# Patient Safety: the optimal lead body design


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Advances in Cardiac Arrhythmias

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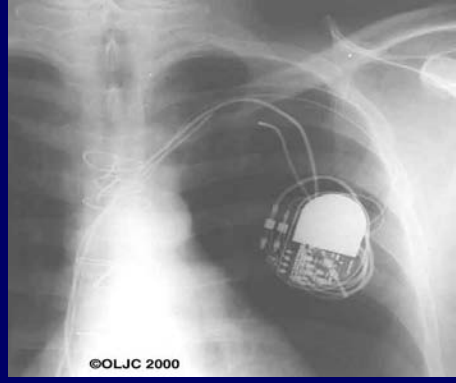
# Lead Malfunction

- In several decades of experience with implanted devices, leads have shown to be the weakest point in the system

- ICD leads in particular are showing worring failure rates and their reliability has become one of the major 'hot topic' of the moment among CRM community

# Lead Malfunction




**Incidence:**

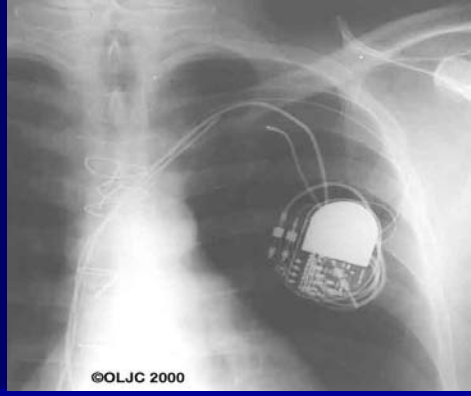
Pacing leads → up to 28% after 10 years[1]
ICD leads → up to 40% after 10 years[2]
CS leads → about 10% after 5 years[3]

**Depending on:**

- Definition of lead malfunction
- Performance of different lead models
- Patient characteristic
- Physician implantation techniques

1 Fortesque, et al, Heart Rhythm 2004 1:150-159;
2 Maisel, et al. Circulation 2008;117:2721-2723;
3 Lau *PACE 2009; 32:1466-1477*

# Lead Malfunction
# Pacing vs ICD




**Pacing leads →** Malfunction up to 28% after 10 years

Definition of malfunction

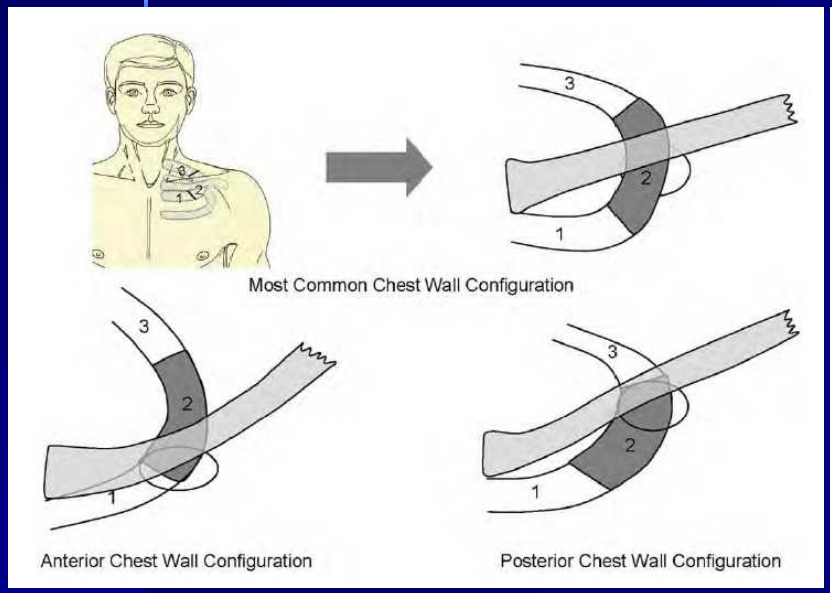
Different lead models
- SJM 1010T
- MDT 4004
- Telectronics Accufix

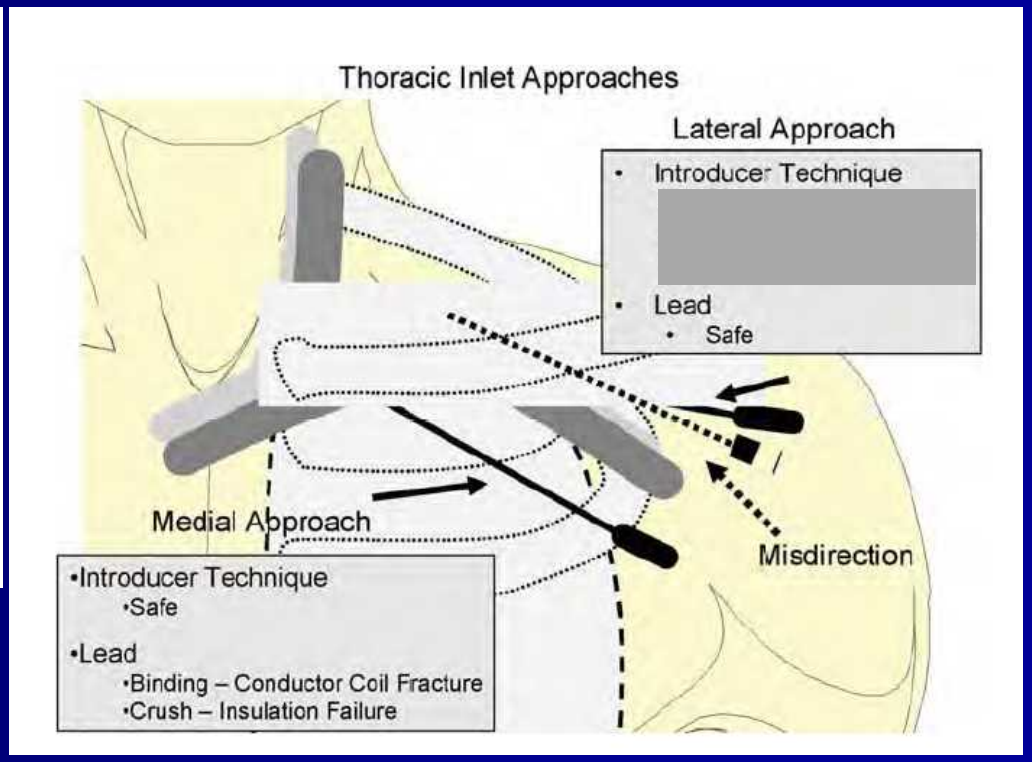
Patient characteristic
- Age
- Activity

Implant techniques

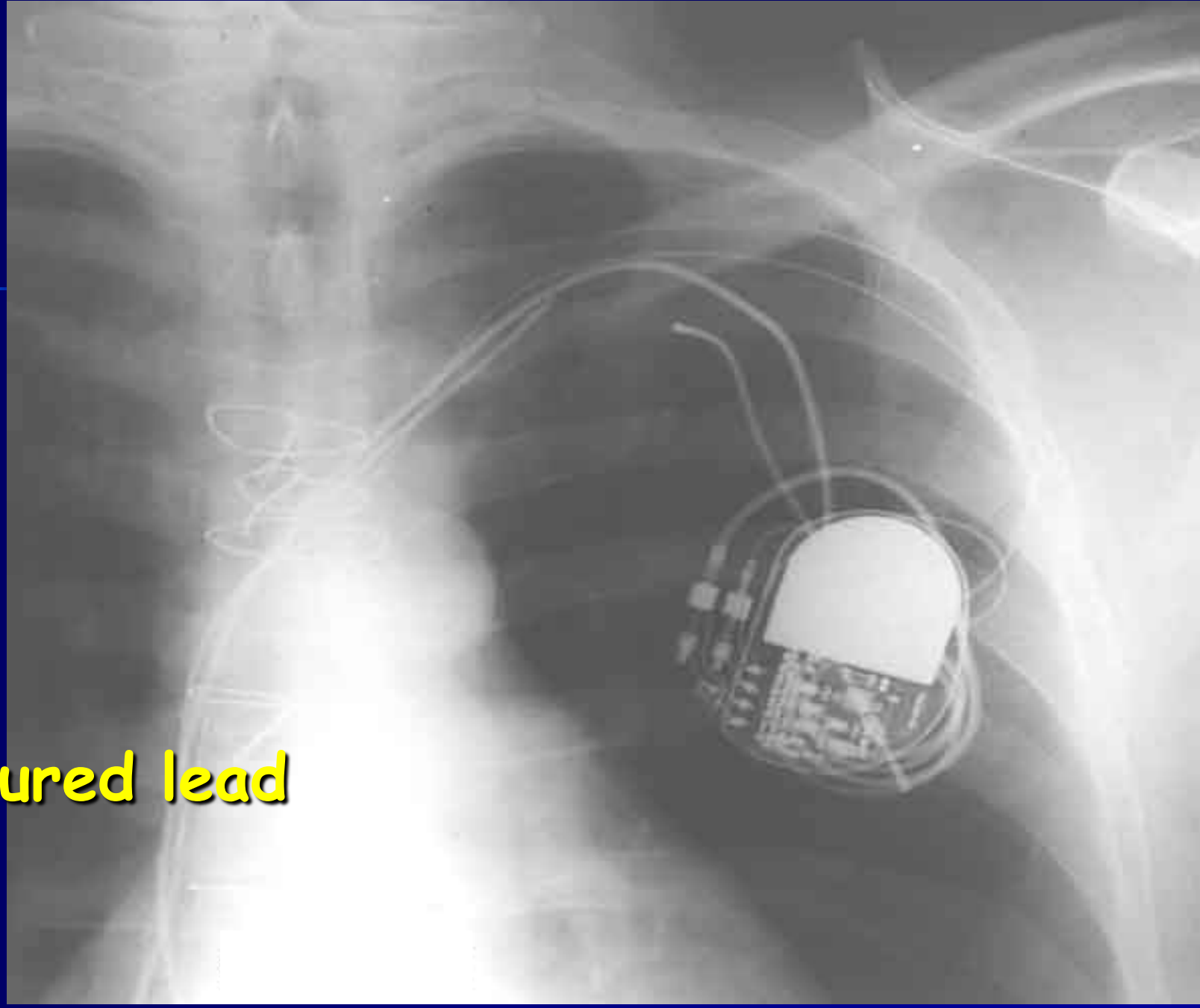
# Implant Technique

- Cefalic vein (use introducer)
- Extratoracic subclavian vein puncture



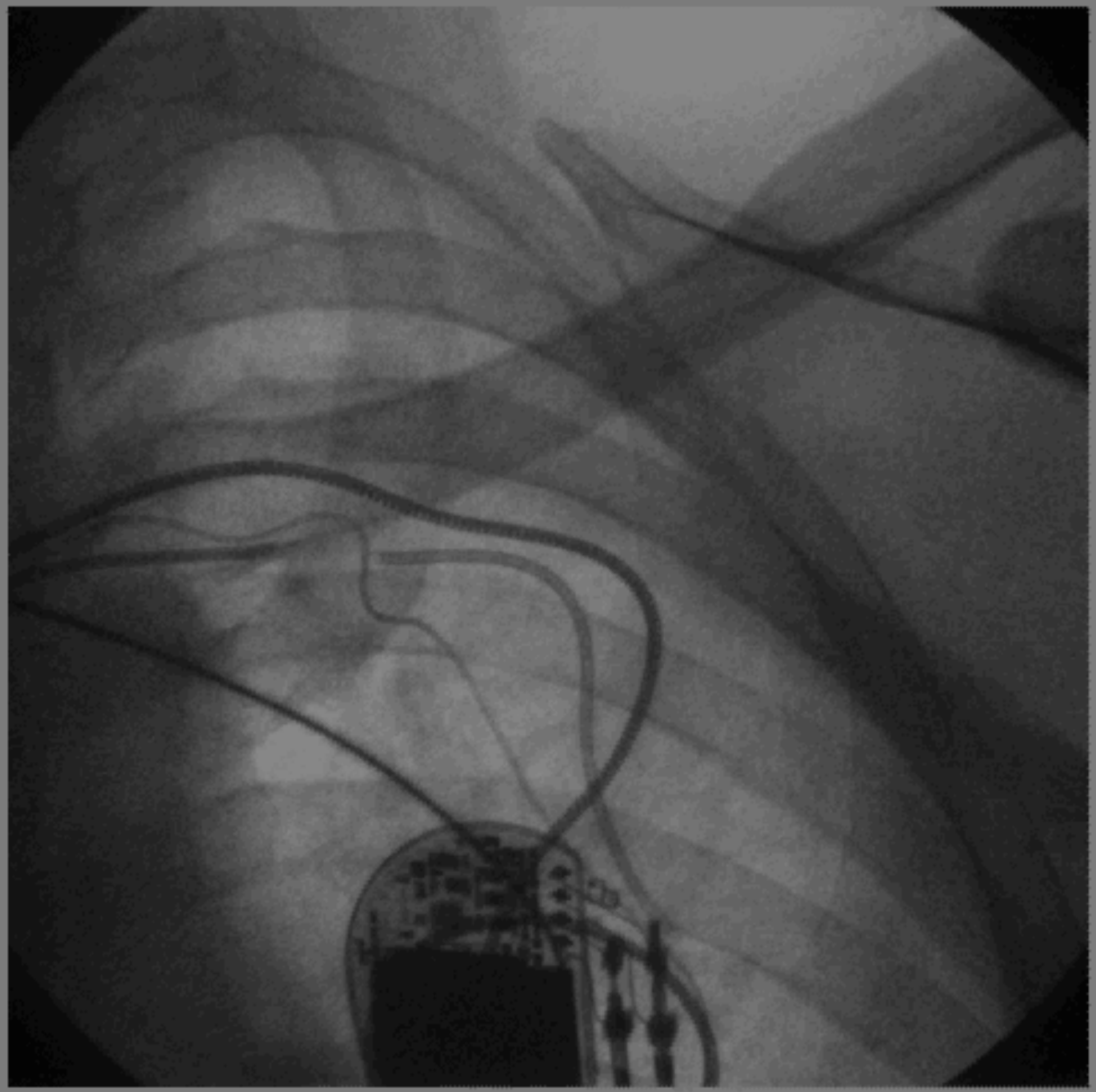

Byrd CL: **Managing Device-Related Complications and Transvenous Lead Extraction.** In *Clinical Cardiac Pacing, Defibrillation and Resynchronization Therapy.* Edited by Ellenbogen KA, Kay GN, Lau CP, Wilkoff BL. Philadelphia: WB Saunders Co.; 2007:855-930.



# Fractured lead

# Technique Failure

Courtesy of
Prof. B. Wilkoff



# Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

## Study Limitations

As all implants originated from a single implanting center, our observations and conclusions may not necessarily be generalizable. However, ICD implantation procedures were performed by surgeons who had >10 years of experience with pacemaker and defibrillator implants and performed >95% of all implantations and generator replacements.

About 95% of the leads were implanted with the subclavian technique. As subclavian puncture is known to have a higher lead complication rate, these results may not be extended to leads that are implanted via more desirable access routes such as the cephalic vein.

Because of the long implant duration, lead extraction was not performed routinely. Therefore, the precise cause of lead failure could not be clarified in detail. The reliability of the estimated lead survival rates is decreased because of inconsistent follow-up, loss of patients over time to death from heart failure, and other causes. The number of lead failures has presumably been underestimated.

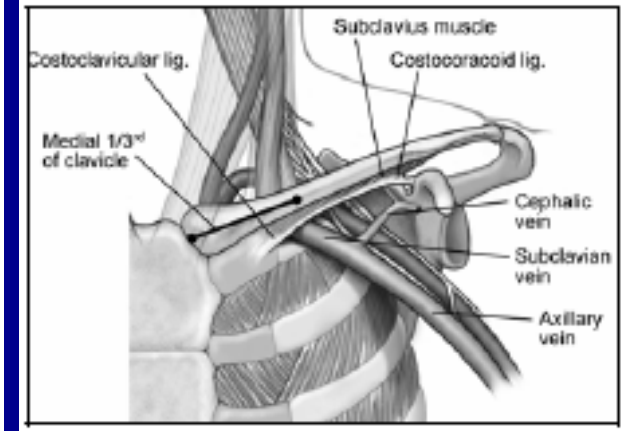
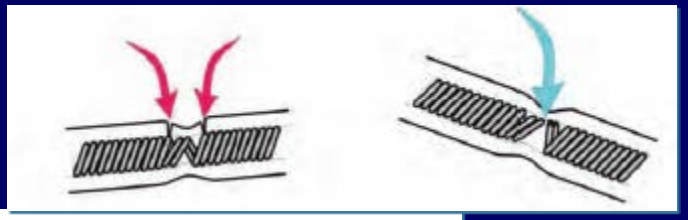
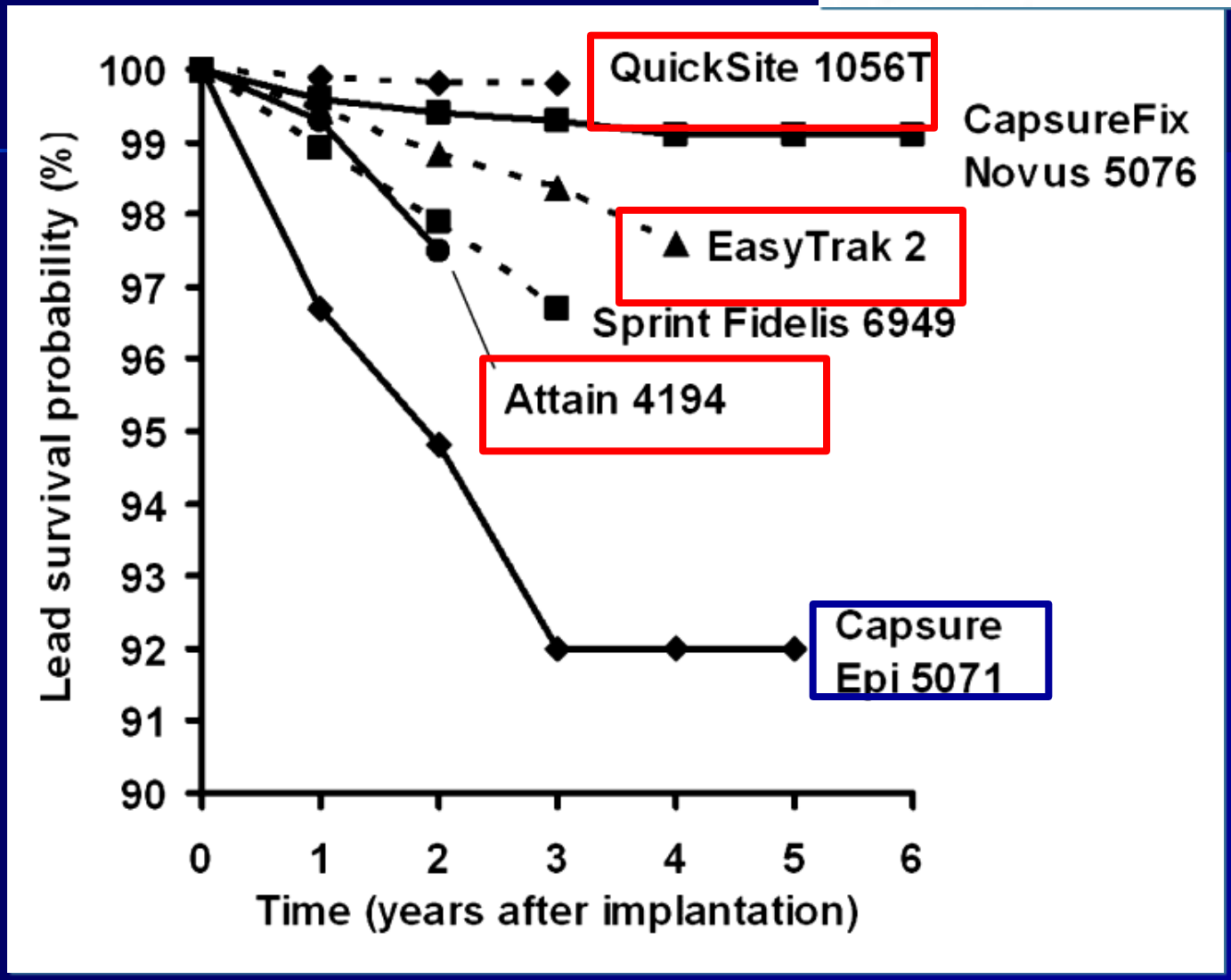



Figure 1. Common lead introduction sites.

Thomas Kleemann. (*Circulation*. 2007;115:2474-2480.)

# LV Lead Failures






Lau EW, PACE 2009; 32:1466-1477

# Lead Malfunction

## Inappropriate implantable cardioverter-defibrillator discharges unrelated to supraventricular tachyarrhythmias

Europace (2006) 8, 863–869

Eraldo Occhetta*, Miriam Bortnik, Andrea Magnani, Gabriella Francalacci, and Paolo Marino

REVIEW

## Ventricular ov… implanted cardiac defibri…ons, and solutions

Lead malfunction is the most common long term complications

Europace (2007) 9, 1041–1047

T. Rauwolf*†, M. Guenther†, N. Hass, A. Schnabel, M. Bock, M.U. Braun, and R.H. Strasser

## Complications of Implantable Cardioverter Defibrillator Therapy in 440 Consecutive Patients

PETER ALTER,* STEFAN WALDHANS,† EVELINE PLACHTA,* RAINER MOOSDORF,† and WOLFRAM GRIMM*

From the *Department of Internal Medicine-Cardiology, and †Department of Cardiovascular Surgery, Philipps University of Marburg/Lahn, Marburg, Germany

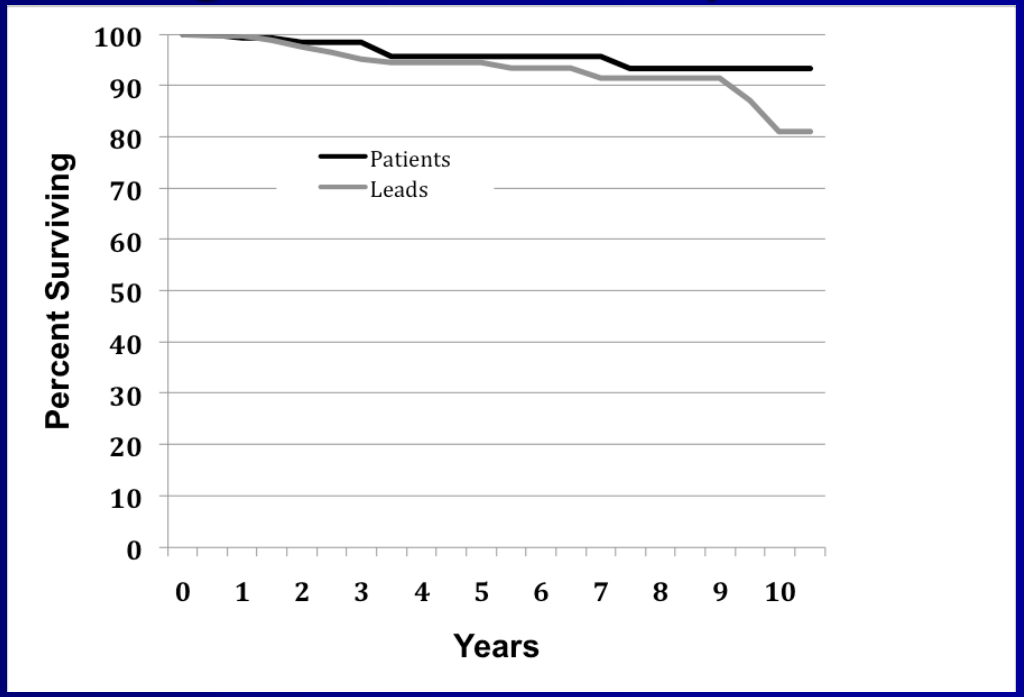
PACE 2005; 28:926–932

# Need for lead reliability

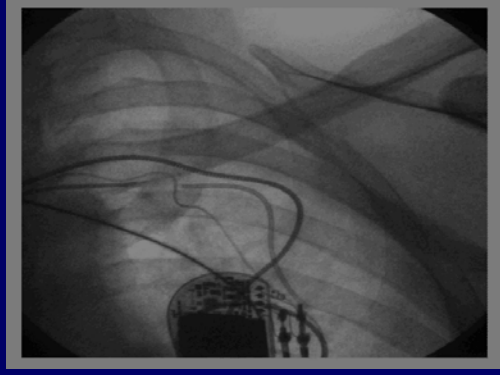
**As patients live longer and younger and more active patients get devices, there is an increasing need for leads with long-term reliability**

Hauser study – Survival of patients and high voltage implantable cardioverter-defibrillator leads.[2]

Hauser R, Maron BJ, Marine JE, et al. Safety and Efficacy of Transvenous High-Voltage Implantable Cardioverter-Defibrillator Leads in High-Risk Hypertrophic Cardiomyopathy Patients. Heart Rhythm Society. 2008;5:1517-1522.




# Need for lead reliability



- Literature reports values for inappropriate therapies due to lead failure up to 14% in pediatric patients [1-2]
- Up to 76% of failing ICD leads are reported to result in inappropriate therapies [3]


1- Berul CI et al, JACC Vol. 51, No. 17, 2008

2- Korte T. et al, PACE 2004; 27:924-932

3- Eckstein et al, Circulation 2008; 117:2727-2733


# Noise, Artifact, and Oversensing Related Inappropriate ICD Shock Evaluation: ALTITUDE NOISE Study


***Background:*** *Approximately 12–21% of implantable cardioverter defibrillator (ICD) patients receive inappropriate shocks. We sought to determine the incidence and causes of noise/artifact and oversensing (NAO) resulting in ICD shocks.*

***Methods:*** *A random sample of 2,000 patients who received ICD and cardiac resynchronization therapy defibrillator shocks and were followed by a remote monitoring system was included. Seven electrophysiologists analyzed stored electrograms from the 5,279 shock episodes. Episodes were adjudicated as appropriate or inappropriate shocks.*

***Results:*** *Of the 5,248 shock episodes with complete adjudication, 1,570 (30%) were judged to be inappropriate shocks. Of these 1,570, 134 (8.5%) were a result of NAO. The 134 NAO episodes were determined to be due to external noise in 76 (57%), lead connector-related in 37 (28%), muscle noise in 11 (8%), oversensing of atrium in seven (5%), T-wave oversensing in two (2%), and other noise in one (1%). The ICD shock itself resulted in a marked decrease in the level of noise in 60 of 134 (45%) NAO episodes, and the magnitude of this effect varied with the type of NAO (58% for external noise, 35% for*

*3). There was no significant difference in*

*)2 vs dedicated bipolar 9/140, P = 0.67).*

*the primary causes, while T-wave*

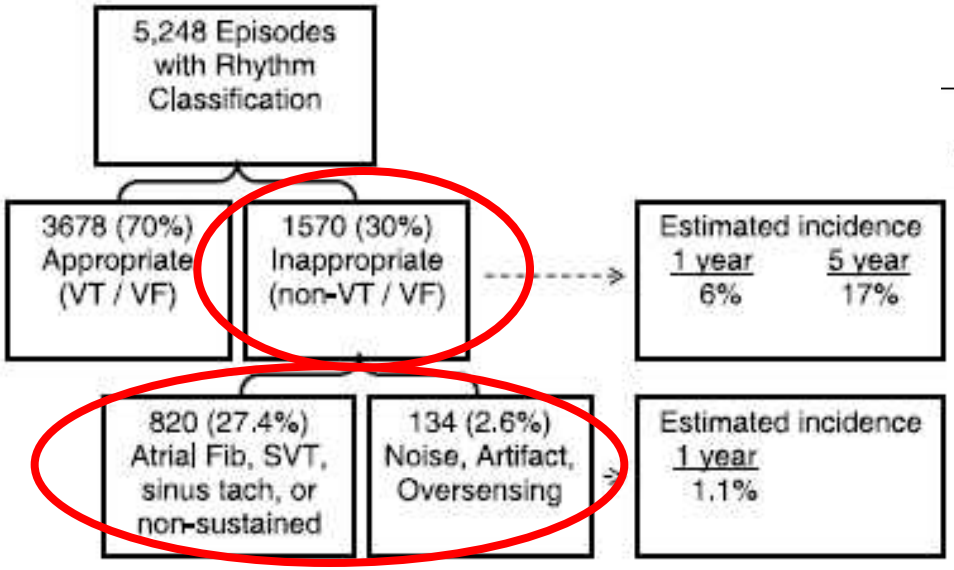
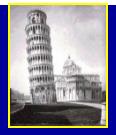




**Table II.**

Mechanism for Noise, Artifact, and Oversensing that Resulted in ICD Shocks

| Classification | Percent of NAO Episodes |
|---|---|
| External noise | 56.7% |
| Lead/Connector | 27.6% |
| Muscle noise | 8.2% |
| Ventricular lead oversensing of | 5.2% |
| T-wave oversensing | 1.5% |
| Other noise, oversensing | 0.7% |
| Total | 100.0% |

B.D. Powell et al, PACE 2012, in press



# Cost implications of defibrillator lead failures

**John D. Groarke[1,2]*, Una Buckley[2], Damien Collison[1], James O'Neill[2], Niall G. Mahon[2], and Brendan Foley[1]**

[1]Department of Cardiology, St James's Hospital, James's Street, Dublin 8, Ireland; and [2]Department of Cardiology, Mater Misericordiae University Hospital, Eccles Street, Dublin 7, Ireland

*Received 6 November 2011; accepted after revision 4 January 2012; online publish-ahead-of-print 14 February 2012*

**Aims** The prevalence of lead failures is increasing with a growing population of implantable cardioverter defibrillator (ICD) recipients. The cost of managing defibrillator lead failures requires investigation.

**Methods and results** A retrospective cohort study of patients requiring lead replacement for defibrillator lead failure was performed. Details pertaining to admissions were recorded. The cost per lead replacement was determined. Twenty-three patients {mean age [standard deviation (SD); range] = 56 (17; 18–83) years; 87% male} underwent lead replacement at a mean (SD; range) interval from implant of 3.0 (1.8; 0.9–9.0) years. The median (SD; range) length of hospital stay was 4.5 (8.6; 1–43) days. Procedure-related complications were recorded for three (13%) patients. Thirty days and 1-year mortality were 0 and 4% (1 of 23). The median (SD; range) cost per lead replacement was €7660 (€10 964; €1472–39 663). Bed day costs accounted for 54% of overall costs. Extraction of the failed lead by manual traction at time of lead replacement did not significantly increase costs. The median (SD; range) cost of lead replacement was higher in patients receiving a new ICD generator ($n = 6$), compared with patients retaining existing generators ($n = 17$): €23 394 (€5026; €17 266–31 245) vs. €4470 (€9080; €1472–39 663); $P = 0.005$. The median (SD; range) cost of lead replacement among patients who remained in hospital pending lead replacement ($n = 16$) was higher than for patients who underwent replacement on an emergent outpatient basis ($n = 7$): €8508 (€11 920; €1472–39 663) vs. €4372 (€7256; €1555–20 478); however, this observation was not statistically significant, $P = 0.21$.

**Conclusions** Defibrillator lead failures incur significant cost and are likely to undermine overall cost effectiveness of ICDs. Cost-effectiveness analyses of device therapy should include costs related to such complications.

**Keywords** Defibrillator lead fractures • Defibrillator lead failures • Cost implications of lead replacements • Lead revisions

# Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines

*Developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA)*

## HRS/ACC/AHA 2009

## Definitions

TABLE 1 Lead Performance Definitions

Lead Malfunction: Failure of a lead to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the lead. The intended performance of a lead refers to the intended use for which the lead is labeled or marketed (FDA Regulations 803.3(n)). Whenever possible, lead malfunction should be confirmed by laboratory analysis. Malfunctions do not include physician induced damage during the course of implanting, revising, or removing the lead. *Extrinsic malfunctions* are those caused by external factors (e.g., therapeutic radiation, excessive physical damage including subclavian crush and direct trauma to the device pocket, etc.) including, but not limited to, hazards that are listed in product labeling.

Lead Performance: A comprehensive assessment of lead quality, usability, freedom from failure (malfunction), and conformance to applicable labeling.

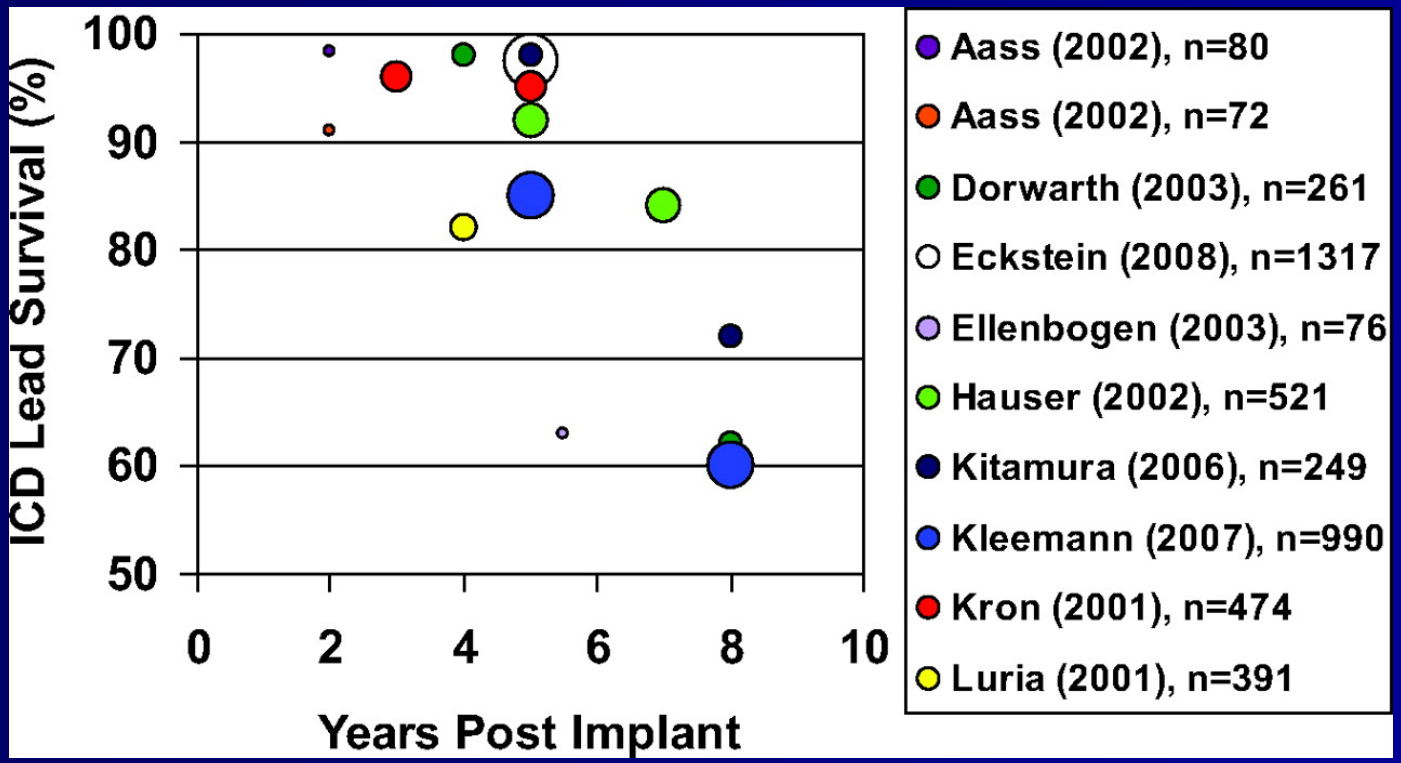
Lead Reliability: A measure of a lead to be free of specific structural and electrical failures, typically expressed at a given point in time or a failure rate per unit of time (e.g., failure rate per month).

Lead Removed from Service Unrelated to Malfunction: A lead that is removed from service (surgical abandonment, extraction, or programmed off) for reasons not related to failure: infection, device upgrade (pacemaker to ICD, for example), pacer/lead incompatibility, cardiac transplantation, mode change not due to lead failure, patient death unrelated to lead failure, etc.

# ICD lead performance

ICD Lead survival varies from

91 to 99% at 2 years
85 to 98% at 5 years
60 to 72% at 8 years




Maisel, W. H. et al. Circulation 2008;117:2721-2723

# ICD lead performance

## Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

Thomas Kleemann, MD; Torsten Becker, MD; Klaus Doenges, MD;

Margi ... MD;

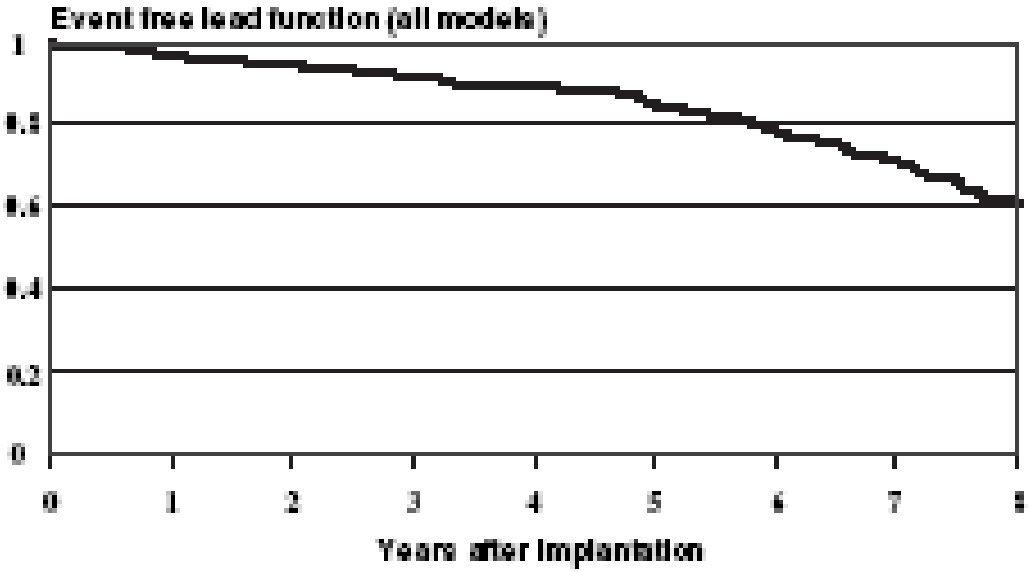



Figure 1. Kaplan-Meier curves of event-free lead function of all lead models ($n$=990).

*Background*—Tl ... rter-defibrillator is increasing ... , the long-term reliability of ... he present study was to assess ... ad implantation.

*Methods and R* ... an implantable cardioverter-d ... was 934 days (interquartile ... e estimated lead survival rates ... e rate increased progressively ... defects affected newer as well ... re often female. Multiple lead ... .06). The major lead complicat ... ), abnormal lead impedance (1( ...

*Conclusions*—A ... reached 20% in 10-year-old leads. Patients with lead defects are younger and more often female. (*Circulation*. 2007;115:2474-2480.)

# Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

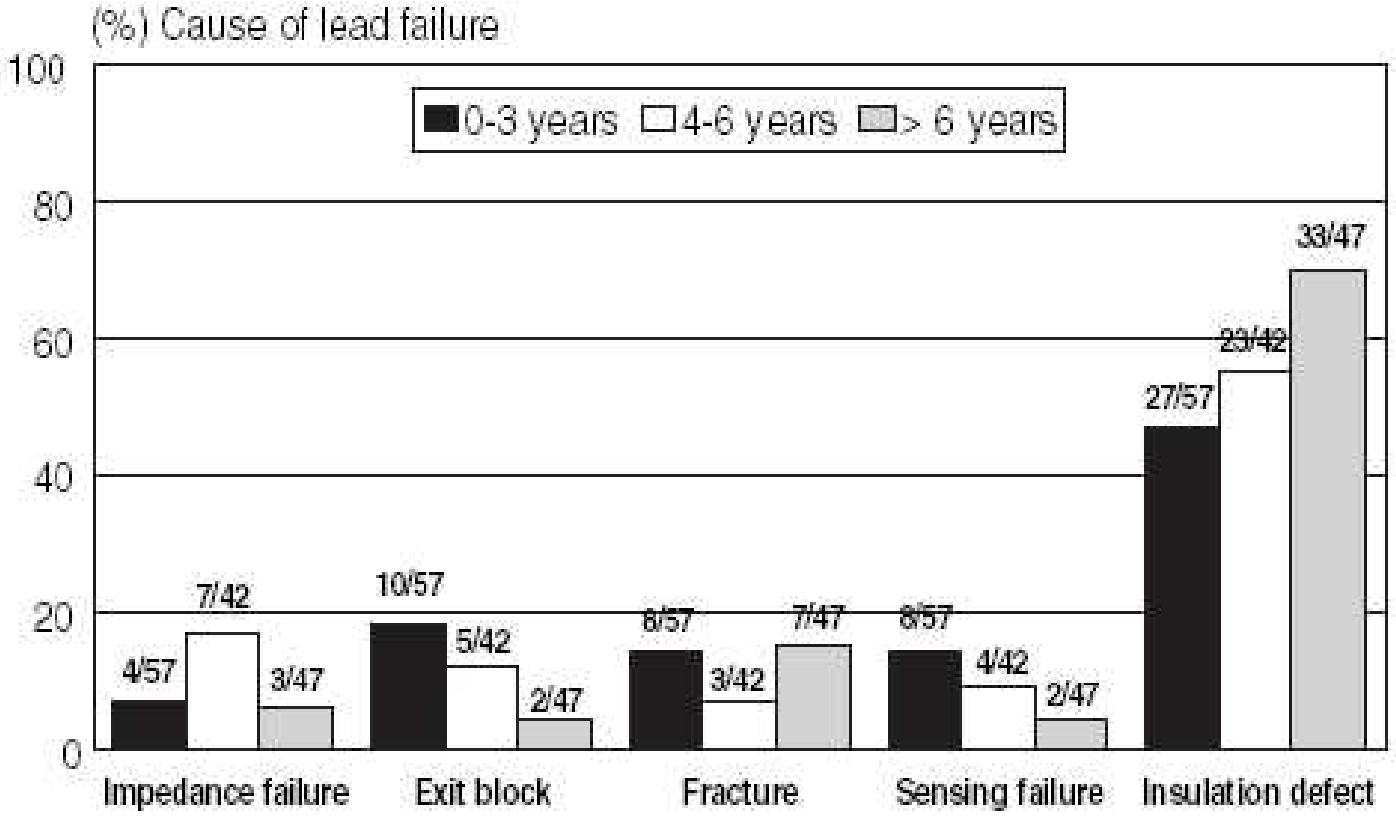
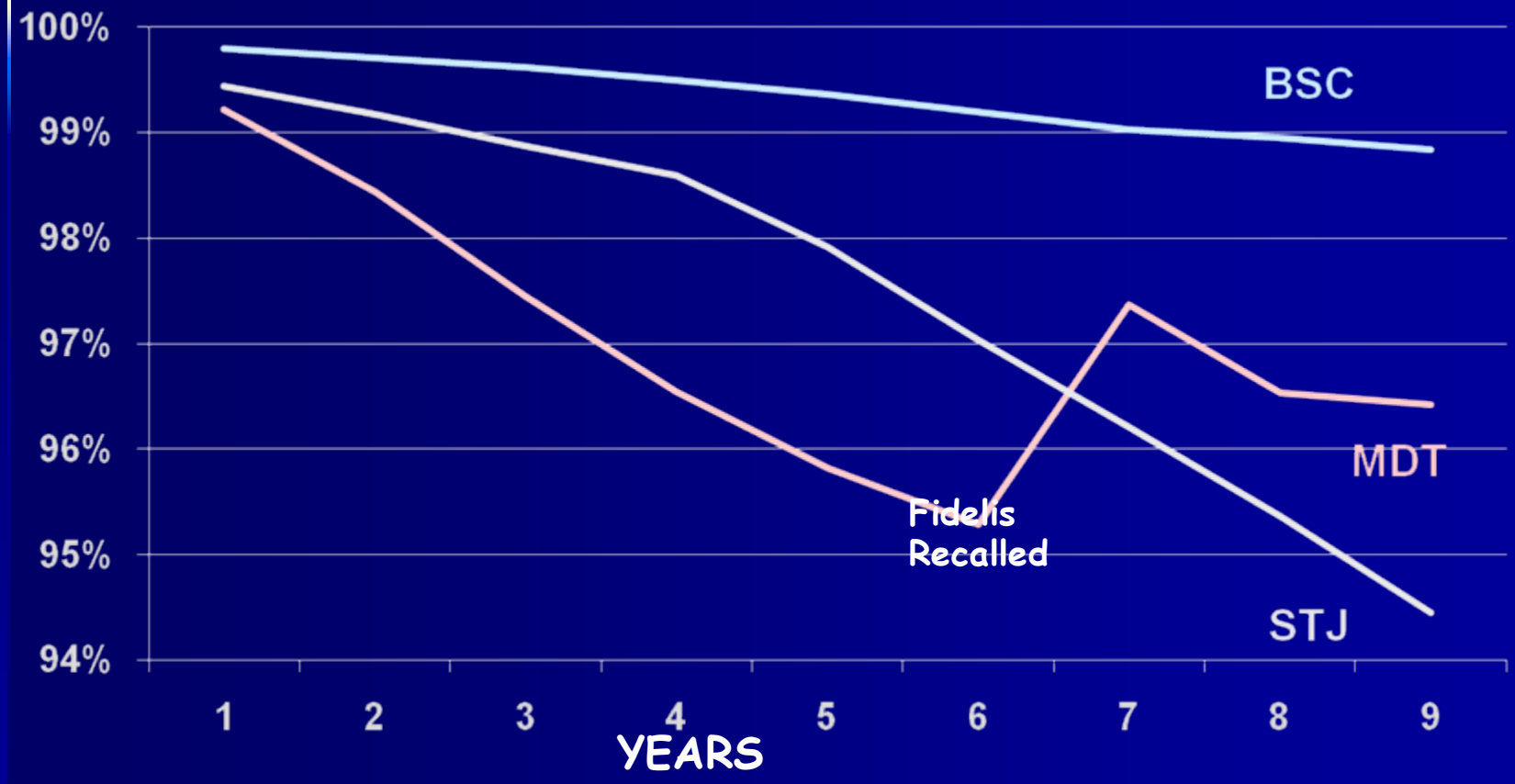



**Figure 3.** Incidence of different causes of lead defects versus time after lead implantation.

Thomas Kleemann. (*Circulation*. 2007;115:2474-2480.)

# Industry data on lead survival

## Lead survival rate including all leads



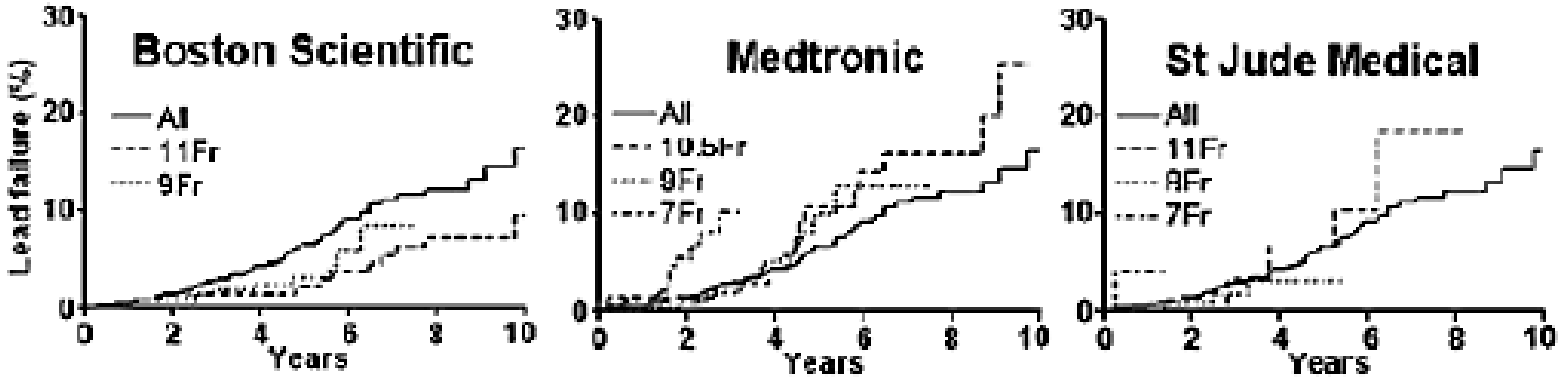

*All data from 2011 PPR report from BSC, MDT and SJM

# Performance of different technologies

Leiden University in the Netherlands conducted a long term study* to determine the ICD lead survivability over multiple manufacturers:

- Large number of ICD leads (n=2161)
- Implanted over a 16 year period
- 4 Manufacturers

*Figure 2.* **Average Failure Rate Across all Manufacturers**



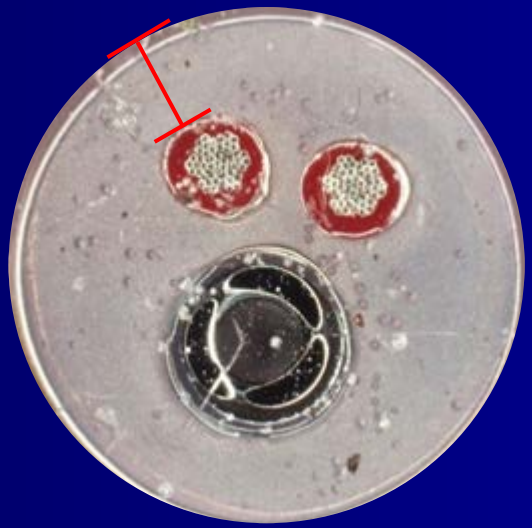

[1] Borleffs W, vanErven, J. van Bommel R, et al. Risk of Failure of Transvenous Implantable Cardioverter Defibrillator Leads. *Circulation of Arrhythmia and Electrophysiology* (2009), DOI: 0.1161/CIRCEP.108.834093.

*Borleffs et al., Risk of Failure of Transvenous Implantable Cardioverter-Defibrillator Leads. Circ Arrhythm Electrophysiol 2009;2:411-416

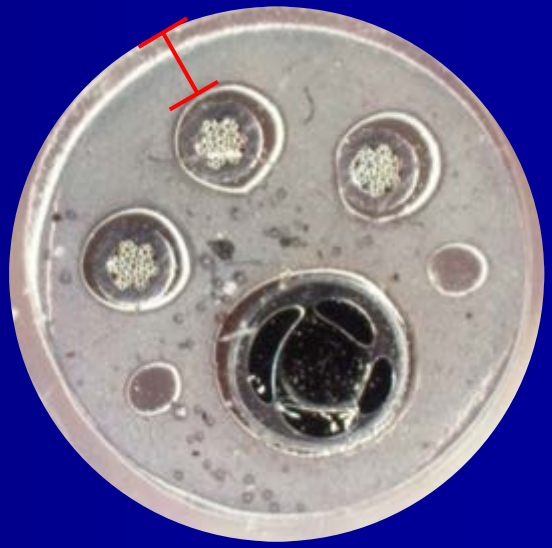
# Lead body design comparison

St. Jude
Riata®
6.8 F (2.3mm)

BSC
RELIANCE®
8.1 F (2.7mm)



Medtronic
Sprint Quattro® Secure
8.4 F (2.8mm)



**Wall size:** Indicates the insulation thickness between conductors and outer lead body

Images taken from "Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy",
3rd edition. Ellenbogen, Kay, Lau and Wilkoff.

Letter to the Editor

# Sprint Fidelis defibrillator leads—Should we keep the faith?

Zia Zuberi *, Paresh Mehta, Senthil Kirubakaran, C. Aldo Rinaldi

*Department of Cardiology, 6th Floor East Wing, St Thomas' Hospital, Westminster Bridge Road, London, United Kingdom*

**Zuberi Z, et al, Sprint Fidelis defibrillator leads—Should we keep the faith?, Int J Cardiol (2012), doi:10.1016/j.ijcard.2012.06.043**

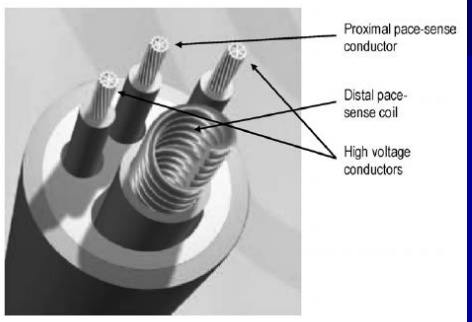



**Figure 1** Cross-section of Sprint Fidelis model 6949 lead.

# Conductor externalization of the Riata internal cardioverter defibrillator lead: tip of the iceberg? Report of three cases and review of literature

**H.G. Reinhart Dorman*, Jurren M. van Opstal, Jeroen Stevenhagen, and Marcoen F. Scholten**

**Figure 2** Extracted Riata lead demonstrating that the conductors are outside the lead body.

Europace (2012) 14, 1161–1164

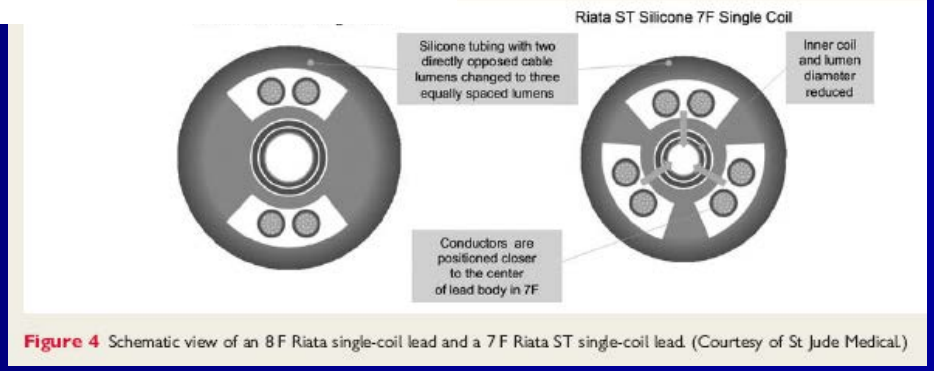



**Figure 4** Schematic view of an 8 F Riata single-coil lead and a 7 F Riata ST single-coil lead. (Courtesy of St Jude Medical.)

# Fidelis Lead Advisory

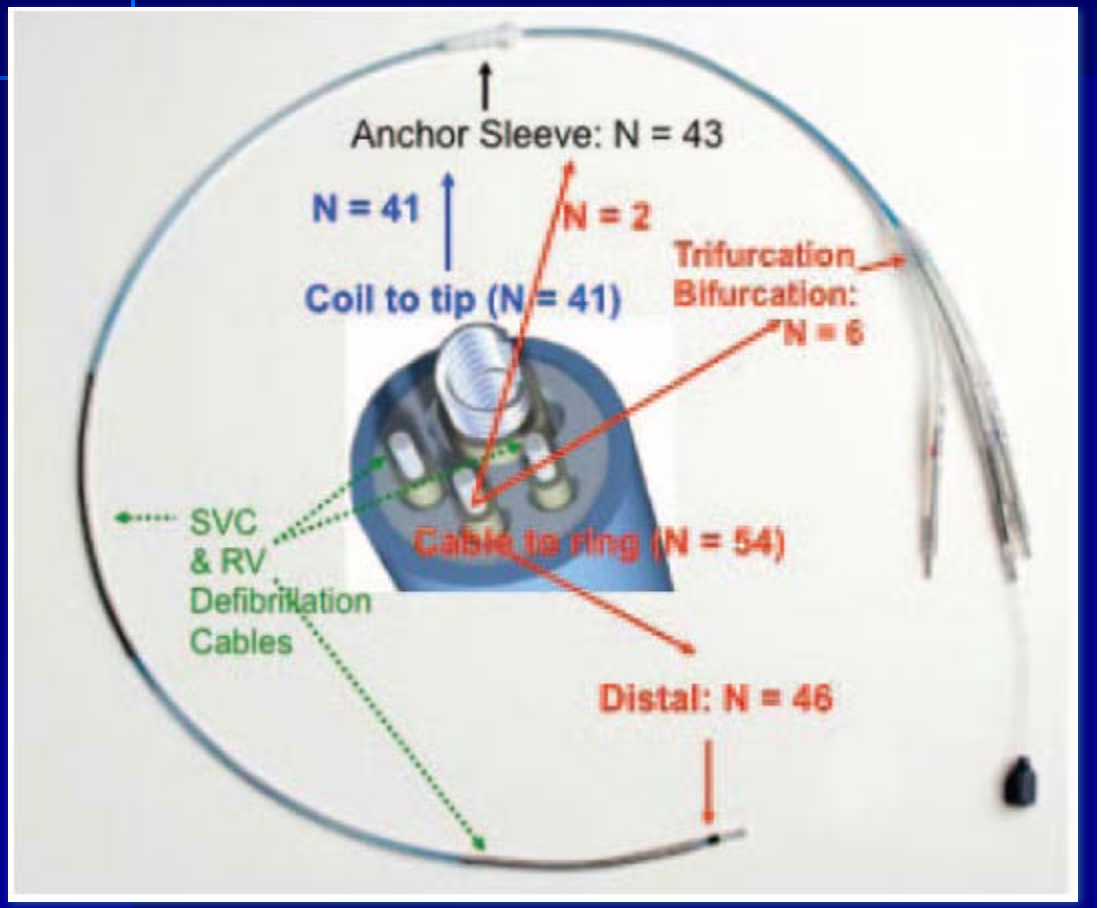
- Voluntary recall October 2007
- Initial 2.3% 30 month failure rate
- 3 year failure rate: 5%
- Increasing failure rate: 3.75%/year

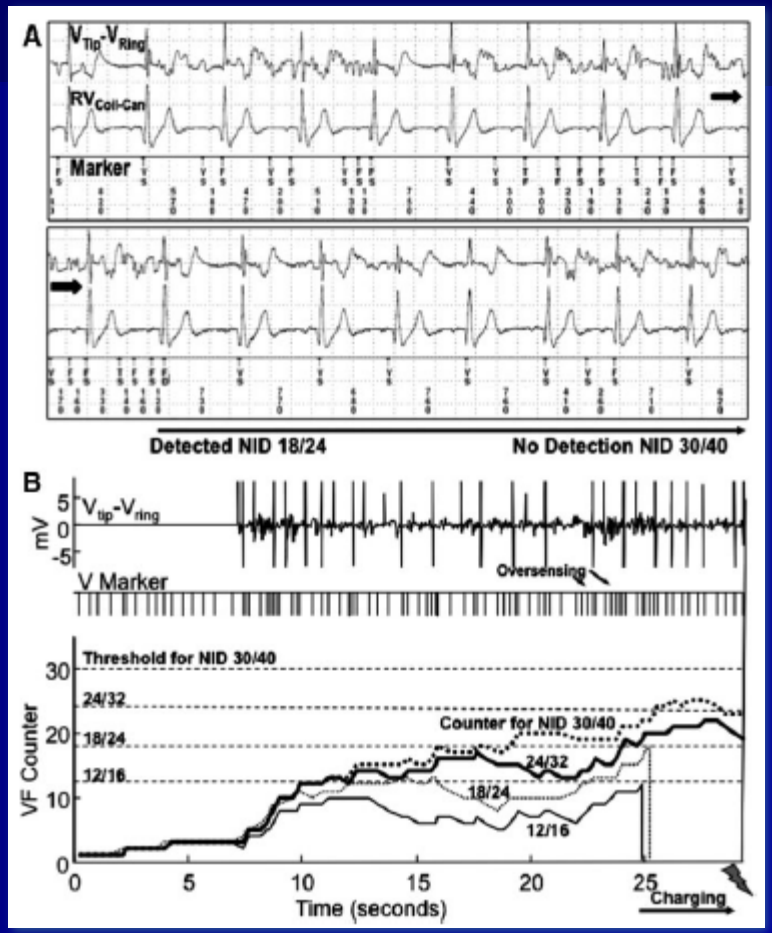
Medtronic Sprint Fidelis Performance reports; Hauser, Heart Rhythm 2009


Risk of not extracting

Risk of extracting

# ICD Lead Failure Sprint Fidelis




Swerdlow CD et al, Circulation 2008; 118: 2122-2129

# Longevity of Sprint Fidelis Implantable Cardioverter-Defibrillator Leads and Risk Factors for Failure

## Implications for Patient Management

Hauser, Circulation 2011

***Methods and Results***—This 3-center study included adults ≥18 years of age who received Fidelis or Quattro leads for the prevention of sudden cardiac death. From November 2001 to January 2009,1023 Fidelis and 1668 Quattro leads were implanted and followed up. The failure rate for Fidelis leads was 2.81%/y compared with 0.43%/y for Quattro leads ($P<0.0001$). No deaths or injuries occurred as a result of lead failure, but 42% of fractures caused inappropriate shocks. The survival of Fidelis leads at 4 years was 87.0% (95% confidence interval, 83.6 to 90.1) compared with 98.7% (95% confidence interval, 97.9 to 99.4) for Quattro leads ($P<0.0001$). Multivariate predictors of Fidelis failure were younger age (hazard ratio, 0.98; 95% confidence interval, 0.96 to 0.99), female gender (hazard ratio, 0.61; 95% confidence interval, 0.40 to 1.00), and cardiac disease ($P=0.041$).

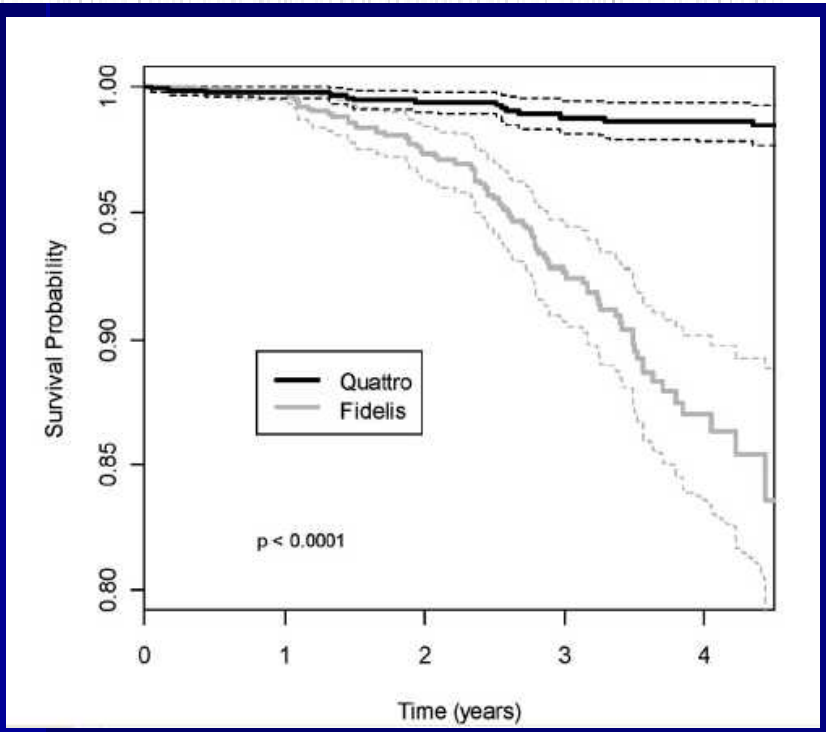


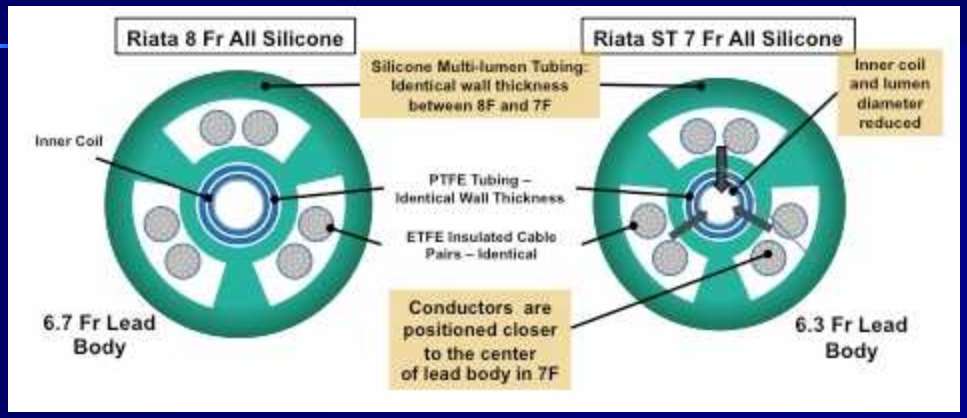

**Table 5. Multivariable Analysis of Clinical Variables Associated With Fidelis Lead Failure**

| Variable | *P* | Hazard Ratio (95% CI) |
|---|---|---|
| Age | 0.007 | 0.98 (0.96–0.99) |
| Male gender | 0.048 | 0.61 (0.40–1.00) |
| Cardiac disease | 0.041 | |
| HCM | | 3.66 (1.62–8.31) |
| ARVD and channelopathies | | 2.50 (0.91–6.88) |
| Ischemic heart disease | | 2.08 (1.11–3.89) |
| Idiopathic VT/VF | | 1.97 (0.45–8.70) |

C=0.65 for this model.

These findings have significant implications for the management of patients who have Fidelis leads, and they demonstrate the importance of weighing clinical variables in assessments of ICD lead performance.

# RIATA Lead Advisory (278,000 worldwide)



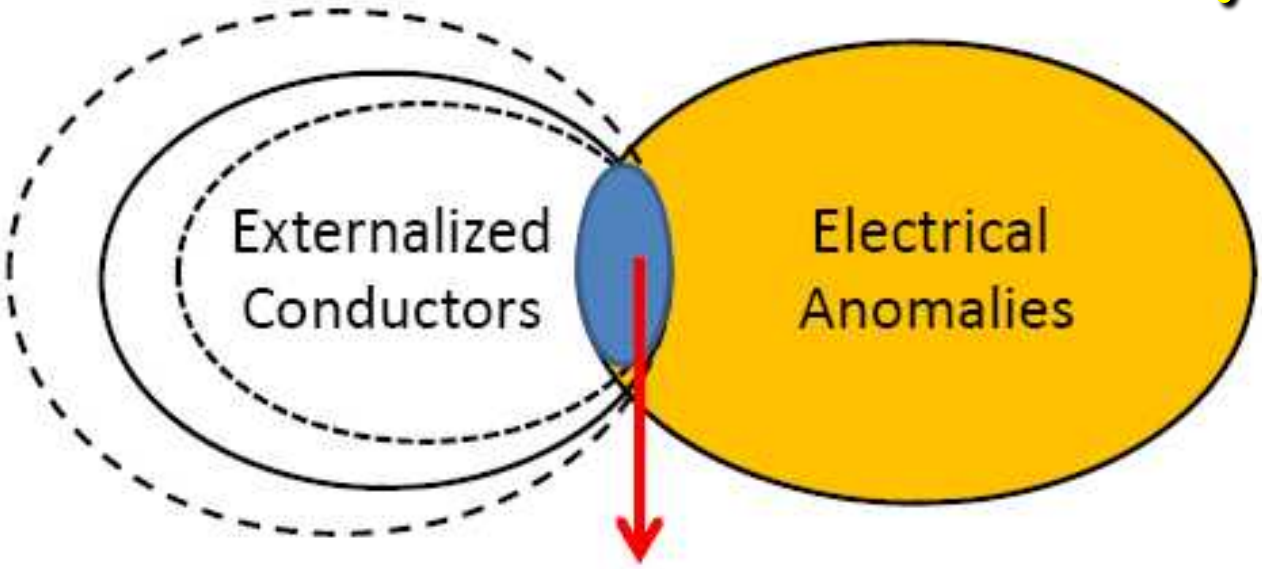

Externalized Conductors up to 15% (25 out of 165 patients) , including 5 leads (3%) that were associated with an electrical abnormality. (Belfast Experience)

Riata (8Fr) single shock coil models exhibit a significantly higher incidence rate of externalized conductors than all other Riata (8Fr) and Riata ST (7Fr) models.

Externalized Conductors: 85% inside-out and 15% outside-in

Lead movement associated with a patient's heart beat → location of the externalization within 8 centimeters proximal to the RV shock coil

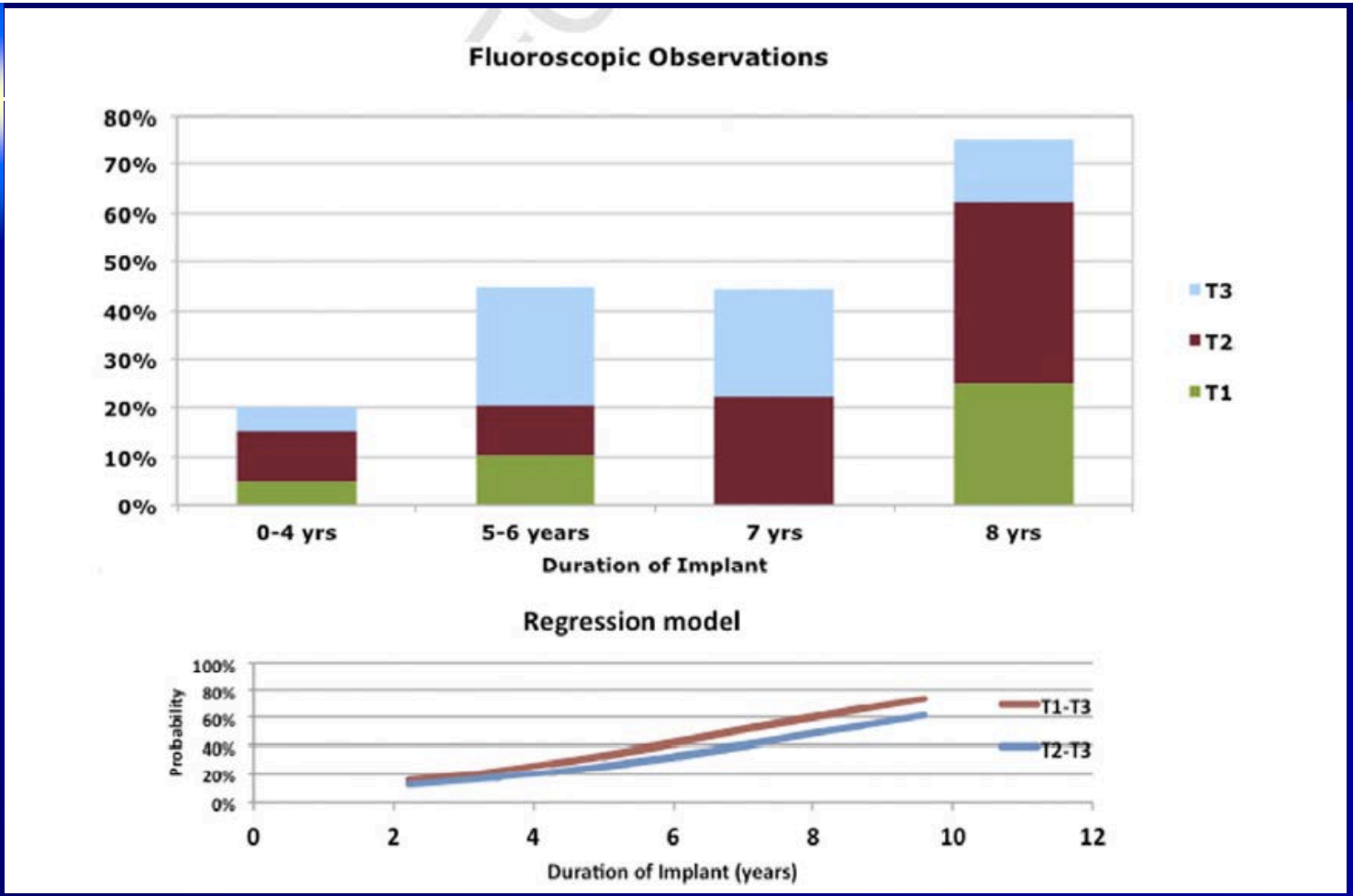
# RIATA Lead Advisory





HRS Riata Webinar & SJM Returned Product Analysis

# High prevalence of insulation failure with externalized cables in St Jude Medical Riata family ICD leads: Fluoroscopic grading scale and correlation to extracted leads




Parvathaneni, et al, Heart Rhythm 2012

# Class I recall of defibrillator leads: A comparison of the Sprint Fidelis and Riata families

Jeffrey Liu, MD, Genevieve Brumberg, MD, Rohit Rattan, MD, Sandeep Jain, MD, FHRS, Samir Saba, MD, FHRS

*From the Cardiac Electrophysiology Section, Heart and Vascular Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania.*

Heart Rhythm, Vol 9, No 8, August 2012

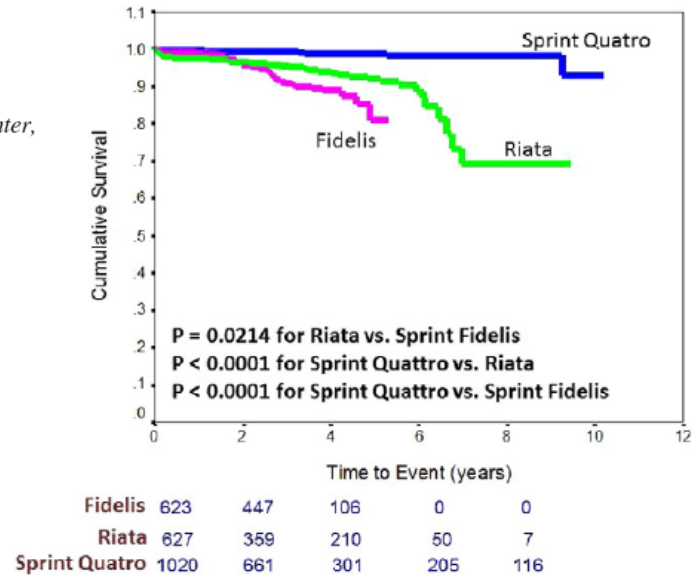



**Figure 1** Kaplan-Meier curves showing the failure-free survival for the Sprint Fidelis, the Riata, and the Sprint Quattro leads from the time of implantation.

**Table 2** Outcomes

| | Riata (n = 627) | Fidelis (n = 623) | Quattro (n = 1020) | *P* (SQ vs SF) | *P* (SQ vs R) | *P* (R vs SF) |
|---|---|---|---|---|---|---|
| Deaths | 31.6% | 12.4% | 25.9% | <.0001 | .993 | <.001 |
| Failed leads | 6.1% | 7.5% | 1.1% | <.0001 | <.0001 | .298 |
| Functional leads removed | 3.7% | 15.7% | 3.0% | <.0001 | .823 | <.001 |
| Active leads | 58.6% | 64.4% | 69.3% | <.001 | <.001 | <.001 |
| Failed leads before recall | 5.9% | 1.3% | 1.1% | .743 | <.0001 | <.001 |

R = Riata; SF = Sprint Fidelis; SQ = Sprint Quattro.

# Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines

## *Developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA)*

**TABLE 4** Recommendations for Clinicians Managing Lead Advisory Notices

1. Conservative non-invasive management with periodic device monitoring (remote or in-person, as appropriate) should be strongly considered particularly for:
   - Patients who are not pacemaker dependent*
   - Patients with an ICD for primary prevention of sudden cardiac death who have not required device therapy for a ventricular arrhythmia
   - Patients whose operative risk is high or patients who have other significant competing morbidities even when the risk of lead malfunction or patient harm is substantial.
2. Lead revision or replacement should be considered if in the clinician's judgment:
   - The risk of malfunction is likely to lead to patient death or serious harm, and
   - The risk of revision or replacement is believed to be less than the risk of patient harm from the lead malfunction.
3. Reprogramming of the pacemaker or ICD should be performed when this can mitigate the risk of an adverse event from a lead malfunction.

*Pacemaker dependence refers to patients who have no hemodynamically stable underlying heart rhythm in the absence of pacing.

When Managing Normally Functioning Leads Subject to Advisory

*All factors should be considered when formulating a clinical plan for individual patients. No single factor should determine the clinical management plan.

PATIENT
- Pacemaker dependence†
- Prior history of ventricular arrhythmia
- Patient prognosis
- Risk of future arrhythmia
- Surgical risk of revision/replacement procedure
- Patient anxiety about lead failure
- Impending battery depletion

LEAD
- Rate of abnormal performance (observed or projected) in Advisory Lead
- Lead failure rates
- Malfunction characteristics (gradual vs. sudden, predictable vs. unpredictable, etc.)
- Identified lead subset with higher failure rate (Serial numbers, vascular access, etc.)
- Malfunction mechanism known/understood
- Adverse clinical consequences of lead failure
- Availability of reprogramming to Mitigate Clinical Risk
- Availability of algorithms for early detection of lead abnormality

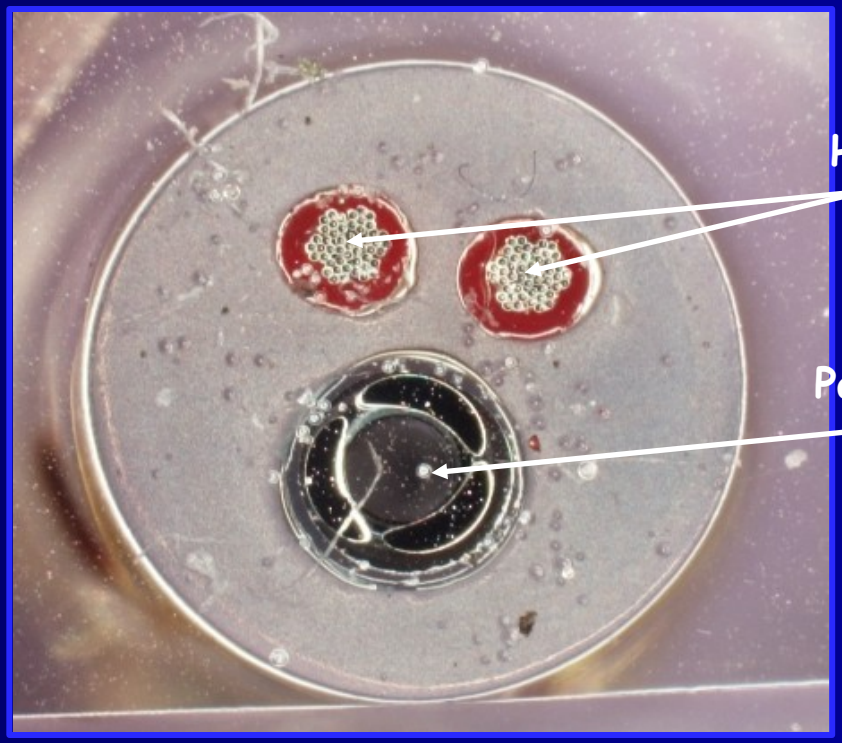
†Pacemaker dependence refers to patients who have no hemodynamically stable underlying heart rhythm in the absence of pacing.

# ENDOTAK Lead Technology

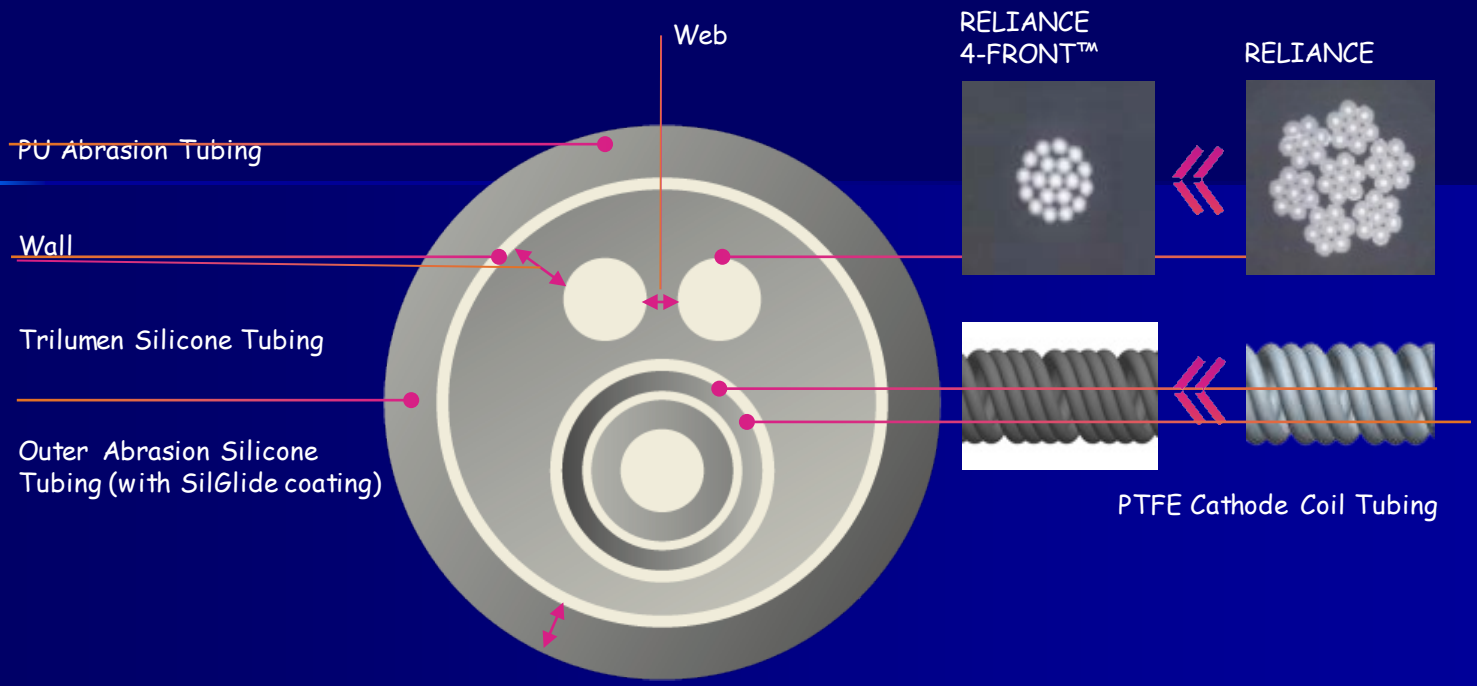
Trilumen lead

- Design that maximizes insulation thickness
- Designed to be durable and crush resistant

ENDOTAK Reliance™




# Reliance vs 4-Front



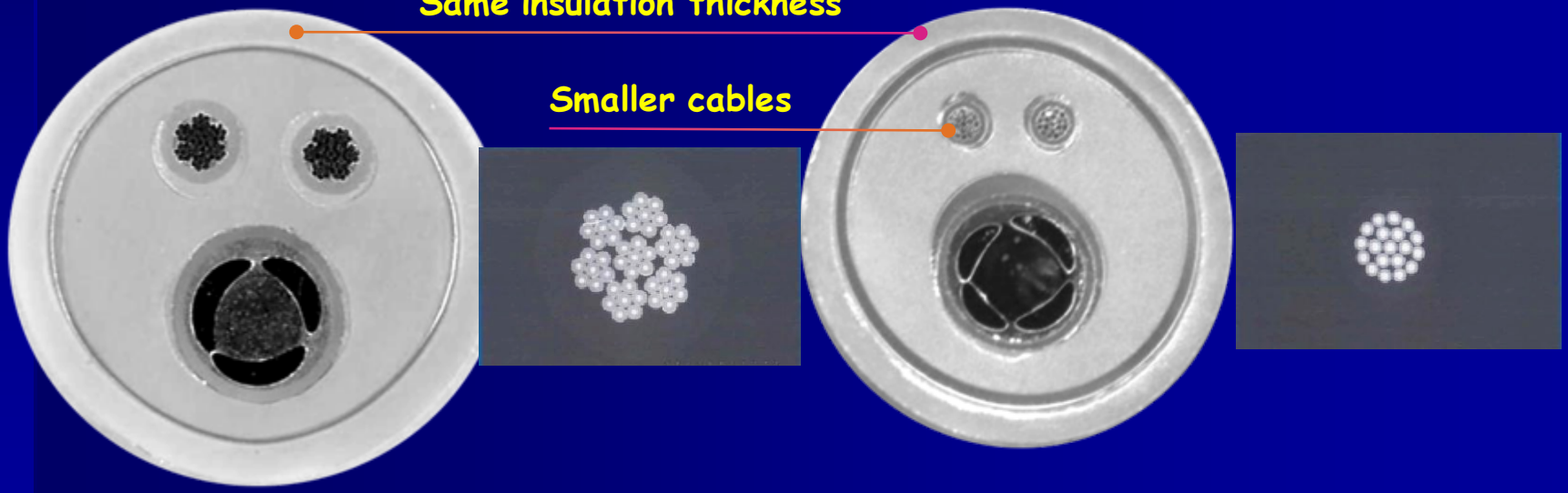

| Lead | Trilumen Silicone | Abrasion Silicone (wall thickness) | Abrasion PU (wall thickness) | PTFE (wall thickness) |
|---|---|---|---|---|
| RELIANCE 4-FRONT | Silicone<br>Wall Thick > 0.178 mm<br>Web Thick > 0.127mm | 0.229 mm | 0.051 mm | 0.051 mm |
| RELIANCE | Silicone<br>Wall Thick > 0.178 mm<br>Web Thick > 0.127 mm | 0.229 mm | 0.051mm | 0.051 mm |

# Reliance 4-Site vs 4-Front

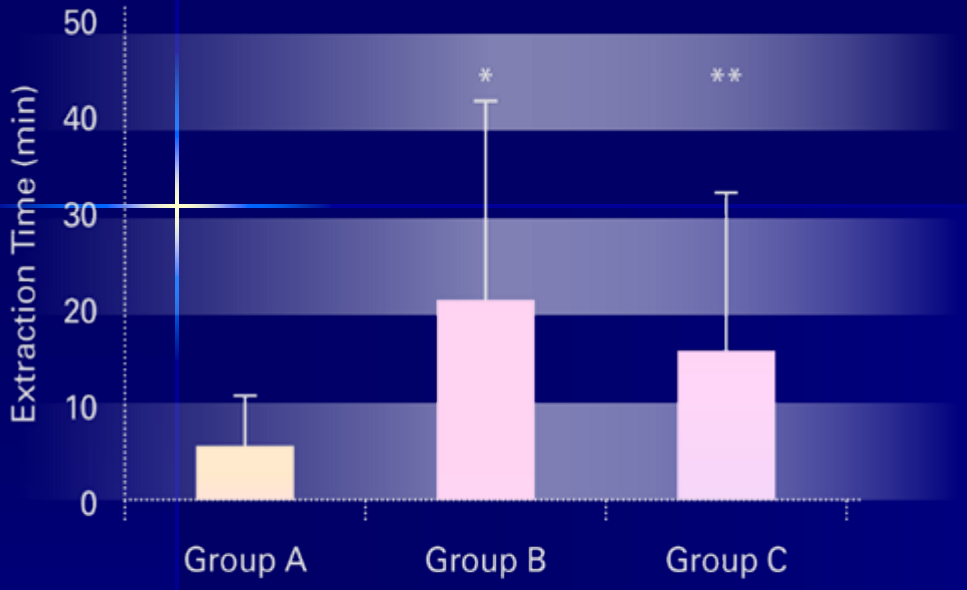
- Built on the RELIANCE platform, 4-FRONT is smaller without compromising insulation thickness.
- Reduced high voltage cables thickness.

RELIANCE 4-SITE™
8.1F (2.7mm)

RELIANCE 4-FRONT™
7.3F (2.4mm)




# Incorporation of GORE™




* Group A vs Group B $p<0.05$

** Group A vs Group C $p<0.05$

- Group A = RELIANCE™ G n = 17
- Group B = Sprint Quattro™ 6944 n = 20
- Group C = Riata™ 1570 n = 36

**Easier extraction due to ePTFE**

**Conventional**


**GORE™**


Di Cori A, Bongiorni MG, Zucchelli G, et al. Transvenous Extraction Performance of Expanded Polytetrafluoroethylene Covered ICD Leads in Comparison to Traditional ICD Leads in Humans. PACE. 2010; 33:1376-1381.

Division of Cardiovascular Diseases - University Hospital of Pisa (Italy)

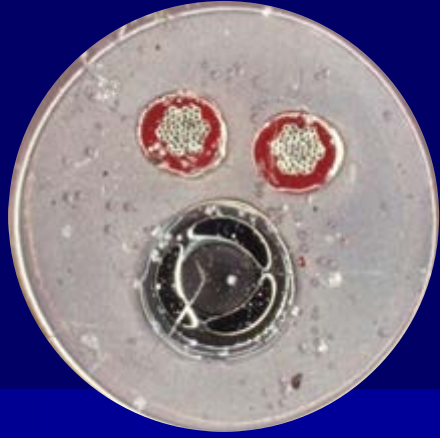

# Multicenter Experience With Extraction of the Sprint Fidelis Implantable Cardioverter-Defibrillator Lead

J Am Coll Cardiol 2010;56:646–50

Melanie Maytin, MD,* Charles J. Love, MD,† Avi Fischer, MD,‡ Roger G. Carrillo, MD,§
Juan D. Garisto, MD,§ Maria Grazia Bongiorni, MD,‖ Luca Segreti, MD,‖ Roy M. John, MD, PHD,*
Gregory F. Michaud, MD,* Christine M. Albert, MD, MPH,* Laurence M. Epstein, MD*

**349 Sprint Fidelis leads were extracted from 348 patients. All leads were removed completely. There were no major procedural complications or deaths.**

# Optimal lead body design



- Average body thickness
- Maximized insulation thickness
- Single coil
- Isodiametric
- Fibrosis ingrowth prevention