

# MEDTRONIC CARDIAC DEVICE RECALL

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DISCLAIMER: This information is not intended to replace the advice of a doctor. Please use this information to help in your conversation with your doctor. This is general background information and should not be followed as medical advice. Please consult your doctor regarding all medical questions and for all medical treatment.



## TYPES OF MEDTRONIC DEVICES RECALLED IN 2005

### 1. ICD Implanted Cardioverter Defibrillator

- Marquis and Maximo

### 2. CRT Dimplanted Cardiac Resynchronization Therapy Device

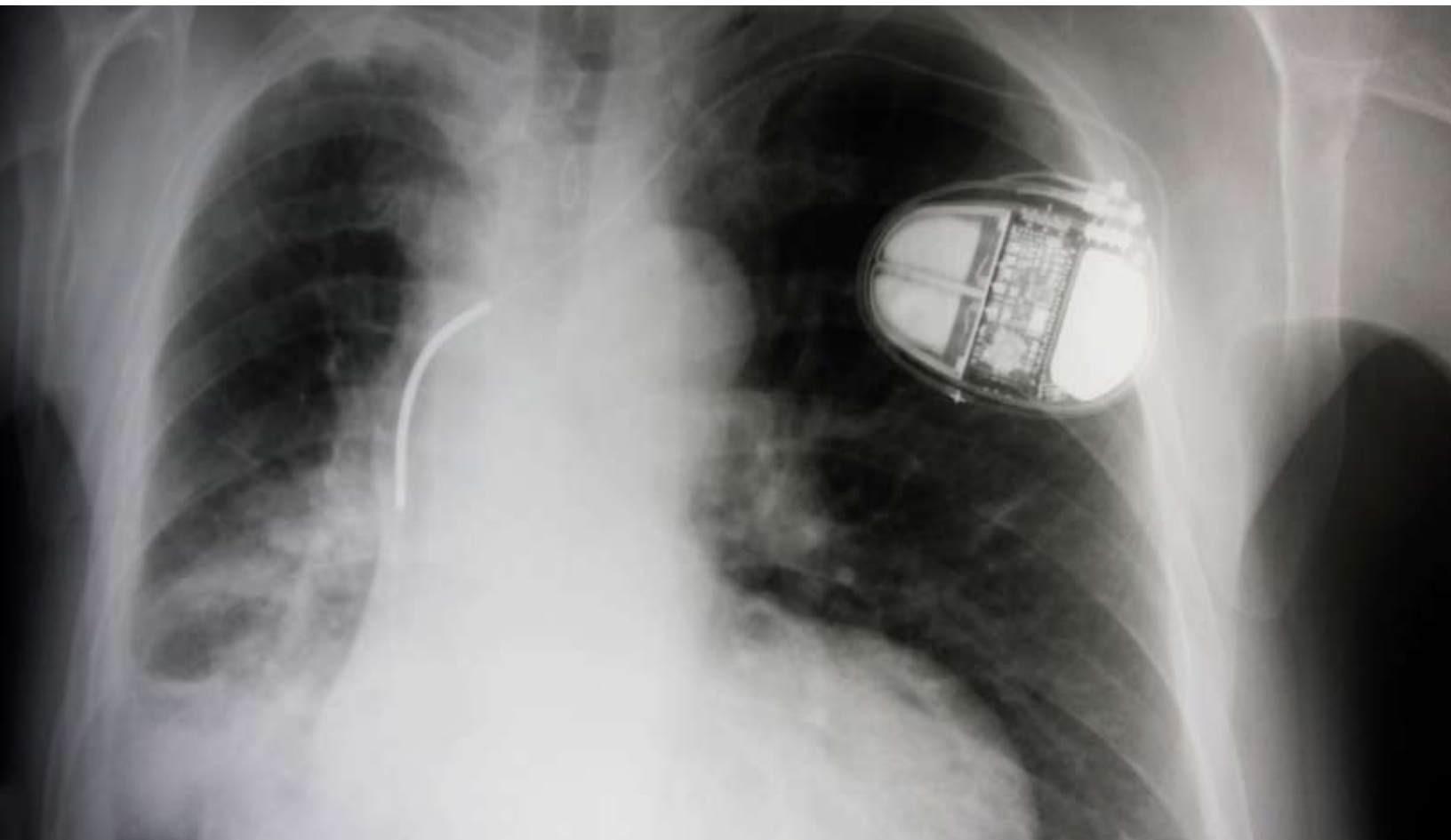
- InSync

### 3. ECD External Cardioverter Defibrillator

- LIFEPAK 12 and LIFEPAK 20

### 4. AED Automated External Defibrillator

- LIFEPAK 500 (also subject to previous recalls)



## DIFFERENTIATION OF ICD, CRT-D, ECD, AND AED DEVICES

### 1. ICD (Implanted cardioverter defibrillator)

An ICD is used for recurring, sustained, ventricular tachycardia and/or ventricular fibrillation. Lead wires are placed inside the heart and run from there to the unit implanted in the chest, which houses a pulse generator. The lead wires sense cardiac rhythm and deliver this information electronically to the ICD unit. When ventricular tachycardia or fibrillation is detected, the pulse generator shocks the heart to restore normal rhythm.

- **Current generation devices also provide:**
  - overdrive pacing to electrically convert a sustained ventricular tachycardia to normal rhythm;
  - backup pacing if bradycardia occurs; and
  - Various other functions, such as storage of detected arrhythmic events and the ability to do noninvasive electrophysiologic testing.

Medtronic Marquis DR Implanted Cardioverter Defibrillator  
Medtronic Maximo DR ICD

### 2. CRT-D (Cardiac Resynchronization Therapy Device)

Used to treat congestive heart failure .Atrial-synchronized, biventricular pacing using standard pacing technology combined with a special third lead in a cardiac vein to sense and/or pace the left ventricle. Following a sensed atrial contraction or atrial-paced event, both ventricles are stimulated to synchronize their contraction. Ventricular resynchronization reduces mitral regurgitation and improves left ventricular filling and heart function.

Medtronic InSync Maximo CRT-D  
Medtronic InSync Marquis CRT-D



## Device model numbers for implanted devices recalled in 2005

- **ICD models**

1. Model 7230 Marquis VR
2. Model 7274 Marquis DR
3. Model 7232 Maximo VR
4. Model 7278 Maximo DR

- **CRT-D models**

1. Model 7277 InSync Marquis
2. Model 7289 InSync II Marquis
3. Model 7279 InSync III Marquis
4. Model 7285 InSync III Protect

### The problem is the same for all ICD and CRT-D implanted devices

“Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism.”

“There is no provocative testing that predicts which of these Devices will experience this issue. Once a short occurs, depletion can take place within a few hours to a few days, after which there is complete loss of device function. It is also possible that as the battery depletes quickly...”



## 3. ECD (EXTERNAL CARDIOVERTER DEFIBRILLATOR)

- **Uses the same technology as an ICD.**
- **Performs the same functions as an ICD plus external monitoring screen.**
- **Ordinarily used in hospitals.**

Medtronic LIFEPAK 20 ECD  
Medtronic LIFEPAK 12 ECD

## 4. AED (AUTOMATED EXTERNAL DEFIBRILLATOR)

- **Portable units used by first responders and mounted in public places.**
- **No monitor.**
- **Used in emergency situations to defibrillate.**

Medtronic LIFEPAK 500 AED



## Summary of 2005 recalls

- **Implanted Maximo and Marquis ICD models used for tachycardia.**
- **Implanted InSync CRT-D models used for congestive heart failure.**
- **External LIFEPAK 12 and 20 ECD models used in hospitals.**
- **External LIFEPAK 500 AED models used by first responders.**

Like most people, we advertised for implanted devices only

### **Guidant and Medtronic implanted cardiac defibrillators and pacemakers recalled**

Nearly 200,000 electronic heart devices, comprised of many different model names and numbers, are being recalled because of manufacturing defects that can cause life-threatening device failure. Implanted cardiac defibrillators, also called cardioverters or ICD's, made by both Medtronic and Guidant, along with Medtronic pacemakers, are included in the recalls.

Contact us for information about the models covered and about the legal rights of people affected by defects in these devices.

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## THERE ARE PROBABLY NOT MANY EXTERNAL DEVICE CASES

- **External devices by their nature don't need explanted, so there is no case for a person on whom a recalled external device was used in the absence of a documented adverse event.**
- **Most of the recalled external AEDs (LIFEPAK 500) were never used.**
- **Problems with external devices are different than the battery problems with implanted devices.**

## HOW MANY IMPLANTED CASES?

65,000 recalled devices in the United States means there are 65,000 cases are out there somewhere.



## IDENTIFICATION OF RECALLED MEDTRONIC IMPLANTED DEVICES

You have just entered the device identification web page.

### **The MARQUIS device family physician communication dated February 2005**

You may use this web page to determine whether any Medtronic device is within the population of devices described in Medtronic's letter to physicians dated February 2005 regarding the following device models:

- Model 7230 Marquis VR
- Model 7274 Marquis DR
- Model 7232 Maximo VR
- Model 7278 Maximo DR
- Model 7277 InSync Marquis
- Model 7289 InSync II Marquis
- Model 7279 InSync III Marquis
- Model 7285 InSync III Protect

**Enter serial number into search function box:**

Example: PKC113641H

Note: Serial number must be entered accurately and exactly or search will not work properly. To determine whether any Medtronic device is within the population of devices affected by the field communication, please follow the instructions below:

Type the serial number of the Medtronic device in the search box above. The serial number must have three alpha characters followed by six numeric digits and one alpha character.

If the serial number falls within the population of affected devices, the serial number will appear in a box and will state that the device IS subject to the physician communication of February 2005.

If the serial number does not fall within the population of affected devices, the serial number will appear in the box and will state that the device is NOT subject to the physician communication of February 2005. Note: To obtain accurate and reliable results, you must enter the serial number accurately. If you have questions about the results of your search or the use of this web page, please contact your Medtronic representative.

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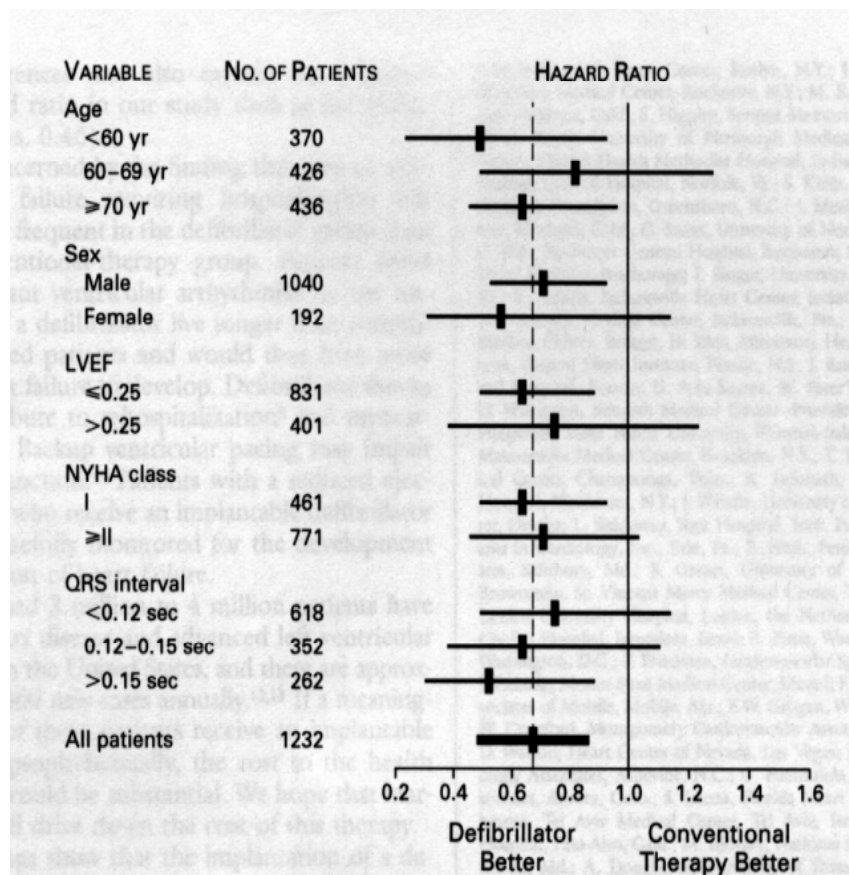
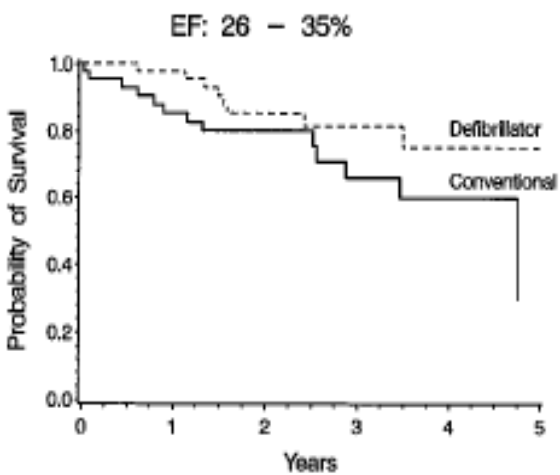
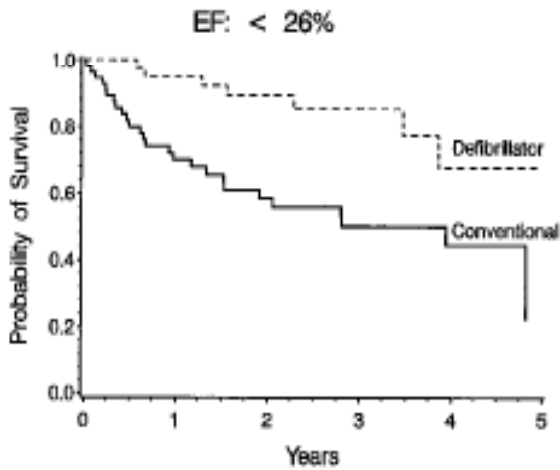
## RISKS AND BENEFITS OF IMPLANTED DEVICES

Primary prevention with the ICD :the sickest people benefit the most

MADIT Trial Moss, Circulation 2000

Primary prevention with the ICD :those with the larger QRSd benefit the most

New England Journal of Medicine March 21, 2002



## Initial Experience With an Implantable Cardioverter-Defibrillator Incorporating Cardiac Resynchronization Therapy

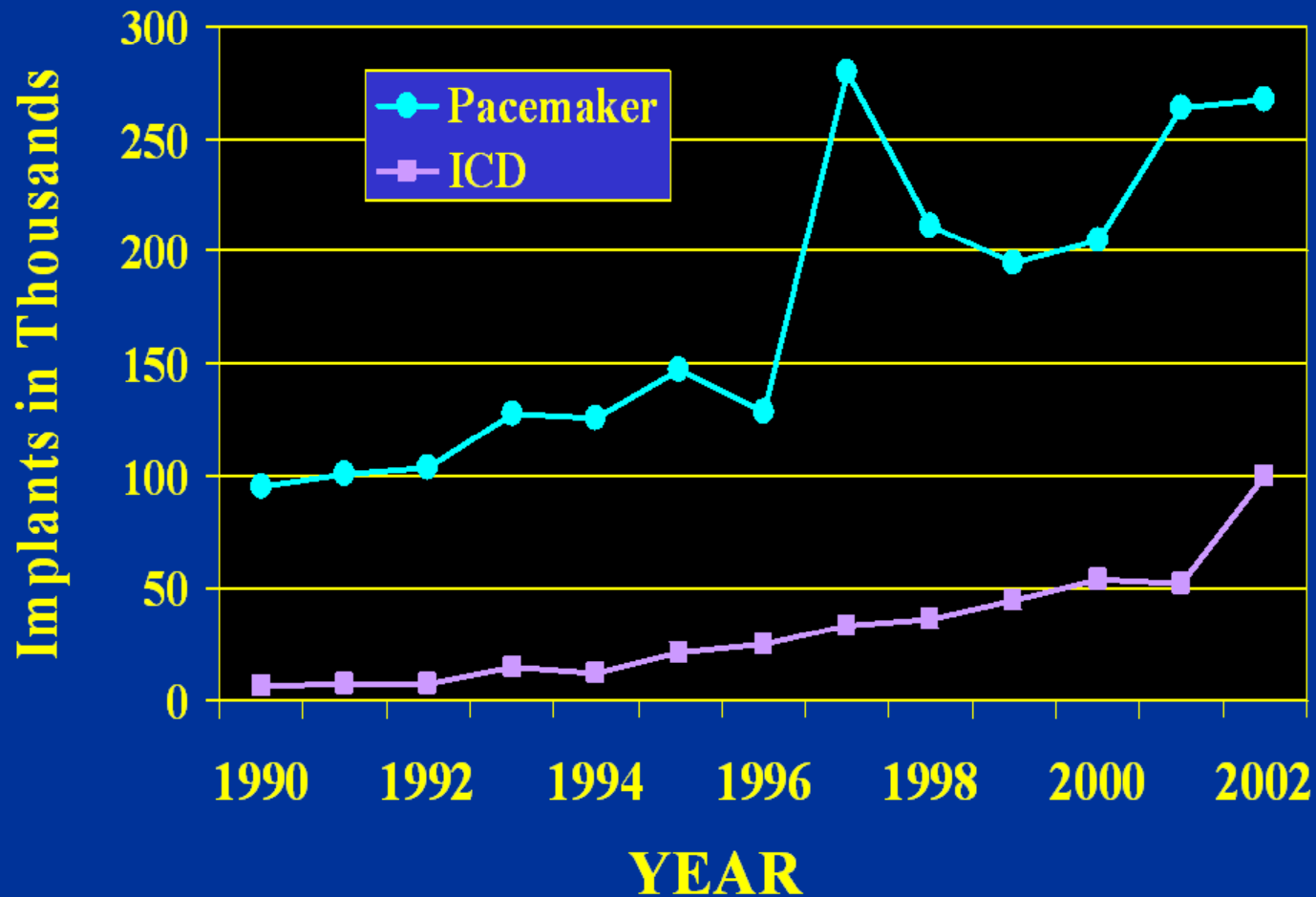
Volker Kühlkamp, MD, for the InSync 7272 ICD World Wide Investigators\*

- **Implant success 96%**
- **Procedure duration : 192±84 minutes**
- **CS lead positioning : 77±64 minutes**
- **Implant related complications : 12%**
- **CS perforation/dissection : 4/84**
- **CS lead dislodgement : 7/84**
- **Infection : 2/84**

THE FOLLOWING PAGES ARE  
SLIDES FROM DR. MAISEL'S  
PRESENTATION TO THE FDA  
ON SEPTEMBER 16, 2005

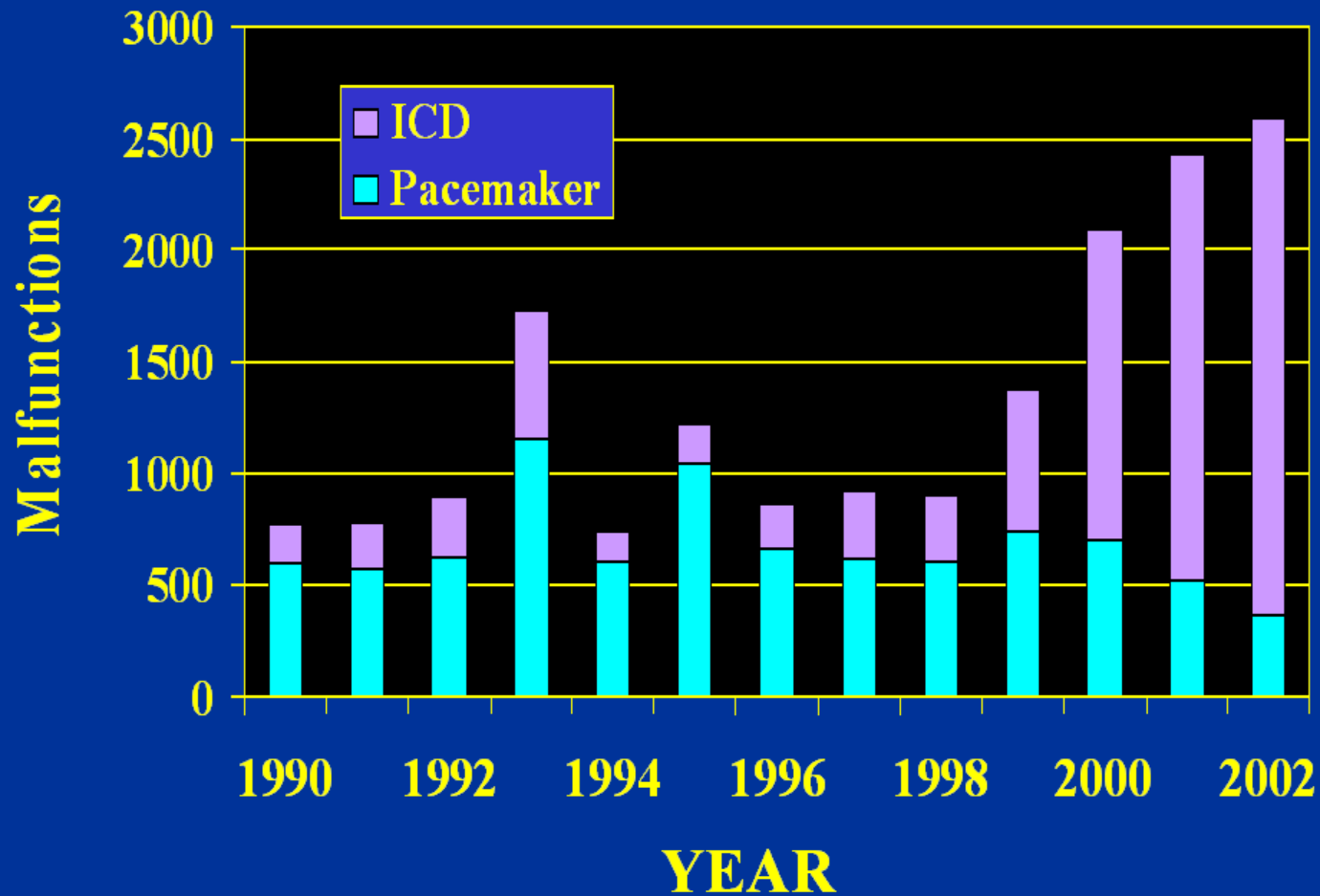


# Annual Pacemaker and ICD Implants in the United States



William Maisel, MD, MPH  
September 16, 2005

# Annual Pacemaker and ICD Malfunctions in the United States

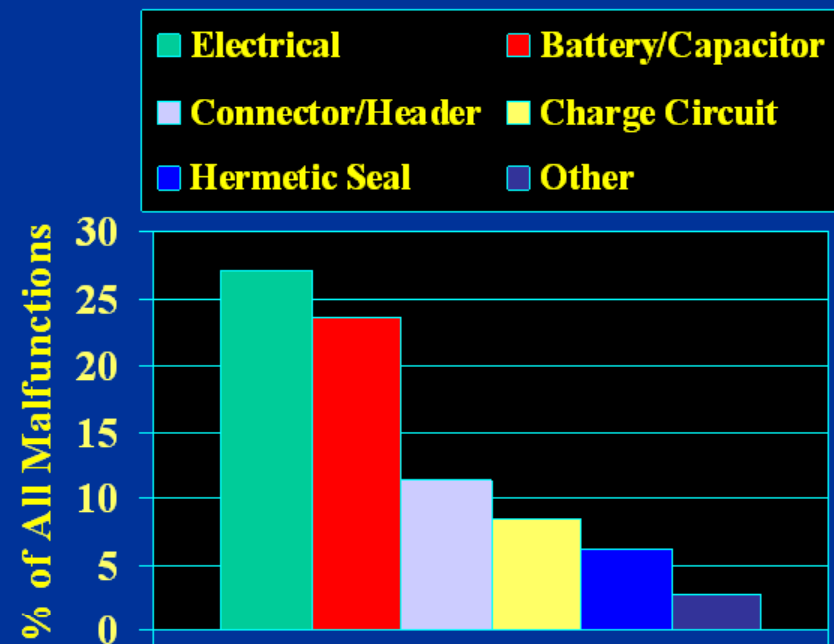


William Maisel, MD, MPH  
September 16, 2005

# Type and Frequency of Malfunctions

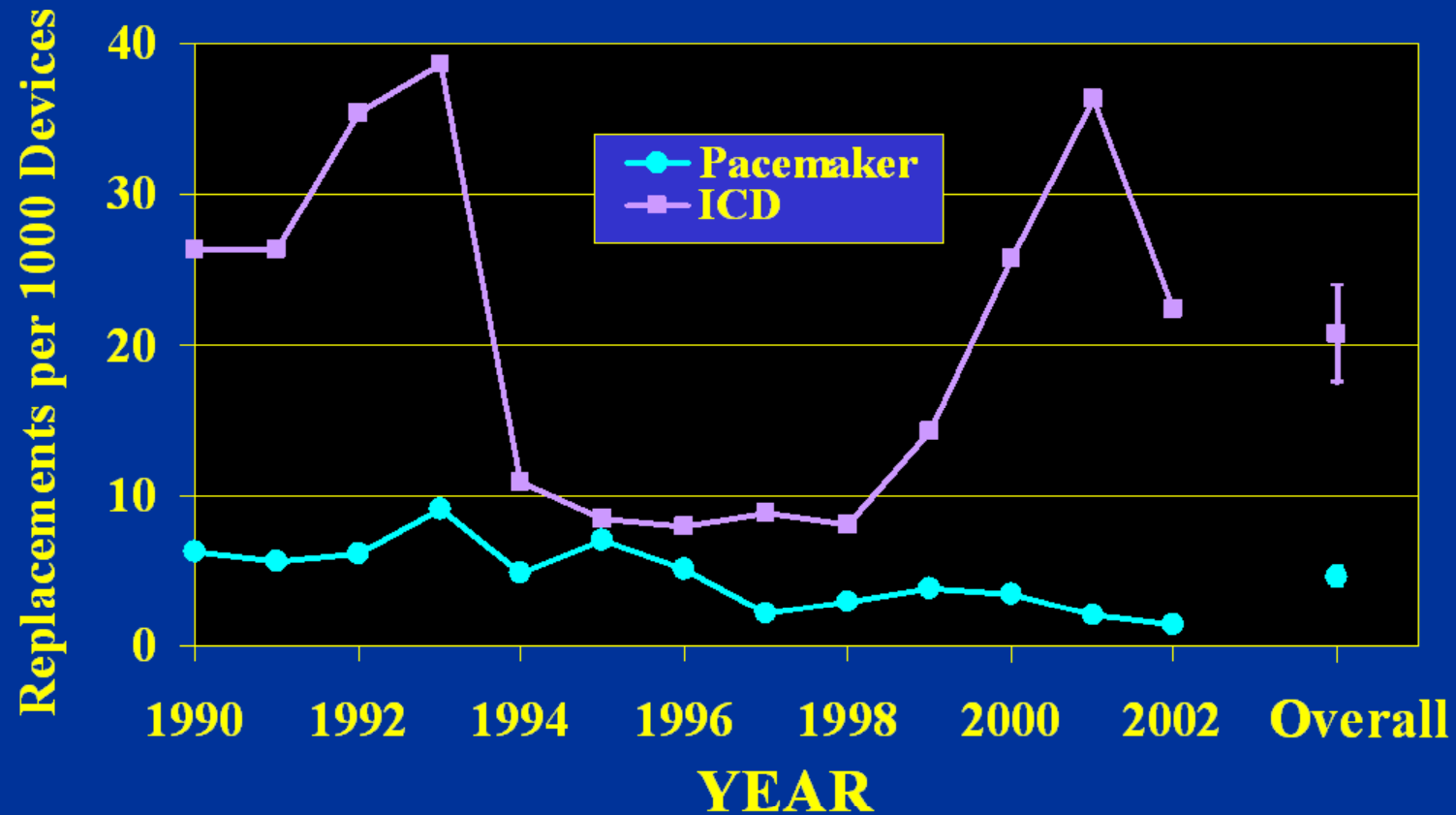
## 17323 PM and ICD Malfunctions

Type of Malfunction	% of All Malfunctions
Hardware	79.8
Firmware	3.6
Miscellaneous	11.8
Inconclusive	4.7



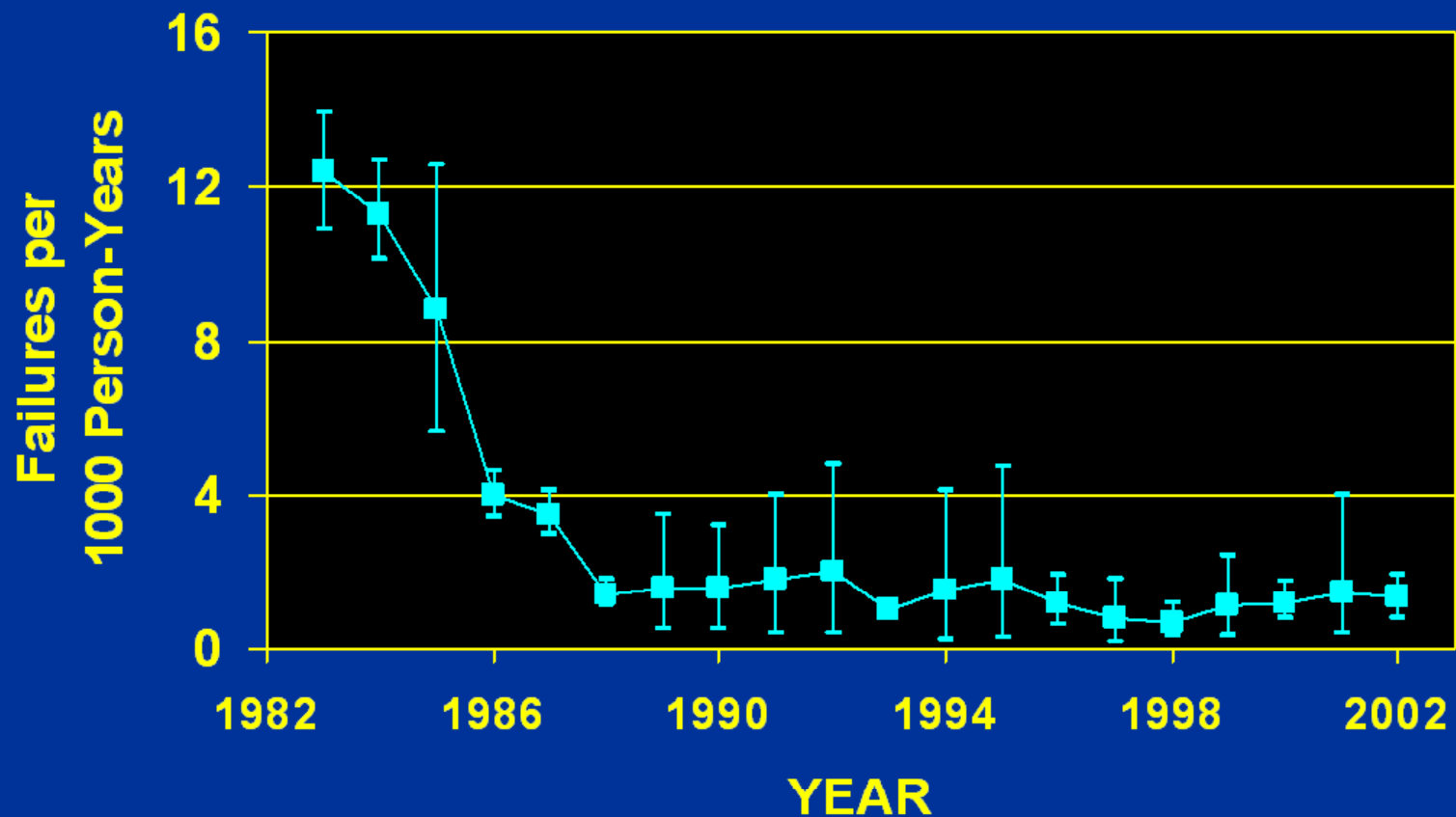
**Hardware Malfunctions**

# Pacemaker and ICD Generator Replacement Rates for Malfunction



# Pacemaker Generator Malfunction Rates

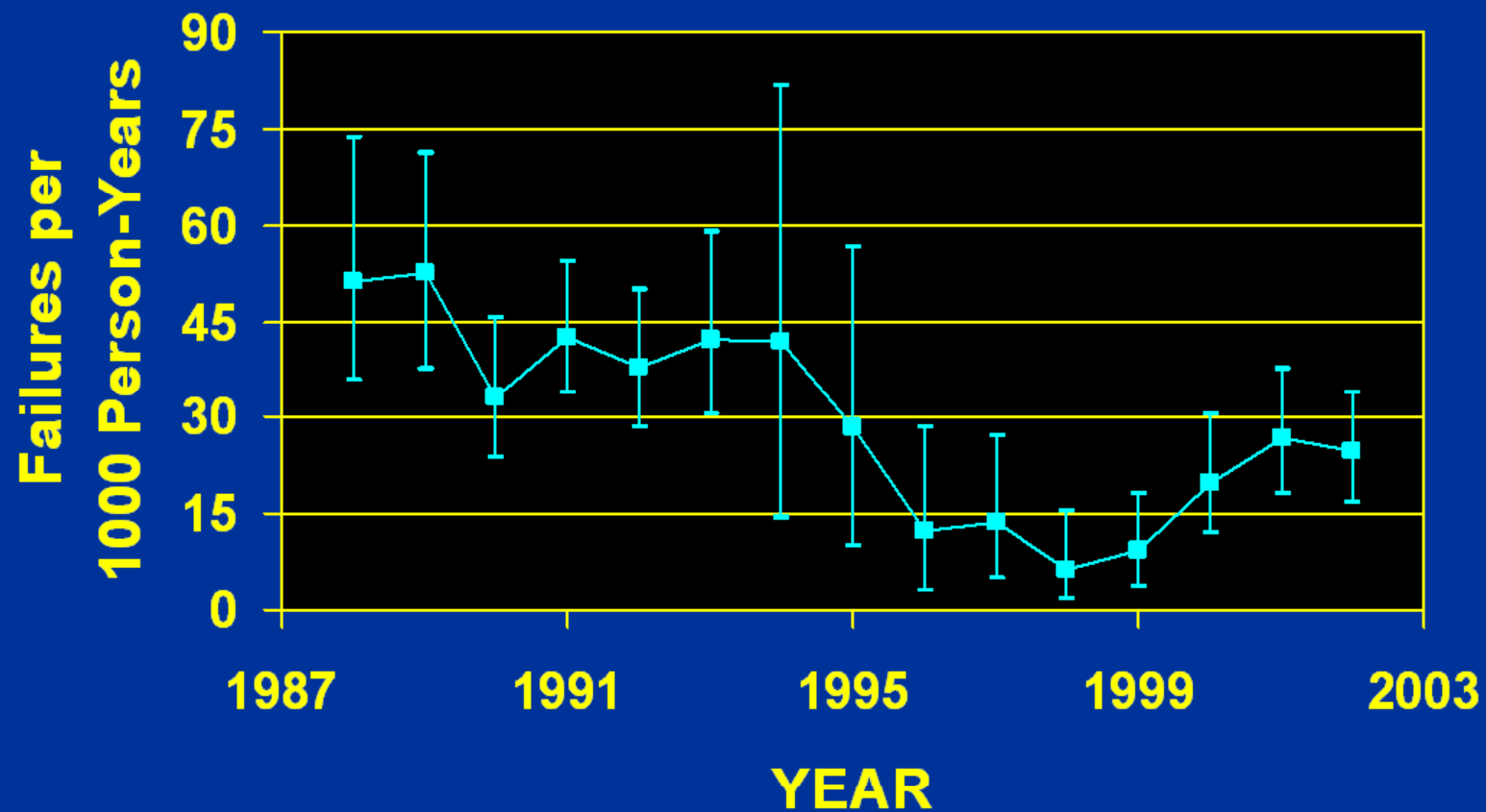
## Meta-Analysis of Non-FDA Published Registries



William Maisel, MD, MPH  
September 16, 2005

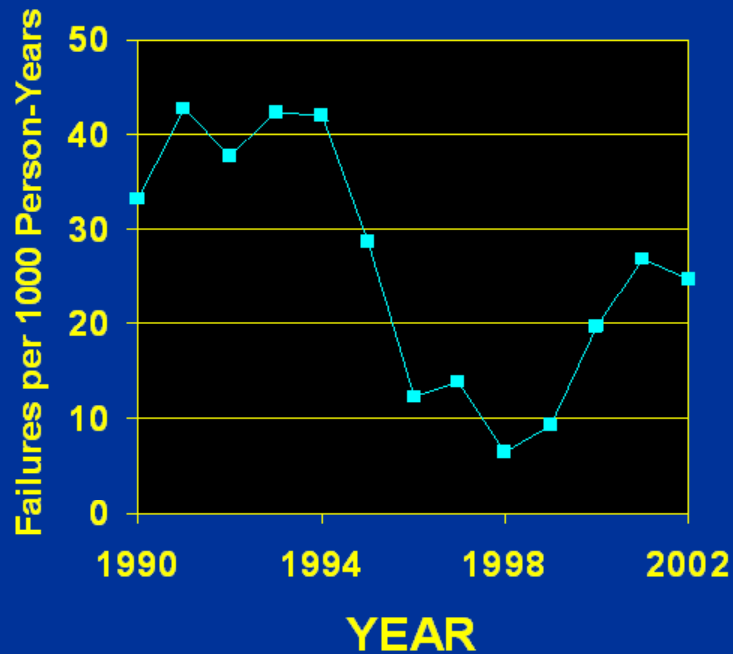
# ICD Generator Malfunction Rates

## Meta-Analysis of Non-FDA Published Registries



# ICD Generator Malfunction Rates

Meta-Analysis of  
Non-FDA Published  
Registries



Analysis of FDA Annual  
Report Data

