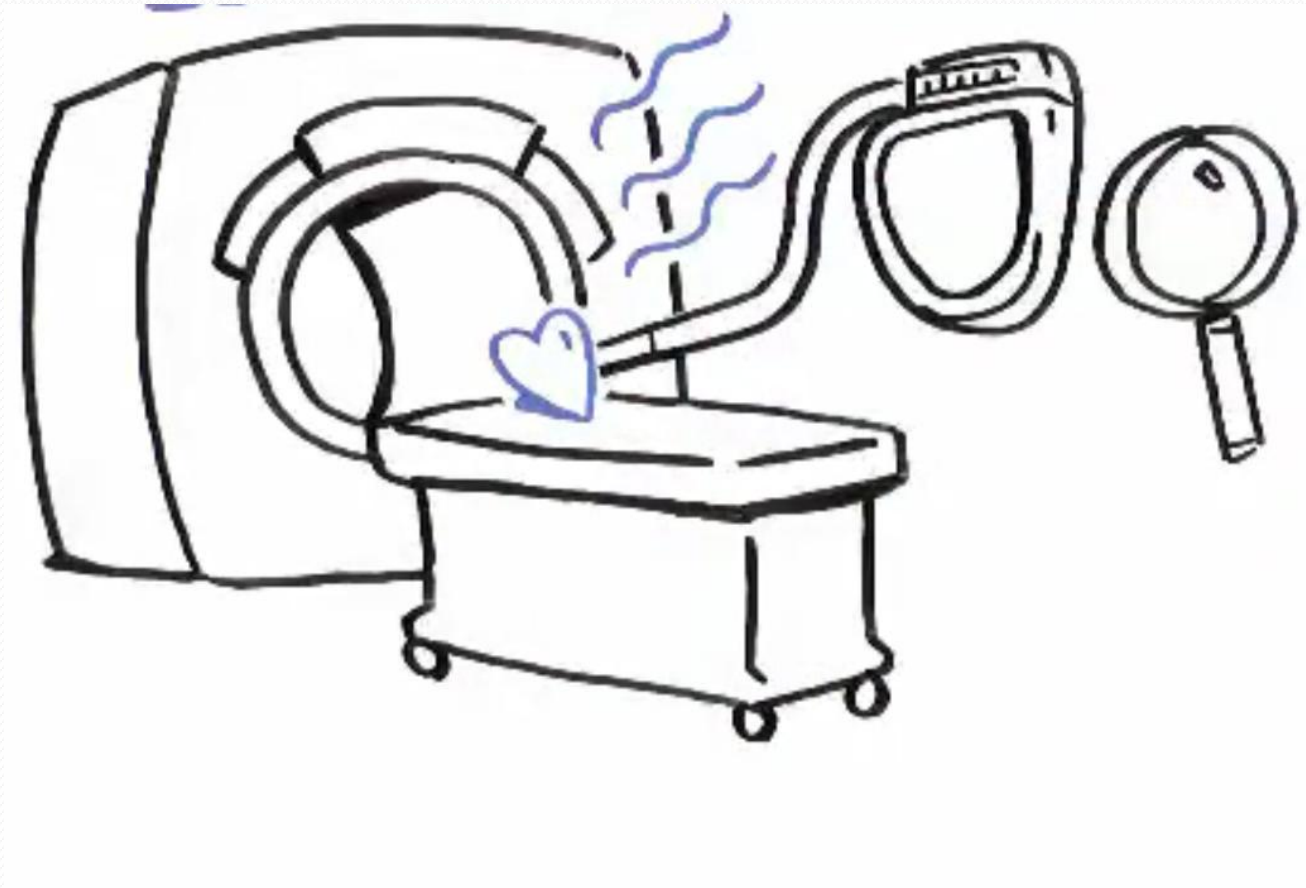


Quadripolar LV catheter



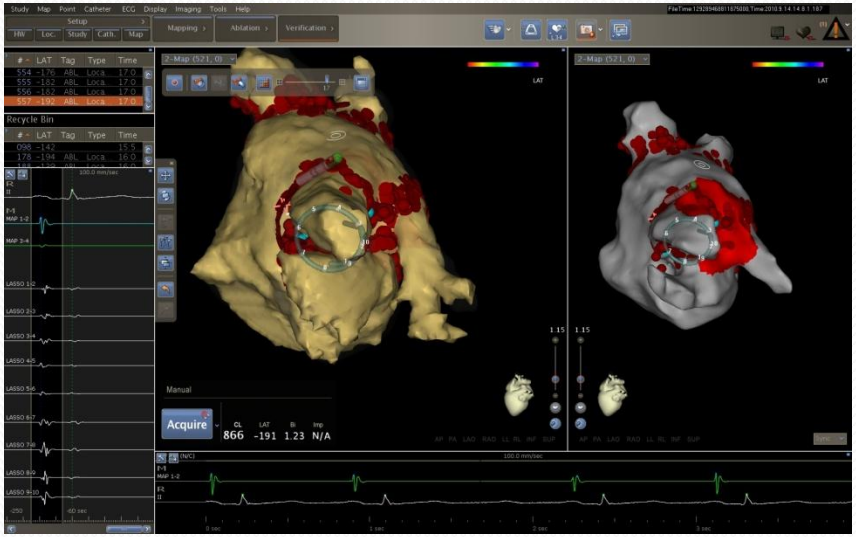


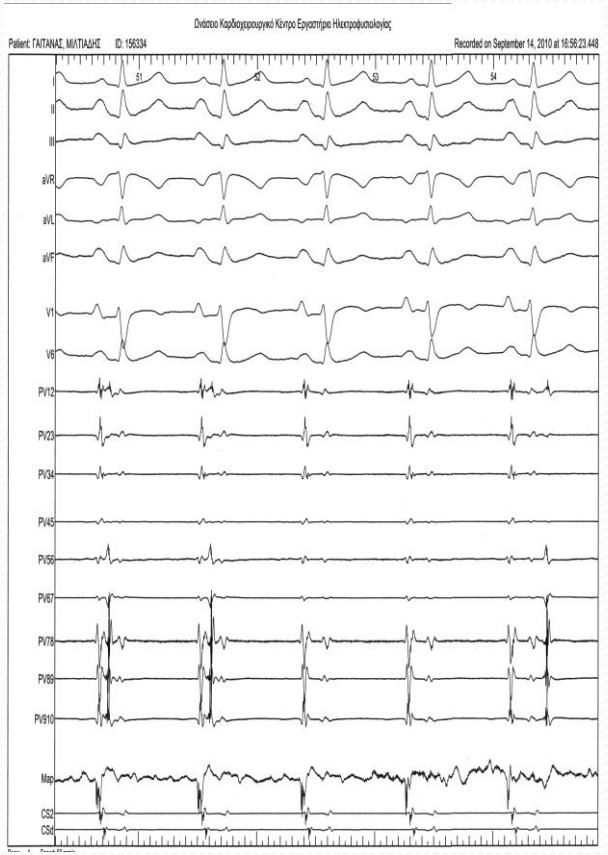
MRI



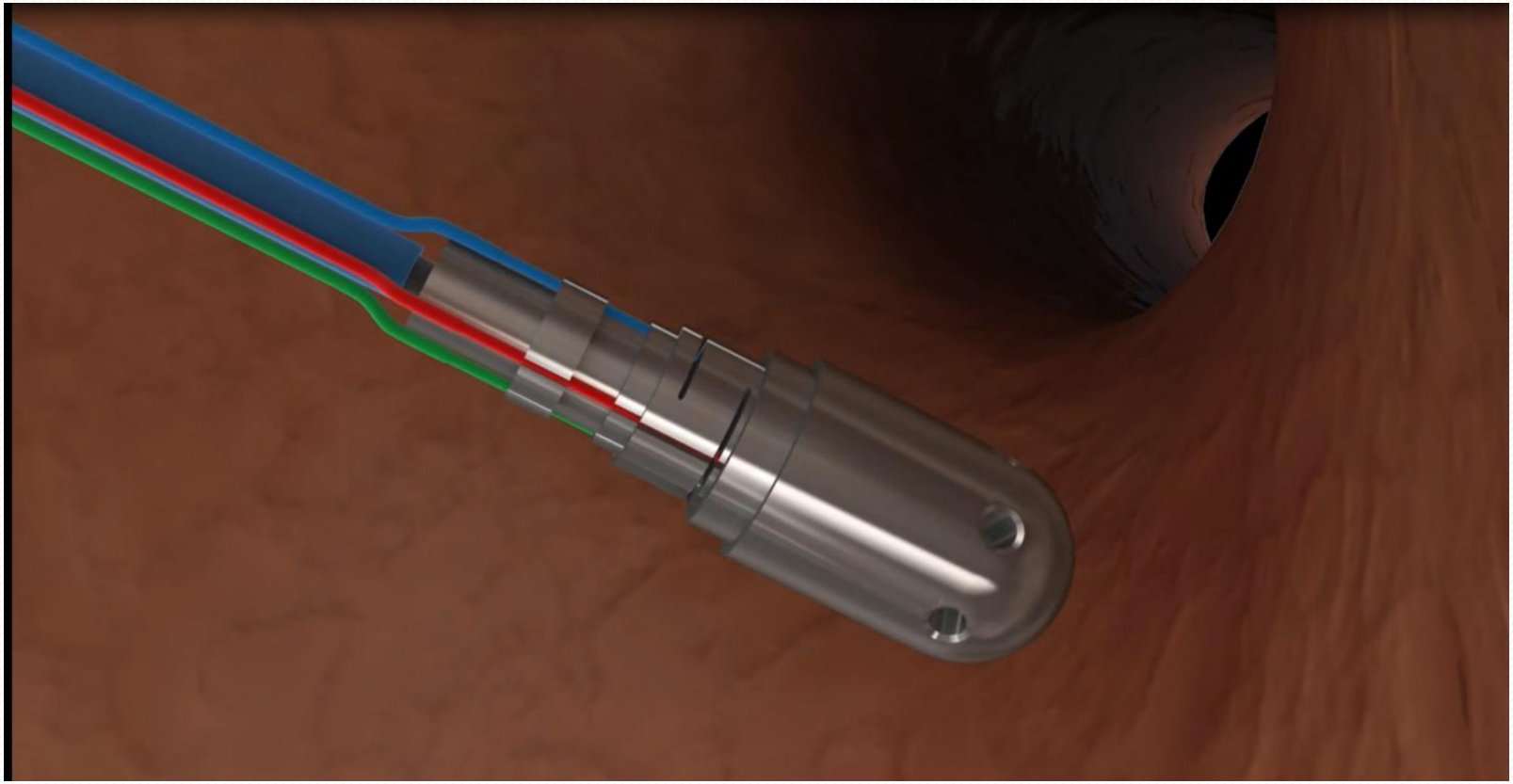
ΚΟΛΠΙΚΗ ΜΑΡΜΑΡΥΓΗ ABLATION

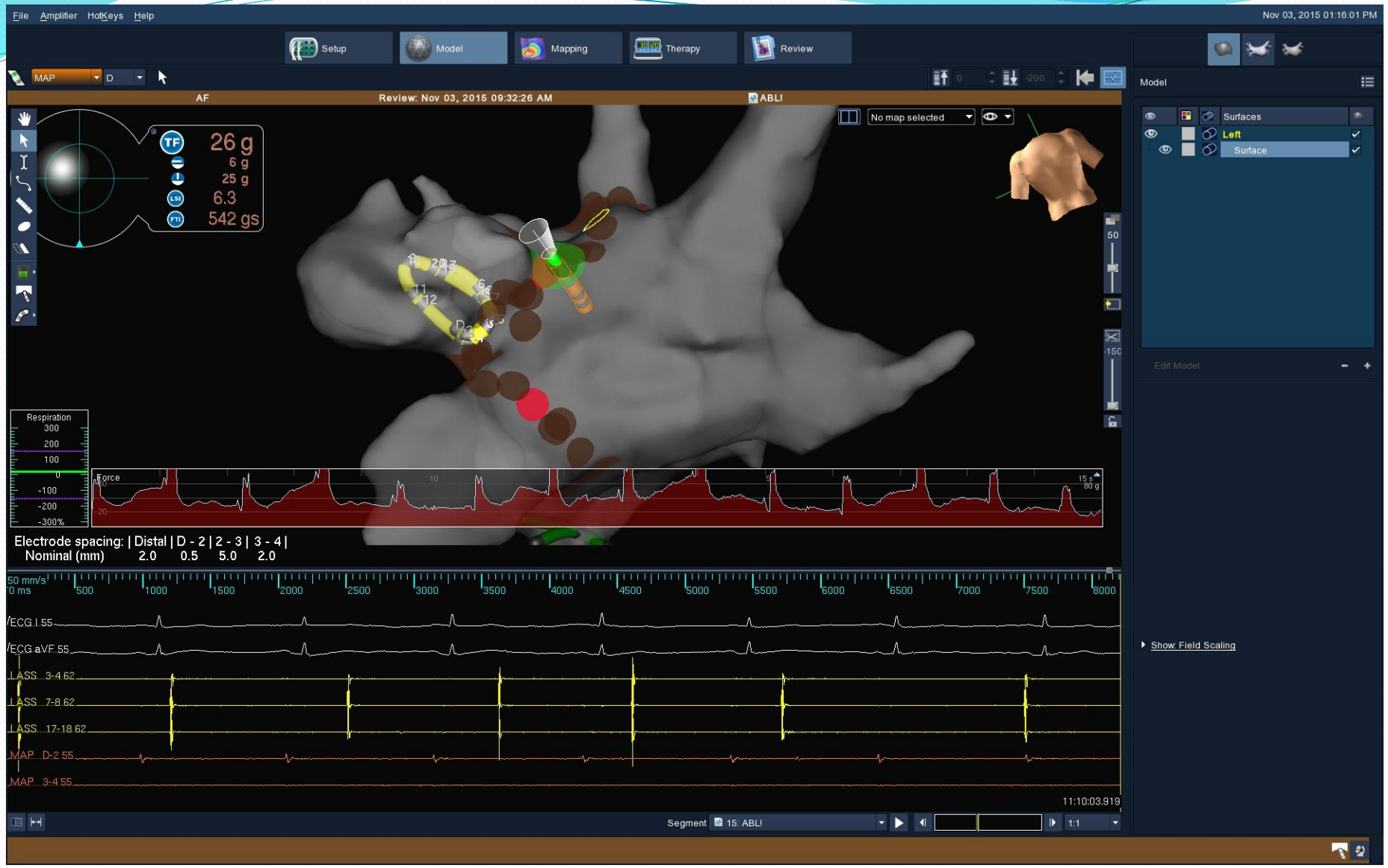
Απομόνωση πνευμονικών φλεβών





Contact Force




File Amplifier HotKeys Help
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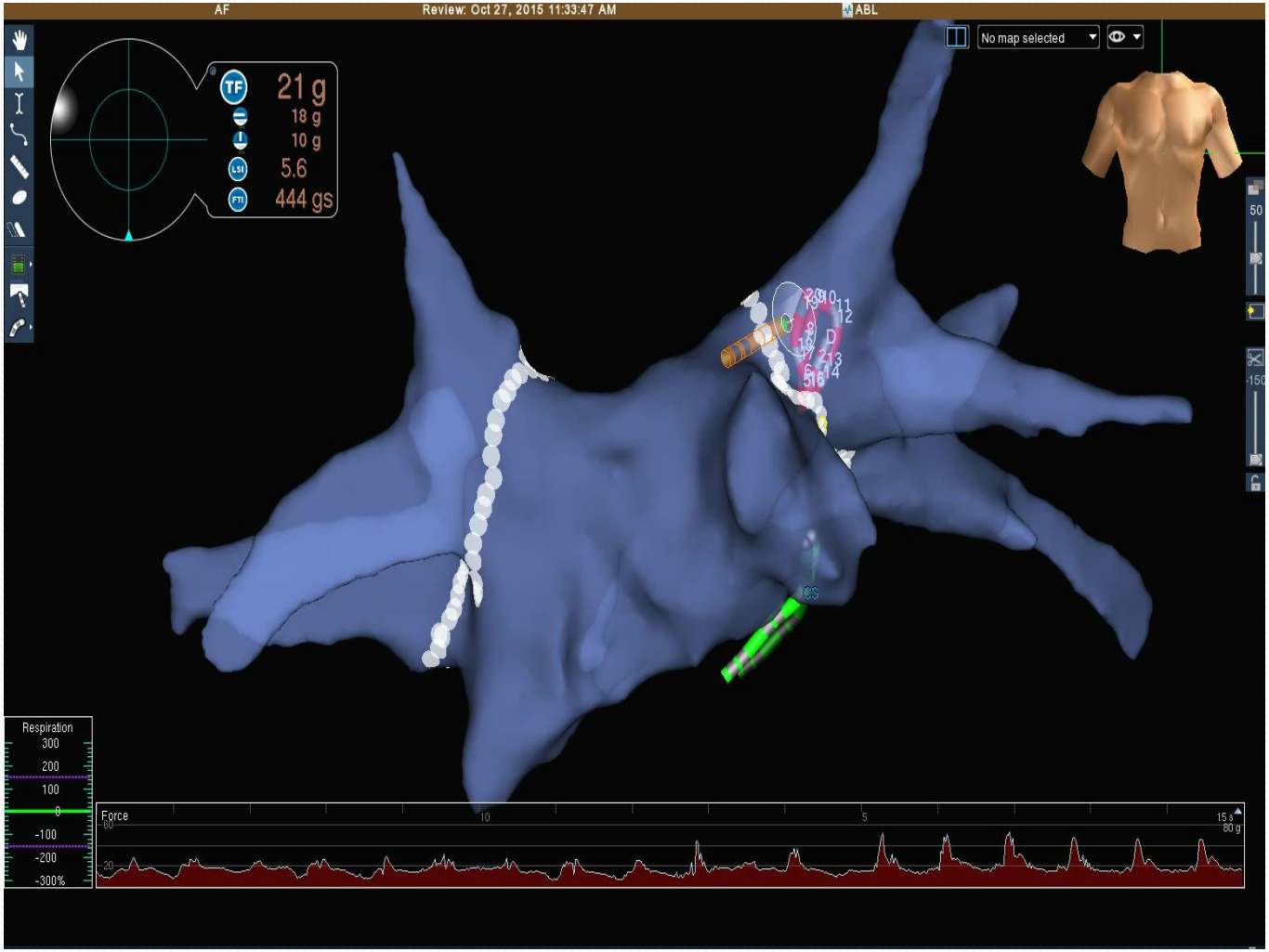
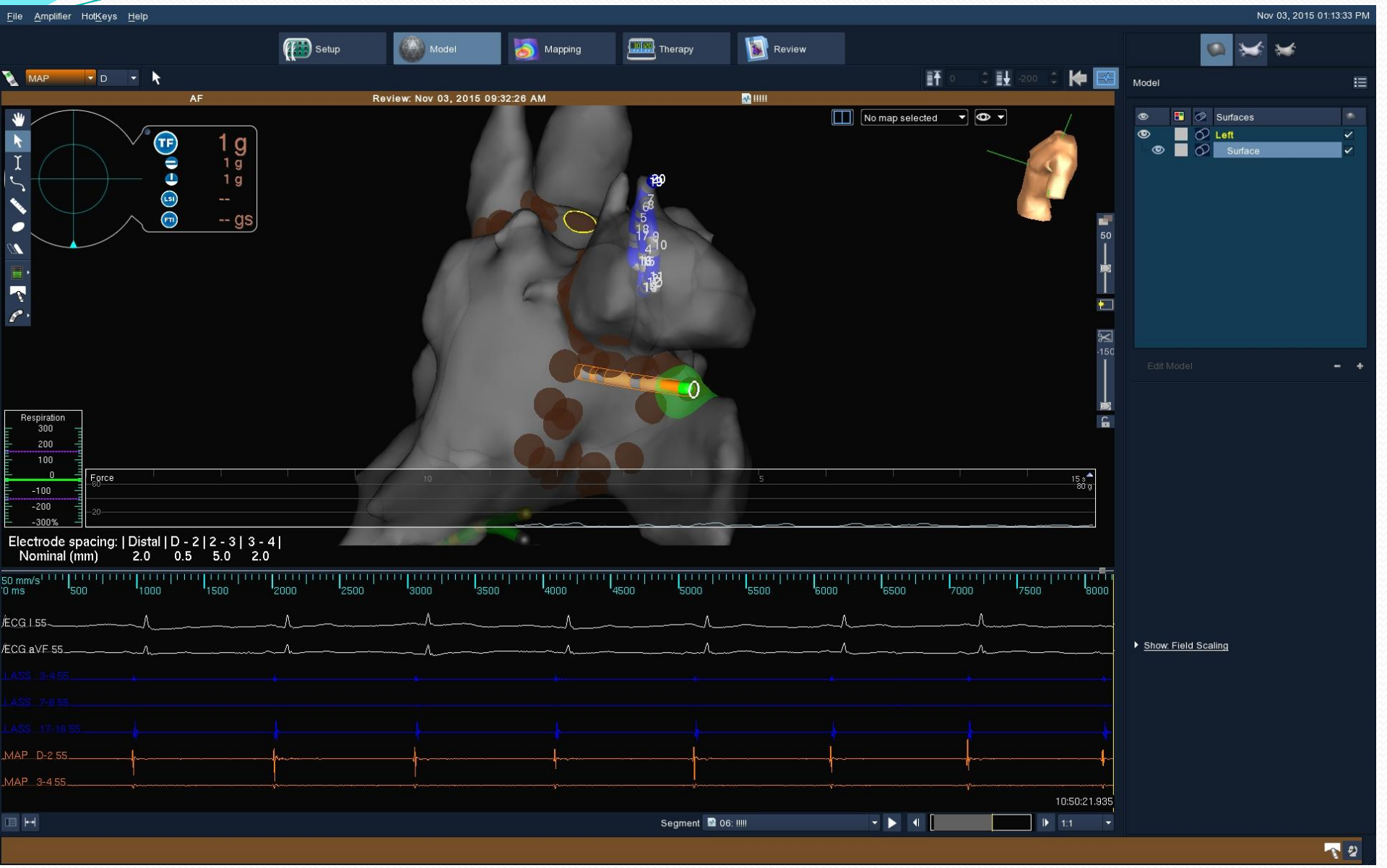
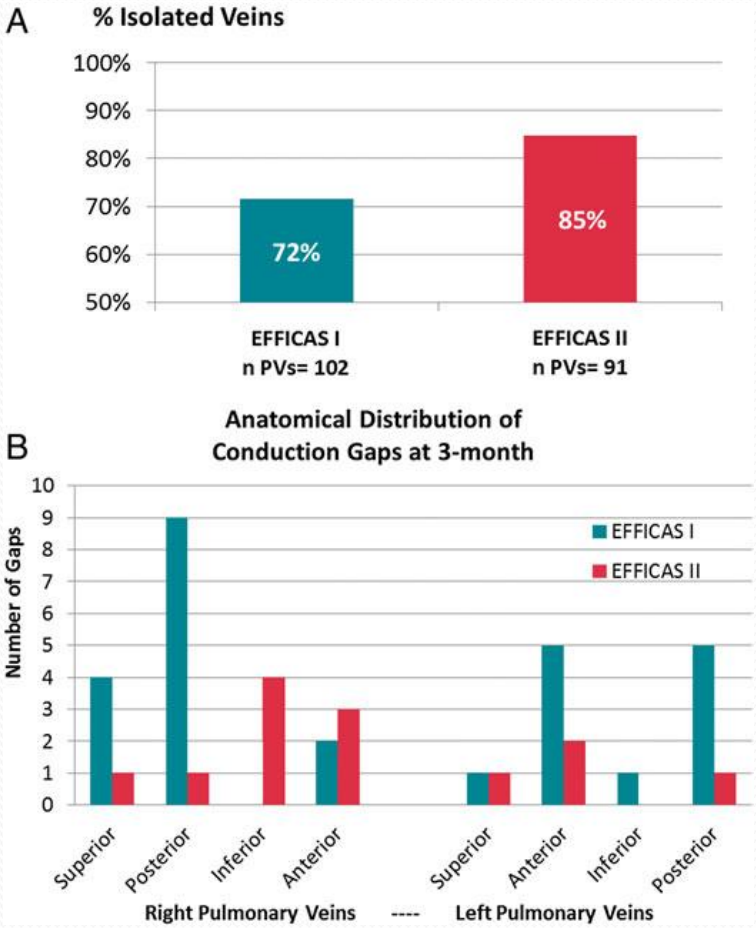
Setup
Model
Mapping
Therapy
Review
MAP
D
AF
Review: Nov 03, 2015 09:32:26 AM
ABLI
No map selected
TF 26 g
6 g
25 g
LSI 6.3
FTI 542 gs
Respiration
300
200
100
0
-100
-200
-300%
Force
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |
Nominal (mm) 2.0 0.5 5.0 2.0
50 mm/s
0 ms
500
1000
1500
2000
2500
3000
3500
4000
4500
5000
5500
6000
6500
7000
7500
8000
ECG I 55
ECG aVF 55
LASS 3-4 62
LASS 7-8 62
LASS 17-18 62
MAP D-2 55
MAP 3-4 55
11:10:03.919
Segment 15: ABLI
1:1
Model
Surfaces
Left
Surface
Edit Model
Show Field Scaling


AF
Review: Oct 27, 2015 11:33:47 AM
ABL
No map selected
TF
21 g
18 g
10 g
LSI
5.6
FTI
444 gs
Respiration
300
200
100
0
-100
-200
-300%
Force
60
20
10
5
15 s
80 g
50
150

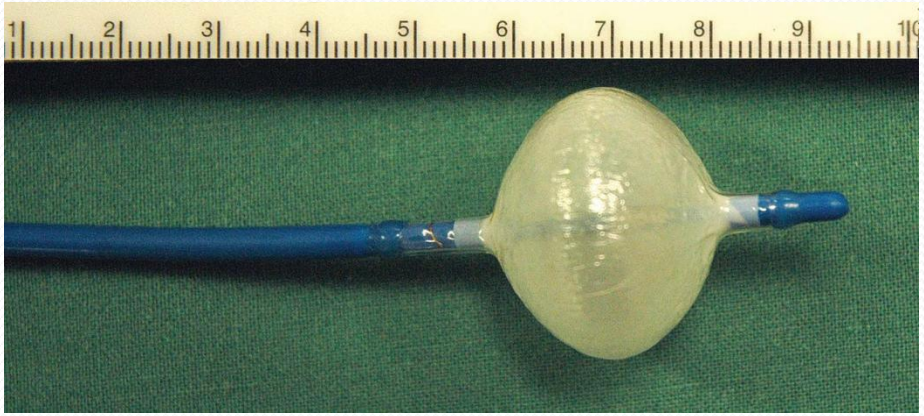

File Amplifier HotKeys Help
Nov 03, 2015 01:13:33 PM
Setup
Model
Mapping
Therapy
Review
MAP
D
AF
Review: Nov 03, 2015 09:32:26 AM
No map selected
TF
1 g
1 g
1 g
LSI
--
FTI
-- gs
Model
Surfaces
Left
Surface
Edit Model
Respiration
300
200
100
0
-100
-200
-300%
Force
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |
Nominal (mm) 2.0 0.5 5.0 2.0
50 mm/s
0 ms
ECG I 55
ECG aVF 55
LASS 3-4 55
LASS 7-8 55
LASS 17-18 55
MAP D-2 55
MAP 3-4 55
Show: Field Scaling
10:50:21.935
Segment
06:
1:1

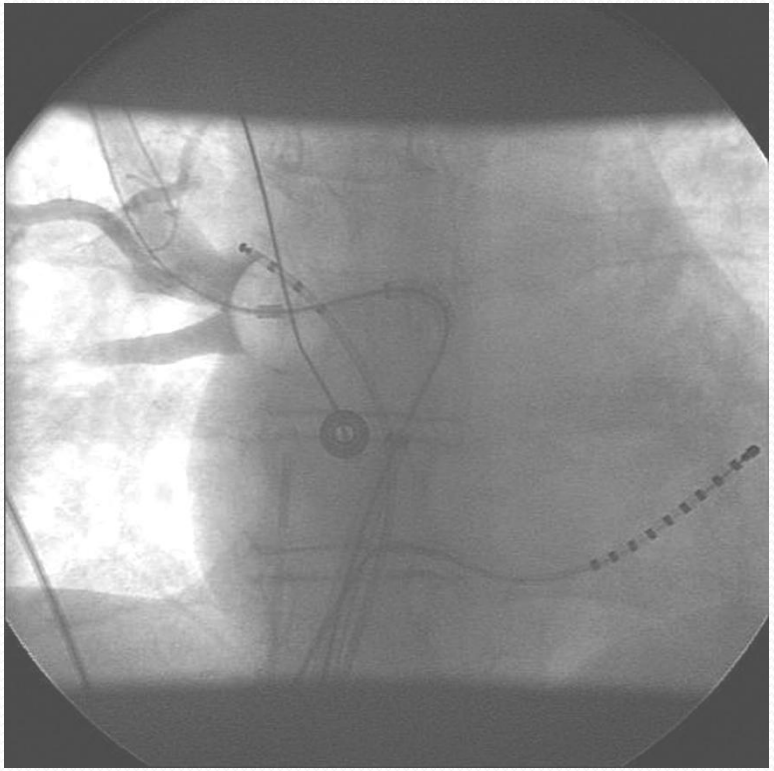
Contact force

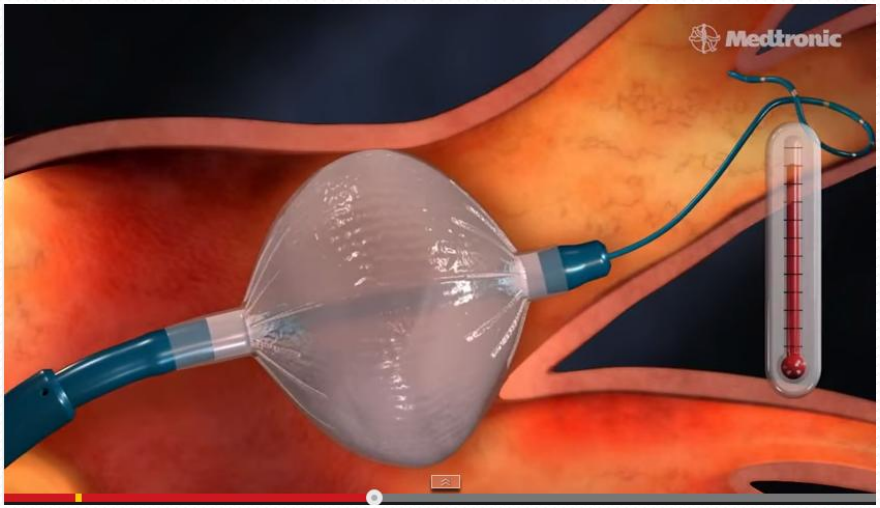


Dataset	No. of Pts	12-Month Success (AF/AT-free)
SMART-AF (≥80% time within preselected contact force range)	51	81%
SMART-AF (<80% time within preselected contact force range)	57	66%
Non Force-Sensing Open-Irrigated Catheter*	106	66%

Cryobaloon







Cryoballoon Versus Open Irrigated Radiofrequency Ablation in Patients With Paroxysmal Atrial Fibrillation

The Prospective, Randomized, Controlled, Noninferiority FreezeAF Study

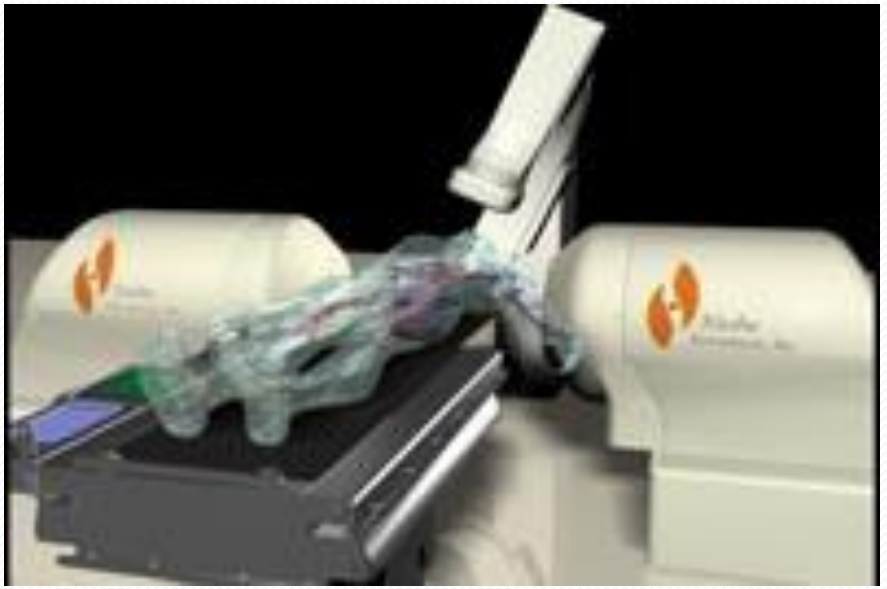
Armin Luik, MD; Andrea Radzewitz, PsyD; Meinhard Kieser, ScD; Marlene Walter; Peter Bramlage, MD; Patrick Hörmann, MD; Kerstin Schmidt, MD; Nicolas Horn, MD; Maria Brinkmeier-Theofanopoulou, MD; Kevin Kunzmann, MSc; Tobias Riexinger, MD; Gerhard Schymik, MD; Matthias Merkel, MD; Claus Schmitt, MD

		RF	CB	RD (95% CI)*	*P* Value*
ITT population					
At 6 mo	Combined end point†	99/157 (0.631)	98/153 (0.641)	0.010 (–0.097 to 0.116)	0.002
At 12 mo	Combined end point‡	104/147 (0.707)	106/144 (0.736)	0.029 (–0.074 to 0.132)	<0.001
	Only single procedure	90/147 (0.612)	87/144 (0.604)	…	…
PP population					
At 6 mo	Combined end point	99/154 (0.643)	98/150 (0.653)	0.010 (–0.096 to 0.117)	0.002
At 12 mo	Combined end point	103/141 (0.730)	105/141 (0.745)	0.014 (–0.089 to 0.117)	<0.001

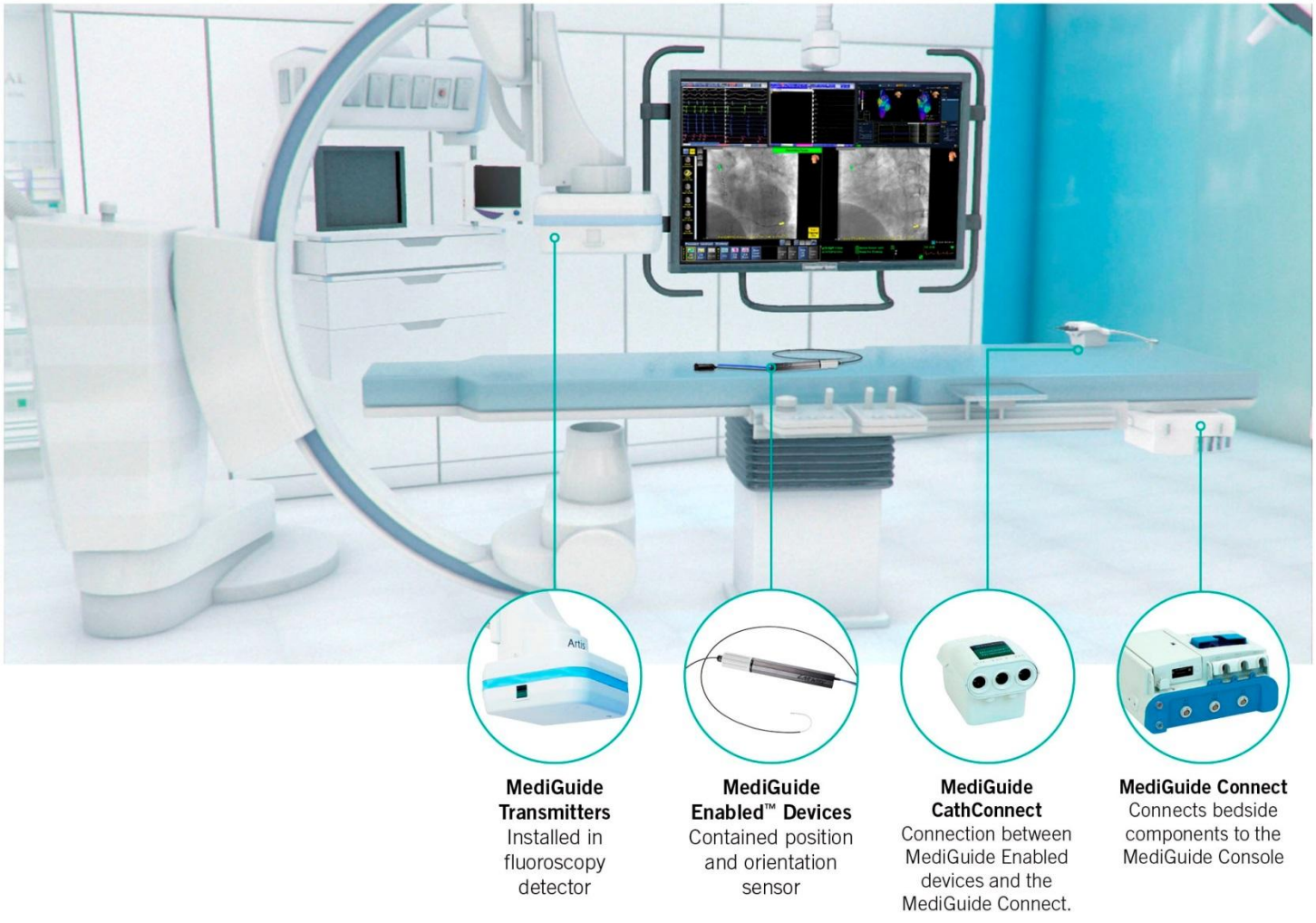
Table 7. Number of Patients with Periprocedural Complications During the Index Procedure

	Total (n=315), n (%)	RF (n=159), n (%)	CB (n=156), n (%)	*P* Value
Vascular	13 (4.1)	5 (3.1)	8 (5.1)	0.372
Major events	9	3	6	
Minor events	4	2	2	
Pericardial effusion	5 (1.6)	3 (1.9)	2 (1.3)	0.683
Major events	2	0	2	
Minor events	3	3	0	
PV stenosis	0	0	0	NA
Major events	0	0	0	
Minor events	0	0	0	
Phrenic nerve palsy	9 (2.9)	0 (0)	9 (5.8)	0.002
Major events	3	0	3	
Minor events	6	0	6	
TIA/stroke	0	0	0	NA
Total	27 (8.6)	8 (5.0)	19 (12.2)	0.022
Major events	14 (4.4)	3 (1.9)	11 (7.1)	
Minor events	13 (4.1)	5 (3.1)	8 (5.1)	

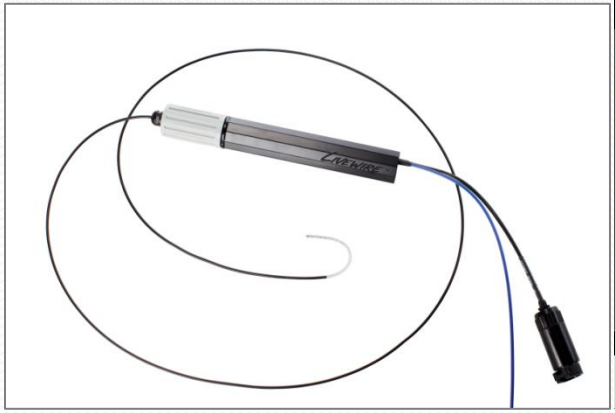
STEREOTAXIS

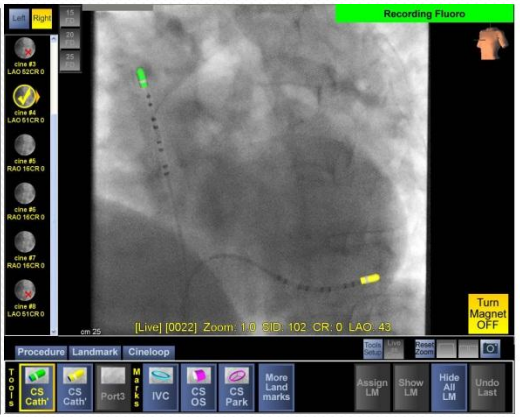


Mediguide


Artis
MediGuide Transmitters
Installed in fluoroscopy detector
MediGuide Enabled™ Devices
Contained position and orientation sensor
MediGuide CathConnect
Connection between MediGuide Enabled devices and the MediGuide Connect.
MediGuide Connect
Connects bedside components to the MediGuide Console

Mediguide



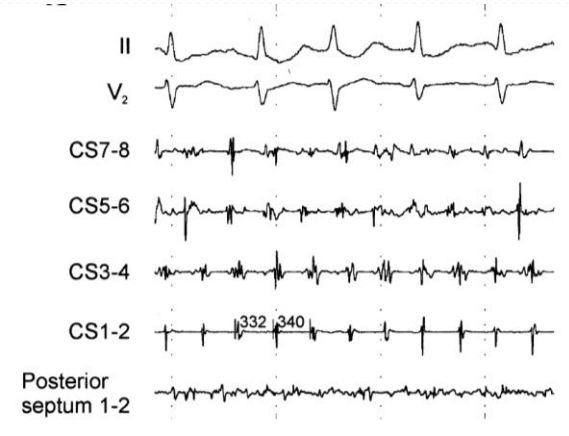

Recording Fluoro
Turn Magnet OFF
[Live] [0022] Zoom: 1.0 SID: 102 CR: 0 LAO: 43
Procedure
Landmark
Cineloop
CS Cath'
CS Cath'
Port3
IVC
CS OS
CS Park
More Land marks
Assign LM
Show LM
Hide All LM
Undo Last

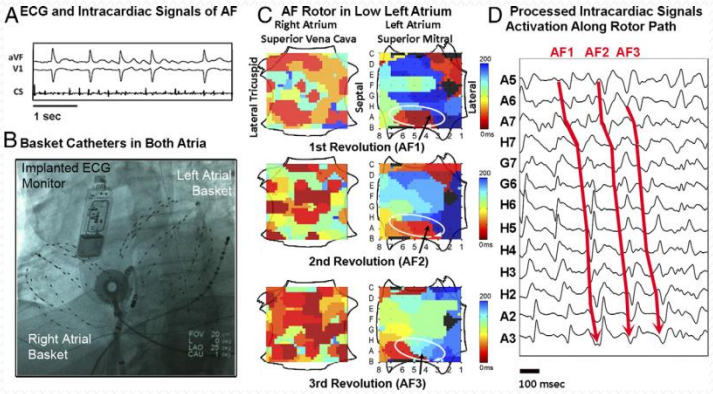

[Cine #4] [0008] Zoom: 1.0 SID: 104 CR: 0 LAO: 51
ST. JUDE MEDICAL
gCS-G@P-1:Valid
gCS-Y@P-2:Valid
Motion Sensor: valid
Ready For Cineloop
107 BPM

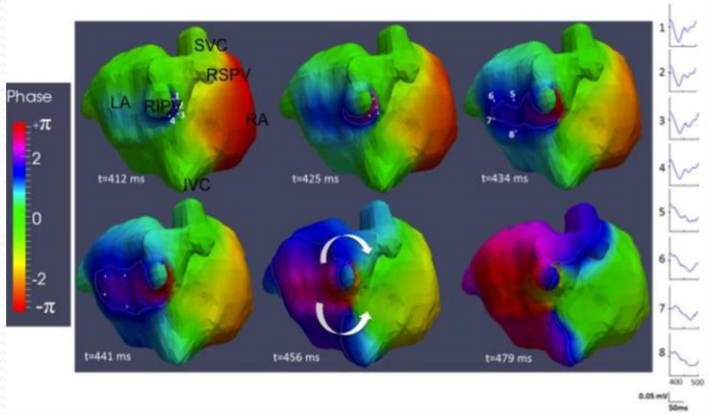
Mediguide

Εμμένουσα κολπική μαρμαρυγή

Γραμμικές βλάβες, CAFÉ, Rotors, Driver domains







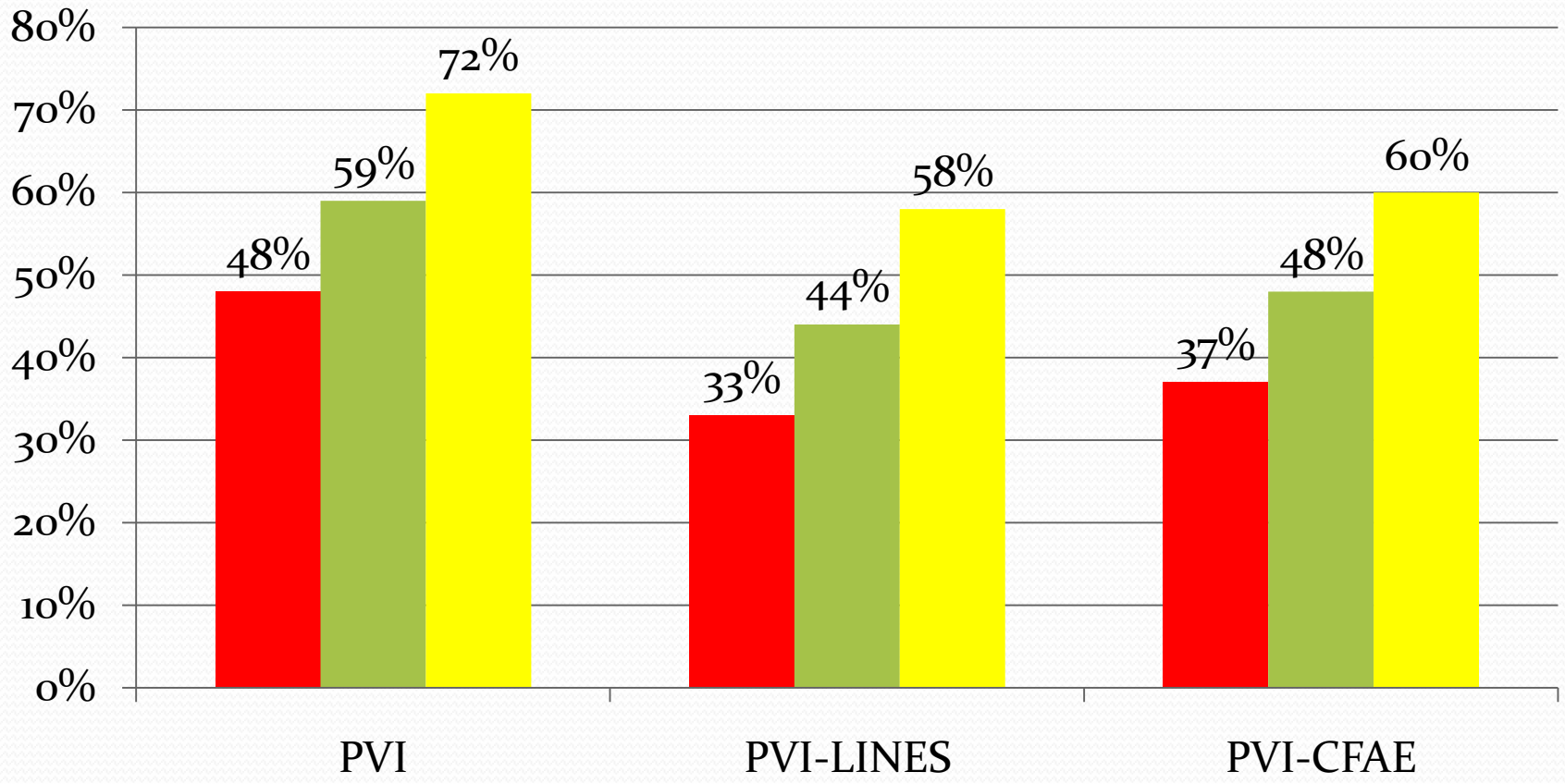
Ανασκόπηση, Brooks, AG Heart Rhythm 2010

	ΜΙΑ ΕΠΕΜΒΑΣΗ	ΠΟΛΛΑΠΛΕΣ ΕΠΕΜΒΑΣΕΙΣ	+ΦΑΡΜΑΚΑ
PVI	21-22%	37-43%	54%
PVA	37-56%	59%	77%
PVA+ΓΡΑΜΜ. ΒΛΑΒΕΣ	11-74%	17-74%	28-87%
PVI+ΟΤ ΑΠΟΜΟΝΩΣΗ	42-50%	60-63%	88%
CFAE	24-63%	52-77%	
PVI+CFAE	36-68%	60-80%	
STEPWISE	38-62%	70-88%	84-90%
ΣΥΝΟΛΙΚΑ	47%	65%	79%

STAR AF 2

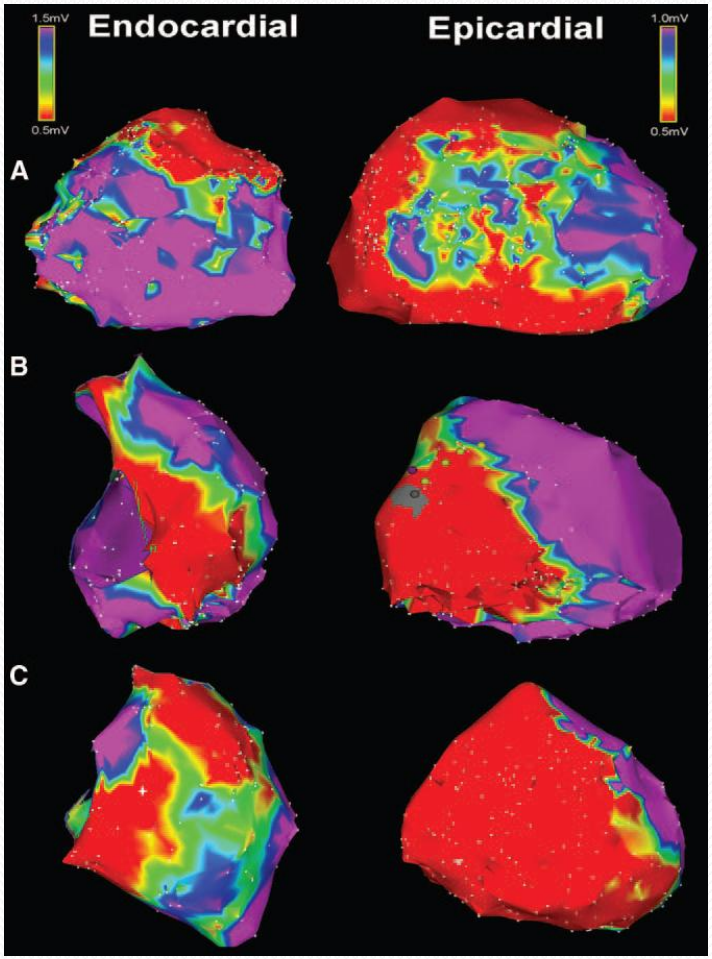
Verma, N Engl J Med 2015

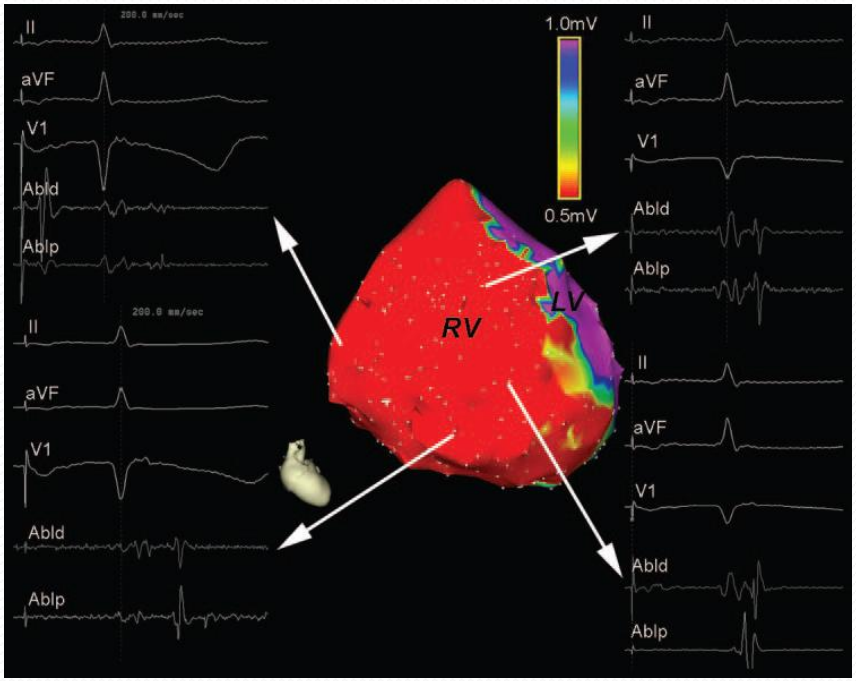
ελεύθεροι υποτροπής ΚΜ χωρίς αντιαρρυθμικά μετά 1 επέμβαση ή με αντιαρρυθμικά μετά 1 ή 2 επεμβασεις



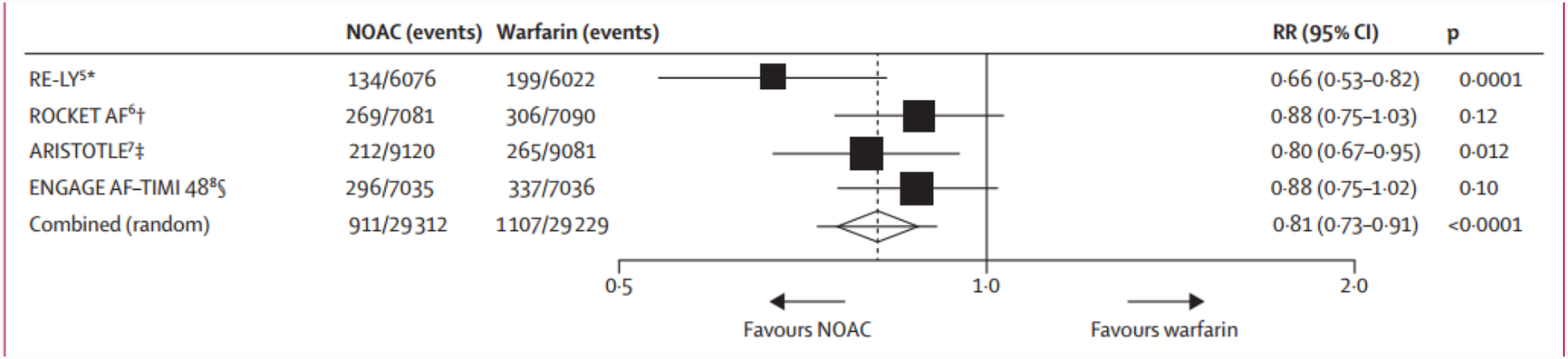
P=NS

ΕΠΙΚΑΡΔΙΑΚΟ ABLATION





Νεώτερα αντιπηκτικά



Idarucizumab N Engl J Med 2015

Idarucizumab for Dabigatran Reversal

Charles V. Pollack, Jr., M.D., Paul A. Reilly, Ph.D., John Eikelboom, M.B., B.S., Stephan Glund, Ph.D., Peter Verhamme, M.D., Richard A. Bernstein, M.D., Ph.D., Robert Dubiel, Pharm.D., Menno V. Huisman, M.D., Ph.D., Elaine M. Hylek, M.D., Pieter W. Kamphuisen, M.D., Ph.D., Jörg Kreuzer, M.D., Jerrold H. Levy, M.D., Frank W. Sellke, M.D., Joachim Stangier, Ph.D., Thorsten Steiner, M.D., M.M.E., Bushi Wang, Ph.D., Chak-Wah Kam, M.D., and Jeffrey I. Weitz, M.D.

N Engl J Med 2015; 373:511-520 | August 6, 2015 | DOI: 10.1056/NEJMoa1502000

FDA Approves Praxbind

FDA Approves Praxbind (idarucizumab) as a Reversal Agent for the Anticoagulant Pradaxa

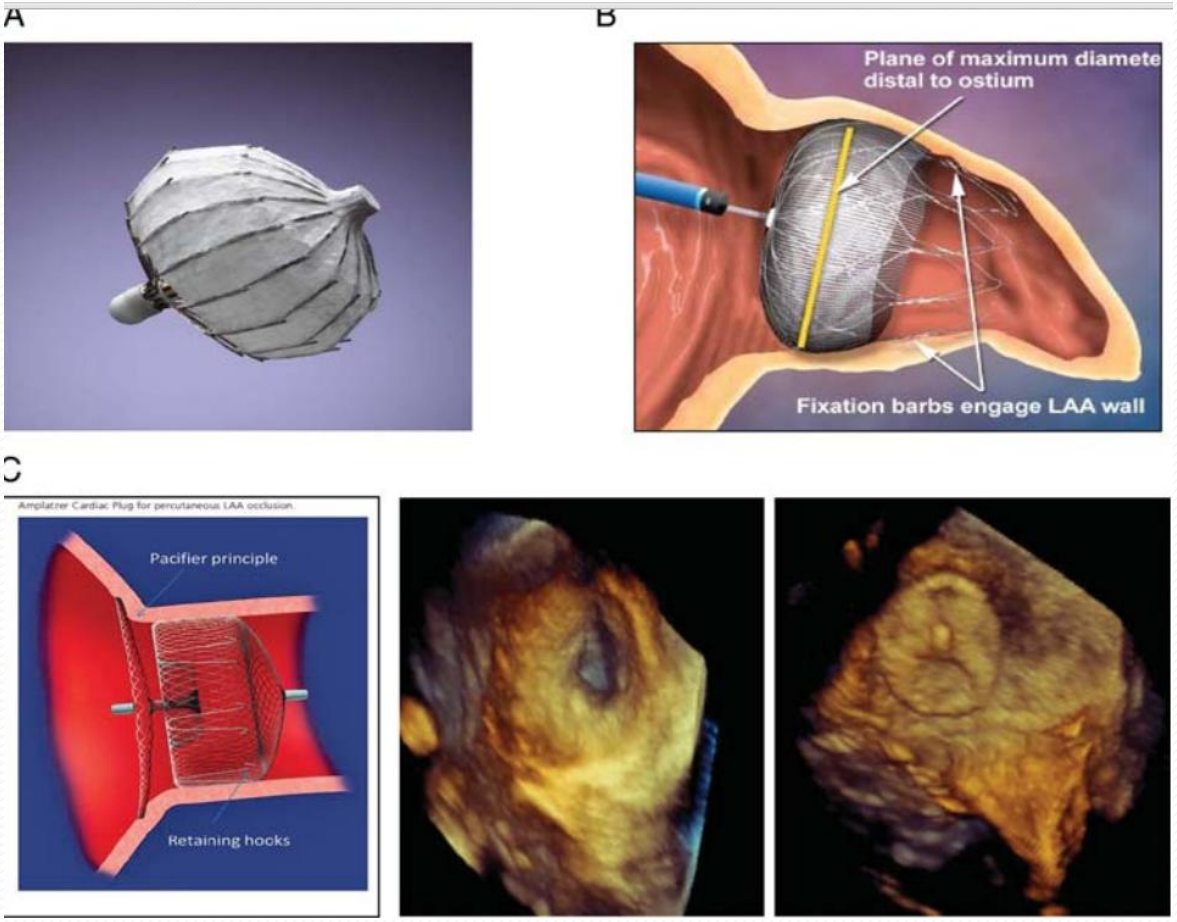
October 16, 2015 -- The U.S. Food and Drug Administration today granted accelerated approval to Praxbind (idarucizumab) for use in patients who are taking the anticoagulant Pradaxa (dabigatran) during emergency situations when there is a need to reverse Pradaxa's blood-thinning effects.

EMA Recommends Approval of Idarucizumab (*Praxbind*), a Dabigatran-Specific Antidote

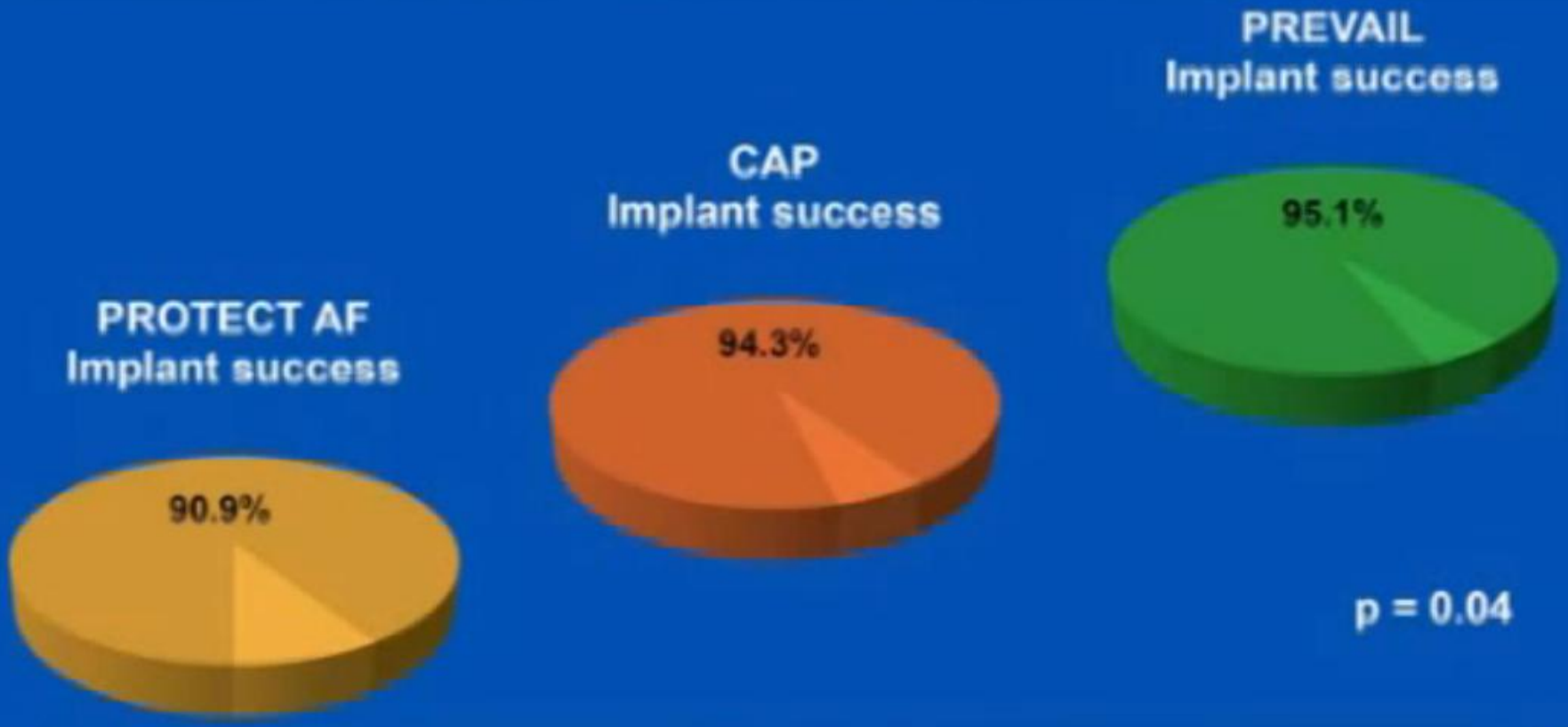
Michael O'Riordan

Disclosures | September 25, 2015

Διαδερμική σύγκλειση του ωτίου του αριστερού κόλπου

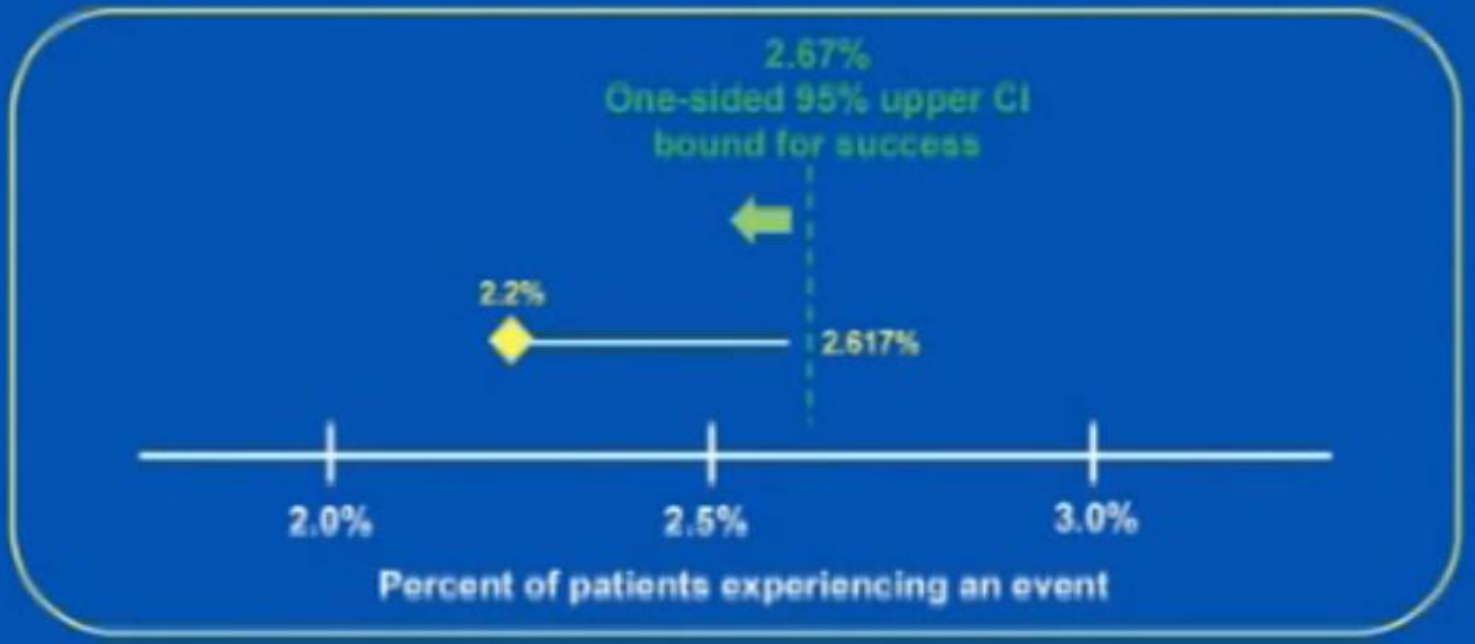


Procedure Implant Success



Implant success defined as deployment and release of the device into the left atrial appendage

First Primary Endpoint
Acute (7-day) Procedural Safety

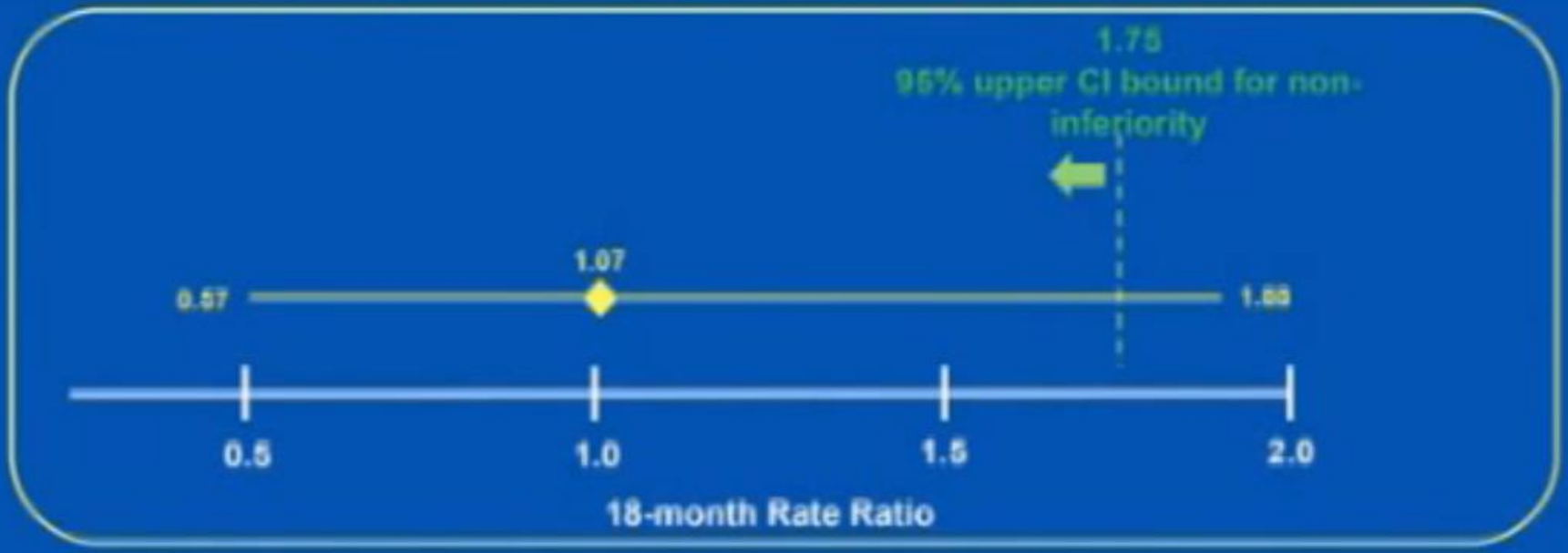


- 6 events in device group = 2.2% (6/269)
- Pre-specified criterion met for first primary endpoint (95% Upper confidence bound < 2.67%)
  - 95% CI = 2.618%

Results are preliminary; final validation not yet complete

Death, ischemic stroke, SE and procedure or device related complications requiring major CV or endovasc intervention

Second Primary Endpoint
Composite 18-month Efficacy



- Similar 18-month event rates in both control and device groups = 0.064
- Upper 95% CI bound slightly higher than allowed to meet success criterion (<1.75)
  - Limited number of patients with follow-up through 18 months thus far (Control = 30 pts, Device = 58 pts)

Results are preliminary; final validation not yet complete

MAYO

ΓΟΝΙΔΙΑΚΟΣ ΕΛΕΓΧΟΣ ΓΙΑ ΔΙΑΓΝΩΣΗ

2. Long QT Syndrome (LQTS) *Expert Consensus Recommendations on **LQTS Diagnosis***

1. LQTS is diagnosed:
   a. In the presence of an LQTS risk score ≥3.5 in the absence of a secondary cause for QT prolongation *and/or*
   b. In the presence of an unequivocally pathogenic mutation in one of the LQTS genes *or*

4. Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) *Expert Consensus Recommendations on CPVT Diagnosis*

1. CPVT ***is diagnosed*** in the presence of a structurally normal heart, normal ECG, and unexplained exercise or catecholamine-induced bidirectional VT or polymorphic ventricular premature beats or VT in an individual <40 years of age.
2. CPVT ***is diagnosed*** in patients (index case or family member) who have a pathogenic mutation.

5. Short QT Syndrome (SQTS) *Expert Consensus Recommendations on **Short QT Syndrome Diagnosis***

1. SQTS ***is diagnosed*** in the presence of a QTc ≤330 ms.
2. SQTS ***can be diagnosed*** in the presence of a QTc <360 ms and one or more of the following: a pathogenic mutation, family history of SQTS, family history of sudden death at age ≤40, survival of a VT/VF episode in the absence of heart disease.

*Expert Consensus Recommendations on **Idiopathic Ventricular Fibrillation Evaluation***

Class IIa 1. Genetic testing in IVF ***can be useful*** when there is a suspicion of a specific genetic disease following clinical evaluation of the IVF patient and/or family members.

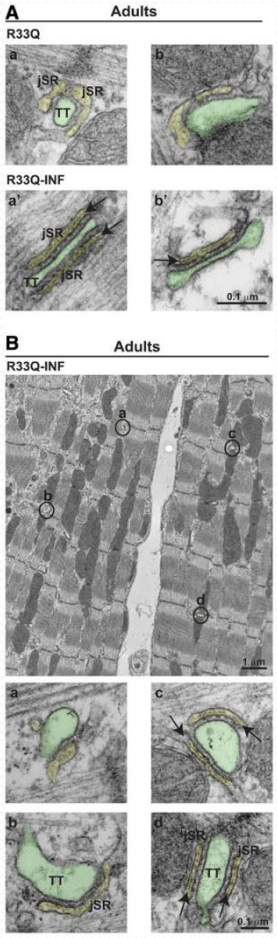
*Expert Consensus Recommendations on **Sudden Unexplained Death Syndrome Evaluation***

Class I
1. It **is recommended** that personal/family history and circumstances of the sudden death are collected for all SUDS victims.
2. It **is recommended** that all sudden death victims diagnosed as SUDS undergo expert cardiac pathology to rule out the presence of microscopic indicators of structural heart disease.
3. Collection of blood and/or suitable tissue for molecular autopsy/postmortem genetic testing **is recommended** in all SUDS victims.

Class IIa
4. An arrhythmia syndrome focused molecular autopsy/postmortem genetic testing **can be useful** for all SUDS victims.

ΓΟΝΙΔΙΑΚΗ ΘΕΡΑΠΕΙΑ Denegri, Circ 2014

- Μεταφορά με ιό του γονιδίου CASQ2 in vivo και in vitro σε καρδιά μυών με μετάλλαξη CASQ2 (πειραματικό μοντέλο CPVT)
- Φυσιολογική λειτουργια CASQ2 > 1 έτος
- Απουσία αρρυθμιών



ΣΥΜΠΕΡΑΣΜΑΤΑ

- Οι εξελίξεις κατά τα τελευταία έτη σ'όλους τους τομείς της ηλεκτροφυσιολογίας είναι αλματώδεις
- Η εφαρμογή της υψηλής αυτής τεχνολογίας σέ κοινωνίες με ένα ολοένα γηράσκοντα πληθυσμό συνεπάγεται ένα τεράστιο κόστος που ακόμα και για τις πιο πλούσιες καθίσταται δυσβάστακτο
- Αυτό ισχύει κατά μείζονα λόγο σε χώρες που διέρχονται κρίση, οι οποίες αναγκαστικά πρέπει να θεσπίσουν περιορισμούς και κριτήρια εφαρμογής των θεραπειών αυτών