PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA
Centro Congressi
di Confindustria
Auditorium
della Tecnica

9ª Edizione

30 Settembre
1 Ottobre
2022

Sessione:
PREVENZIONE E TRATTAMENTO DELLE INFEZIONI DEI DISPOSITIVI CARDIACI IMPIANTABILI

Relazione:

Malfunzionamento dei dispositivi cardiaci elettronici impiantabili: entità del problema e quali prospettive.

Eraldo Occhetta - Novara

Eraldo Occhetta
Novara/Vercelli

No disclosures

ESC European Society of Cardiology

Europace (2018) **20**, 1217
doi:10.1093/europace/euy050

EHRA CONSENSUS DOCUMENT

2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS

Indications for lead extraction

In order to clarify the indications for lead extraction the following definitions are proposed (see *Table 1*).

Infection

This was the most frequent indication for TLE in the ELECTRa registry amounting to 52.8% (of which approximately two-thirds were local infections).[4] Several entities exist, which should be specified.

Table 1 CIED-related infection types

Clinical scenarios	Infection types	Definitions
Superficial incisional infection	Superficial local	Involves only skin and subcutaneous tissue
Isolated pocket infection	Local	Clinically associated with local signs of inflammation at the generator pocket or along the lead course, including erythema, warmth, fluctuance, wound dehiscence, tenderness, or purulent drainage, with negative blood cultures[8–10]
Isolated pocket erosion	Local	Device and/or lead(s) are exposed through the skin (the device should however, be considered infected, whatever the mechanism for erosion)
Bacteraemia	Systemic	Positive blood cultures with or without systemic infection symptoms and signs
Pocket infection (open or closed) with bacteraemia	Systemic	Local signs of pocket infection and positive blood cultures, without lead or valvular vegetation(s)
CIED-related endocarditis without pocket infection	Systemic	Bacteraemia and lead or valvular vegetation(s), without local signs of pocket infection
Pocket infection with lead/valvular endocarditis	Systemic	Local signs of pocket infection and positive blood cultures and lead or valvular vegetation(s)
Occult bacteraemia with probable CIED infection	Systemic	Bacteraemia without an alternative source

Lead dysfunction

In case of lead dysfunction, there is the option of abandoning the lead or extracting it (e.g. to reduce intravascular lead burden or regain access in the presence of venous occlusion). Lead dysfunction was the second most frequent reason for lead extraction in the ELECTRa registry, amounting to 38.1% of cases.[4] Causes for lead dysfunction may be lead fracture or insulation failure resulting in issues with lead impedance, sensing or capture. In some cases, the electrical parameters may still be normal, but the integrity of the lead is clearly compromised (e.g. inside out cable externalization of Riata leads, radiological evidence of subclavian crush etc.).

Table 2 Definitions of terms for non-infected leads

Non infected leads	Definitions
Lead function	Any lead function, including pacing, sensing, and/or defibrillation
Lead failure	Loss of any lead function
Non-functional lead	Lead not usable for pacing and/or defibrillation due to loss of functional integrity
Abandoned lead	Lead left in place in the heart and not connected to a CIED. It may be functional or non-functional. 'Redundant' lead is sometimes used to describe an abandoned lead
Recall	Firm's removal or correction of a marketed product that the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) consider to be in violation of the laws it administers and against, which the agency would initiate legal action. Recall does not include a market withdrawal or a stock recovery
Class 1	Dangerous or defective products with reasonable probability of causing serious health problems or death (e.g. short circuit without warning)
Class 2	Products that might cause a temporary health problem, or pose a slight threat of a serious nature (e.g. premature battery depletion)
Class 3	Products that are unlikely to cause any adverse health reaction, but that violate FDA or EMA labelling or manufacturing regulations

Cardiac Implantable Electronic Devices (CIED) malfunctions:

- Devices (Pacemakers – ICDs – CRT devices)

- Leads (pacing-sensing – Defibrillation)

Devices malfunctioning (Recall):

Class 1	Dangerous or defective products with reasonable probability of causing serious health problems or death (e.g. short circuit without warning)	→ Mandatory Replacement
Class 2	Products that might cause a temporary health problem, or pose a slight threat of a serious nature (e.g. premature battery depletion)	→ Carefully monitoring Possible Replacement
Class 3	Products that are unlikely to cause any adverse health reaction, but that violate FDA or EMA labelling or manufacturing regulations	→ Carefully monitoring

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Medtronic Recall

ICD: Marquis – 2005 (sudden battery depletion 0.2-1.5% risk)
PM: Sigma – 2005 (hybrid circuit problems 0.17-0.30% risk)

News | Cardiac Resynchronization Therapy Devices (CRT) | February 26, 2018

Medtronic Recalls CRT-Ds and ICDs Due to Manufacturing Error Preventing Electrical Shock Delivery

Defect cited in Class I recall causes an out-of-specification gas mixture inside the device that may prevent shock delivery

News | Pacemakers | February 20, 2019

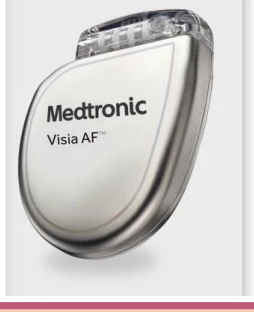
Medtronic Recalls Dual-Chamber Pacemakers

Class I recall identifies possible circuit error that can result in a lack of pacing

Feature | EP Lab | April 12, 2021

Medtronic Recalls its ICDs and CRT-Ds Due to Risk of Rapid Battery Depletion

Class I recall includes Evera, Viva, Brava, Claria, Amplia, Compia and Visia implantable cardioverter defibrillators and cardiac resynchronization therapy devices



FDA announces recall of nearly 88,000 implantable cardiac devices due to risk of serious injury or death

Michael Walter | August 19, 2022 | Heart Rhythm

Boston Scientific – Guidant Recall

Recall of Guidant Pacemakers, ICDs

Thousands of Patients Implanted With Possibly Faulty Heart Devices

By Miranda Hitti

Medically Reviewed by Louise Chang, MD on June 27, 2006

FROM THE WEBMD ARCHIVES

June 27, 2006 -- Boston Scientific says 27,200 patients -- 13,800 in the U.S. -- have been implanted with possibly faulty heart devices made by its recently acquired subsidiary, Guidant.

Boston Scientific is recalling:

- Some Insignia and Nexus pacemakers
- Contak Renewal TR and TR 2 cardiac resynchronization pacemakers
- Ventak Prizm 2, Vitality, and Vitality 2 ICDs (implantable cardioverter defibrillators)

Boston Scientific Corporation Recalls EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator) System Due to Risk of Short-Circuit

Subscribe to Email Updates | Share | Tweet | LinkedIn | Email | Print

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

December 2, 2020

MEDTECH

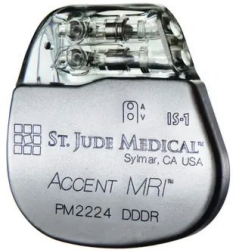
Boston Scientific recalls a decade's worth of Ingenio pacemakers over risk of unexpected system resets

By Andrea Park • Aug 10, 2021 07:20am

St.Jude – Abbott Recall

Hacking risk leads to recall of 500,000 pacemakers due to patient death fears

FDA overseeing crucial firmware update in US to patch security holes and prevent hijacking of pacemakers implanted in half a million people



Abbott recalls pacemakers that may short circuit

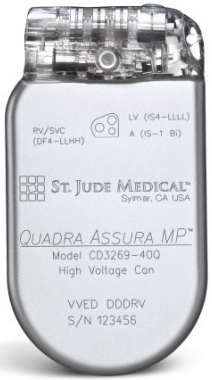
May 13, 2021 By Nancy Crotti

Abbott is recalling certain pacemakers that may short circuit because they can allow moisture inside, according to the FDA.

The recall covers 61,973 Assurity and Endurity pacemakers manufactured by St. Jude Medical and distributed from April 2015 to February 2019. (Abbott acquired St. Jude in 2017).

FDA updates Class I recall of St. Jude Medical's ICDs and CRT-Ds to mention new battery alert tool

20th October 2017 4408



Biotronik Recall

BIOTRONIK
excellence for life

Urgent Field Safety Notice

Potential premature battery depletion in a subset of ICD and CRT-D devices

BIOTRONIK reference: BIO-LQC

Berlin, March 2021

Dear Healthcare Professional,

BIOTRONIK has become aware of an increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators ("ICDs") and Cardiac Resynchronization Therapy Defibrillators ("CRT-Ds").

Idova, Iforia, Ilesto / Inventra, Iperia, Itrevia / Ilivia, Inlexa, Intica / Ilivia Neo, Intica Neo ICDs and CRT-Ds

Class 2 Device Recall BIOTRONIK INTICA

Class 2 Device Recall BIOTRONIK ILIVIA

See Related Information

Date Initiated by Firm	March 08, 2021
Create Date	April 21, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-1465-2021
Recall Event ID	87549
PMA Number	P980023S093
Product Classification	Implantable cardioverter defibrillator (non-CRT) - Product Code LWS

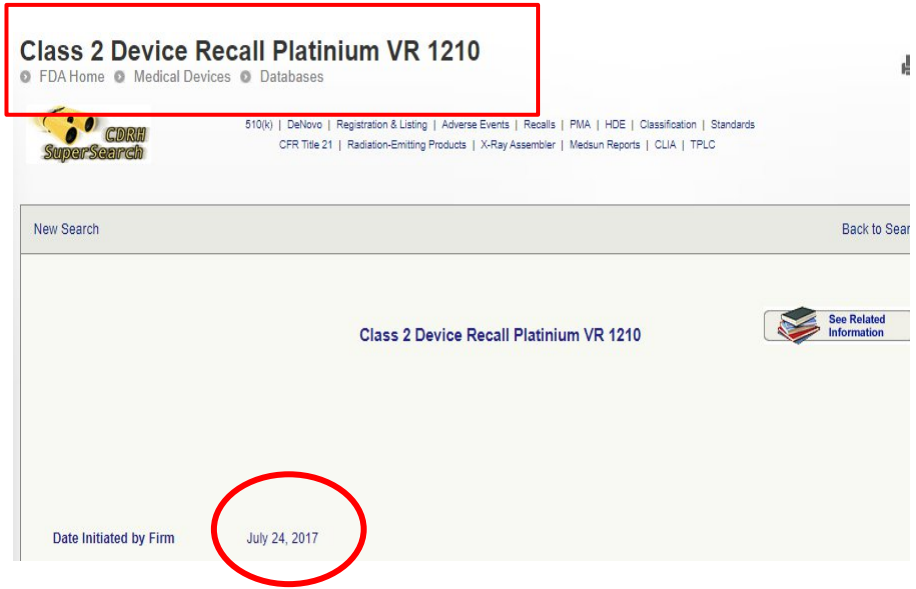
Elamedical-Livanova-Microport Recall

ICD 2003-2004:

Serie Alto modelli DR 614, VR 615, MSP 617, DR 624, VR 625, MSP 627 - premature battery depletion (2.6%)

PM 2003:

Modelli Symphony DR 2550, Rhapsody DR+ 2530, Rhapsody DR 2510, Rhapsody D 2410, Rhapsody SR 2210 -> no output (0.75%)



What to do?

VISIT THE FDA WEBSITE FOR THIS MOST RECENT RECALL –

FDA WEBSITE FOR RECALLS

AIAC
Associazione Italiana Aritmologia e Cardiostimolazione

Gestione Avvisi di Sicurezza

Archivio delle raccomandazioni AIAC sulla gestione dei pazienti portatori di dispositivi cardiaci impiantabili oggetto di recall.

Cosa fare in caso di malfunzionamento di un dispositivo?

Devices malfunctioning Recall:

Class 1	Dangerous or defective products with reasonable probability of causing serious health problems or death (e.g. short circuit without warning)	→ Mandatory Replacement
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Device Replacement:

- **Easy procedure** (not leads removing)

  …..but

  - **Additionaly unnecessary pocket opening (increased infective risk)**
  - **Additional Hospital costs**

Device Carefully monitoring:

- **Not additional risk related to opening pocket**

  …but

  - **Additional time consuming follow up (home monitoring mandatory)**
  - **Additional Hospital costs**

Recall Device Replacement: CIEDS Companies economic problem

FDA announces recall of nearly 88,000 implantable cardiac devices due to risk of serious injury or death

Michael Walter | August 19, 2022 | Heart Rhythm

Hacking risk leads to recall of 500,000 pacemakers due to patient death fears

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FROM THE WEBMD ARCHIVES

June 27, 2006 -- Boston Scientific says 27,200 patients -- 13,800 in the U.S. -- have been implanted with possibly faulty heart devices made by its recently acquired subsidiary, Guidant.

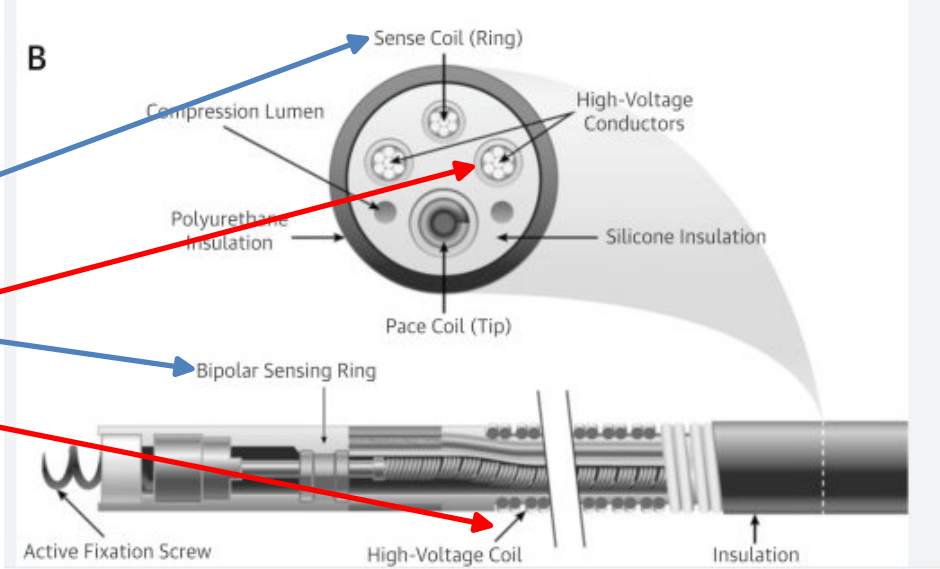
Real default risk: 0.5-3%....

…possible > 90% useless replacement

Leads (pacing-sensing-defibrillation) malfunctions:

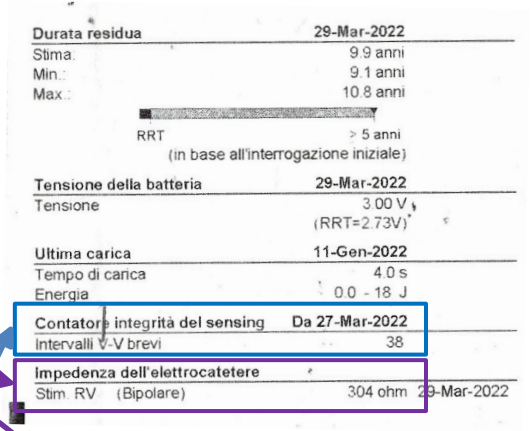
Related problems:

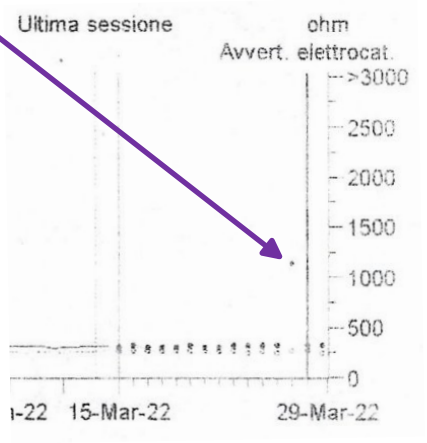
- **Spiral Fracture**
  - partial (pacing-sensing conductor – defibrillation coils)
  - complete
- **Insulation leak**
- **Spiral externalization**



Pacing-sensing ICD lead partial fracture

- **Noise -> oversensing**
  - **Sudden impedances increasing**
  - **Very short and irregular RR cycles**
  - **Inappropriate ICD shocks**
  - **Pseudo-arrhythmic storm**
  - **No Pacing**





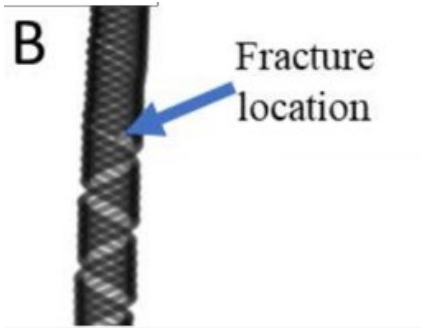
Class 1 Device Recall Medtronic Sprint Fidelis Lead

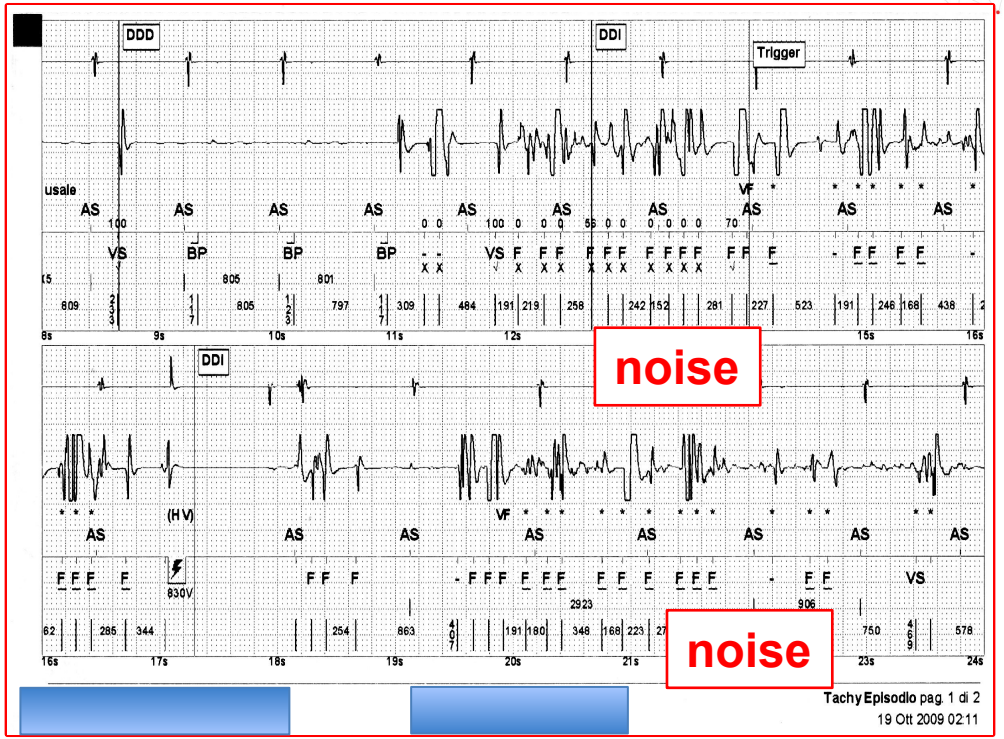
FDA Home ◉ Medical Devices ◉ Databases

Date Initiated by Firm	October 15, 2007
Quantity in Commerce	235,000 for all models

Pacing-sensing ICD lead partial fracture

- Noise -> oversensing
  - Sudden impedances increasing
  - Very short and irregular RR cycles
  - Inappropriate ICD shocks
  - Pseudo-arrhythmic storm
  - No Pacing





Dispositivo: **EnTrust D154VRC**
Num. di serie: **PNT603987S**

Data della visita: **01-Ott-2009 11:26:47**
9987 Versione software 1.5

Rapporto Quick Look **Pagina 4**

% Stim. (% di tempo dal 15-Set-2009)

VS	100.0 %
VP	<0.1 %

OSSERVAZIONI (2)

- Problema di sensing: 18909 intervalli V-V brevi da 21-Set-2009 23:48:58. Controllare le onde R contate doppie, l'eventuale rottura dell'elettrocatetere o l'eventuale allentamento della vite di fissaggio.
- Funzione Patient Alert: >3000 ohm imped. elettrocat. Stim. RV.

Prevention Algorithm (LIA)

V-V short intervals -> 3000 Ohms impedance

↓

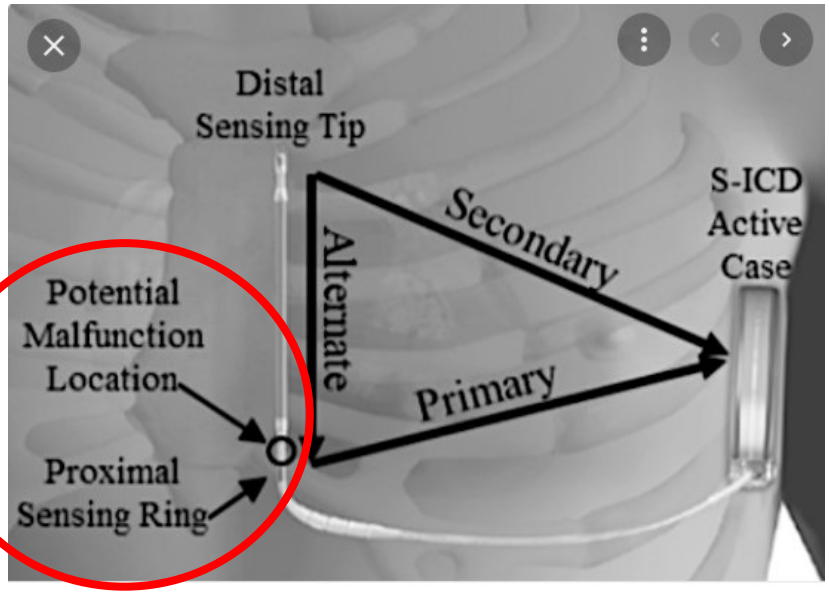
ALARM

↓

Lead replacement before inappropriate ICDs shocks

Boston Scientific Recalls EMBLEM S-ICD Subcutaneous Electrode (Model 3501) Due to Risk of Fractures

- Devices Recalled in the U.S.: 19,919
- Date Initiated by Firm: December 2, 2020



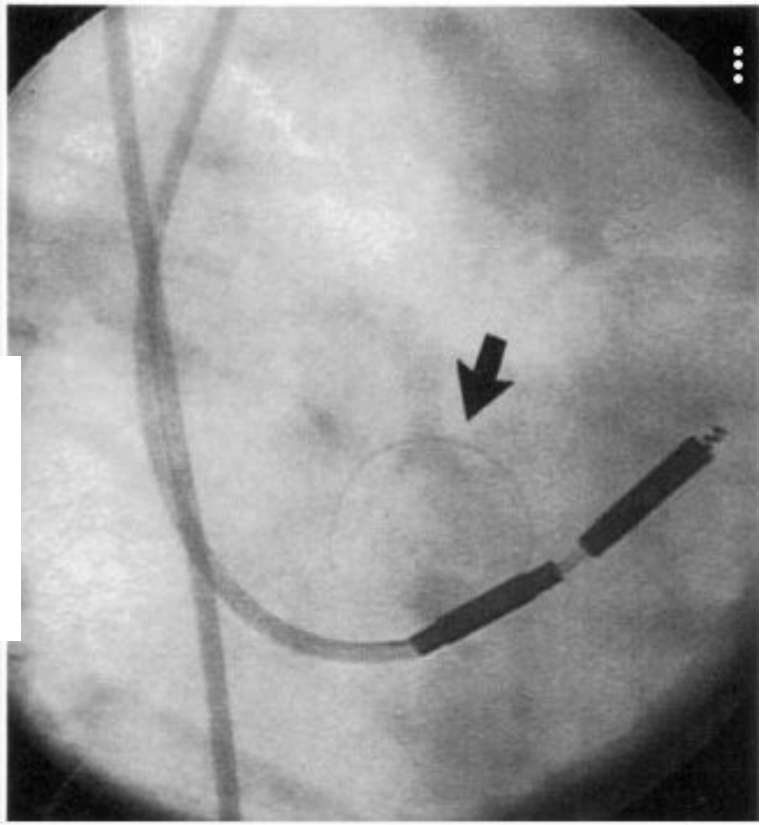
Leads (pacing-sensing-defibrillation) malfunctions:

- **Insulation leak**
- **Spiral externalization**

Telectronics Accufix pacing lead Class I recall affects about 36,500 devices.

This article was originally published in The Gray Sheet

02 Jan 1995



Leads (pacing-sensing-defibrillation) malfunctions:

- **Insulation leak**
- **Spiral externalization**

Public Health & Policy > FDA General

FDA Recalls St. Jude ICD Leads

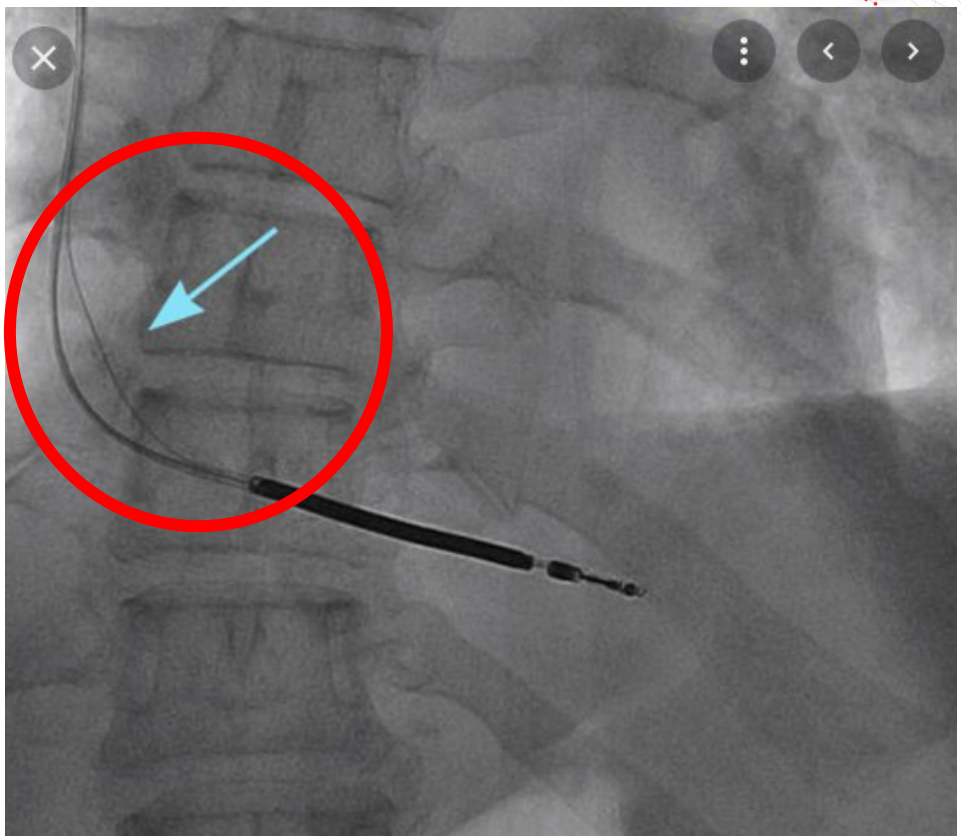
by Cole Petrochko, Associate Staff Writer, MedPage Today December 22, 2011

WASHINGTON -- The FDA has issued a Class I recall for several models of endocardial defibrillation leads because of premature abrasion of the insulation, which may cause a device failure.

St. Jude Medical's Riata (8F) and Riata ST (7Fr) Silicone Endocardial Defibrillation Leads may wear out their silicone insulation prematurely, which externalizes the leads' conductors. This can cause electrical dysfunctions and the device may malfunction, no longer delivering life-saving therapy, an FDA statement said.

News | Leads Implantable Devices | January 25, 2016

FDA Issues Serious Warning on St. Jude Optisure High-voltage Leads



Leads malfunction without leads damage and with Device OK:

- Lead (s) Displacement
- Perforation
- High pacing threshold
- Sensing malfunction

Malfunctioning PM-ICD-CRT Lead ?
No reprogrammation resolution?

Malfunctioning lead(s) extraction
+
New lead(s) implantation

Malfunctioning lead(s) abandoning
+
New lead(s) implantation

Malfunctioning lead(s) abandoning
+
New lead(s) implantation

PRO

- Less procedural risks (no related extraction risks)

CONTRO

- New lead(s) access difficulty
  (possible controlateral and tunnellization necessity)
- Interference between new and old leads risk
- Connectors compatibility
- MRI future incompatibility with abandoned leads

Malfunctioning lead(s) extraction
+
New lead(s) implantation

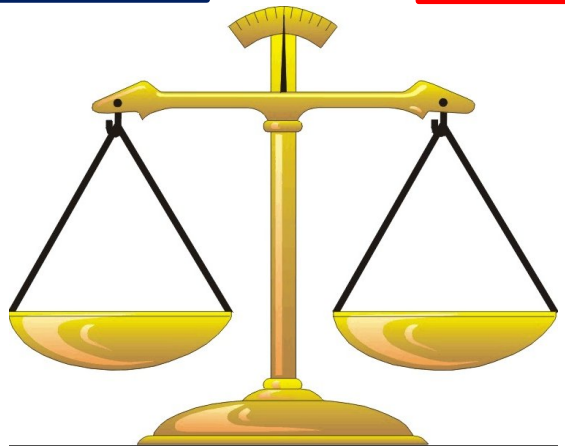
Extraction related probems:

- Possible lead break during extraction -> partial removing
- Displacememt risk of concomitant lead(s)
- New lead(s) access difficulty
- Vascular damage (death?) risk
- CCH stand-by

More difficult (and dangerous):

- Complete lead fracture (possible difficulty to mandrine insertion)
- Spiral inportant Extroflexion
- Perforation (pericardial tamponade)
- Old passive fixation lead
- Double-coil ICD lead-

Malfunctioning lead(s) abandoning



- Very aged patient
- Low probability future RMN
- Low interference leads risk
  (new lead far vs old lead)
- Necessity of simpler and faster procedure

Malfunctioning lead(s) extraction

- Non very aged patient
- Presence of more leads
- Not very aged Leads
  (better active fixation and single coil)
- Necessity of future RMN
- Better extraction material

ALWAYS EXTRACTION:

- Dangerous leads
(extroflexion/Perforation)
- Infective leads/system

NEWS • Daily News

Safe to Leave Recalled Sprint Fidelis ICD Leads in Place? Debate Continues

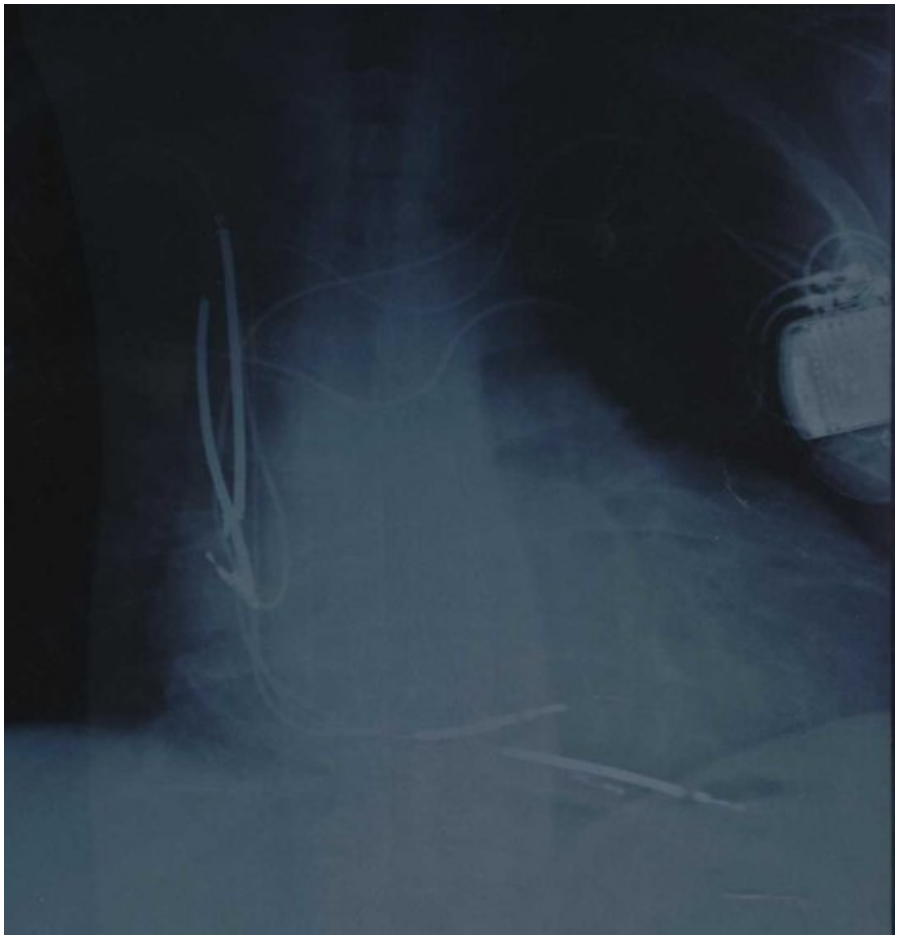
Lead abandonment as opposed to extraction led to few problems and no deaths at a single center. But not everyone is convinced.

by Todd Neale | AUGUST 28, 2019

To avoide

«Full Metall Jacket»

patient….



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