

Dispositivi impiantabili attivi compatibili con MRI

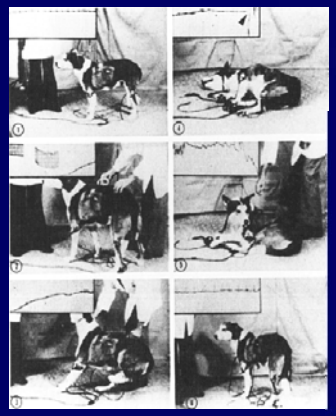
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CIEDs and MRI: two long stories that never met...



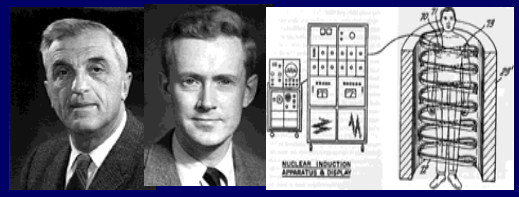
1957







Mirowski 1980



Felix Bloch ed Edward Purcell 1946



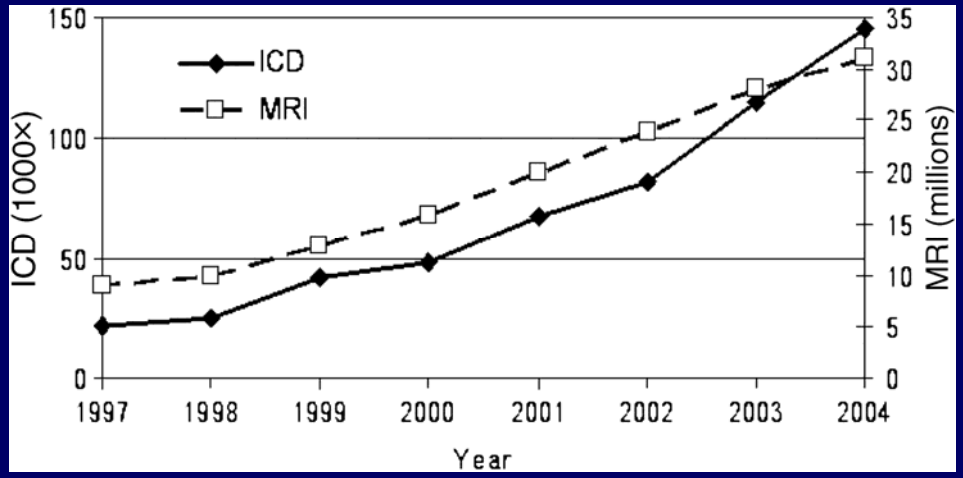
Paul C.Lauterbur e Sir Peter Mansfield

- 2D e 3D images
- Images in few minutes

NOBEL for medicine in 2003



A large unmet clinical need

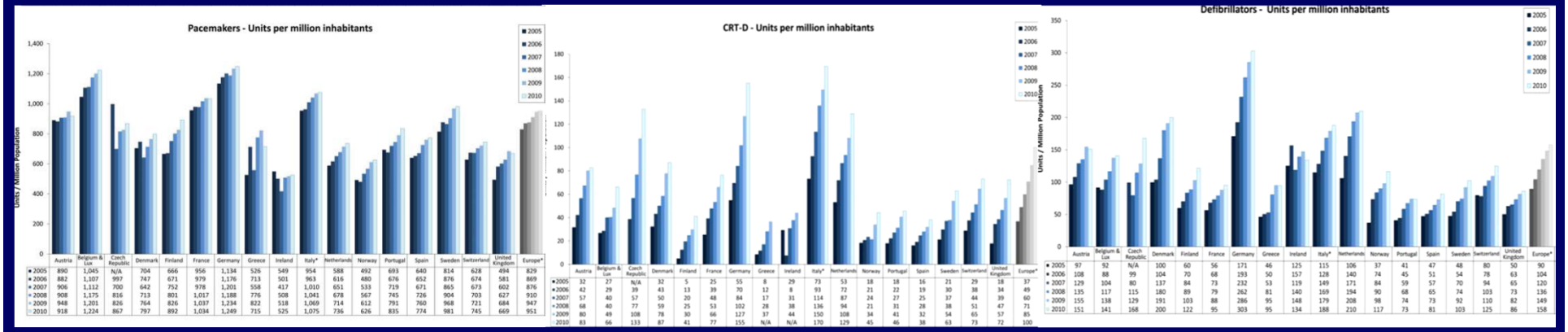


Number of annual MRI scans and of newly implanted ICDs in US[1]

WHY CIEDs IMPLANTS ARE INCREASING?

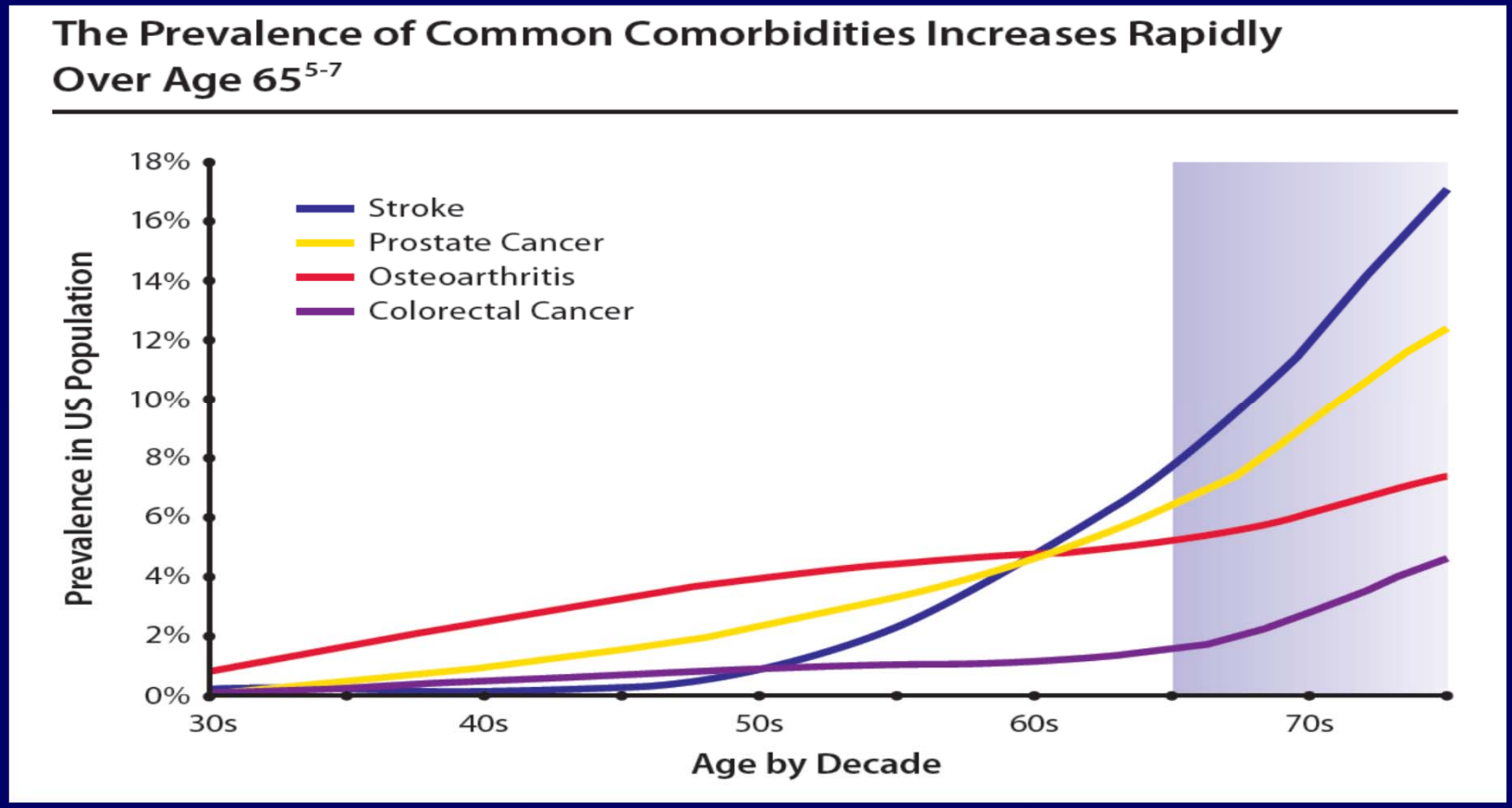
1. Expanding Indications
2. Extending Life expectancy

1. Roguin A, et al. *Europace*. 2008;10:336-346
2. Dubner S, et al. Europace 2012, 14: 278-293



The same in Europe…[2]

Prevalence of common co-morbidities, many of which rely on MRI, increases rapidly over age 65



Limitazioni alla MRI

- La probabilità di effettuare una RMN raddoppia per I pazienti con un età superiore ai 65 anni[1]
- In un periodo di follow-up di 12 mesi, il 17 % dei pazienti portatori di PMK necessita di un esame diagnostico RMN[2]
- Al 50-75% dei pazienti portatori di device sarà negata la possibilità di sottoporsi alla RMN per l'intera durata della batteria del device[3].

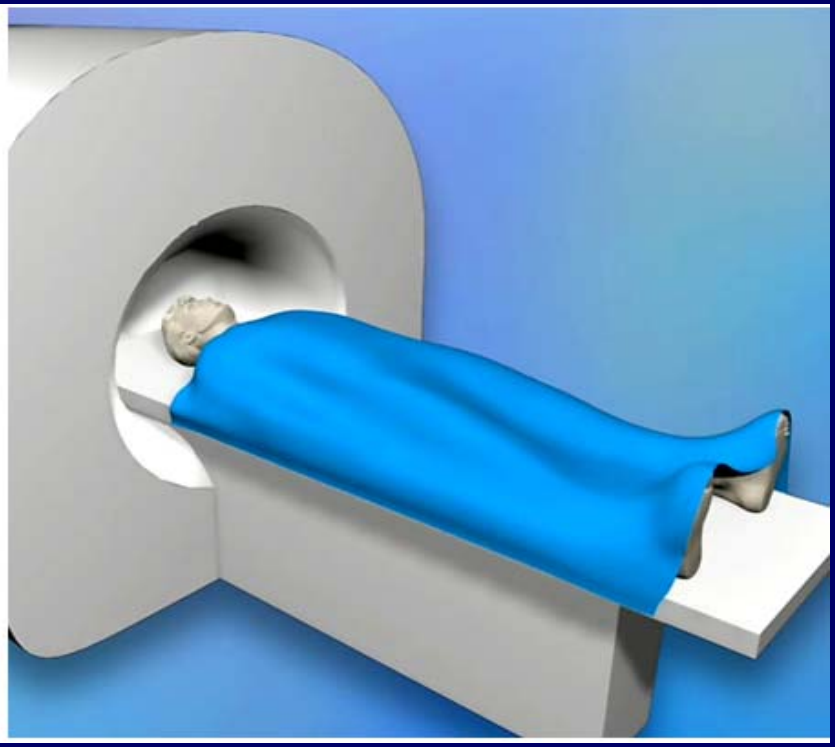
	Pacemakers	ICDs	CRTs
North America	564,074	234,780	148,092
Europe	683,472	87,747	61,010

1. Magnetic Resonance Imaging (MRI) Equipment – A Global Strategic Business Report, Global Industry Analysts, Inc., San Jose, CA. 2002
2. Sakakibara et al., Jpn Heart J 1999
3. Roguin A. Europace 2008; 10: 336–346



Rischi per un PMK nella MRI

		Field		
		B_0	G_x G_y G_z	B_1
Potential Hazard	Force, Torque	√		
	Cardiac arrhythmia		√	√
	Pacemaker component damage	√	√	√
	Interference with pacemaker function		√	
	Electrical reset	√	√	√
	Lead Tip Heating			√



Main magnetic field B0	(static)	0.5-3.0 Tesla (T)
Gradient field G x,y,z	(time-varying)	slew rate: □ 200 T/m/s
		max. strength: □ 60 mT/m
RF-field B1	(time-varying)	frequency:21-128 MHz
		power: some kW

STATO DELL'ARTE: Storia PMK e MRI

- 13 casi di decesso di pazienti portatori di pacemaker attribuiti a RMN
- I dati sono probabilmente sottostimati
- Irnich segnala già 6 casi di morte in Germania tra il 1992 e il 2001:

Table 4 Cause of death, magnet rate of models and magnetic field strength of MRI units of the six cases of Table 3

Case	Fibrillation	Mag. rate	PM brand/type	MRI/strength
# 1	Unknown	100 min^{-1}	Vitatron/TX 915	Picker/0.5 T
# 2	Yes	65 min^{-1}	Medtronic/Minix	Philips/0.5 T
# 3	Yes	55 min^{-1}	Medtronic/Pasys	Philips/0.5 T
# 4	Unknown	100 min^{-1}	Siemens/Prolog	Philips/1.5 T
# 5	Yes	70 min^{-1}	Biotronik/NeosLP	G. E./1.5 T
# 6	Unknown	100 min^{-1}	Vitatron/Ceryx 3	Siemens/1.0 T

Fibrillation means "ventricular fibrillation". PM = pacemaker, Mag. = magnet, MRI = magnetic resonance imaging.

Irnich W. Europace 2005; 7: 353-365

Rischi principali per un paziente portatore di PMK durante un esame in MRI

- Oversensing e Inibizione
- Pacing Asincrono e induzione di Aritmie
- Riscaldamento delle punta del catetere e perdita di cattura
- Malfunzione del device/Danneggiamento
  - Interferenza nel Sensing a causa del RF/gradient-induced current
  - Interferenza nel Pacing a causa del RF/gradient-induced current
  - Integrità meccanica e riscaldamento della cassa a causa del B0-related
  - Programming interference/Re-programming due to RF
  - Circuito/componenti danneggiati
  - Dislocazione del catetere o danni meccanici sia alla cassa che al catetere a causa del campo magnetico, responsabile di indurre vibrazione e torsione.

Quali Rischi?

I sistemi di RMN sottopongono il paziente:

Campo Magnetico Statico
Bo

↓

Inibizione dello stimolo del PMK o reversione della programmazione in modalità asincrona

Gradienti
G x,y,z

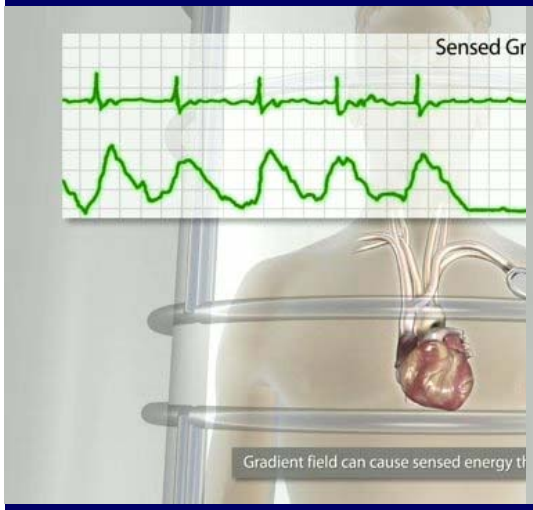
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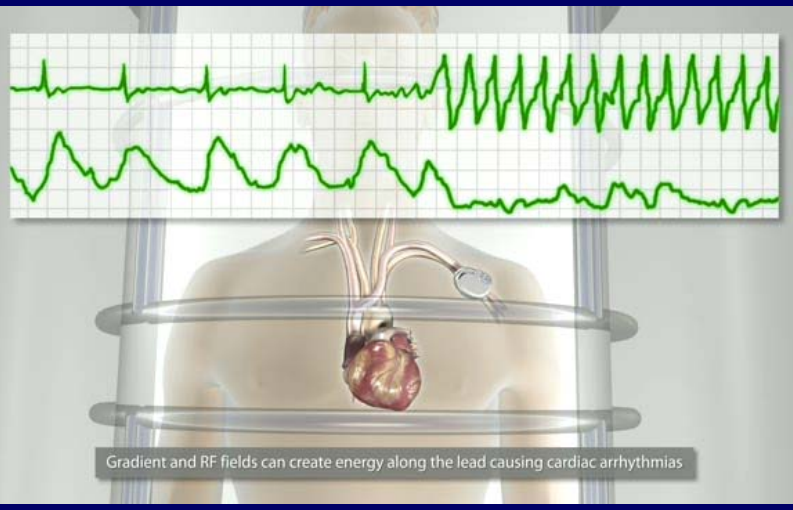
Il gradiente magnetico e la radiofrequenza possono indurre un voltaggio nell'elettrocatetere che provoca un'aritmia pericolosa

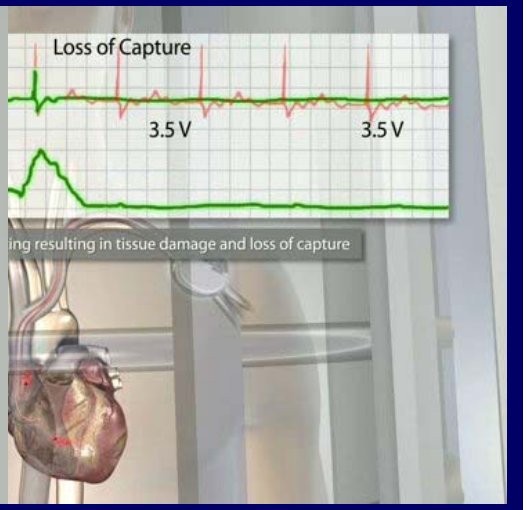
Campo Elettromagnetico a radiofrequenza
B1

↓

Passaggio di corrente nell'elettrocatetere: surriscaldamento e danno termico

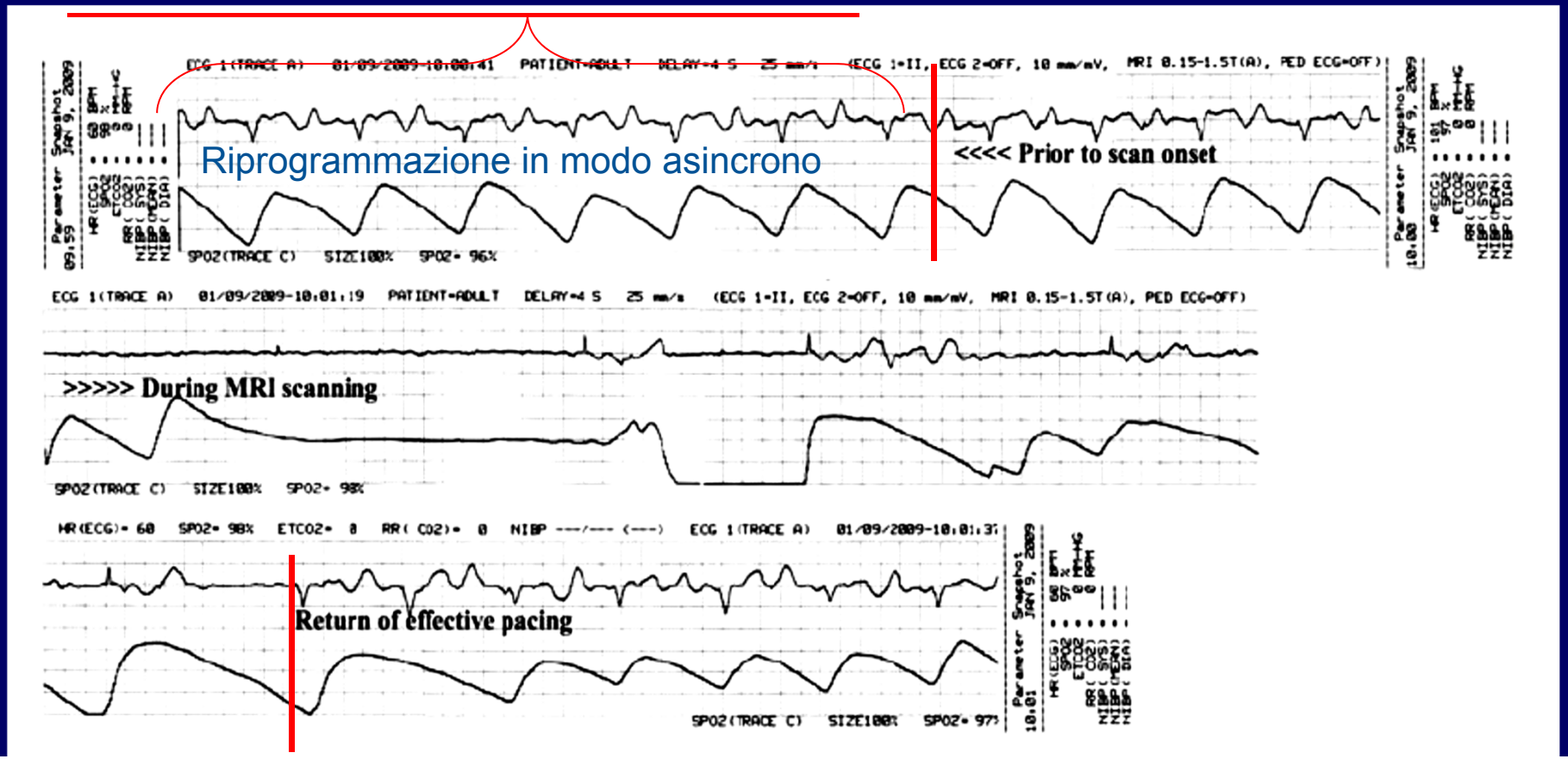




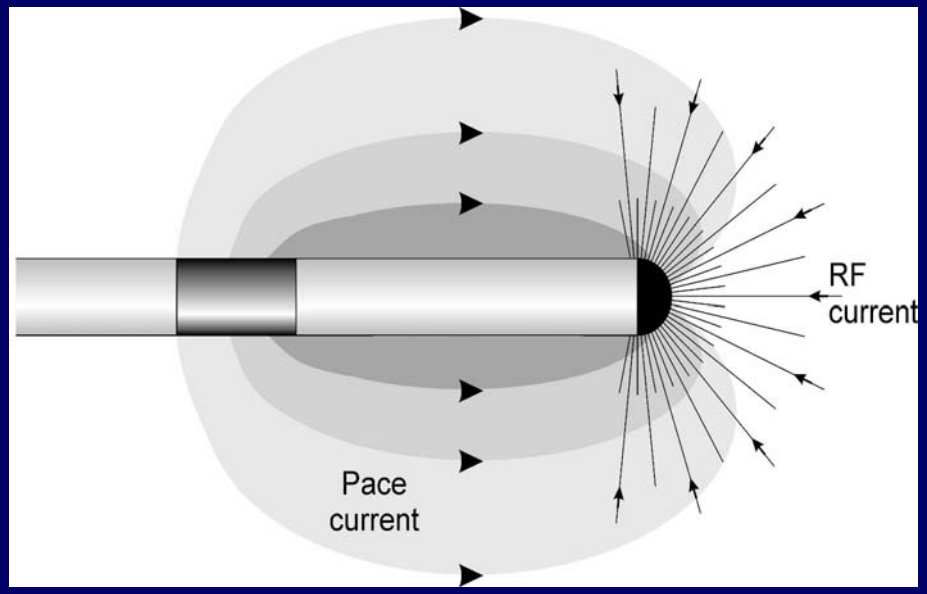


Reset Mode – Back up mode – Back up VVI:

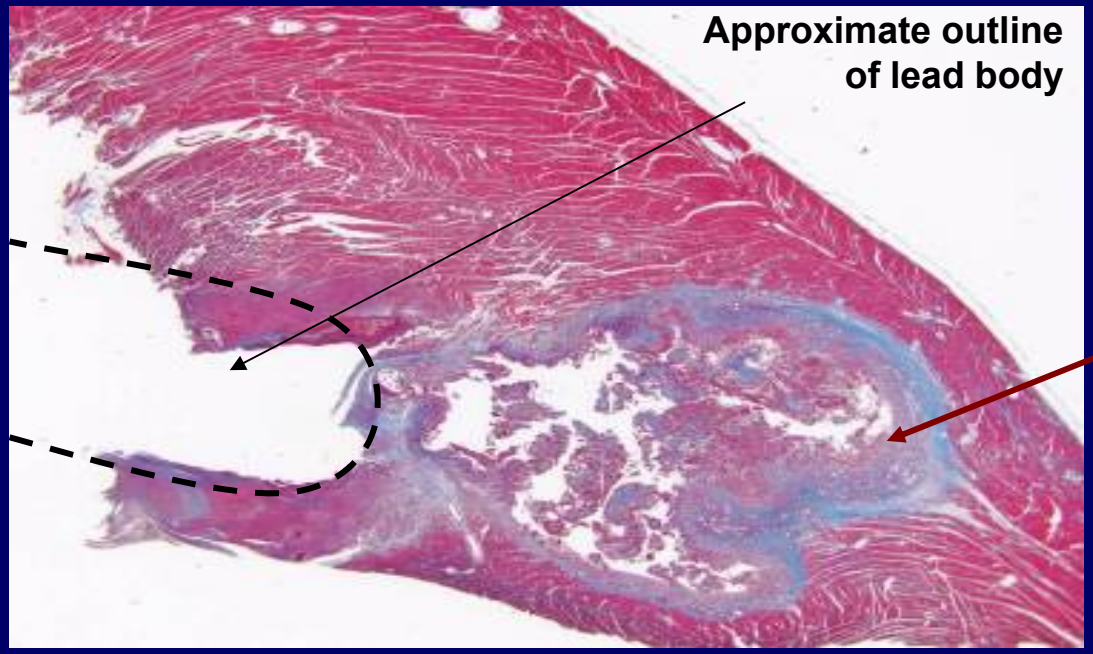
Anche se programmato in modalità asincrona, il pacemaker può andare incontro a reset elettrico. Questo fa si che il device possa “sentire” le interferenze magnetiche da RF ed interpretarle come sensing, lasciando il paziente senza “pacing”, indipendentemente dalla riprogrammazione iniziale.



Heating



- Perdita di cattura
- Perforazione del miocardio



Myocardial histology:
A non-MRI lead scanned and removed post scan
Note the area of myocardial injury

ICD

- Expected problems are similar to those for pacemakers
- Three special considerations:

  Larger batteries and larger capacitors can result in higher magnetic torque forces

  (despite dramatic reduction in size and weight, new generation ICDs have 10 times higher magnetic force and torque than pacemakers)

  The ICD lead is more complex than the pacemaker one, and it is as critical to the function of the ICD system as the ICD itself

  ICD patients are usually sicker than those wearing a simple PPM, often due to a worse cardiac performance and severe co-morbidities

MRI Scanning in ICD Patients[1]

- ICDs may falsely detect the MR RF field as VF, charge capacitors, and deliver ATP, cardioversion, or defibrillation therapies
  - Can still occur if therapy delivery has been deactivated because of electrical reset with subsequent therapy activation

- Devices may not be able to deliver ICD therapy in the static magnetic field *(needs further investigation)*
  - ICD transformer will be magnetically saturated and may not have the voltage necessary to charge the capacitor
  - Can lead to permanent device failure as some devices become permanently inactive after a given number of unsuccessful attempts to charge the capacitor
  - Magnetic fields may prevent detection of VT or VF

- The heating problem of ICD leads can be expected to be comparable with that of pacemaker leads

1. Roguin A, et al. *Europace*. 2008;10:336-346.

Linee guida: cosa c'è di nuovo?

Le linee guida non danno alcuna indicazione
nè incitano a superare la "barriera"

American Heart Association
Learn and Live

Table 2. Recommendations for the Performance of MR Examinations in Patients With Pacemakers or ICDs

General recommendations:

MR examination of non–pacemaker-dependent patients is discouraged and should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks

MR examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks

MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks

Decision should be weighed principally on risk-benefit ratio and the urgency of the clinical indication for MRI.[1,2]

If risk-benefit ratio favors MRI and there is no imaging alternative, then one should proceed, but with precautions including:[1,2]

- Performing it only at "extremely-experienced" centers
- Collaboration between cardiologist and radiologist
- Monitoring
- Reprogramming the device
- Careful follow-up of the patient after MRI

Tutto è lasciato alla decisione finale del medico:
valutazione del Rischio - Beneficio

1. Roguin A, et al. Europace. 2008;10:336-346.
2. Levine GN, et al. Circulation. 2007;116:2878-2891
3. Levine et al. Safety of Magnetic Resonance Imaging in Patients With Cardiovascular Devices, DOI: 10.1161/CIRCULATION AHA.107.187256 published online Nov 19, 2007; Circulation. pp9-10

Incontro di tecnologie



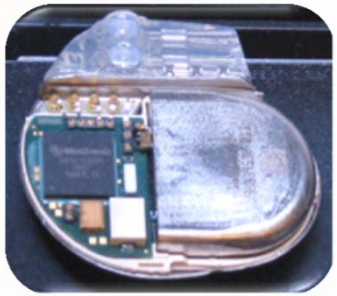




Verso il dispositivo MRI compatibile. Materiali

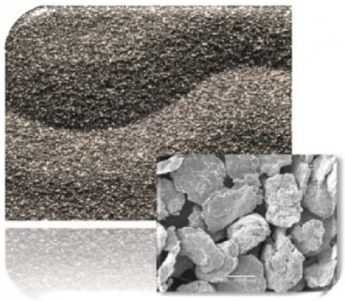
- L'evoluzione tecnologica ha portato negli anni a modificare i materiali di cui sono fatti i dispositivi.
- Le scelte tecnologiche intraprese hanno portato sempre piu' verso la compatibilità magnetica.

Batteria



Negli anni da materiali ferromagnetici (nichel-cromo etc) si è giunti agli ioni di lito.

Cassa



Il titanio è un materiale non magnetico che opportunamente trattato presenta una ridottissima permeabilità magnetica

Cateteri



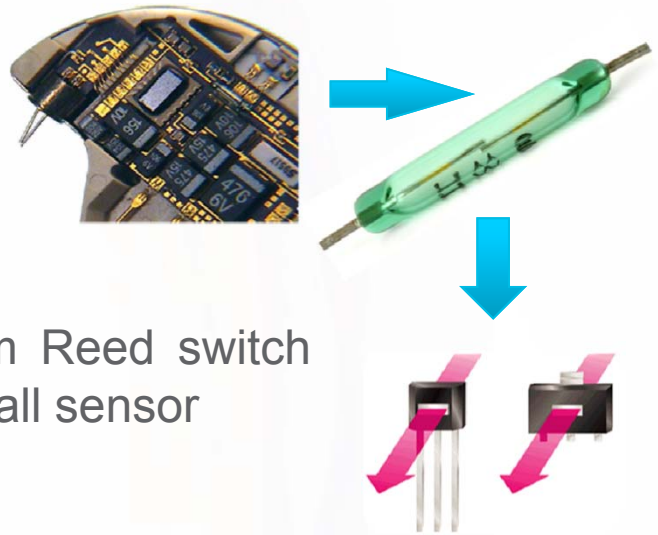
Sono composti di una lega metallica MP35N (lega di nichel,cobalto cromo e molibdeno: =non ferromagnetici)

- In generale i PM possono considerarsi paramagnetici, orientandosi // al campo magnetico (il paziente in genere è sdraiato e già parallelo al campo magnetico).

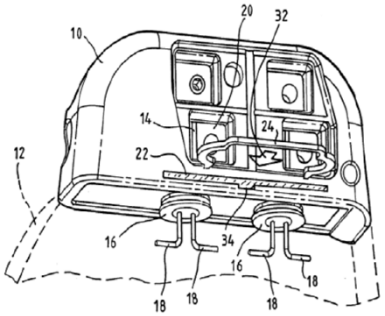
Luechlnger, R.,et al.: Force and Torque Effects ora 1.5-Tesla MRI Scanner on Cardiac Pacemakers and ICDs, PACE 2001; 24:199-205

Componenti elettroniche

Studiando a fondo l'interattività dei materiali con la risonanza sono via via stati sostituiti i componenti' problematici e protette le possibili interferenze



From Reed switch to Hall sensor





Feedthrough : protezione del circuito di alimentazione e della batteria

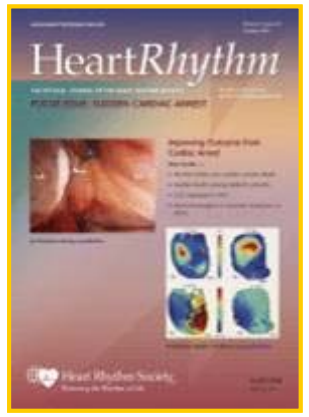
Completo controllo sul pacemaker

Prevenire danni al circuito di alimentazione da correnti indotte e fuori controllo

Surescan Clinical Trial

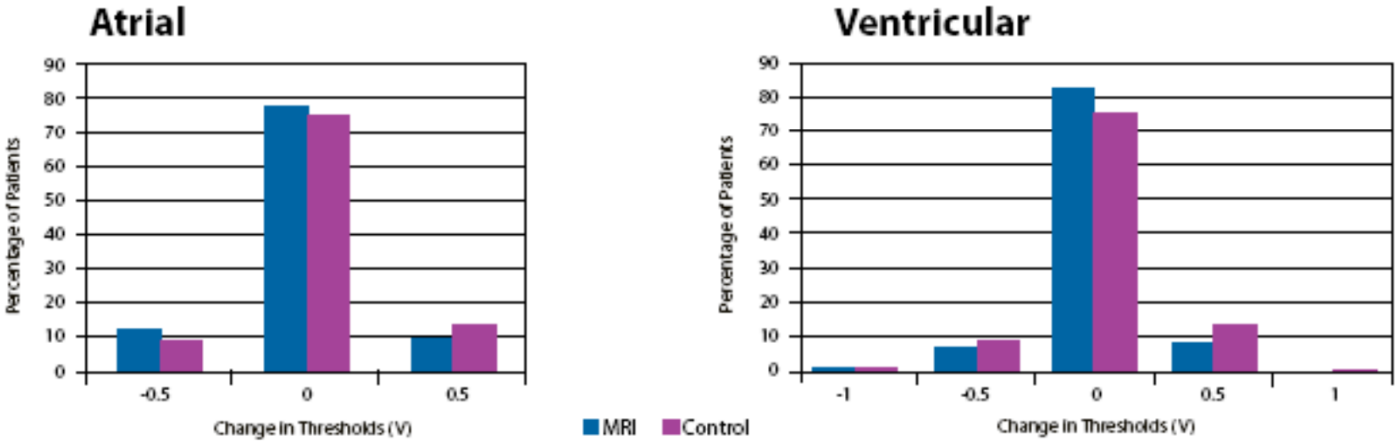
Study Design

- Multicenter, randomised controlled clinical trial[11]
- 464 patients received a SureScan Pacing System
- Randomised to elective MRI (MRI Group) or no MRI (Control Group)
- Follow-up: 11.2 ± 5.2 months (mean)
- Pacemakers interrogated immediately after implant and at regular intervals
- MRI imaging intended to represent commonly used, clinically relevant scans



Key Results

- SureScan Pacing Systems confirmed safe for patients undergoing MRIs
- 100% MRI-related complication-free rate (n = 211, p < 0.001)



Change in Atrial and Ventricular Thresholds among MRI and Control Patients from Pre-MRI/Control Period to 4 Months

Studi clinici: EnRhythm MRI Clinical Study

Endpoints: Sicurezza ed efficacia	Subjects MRI/Control	Success rate MRI/Control
MRI procedure related complication free rate	211 / n.a.	100% / n.a.
% patients ≤ 0.5 V increase in A capture threshold	165 / 164	100% / 100%
% patients ≤ 0.5 V increase in V capture threshold	190 / 184	100% / 99.5%
Atrial signal ↓<50% & >1.5 mV	131 / 139	94.7% / 92.8%
Ventricular signal ↓<50% & >1.5 mV	134 / 136	97.0% / 94.9%
Subjects with sustained ventricular arrhythmias and asystole attributed to MR scan	211 / n.a.	0% / n.a.

Worldwide randomized clinical trial to evaluate new pacemaker system designed for use during Magnetic Resonance Imaging. Wilkoff B, presented at late-breaking trial session during HRS 2009

Sicurezza e Qualità immagini MRI

Advisa MRI Clinical Study

Impact of the Advisa MRI™ Pacing System on the diagnostic quality of cardiac MR images and contraction patterns of cardiac muscle during scans: Advisa MRI randomized clinical multicenter study results

Juerg Schwitter MD, Emanuel Kanal MD, FACR, FISMRM, Matthias Schmitt MD, PhD,MRCP, Frederic Anselme MD, Timothy Albert MD,FACC, David L. Hayes MD,FHRS,CCDS, David Bello MD, Attila To´th MD, Yanping Chang MS, Dirk van Osch MSc and Torsten Sommer MD,PhD, on behalf of the Advisa MRI System Study Investigators

Lo studio clinico su Advisa MRI ha l'obiettivo di valutare la qualità delle immagini diagnostiche, con specifico riferimento alla porzione potenzialmente più inflenzata dalla presenza del sistema di stimolatore: il cuore.

Advisa MRI Study valuta la qualità delle immagini di Risonanza Magnetica Cardiaca e la possibilità di caratterizzare i pattern di contrazione miocardica.



Author's Accepted Manuscript

Impact of the Advisa MRI™ Pacing System on the diagnostic quality of cardiac MR images and contraction patterns of cardiac muscle during scans: Advisa MRI randomized clinical multicenter study results

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PII: S1547-5271(13)00162-8
DOI: http://dx.doi.org/10.1016/j.hrthm.2013.02.019
Reference: HRTHM5226

To appear in: *Heart Rhythm*

Cite this article as: Juerg Schwitter MD, Emanuel Kanal MD, FACR, FISMRM, Matthias Schmitt MD, PhD,MRCP, Frederic Anselme MD, Timothy Albert MD,FACC, David L. Hayes MD,FHRS,CCDS, David Bello MD, Attila Tóth MD, Yanping Chang MS, Dirk van Osch MSc and Torsten Sommer MD,PhD, on behalf of the Advisa MRI System Study Investigators., Impact of the Advisa MRI™ Pacing System on the diagnostic quality of cardiac MR images and contraction patterns of cardiac muscle during scans: Advisa MRI randomized clinical multicenter study results, *Heart Rhythm*, http://dx.doi.org/10.1016/j.hrthm.2013.02.019

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Heart Rhythm, http://dx.doi.org/10.1016/j.hrthm.2013.02.019

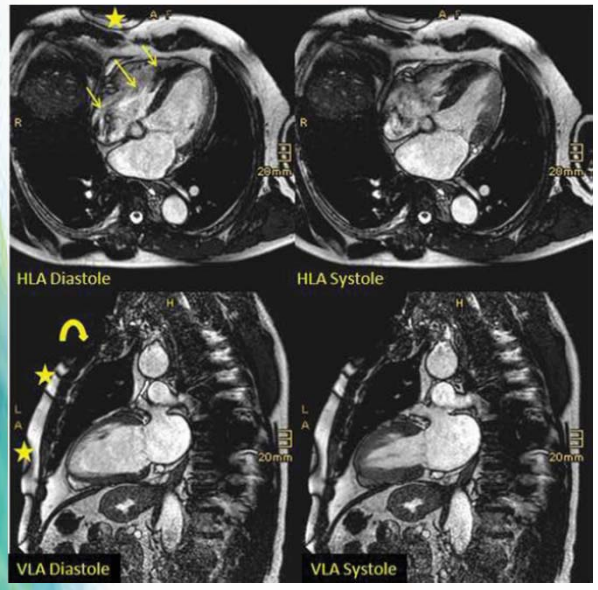
Qualità immagini MRI

I sistemi di stimolazione Medtronic SureScan sono concepiti per permettere ai pazienti portatori di essere sottoposti in sicurezza ad esami di Risonanza Magnetica Total Body

SIUREZZA

Fino ad ora, non si era mai investigato se la presenza del sistema di stimolazione stesso (pacemaker ed elettrocateteri) all'interno del paziente influenzi il risultato qualitativo delle immagini diagnostiche

QUALITA' IMMAGINI



98% delle acquisizioni cardiache di alta o eccellente qualità diagnostica in presenza di sistema Medtronic SureScan

Heart Rhythm, http://dx.doi.org/10.1016/j.hrthm.2013.02.019

Device impiantabili e RMN



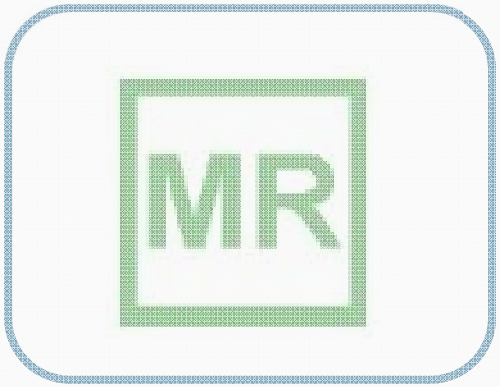
MRI Unsafe

MR Unsafe - an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.



MRI Conditional

MR Conditional - an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.



MRI Safe

MR Safe - an item that poses no known hazards in all MRI environments. Using the new terminology, "MR safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

ASTM Standard F2503

AMST-International American Society of Test and Measurement is the standard that governs medical devices in the MRI environment.

Il pacemaker e gli elettrocateteri siano etichettati “MR Conditional”

Lista di controllo del Radiologo

- ❑ La MRI sia a cilindro chiuso da 1,5T in modalità di funzionamento normale
- ❑ SAR (Specific Absorption Rate) 2 W/Kg per il corpo
- ❑ SAR (Specific Absorption Rate) 3,2 W/Kg per il capo
- ❑ SlewRate massimo del gradiente ≤ 200 T/m/s

Lista di controllo del Cardiologo

- ❑ L’impianto sia stato eseguito da almeno 6 settimane
- ❑ Il sistema sia impiantato nella regione pettorale
- ❑ Nessun altro catetere, device o adattatore presente o abbandonato nel paziente
- ❑ Gli elettrocateteri siano elettricamente integri
  (impedenza compresa tra 200 e 1500 ohm e soglie di cattura non superiori a 2,0 V a 0,4 ms)

La modalità SureScanTM sia programmata su ON prima della scansione e su OFF dopo la scasnsione

Pacemakers MRI Conditional commercialmente disponibili in Europa e Italia

TABLE 3
Characteristics of Commercially Available Premium Tier and Core Tier MRI Conditional Pacemakers

	St. Jude	Biotronik Pro MRI systems	Medtronic SureScan	Boston ImageReady MRI conditional system
Premium Tier MRI conditional pacemakers	ACCENT RF MRI	EVIA MRI (DR/SR)	ADVISA MRI	INGENIO(EL) MRI
RV pace management	VIP (350 milliseconds)	Vp suppression Switch ADI/DDD IRSplus (400 milliseconds)	MVP	RYTHMIQ AVSH+ Dynamic AV Delay (400 milliseconds)
Remote patient monitoring	MERLIN	BIOTRONIK home monitoring	CARELINK	LATITUDE NXT
Core Tier MRI conditional pacemakers		ESTELLA (DR/SR)	ENSURA MRI	ADVANTIO MRI
RV pace management		IRSplus (400 milliseconds)	MVP	AVSH+ Dynamic AV Delay (400 milliseconds)
Preparation for MRI examination	Activate hand-held device	Program device into MRI mode before scanning. Minimum patient height 1.4 m	SureScan feature programmed "On" prior to scanning	Program into MRI mode before scanning
Static magnetic field strength limit	1.5 T	1.5 T	1.5 T	1.5 T
Scan zone restrictions	None	Scan zone restrictions apply	None	None
Maximum permitted slew rate of the scanner	200 T/m/s	216 T/m/s	≤200 T/m/s	≤200 T/m/s
Maximum permitted scan time	N/A	30 minutes. Total duration of examinations should not exceed 10 hours	N/A	N/A
Position restrictions	Lateral decubitus position contraindicated	Dorsal scanning only permitted	No positioning restrictions	No positioning restrictions
Device identifiers	Three radiopaque rings on the proximal portion of the lead identify it to be a Tendril MRI product. The radiopaque letters "MRI" on the device marker identify the implantable pulse generator (IPG) to be MRI conditional	Biotronik's PRO MRI series of IPGs bear a radiopaque hallmark with the Biotronik identifier followed by the letters SF. No radiopaque identifier on the lead	Radiopaque markers (wavy lines on the proximal portion of the leads and a tilde symbol [~] on the pulse generator's device marker) identify the system as an MRI conditional product. First generation MRI conditional IPGs bear the 3-letter code PTA on the device marker. Second generation SureScan IPGs bear the hallmark PVX(16)	A solid triangle followed by the letters BSC on the device marker denotes that the IPG is MRI conditional. No unique markers on the lead to denote MRI conditional status

Medtronic

ST. JUDE MEDICAL

BIOTRONIK

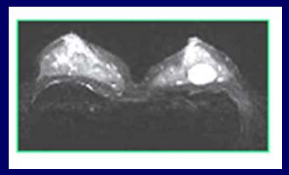
Boston Scientific

Tutte le principali aziende produttrici di dispositvi impiantabili, seppur con differenze nelle condizioni e modalità di certificazione, offrono dispositivi MRI Conditional

Journal of Cardiovascular Electrophysiology Vol. 24, No. 9, September 2013

Quali i candidati a pacemaker MRI conditional?

- pazienti con patologie specifiche e che richiedono la RMN come metodica di diagnosi insostituibile (cancro, patologie tessuti molli,ghiandolari ecc…)



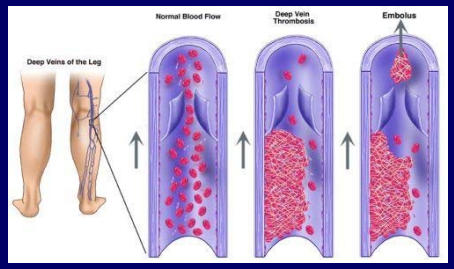
Paziente con lesione mammaria sospetta

- pazienti che in passato hanno avuto necessità di una RMN o che necessitano di controlli periodici attraverso RMN

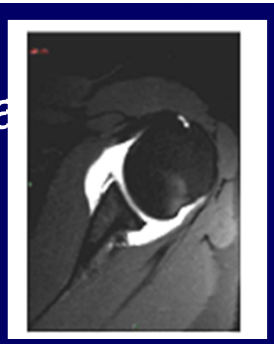


Paziente con ernia discale

- pazienti a rischio di eventi tromboembolici;



- pazienti giovani o con prospetiva di vita elevata (in termine di anni);



Giovane in esiti di trauma alla spalla con lussazione gleno-omerale

Position Paper

Patient Stratification for MRI-Conditional Devices

- Device replacement of a non-MRI lead System
- Life expectancy ≤ 12 month
- Retained non-MRI pacing lead
- MRI contraindications

yes

no

Age ≥ 85 years

Age ≤ 85 years

Conventional Pacing System

MRI-Conditional System