

X Reunión Anual de la  
Sección de  
Electrofisiología y  
Arritmias de la SEC

SOCIEDAD ESPAÑOLA DE CARDIOLOGÍA Sección de Electrofisiología y Arritmias

CON LA COLABORACIÓN DE:  
El grupo de trabajo de Resincronización Cardíaca de la SEC  
El grupo de Arritmias Cardíacas de la SEMES

del 06 al 08 de Abril de 2011  
SEVILLA

EUROPEAN HEART RHYTHM ASSOCIATION Bajo los auspicios de la European Heart Rhythm Association

Grupos Arritmias Cardíacas SEMES

SOCIEDAD ANDALUZA DE Cardiología

## DETECCIÓN PRECOZ DE DISFUNCIÓN DE ELECTRODOS MEDIANTE EL SISTEMA DE MONITORIZACIÓN REMOTA.

*Burgos Mora J \*, González Molinillo I\*\*, Dávila Berrocal A R \**

*\*Enfermero Unidad de Arritmias.*

*\*\* Enfermera área de hospitalización*

*Hospital Virgen de la Victoria de Málaga.*

Varón de 68 años, diagnosticado de miocardiopatía dilatada de origen mixto (isquémica y enólica) con función sistólica severamente deprimida (23%) al que se le implantó un desfibrilador monocameral Medtronic modelo Entrust y un electrodo Medtronic modelo 6949 (Sprint Fidelis). Dispone de dispositivo de monitorización domiciliar Carelink de Medtronic.



**Treated**

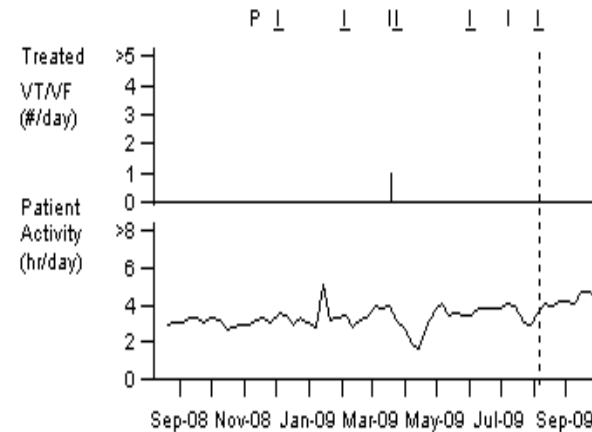
VF 0  
 FVT (Off)  
 VT 0

**Monitored**

VT (Off)  
 VT-NS (>4 beats, >162 bpm) 1,079  
 SVT: VT/VF Rx Withheld 0  
 VT-NS (>4 beats, >162 bpm) 1,079

**Functional**

Patient Activity **Last Week**  
 3.8 hr/day

**Therapy Summary**

Pace-Terminated Episodes  
 Shock-Terminated Episodes  
 Total Shocks  
 Aborted Charges

**VT/VF**

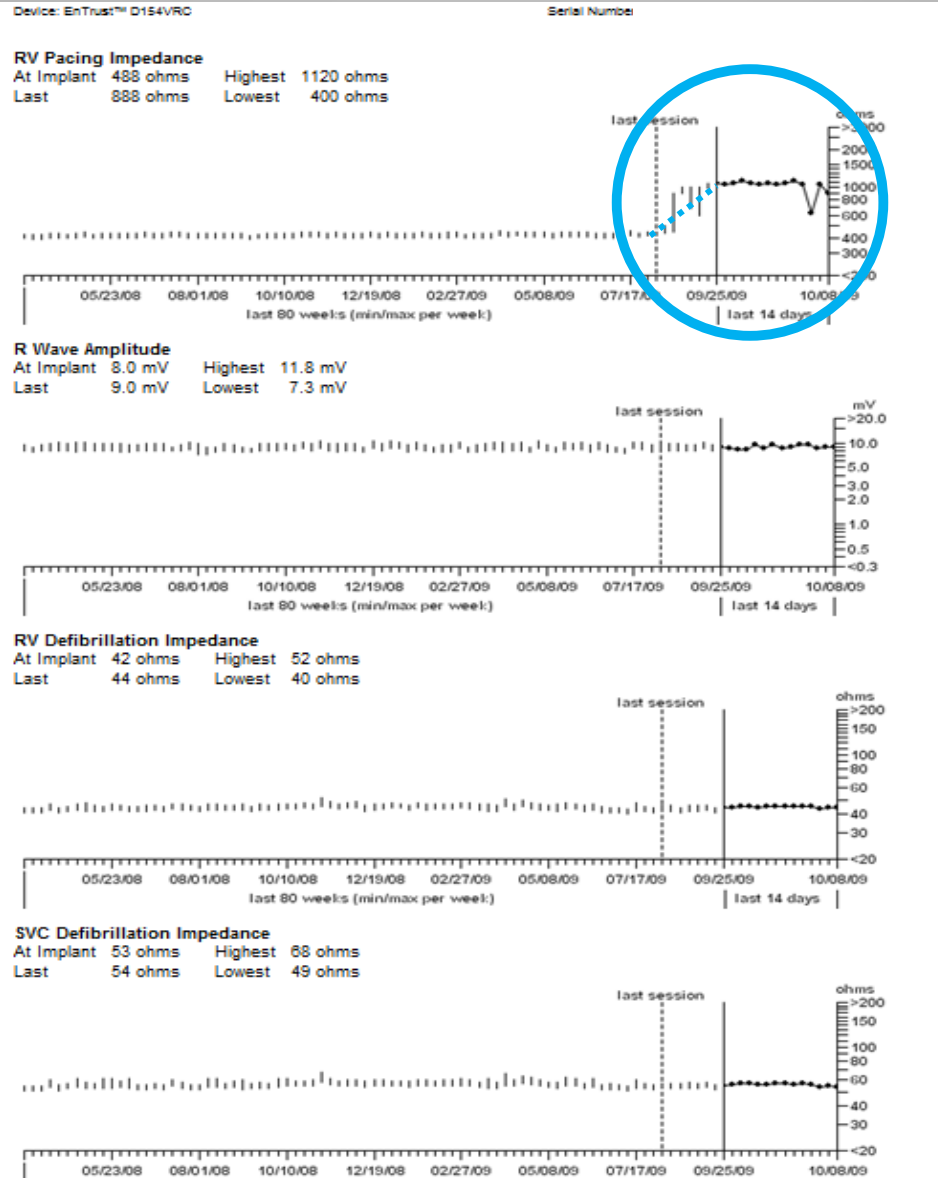
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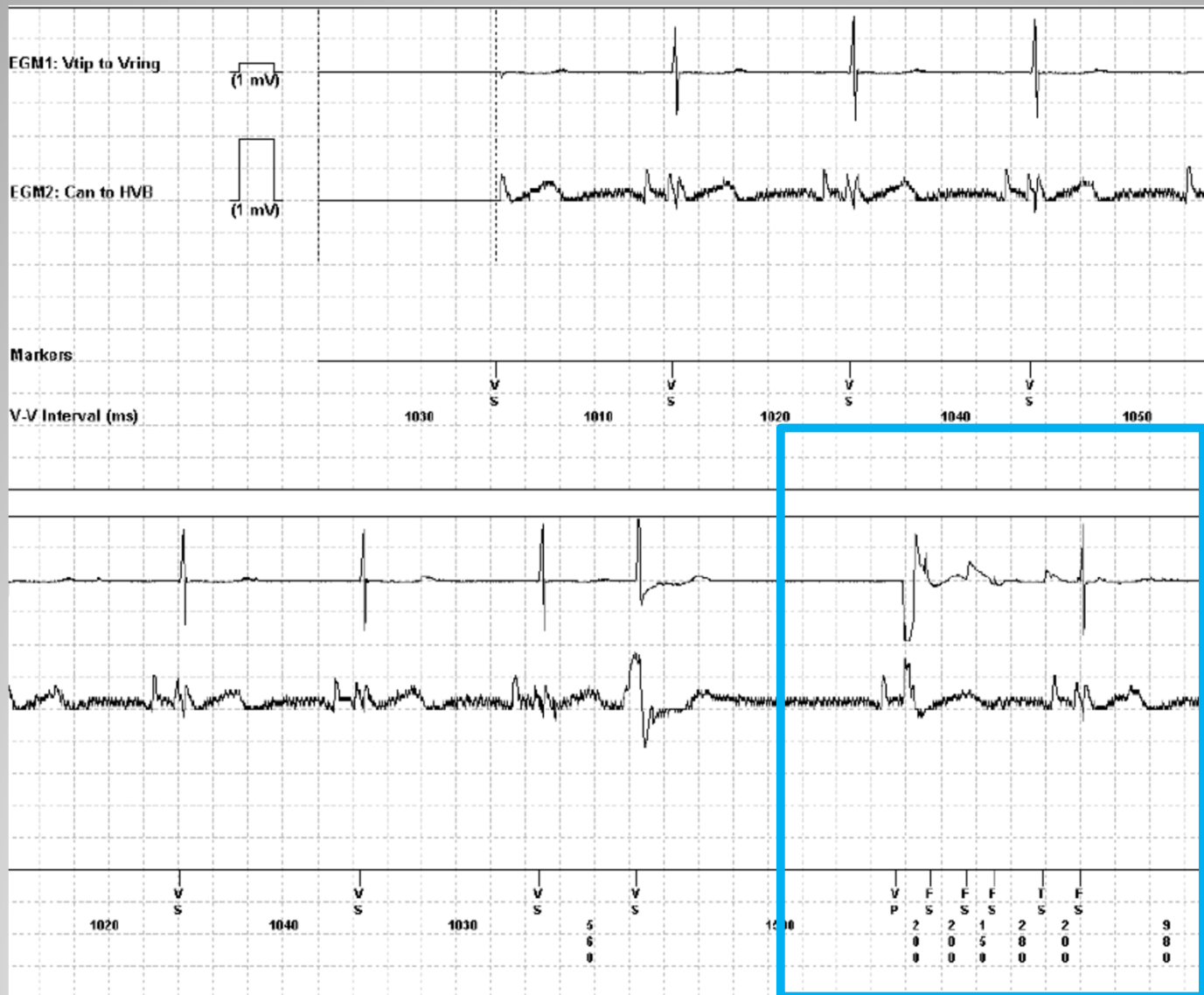
**Pacing (% of Time Since 06-Aug-2009)**

VS 99.7%  
 VP 0.3%

**OBSERVATIONS (3)**

- Sensing issue: 675 short V-V intervals since 18-Aug-2009 05:10:45. Check for double-counted R waves, lead fracture, or loose set screw.
- Patient Alert: RV Pacing lead impedance 1008 ohms.
- VF detection may be delayed: VF Detection Interval is faster than 300 ms (200 bpm).









### Notes

+LeadAlert

### VT/VF Detection

		V. Interval (Rate)	Initial	Redetect
VF	On	250 ms (240 bpm)	30/40	12/16
FVT	OFF			
VT	On	370 ms (162 bpm)	16	12
Monitor	OFF	450 ms (133 bpm)	32	

VT-NS (>4 beats, >162 bpm)

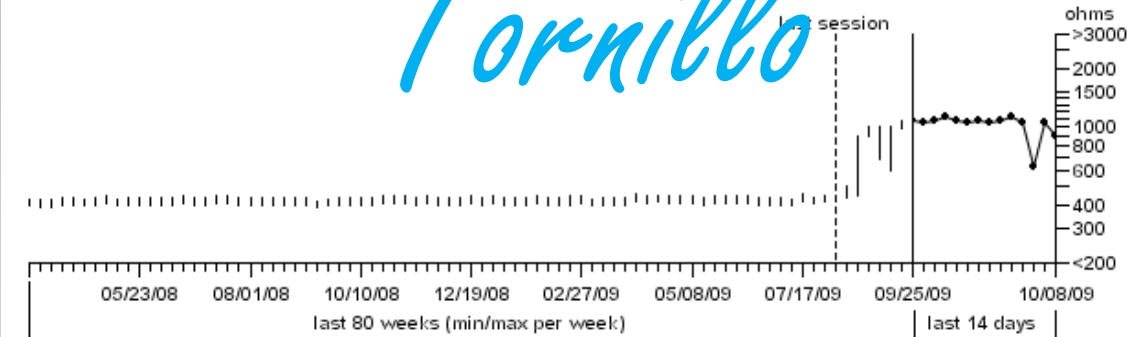
1,079

· Sensing issue: 675 short V-V intervals since 18-Aug-2009 05:10:45. Check for double-counted R waves, lead fracture, or loose set screw.

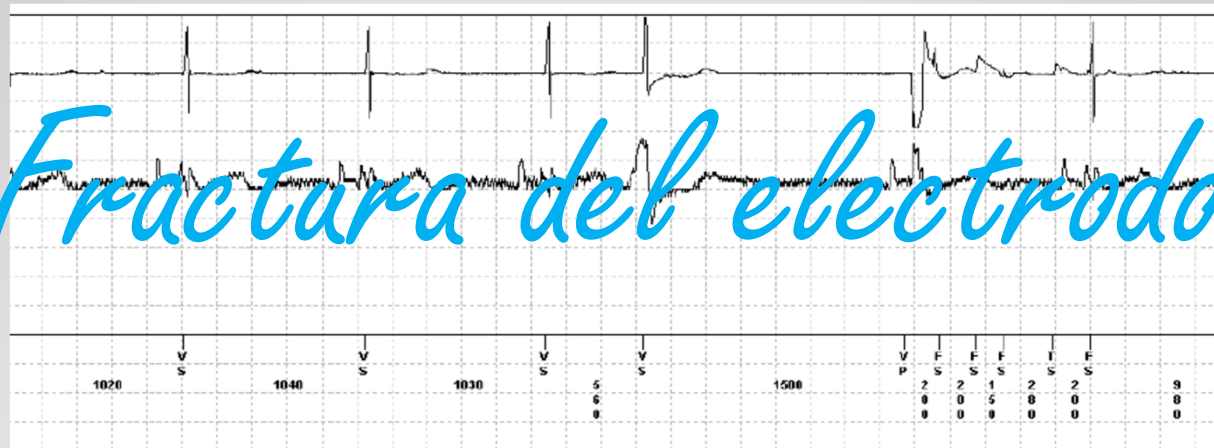
**RV Pacing Impedance**

At Implant 488 ohms    Highest 1120 ohms  
Last 888 ohms        Lowest 400 ohms

*Tornillo*



*Fractura del electrodo*







48 horas...

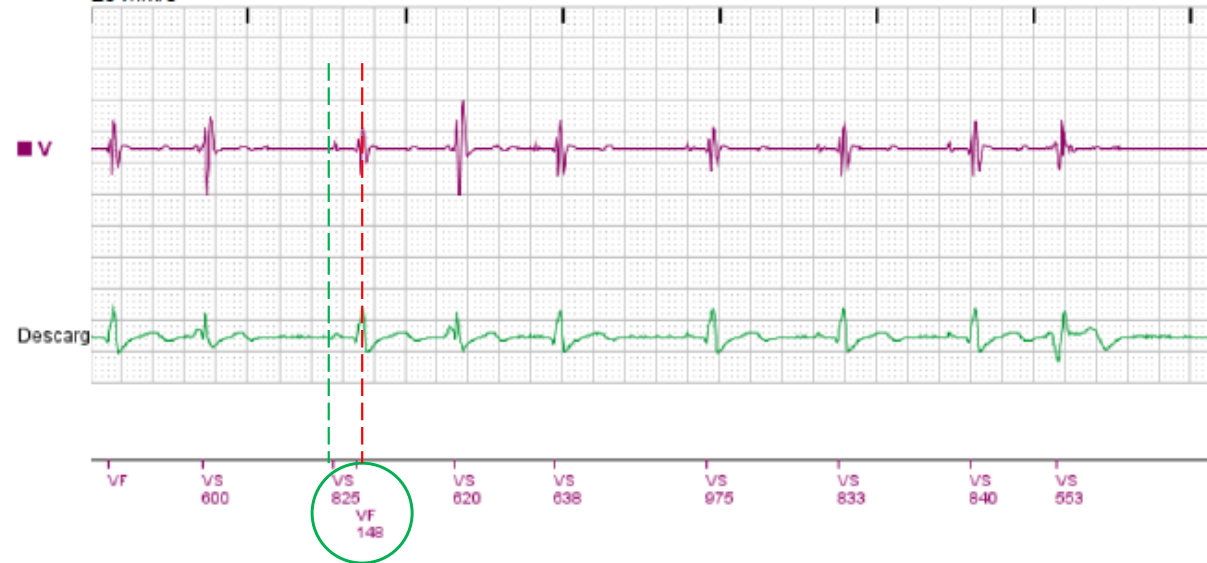


## Caso 2

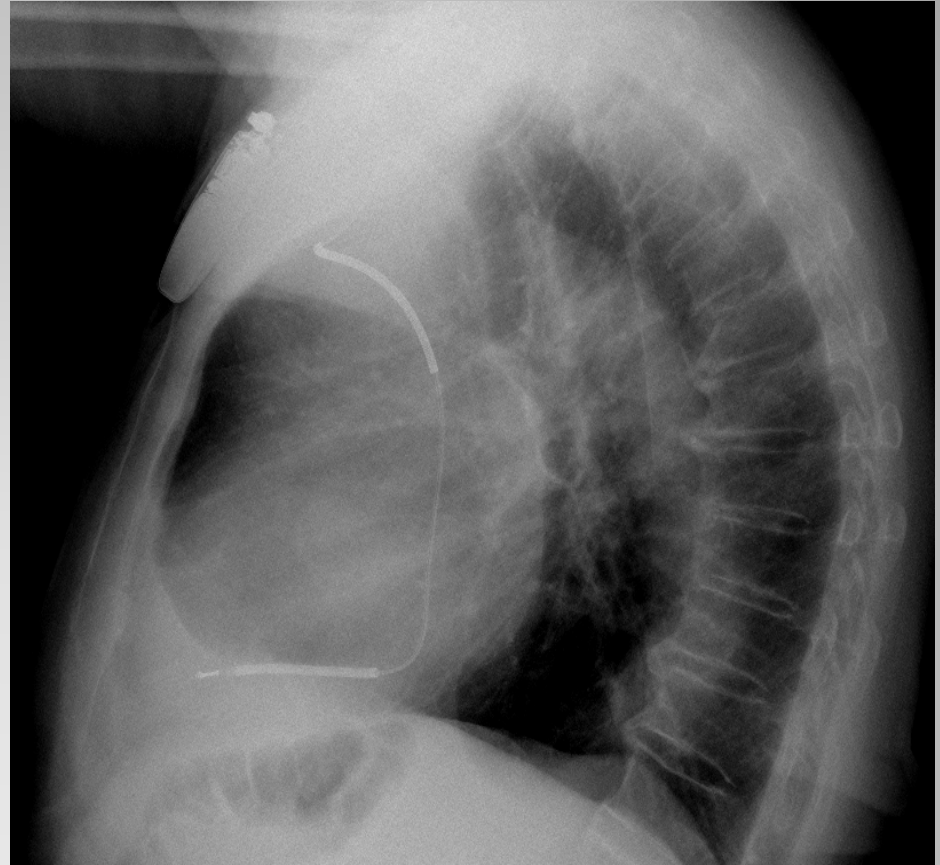
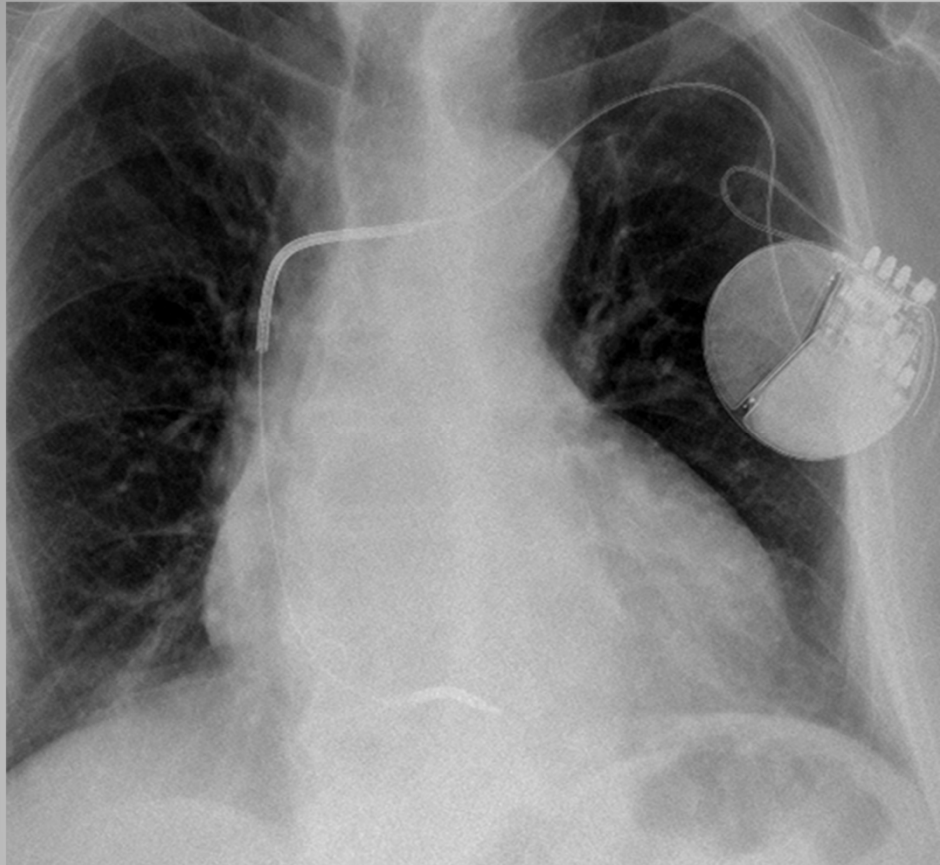
Varón de 74 años con historia de taquicardia ventricular repetitiva y diagnosticado de *Diasplasia Arritmogénica del Ventrículo Derecho (DAVD)*, al que se le implantó un desfibrilador automático monocameral de Boston Scientific modelo Teligen 100 F103 y un electrodo colocado en ápex de ventrículo derecho también de Boston Scientific modelo 0295 (Endotak Reliance). Al paciente se le entrega un transmisor Latitude de Boston Scientific, para la monitorización remota.

EGM de presentación 10 nov 2010

25 mm/s







### Parámetros

#### Configuración Taqui ventricular

Zona FV 200 min<sup>-1</sup> ATP, 41 J, 41 J, 41 J x 6

Zona TV 170 min<sup>-1</sup> ATP x 8, 41 J, 41 J, 41 J x 4

#### Parámetros antibradicardia

Modo bradi VVI

Límite inferior de frec. 40 min<sup>-1</sup>

Frecuencia máxima sensor -- min<sup>-1</sup>

Período refractario V (PRV) -- - 250 ms

Salida de estimulación

Ventricular

3,5 V @ 0,4 ms

Sensibilidad

Ventricular

AGC 0,6 mV

Configuración electrodos (estimul./detec.)

Ventricular

Bipolar

### Parámetros

#### Configuración Taqui ventricular

Zona FV 200 min<sup>-1</sup> ATP, 41 J, 41 J, 41 J x 6

Zona TV 170 min<sup>-1</sup> ATP x 8, 41 J, 41 J, 41 J x 4

#### Parámetros antibradicardia

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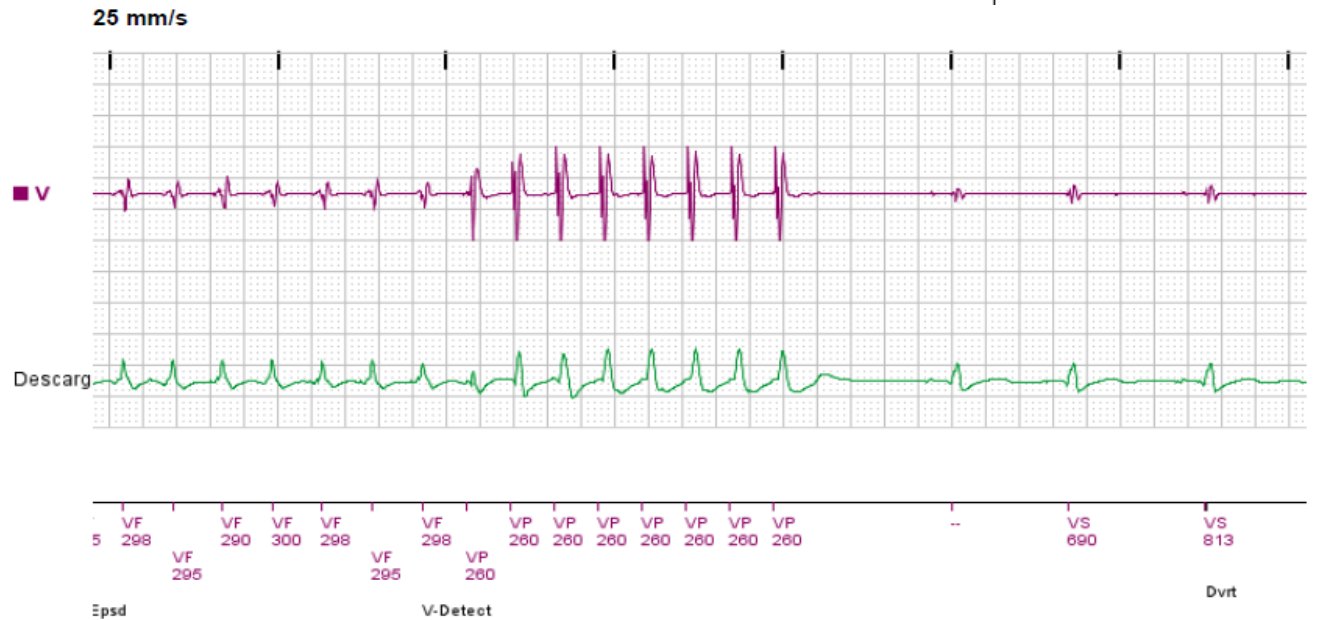
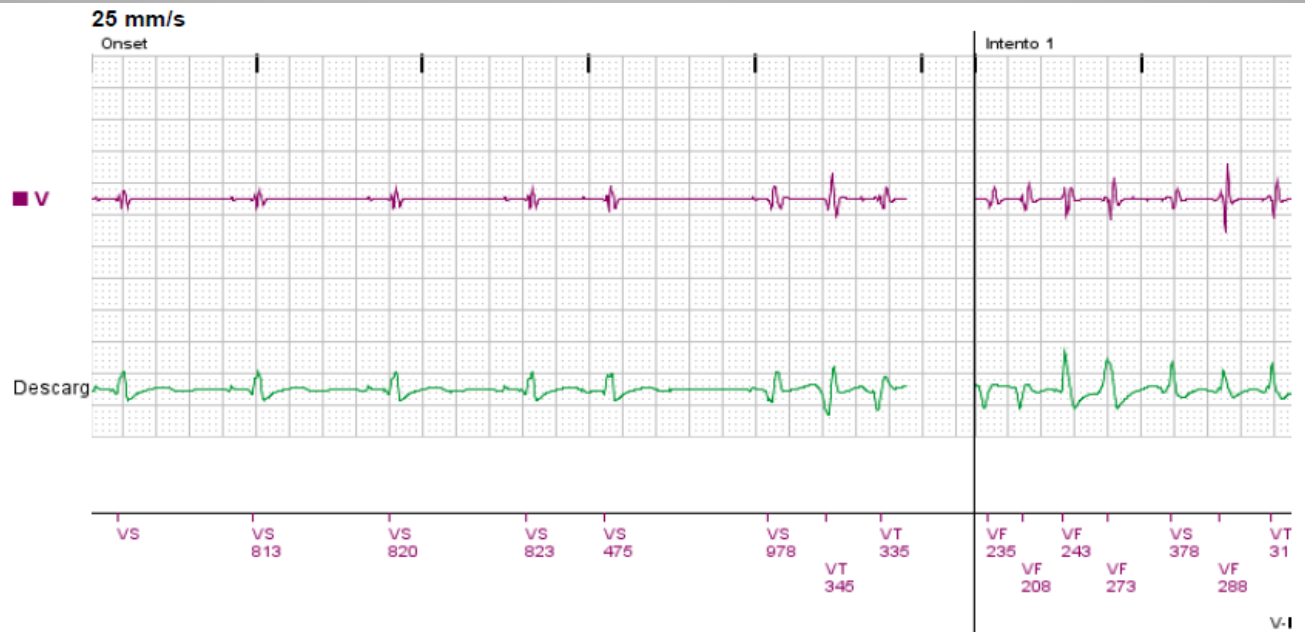
AGC 0,8 mV

Configuración electrodos (estimul./detec.)

Ventricular

Bipolar

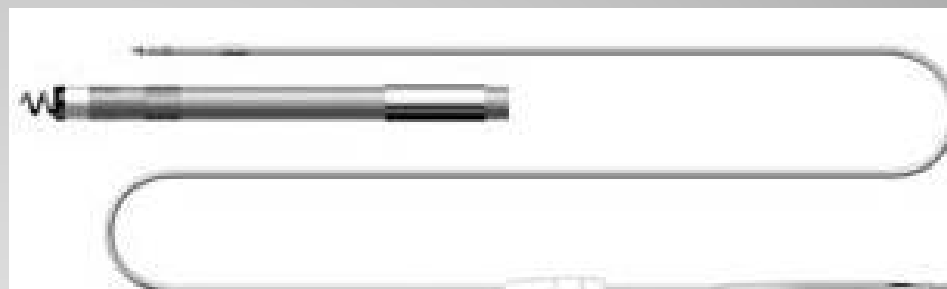




# Discusión



*Electrodo Sprint Fidelis  
mod 6949*



*Electrodo Endotak Reliance  
mod. 0295*

# MEDTRONIC LEAD RECALL CENTER

DEFECTIVE LEADS CAN RESULT IN INJURY / DEATH

Talk To A Lawyer Now And Get  
Your Free Case Review  
Toll Free 1-888-343-5375

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## MEDTRONIC LAWSUIT SEARCH

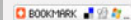
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## FIELDS LAW FIRM

We are a law firm dedicated to helping those injured by Medtronic Sprint Fidelis Defibrillator Lead.



## BOOKMARK THIS SITE



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- Child Defective Leads
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- Medtronic Quick Set Recall
- Medtronic Recall Deadlines
- Medtronic Recall Lead 6930
- Medtronic Recall Lead 6931
- Medtronic Recall Lead 6948
- Medtronic Recall Lead 6949
- Sprint Fidelis Recall
- Uncategorized

## STAY UPDATED

Email Address

## Medtronic Lead Recall

Medtronic Heart Lead Recall States | September 8th, 2010  
The Medtronic **Sprint Fidelis 6949** is one of the manufacturer's heart defibrillator leads that was subject to the Medtronic lead recall in 2007. These defective leads were also used in non-Medtronic heart defibrillators and pacemakers.

**What is the function of defibrillator leads?**  
Defibrillators are implanted heart devices that shock abnormal heart rhythms back to a normal rhythm. A "lead" is a wire that connects the defibrillator to the heart. More than 288,000 Medtronic **Sprint Fidelis** leads have been implanted worldwide, according to the manufacturer.

**What happened in Medtronic Sprint Fidelis 6949 leads?**  
The defective **Sprint Fidelis 6949** leads break after the defibrillator has been implanted. Medtronic suspended distribution of these defibrillator leads in 2007. Suspending the distribution of the defibrillator leads is classified as a "recall." The Medtronic recall was prompted when the manufacturer identified five patient deaths in which a Medtronic **Sprint Fidelis** lead fractured and was a likely contributing cause of death. However, this does not mean that the leads should be taken out of patients. The FDA stated in a news release that: "We recognize that some patients and health care professionals might inappropriately interpret the word 'recall' to mean that the devices must be surgically removed and returned to the manufacturer. Although the leads should no longer be implanted in patients, we do not mean to imply that these leads should be surgically removed." There is no test to predict which leads will fail.

**What should patients do about the defective leads?**  
Patients with **Sprint Fidelis 6949** leads should first consult with their doctor. If you have a defibrillator and do not know the manufacturer and model of the lead, you should quickly contact your doctor. If it is determined that you have a device with potentially defective leads, you should see your doctor right away.

The FDA agrees with Medtronic that defibrillator settings be adjusted at the patient's next scheduled follow-up visit with their doctor. Doing so may increase the likelihood that a fractured lead will be detected before a patient is harmed, according to the FDA. Doctors should "weigh the risks and benefits of either continuing to use the lead with careful monitoring or capping the lead so it is no longer useable and implanting a different model," according to the FDA.

If you have a Medtronic device with defective leads, you should contact an experienced attorney. There is no class action lawsuit.

## MEDTRONIC RECALL INSULIN INFUSION SETS

## Help And Information For Patients

## MEDTRONIC RECALL RESOURCES

U.S. Food & Drug Administration Statement On Medtronic Sprint Fidelis Defibrillator



Medtronic Suspends Sprint Fidelis Defibrillation Leads (PDF)

U.S. FDA Class 1 Recall Report

## FREE CASE CONSULTATION

If you or a loved one have been injured by the Medtronic Sprint Fidelis lead please contact us immediately. You may be entitled to compensation.

Name:   
Email:   
Phone:   
State:   
Message:

## MEDTRONIC RECALL & LAWSUIT NEWS

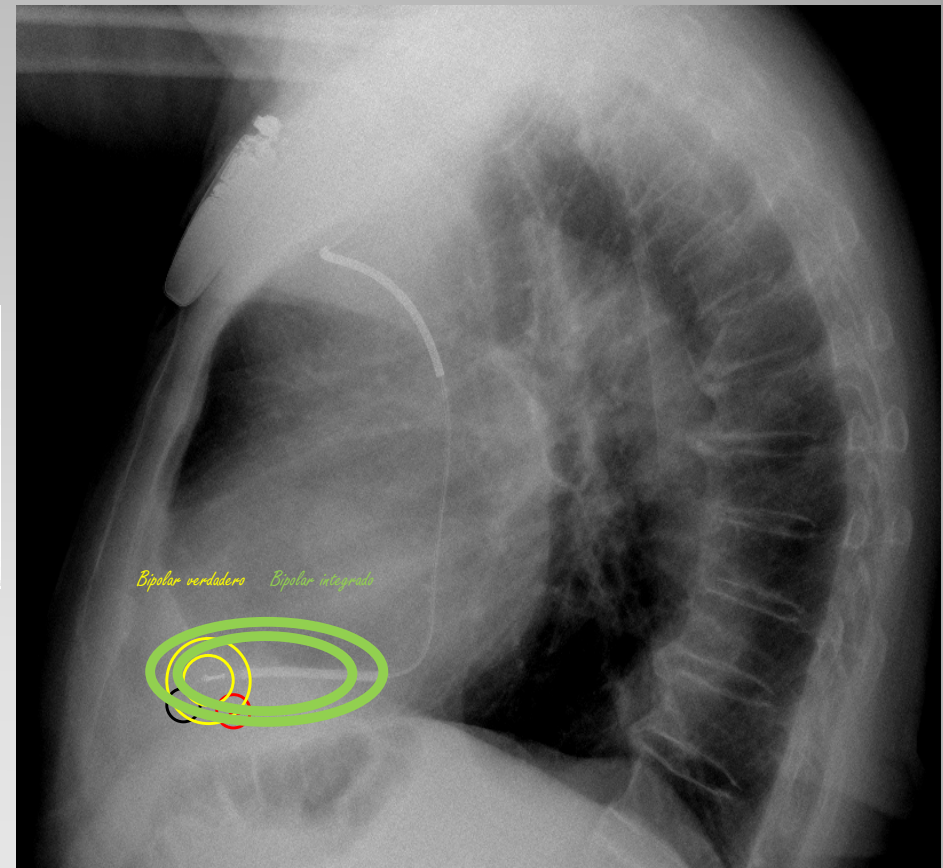
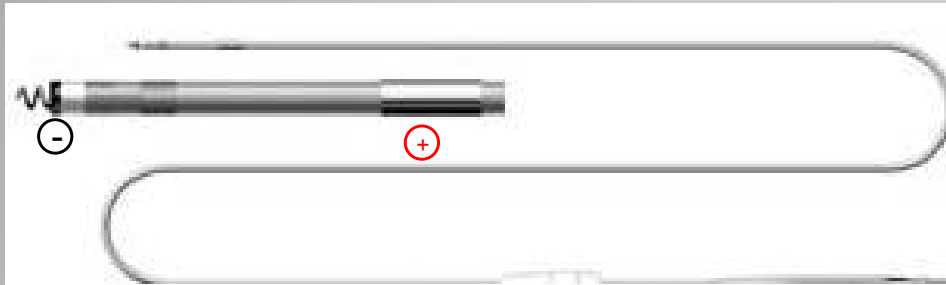
**Medtronic Lead Recall**  
The Medtronic Sprint Fidelis 6949 is one of the manufacturer's heart defibrillator leads that was subject to

*Discusión*



*Electrodo Sprint Fidelis  
mod 6949*

# Discusión



*Electrodo Endotak Reliance mod. 0295*



# Conclusiones

Los dispositivos de monitorización remota han mostrado eficacia en la detección rápida y el acortamiento en los tiempos de decisión clínica en pacientes portadores de desfibrilador automático implantable <sup>1</sup>.

El seguimiento de los dispositivos implantables, puede ser realizado con eficacia y seguridad por un equipo de enfermería cualificado y supervisado por un equipo médico especializado <sup>2</sup>.

1.- Crossley GH, Boyle A, Vitense H, et al The CONNNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) Trial. *J Am Coll Cardiol*, 2011; 57. En prensa.

2.- Ricci RP, Morichelli L, Sartini M. Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization. *Eurpace*. 2008 Feb;10(2):164-70. Epub 2008 Jun 16.



