SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Modena

Dispositivi medici impiantabili

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La normativa in vigore sui dispositivi medici

Nel 2017 sono stati approvati dal Parlamento Europeo i Regolamenti sui Dispositivi Medici e sui Dispositivi Diagnostici in vitro

Sostituiscono, nei tempi di attuazione previsti, le direttive precedenti:

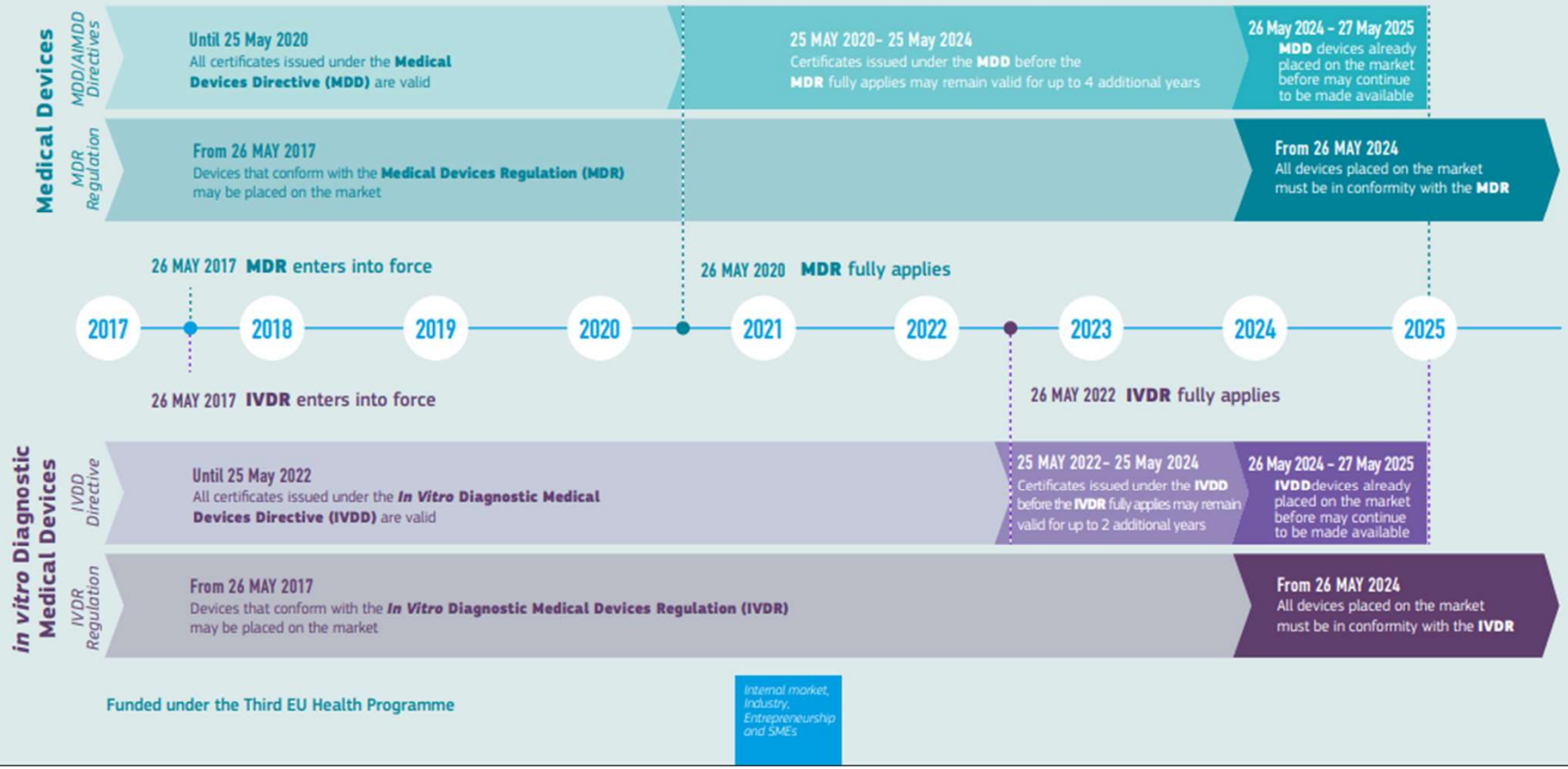
- 93/42 CEE sui dispositivi medici
- 90/385 CEE sui dispositivi medici impiantabili attivi
- 98/79 CEE sui dispositivi diagnostici in vitro

MDR 2017/745 sui dispositivi medici
IVDR 2017/746 sui diagnostici in vitro

European Commission

Transition Timelines from the Directives to the Regulations

Medical Devices and *in vitro* Diagnostic Medical Devices



Funded under the Third EU Health Programme

Internal market, Industry, Entrepreneurship and SMEs

La normativa in vigore sui dispositivi medici

I principali aspetti innovativi dei nuovi regolamenti:

- Dispositivi medici e dispositivi medici impiantabili sono trattati nello stesso quadro normativo definendone i differenti livelli di rischio e sicurezza
- È aumentata la necessità di presentare studi clinici pre-market in particolare per i dispositivi di classe III ed è stata enfatizzata l'attività di post market clinical follow up
- L'attività di vigilanza post-market è stata potenziata
- È stata introdotta la nuova banca dati europea dei dispositivi contenente informazioni rivolte soprattutto all'utilizzatore del dispositivo

Premesse: (48) Nel caso di dispositivi impiantabili e di dispositivi della classe III, i fabbricanti dovrebbero riassumere i principali aspetti relativi alla sicurezza e alle prestazioni del dispositivo e l'esito della valutazione clinica in un documento che dovrebbe essere accessibile al pubblico.

Cos’è un dispositivo medico

«dispositivo medico»: qualunque strumento, apparecchio, apparecchiatura, software, impianto, reagente, materiale
o altro articolo, destinato dal fabbricante a essere impiegato sull'uomo, da solo o in combinazione, per una o più
delle seguenti destinazioni d'uso mediche specifiche:
— diagnosi, prevenzione, monitoraggio, previsione, prognosi, trattamento o attenuazione di malattie,
— diagnosi, monitoraggio, trattamento, attenuazione o compensazione di una lesione o di una disabilità,
— studio, sostituzione o modifica dell'anatomia oppure di un processo o stato fisiologico o patologico,
— fornire informazioni attraverso l'esame *in vitro* di campioni provenienti dal corpo umano, inclusi sangue e tessuti
donati,
e che non esercita nel o sul corpo umano l'azione principale cui è destinato mediante mezzi farmacologici,
immunologici o metabolici, ma la cui funzione può essere coadiuvata da tali mezzi.
Si considerano dispositivi medici anche i seguenti prodotti:
— dispositivi per il controllo del concepimento o il supporto al concepimento,
— i prodotti specificamente destinati alla pulizia, disinfezione o sterilizzazione dei dispositivi di cui all'articolo 1,
paragrafo 4, e di quelli di cui al primo comma del presente punto;

Cos’è un dispositivo medico impiantabile

«dispositivo impiantabile»: qualsiasi dispositivo, compresi quelli che sono parzialmente o interamente assorbiti,
destinato a:
— essere impiantato totalmente nel corpo umano, oppure
— sostituire una superficie epiteliale o la superficie oculare,
mediante intervento clinico e a rimanere in tale sede dopo l'intervento.
È considerato un dispositivo impiantabile anche qualsiasi dispositivo destinato a essere introdotto parzialmente nel corpo umano mediante intervento clinico e a rimanere in tale sede dopo l'intervento per un periodo di almeno 30 giorni;

«dispositivo invasivo»: qualsiasi dispositivo che penetra parzialmente o interamente nel corpo tramite un orifizio del corpo o la superficie corporea;

Requisiti generali

14.2
I dispositivi sono progettati e fabbricati in modo tale da eliminare o ridurre per quanto possibile:
a) il rischio di lesioni connesso con le loro caratteristiche fisiche, compresi il rapporto volume/pressione, le caratteristiche dimensionali e, se del caso, le caratteristiche ergonomiche;

b) i rischi ragionevolmente prevedibili connessi a influenze esterne o a condizioni ambientali, quali campi magnetici, effetti elettrici ed elettromagnetici esterni, scariche elettrostatiche, radiazioni collegate a procedure diagnostiche o terapeutiche, pressione, umidità, temperatura, variazioni di pressione e di accelerazione o interferenze del segnale radio;

c) i rischi connessi all'uso di un dispositivo quando entra in contatto con materiali, liquidi, e sostanze, compresi i gas, ai quali è esposto nelle normali condizioni d'uso;
d) i rischi associati alla possibile interazione negativa tra il software e l'ambiente tecnologico («ambiente IT») in cui opera e interagisce;
e) i rischi derivanti dall'involontaria penetrazione di sostanze nel dispositivo;

f) i rischi d'interferenza reciproca connessi con la presenza simultanea di altri dispositivi normalmente utilizzati per le indagini o per i trattamenti somministrati;

g) i rischi che possono derivare, laddove la manutenzione o la calibrazione non siano possibili (come nei dispositivi impiantabili), dall'invecchiamento dei materiali utilizzati o dal deterioramento della precisione di un meccanismo di misura o di controllo.

Requisiti generali

18.5
I dispositivi sono progettati e fabbricati in modo tale da ridurre, per quanto possibile, i rischi dovuti alla creazione di un'interferenza elettromagnetica che possa pregiudicare il funzionamento del dispositivo in questione o di altri dispositivi o attrezzature nell'ambiente cui sono destinati.

18.6
I dispositivi sono progettati e fabbricati in modo tale da garantire un livello di immunità intrinseca alle interferenze elettromagnetiche che sia adeguato per permettere loro di funzionare in modo conforme alla destinazione d'uso prevista.

Banca dati EUDAMED

Articolo 32

Sintesi relativa alla sicurezza e alla prestazione clinica

1. Nel caso dei dispositivi impiantabili e dei dispositivi appartenenti alla classe III, diversi dai dispositivi su misura od oggetto d'indagine, il fabbricante redige una sintesi relativa alla sicurezza e alla prestazione clinica.

Tale sintesi è scritta in modo da essere chiara per l'utilizzatore previsto e, se del caso, per il paziente ed è resa pubblica attraverso Eudamed.

Requisiti riguardanti le informazioni fornite con il dispositivo

23.4 Informazioni contenute nelle istruzioni per l’uso

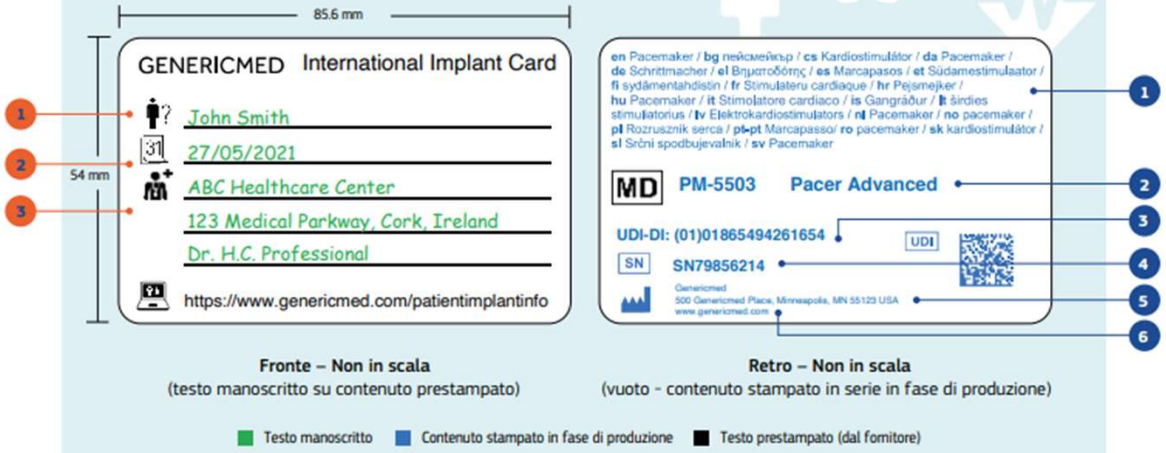
s) informazioni che consentano all'utilizzatore e/o al paziente di essere a conoscenza di ogni avvertenza, precauzione, controindicazione o altra misura da prendere nonché delle restrizioni all'uso del dispositivo. Tali informazioni consentono, se del caso, all'utilizzatore di informare il paziente riguardo a ogni avvertenza, precauzione, controindicazione o altra misura da prendere nonché delle restrizioni all'uso del dispositivo. **Le informazioni riguardano, se del caso**:
— avvertenze, precauzioni e/o misure da prendere in caso di malfunzionamento del dispositivo o di variazione delle sue prestazioni che possa incidere sulla sicurezza,

— **avvertenze, precauzioni e/o misure da prendere per quanto riguarda l'esposizione a fattori esterni o condizioni ambientali ragionevolmente prevedibili, quali campi magnetici, effetti elettrici ed elettromagnetici esterni, scariche elettrostatiche, radiazioni connesse con le procedure diagnostiche o terapeutiche, pressione, umidità o temperatura,**

— avvertenze, precauzioni e/o misure da prendere per quanto riguarda rischi di interferenza connessi con la presenza ragionevolmente prevedibile del dispositivo nel corso di indagini diagnostiche, valutazioni o trattamenti terapeutici o altre procedure, come interferenze elettromagnetiche emesse dal dispositivo che interessano altre attrezzature,

Tessera di impianto

Figura 1: modello di tessera per il portatore di impianto



Obblighi per i fabbricanti

A norma dell'articolo 18, paragrafo 1, lettera a), del regolamento MDR, i fabbricanti devono fornire le seguenti informazioni necessarie sulla tessera per il portatore di impianto (preferibilmente sulla tessera stessa o, in alternativa, con adesivi che dovrà apporre il medico):

1. **denominazione del dispositivo;**
2. **tipologia di dispositivo;**
3. **identificazione unica del dispositivo (UDI) - l'UDI utilizza il formato "identificazione automatica e raccolta dei dati" (AIDC), ad esempio codici a barre lineari o 2D e l'identificativo del dispositivo UDI (UDI-DI) utilizza un formato leggibile dall'uomo;**
4. **numero di serie oppure, se del caso, il numero di lotto o di partita;**
5. **nome e indirizzo del fabbricante del dispositivo medico;**
6. **sito web del fabbricante del dispositivo medico;**

Inoltre il fabbricante progetta la tessera per il portatore di impianto in modo da includere i seguenti campi vuoti che devono essere compilati dall'istituzione sanitaria o dalla struttura sanitaria che effettua l'impianto:

1. **nome del paziente o ID del paziente;**
2. **data di impianto;**
3. **nome e indirizzo dell'istituzione sanitaria che ha effettuato l'impianto.**

Documentazione tecnica

6.1 Dati preclinici e clinici

b) informazioni dettagliate concernenti la progettazione dei test, il protocollo di test completo o il protocollo di studio, metodi di analisi dei dati, oltre a sintesi di dati e conclusioni sui test riguardanti in particolare:
— la biocompatibilità del dispositivo compresa l'individuazione di tutti i materiali a contatto diretto o indiretto
con il paziente o l'utilizzatore,
— la caratterizzazione fisica, chimica e microbiologica,
— la sicurezza elettrica e la **compatibilità elettromagnetica**,

Informazioni presenti nel fascicolo tecnico a disposizione dell'autorità competente -> Ministero

NORME TECNICHE

22) Data l'importanza della normalizzazione nel settore dei dispositivi medici, il rispetto delle norme armonizzate,
quali definite nel regolamento (UE) n. 1025/2012 del Parlamento europeo e del Consiglio ([2]), dovrebbe essere un mezzo grazie al quale i fabbricanti possono dimostrare la conformità ai requisiti generali di sicurezza e prestazione e ad altre prescrizioni giuridiche, come quelle relative alla qualità e alla gestione del rischio stabiliti dal presente regolamento.

IEC 60601-1-2 "*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*"

ISO 14117 "*Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardia resynchronization devices*"

NORME TECNICHE: ISO 14117

1 Scope

This document specifies test methodologies for the evaluation of the electromagnetic compatibility (EMC) of active implantable cardiovascular devices that provide one or more therapies for bradycardia, tachycardia and cardiac resynchronization in conjunction with transvenous lead systems.

NOTE This document was designed for pulse generators used with endocardial leads or epicardial leads. At the time of this edition, the authors recognized the emergence of technologies that do not use endocardial leads or epicardial leads for which adaptations of this part will be required. Such adaptations are left to the discretion of manufacturers incorporating these technologies.

It specifies performance limits of these devices, which are subject to interactions with EM emitters operating across the EM spectrum in the two following ranges:

— 0 Hz ≤ f < 385 MHz;

— 385 MHz ≤ f ≤ 3 000 MHz

This document also specifies requirements for the protection of these devices from EM fields encountered in a therapeutic environment and defines their required accompanying documentation, providing manufacturers of EM emitters with information about their expected level of immunity.

4 Test requirements for the frequency band 0 Hz ≤ f ≤ 3 000 MHz

4.1 General requirements for all devices

Implantable pacemakers, *ICDs* and CRT devices shall not create an unacceptable risk for patients because of susceptibility to electrical influences due to external EM fields, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

DISPOSITIVI MEDICI IMPIANTABILI

ESEMPI

CLASSIFICAZIONE CND

Classificazione funzionale anatomica dei dispositivi presenti sul mercato, presa come riferimento per il sistema di classificazione europeo previsto da MDR (UDI).

È costituita da un albero con una lettera e fino a 14 cifre per la classificazione dei diversi dispositivi

J DISPOSITIVI IMPIANTABILI ATTIVI
J0101 PACE MAKER
J0102 DISPOSITIVI IMPIANTABILI DIAGNOSTICI PER FUNZIONALITA' CARDIACA
J0105 DEFIBRILLATORI IMPIANTABILI

J0202 NEUROSTIMOLATORI SPINALI
J0203 NEUROSTIMOLATORI VAGALI
J0204 NEUROSTIMOLATORI DEL RACHIDE SACRALE
J0205 NEUROSTIMOLATORI PER IL RECUPERO MOTORIO

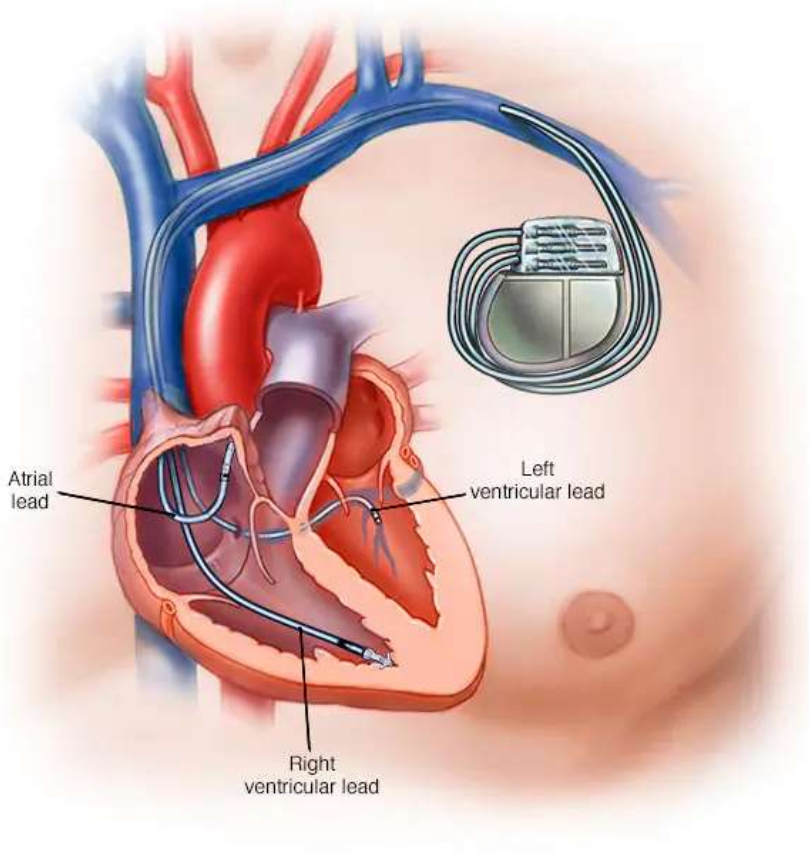
J0301 IMPIANTI COCLEARI
J0302 IMPIANTI ATTIVI PER L'ORECCHIO MEDIO

J04 POMPE IMPIANTABILI (MECCANICHE ED ELETTRONICHE)

P DISPOSITIVI PROTESICI IMPIANTABILI E PRODOTTI PER OSTEOSINTESI

DISPOSITIVI PER FUNZIONALITA' CARDIACA

PACEMAKER



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Dispositivi medici impiantabili attivi che stimolano elettricamente la contrazione cardiaca quando, a causa di un processo patologico, questa non è assicurata autonomamente dal tessuto di conduzione cardiaca (nodo senoatriale).



Costituiti da materiale metallico (titanio), presentano elettrodi a contatto diretto con le cavità cardiache

Post-Implant

- **Protected environments.** Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.
- **Magnetic Resonance Imaging (MRI) exposure.** Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.

  For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. For additional warnings, precautions, and Conditions of Use, refer to "Magnetic Resonance Imaging (MRI)" on page 22.
- **Diathermy.** Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Magnetic Resonance Imaging (MRI)

The following Warnings and Precautions, and Conditions of Use are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System. Refer to the MRI Technical Guide at www.bostonscientific.com/ifu for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System.

MR Conditional Pacing System Warnings and Precautions

WARNING: Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.

For potential adverse events applicable when the Conditions of Use
Technical Guide. For additional warnings, precautions, and Conditio
Imaging (MRI)" on page 22.

WARNING: The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[2]. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[3]. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

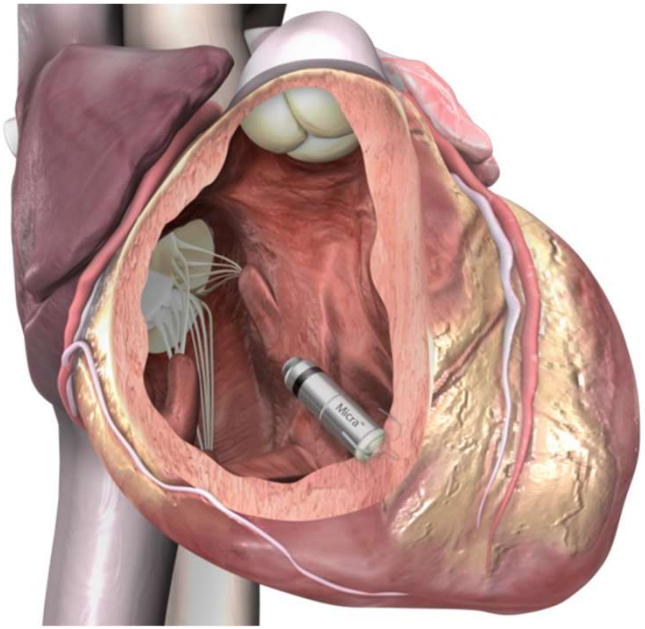
WARNING: Use caution when programming the MRI Protection Mode pacing amplitude for pacing-dependent patients who have high pacing thresholds (> 2.0 V). Programming pacing amplitude below 5.0 V is provided as an option in case of extracardiac stimulation (for example, diaphragmatic stimulation for RV pacing). If pacing amplitude is programmed below 5.0 V, an appropriate safety margin (2X the pacing threshold + 1.0 V) should be maintained. An inadequate safety margin may result in loss of capture.

CAUTION: Consider an individual patient's ability to tolerate the pacing parameters required for MR Conditional scanning in conjunction with the physical conditions required during a scan (for example, prolonged time in a supine position).

DISPOSITIVI PER FUNZIONALITA' CARDIACA



MICRA
Pacemaker monocamerale
leadless



DISPOSITIVI PER FUNZIONALITA' CARDIACA

2.7 Warnings, precautions, and guidance related to electromagnetic interference (EMI) for cardiac device patients

Many cardiac device patients resume their normal daily activities after full recovery from surgery. However, there may be certain situations that patients need to avoid. Because a cardiac device is designed to sense the electrical activity of the heart, the device may sense a strong electromagnetic energy field outside of the body and deliver a therapy that is not needed or withhold a therapy that is needed. The following sections provide important information to share with patients about electrical equipment or environments that may cause interference with their implanted cardiac device. For additional guidance about EMI, contact your Medtronic representative.

General EMI guidelines for patients – Patients should observe the following general guidelines regarding EMI:

- Area restrictions – Before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker or ICD, consult with your doctor.
- Symptoms of EMI – If you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor.

DISPOSITIVI PER FUNZIONALITA' CARDIACA

- Proper grounding of electrical items – To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:
  - Make sure that all electrical items are properly wired and grounded.
  - Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Household and hobby items with motors or other items that cause EMI – Household and hobby items that have motors or items that generate electromagnetic energy fields could interfere with a cardiac device. Keep a cardiac device at least 15 cm away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or electric massagers

The following household and hobby items require special precautions:

- Boat motors – Keep a cardiac device at least 30 cm away from electric trolling motors or gasoline-powered boat motors.
- Electronic body fat scale – Using this type of scale is not recommended for cardiac device patients because it passes electricity through the body and can interfere with the device.
- Electronic pet fences or invisible fences – Keep a cardiac device at least 30 cm away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.
- Home-use electric kilns – Keep a cardiac device at least 60 cm away from home-use electric kilns.
- Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep a cardiac device at least 60 cm away from the heating zone when the induction cook top is turned on.
- Portable electric generators up to 20 kW – Keep a cardiac device at least 30 cm away from portable electric generators.
- UPS (uninterruptible power source) up to 200 A – Keep a cardiac device at least 30 cm away from a UPS. If the UPS is operating by battery source, keep a cardiac device at least 45 cm away.

DISPOSITIVI PER FUNZIONALITA' CARDIACA

Home power tools – Most home power tools should not affect cardiac devices. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.

- Be certain that plug-in tools are properly grounded (or double insulated). Using a ground fault interrupter outlet is a good safety measure (this inexpensive device prevents a sustained electrical shock).

Some home power tools could affect cardiac device operation. Consider the following guidelines to reduce the possibility of interference:

- Electric yard and handheld power tools (plug-in and cordless) – Keep a cardiac device at least 15 cm away from such tools.
- Soldering guns and demagnetizers – Keep a cardiac device at least 30 cm away from these tools.
- Gasoline-powered tools and gasoline-powered yard equipment – Keep a cardiac device at least 30 cm away from components of the ignition system. Turn off the motor before making adjustments.
- Car engine repair – Turn off car engines before making any adjustments. When the engine is running, keep a cardiac device at least 30 cm away from components of the ignition system.

DISPOSITIVI PER FUNZIONALITA' CARDIACA

Industrial equipment – After recovering from implant surgery, you likely will be able to return to work, to school, or to your daily routine. However, if you will be using or working near high-voltage equipment, sources of high electrical current, magnetic fields, or other EMI sources that may affect device operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes
- Electric arc and resistance welding equipment
- Broadcasting antennas of AM, FM, shortwave radio, and TV stations
- Microwave transmitters. Note that microwave ovens are unlikely to affect cardiac devices.
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect cardiac devices.

Radio transmitters – Determining a safe distance between the antenna of a radio transmitter and a cardiac device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be

directed away from a cardiac device, you may need to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

- Two-way radio transmitter (less than 3 W) – These low-power devices present low risk to a cardiac device.
- Portable transmitter (3 to 15 W) – Keep a cardiac device at least 30 cm away from the antenna.
- Commercial and government vehicle-mounted transmitters (15 to 30 W) – Keep a cardiac device at least 60 cm away from the antenna.
- Other transmitters (125 to 250 W) – Keep a cardiac device at least 2.75 m away from the antenna.

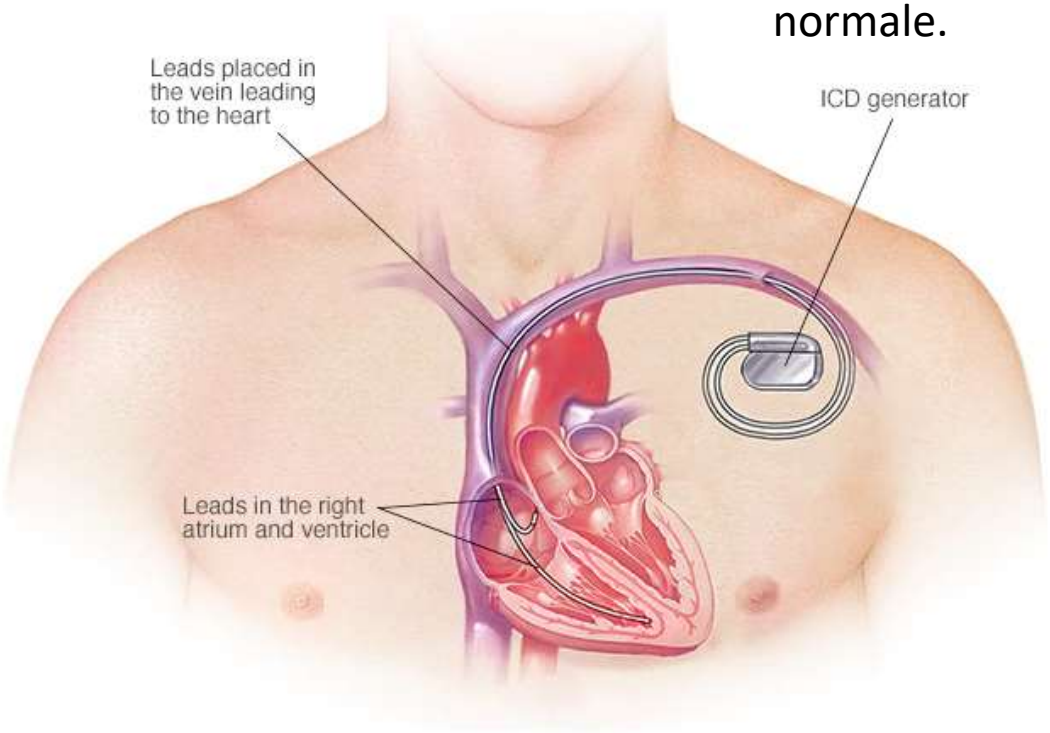
  For transmission power levels higher than 250 W, contact a Medtronic representative for more information.

Security systems – When passing through security systems, follow these precautions:

- Electronic antitheft systems, such as in a store or library, and point-of-entry control systems, such as gates or readers that include radio frequency identification equipment – These systems should not affect a cardiac device, but as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a normal pace. If you are near an electronic antitheft or entry control system and experience symptoms, promptly move away from the equipment. After you move away from the equipment, the cardiac device resumes its previous state of operation.
- Airport, courthouse, and jail security systems – Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect a cardiac device. When encountering these security systems, follow these guidelines:
  - Always carry your cardiac device ID card. If a cardiac device sets off a metal detector or security system, show your ID card to the security operator.
  - Minimize the risk of temporary interference with your cardiac device while going through the security screening process by not touching metal surfaces around any screening equipment.
  - Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.
  - If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your cardiac device.
  - If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator's instructions.

DEFIBRILLATORI

Dispositivi medici impiantabili attivi deputati al riconoscimento di gravi alterazioni del ritmo (in particolare delle tachiaritmie ventricolari) ed alla conseguente erogazione di uno shock elettrico per il ripristino del ritmo cardiaco normale.

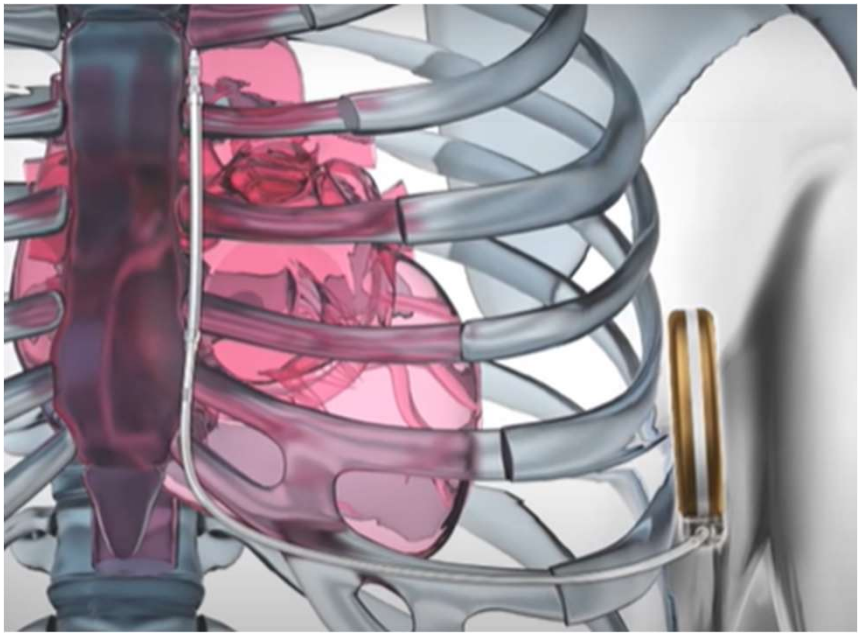


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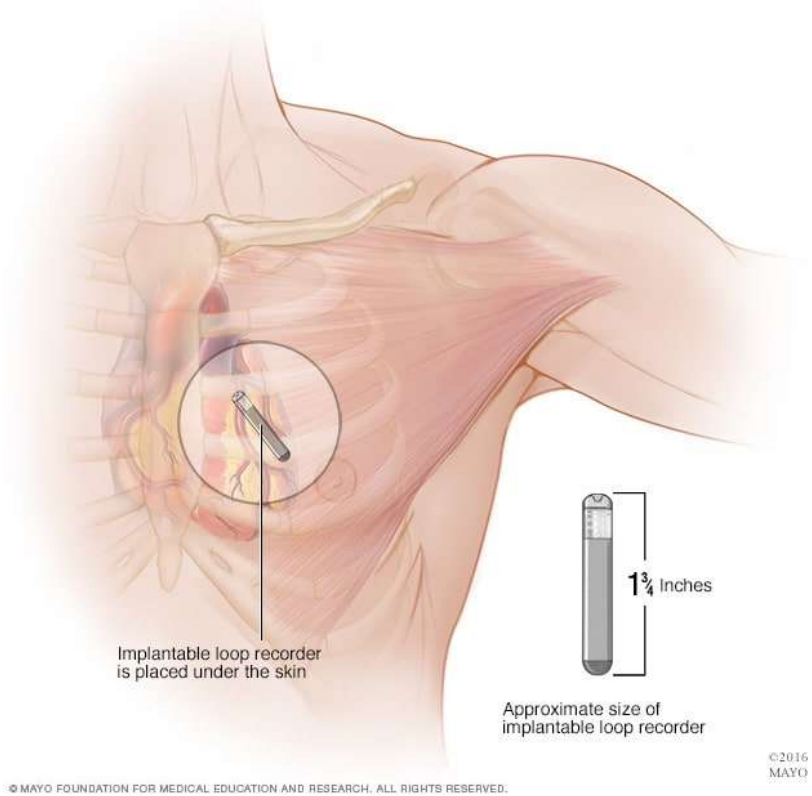


Defibrillatore sottocutaneo



LOOP RECORDER

Sistema impiantabile sottocutaneo di monitoraggio dell’attività cardiaca



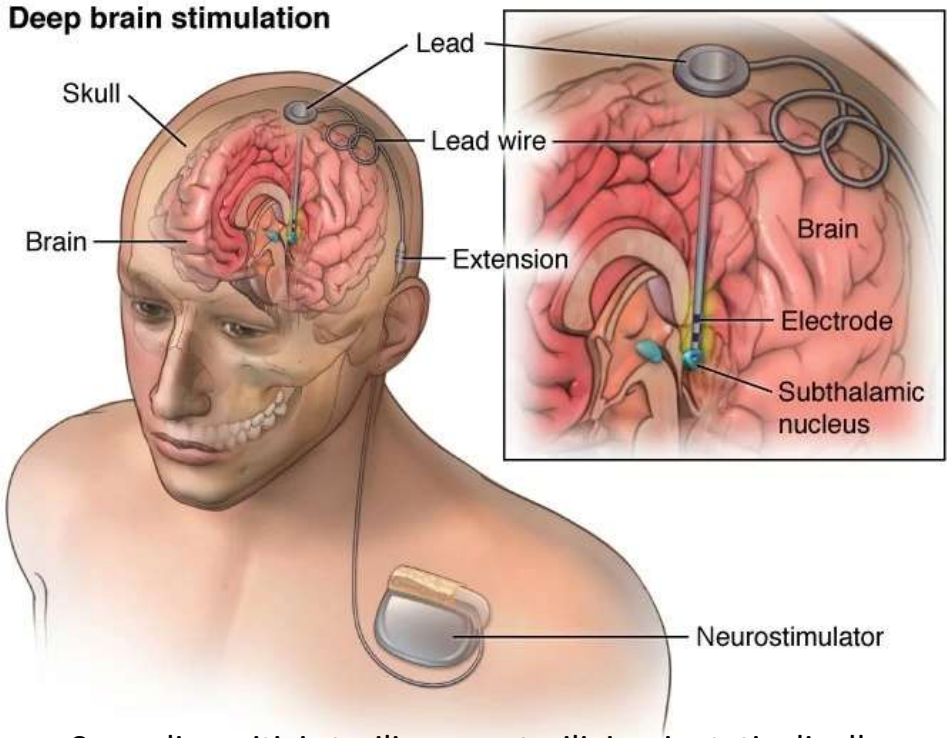
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Dal sito di un produttore:

D: I campi elettromagnetici influiscono sui pacemaker e i defibrillatori impiantabili?
R: La maggior parte dei campi elettromagnetici presenti nell'ambiente domestico influirà raramente sul funzionamento di un pacemaker o di un defibrillatore impiantabile, ma si raccomanda di tenere lontano qualsiasi oggetto contenente magneti (almeno 15 centimetri) dal pacemaker o dal defibrillatore impiantabile.
Il motivo risiede nella presenza di un piccolo interruttore che si attiva per via magnetica integrato nell'elettronica dei pacemaker e dei defibrillatori impiantabili. Questo interruttore interno si chiude quando viene posizionato su di esso un magnete sufficientemente forte.
Quando l'interruttore interno si chiude nel pacemaker, quest'ultimo stimola il cuore a una frequenza prestabilita fissa (che potrebbe essere diversa dalla frequenza programmata dal medico).
Quando l'interruttore interno si chiude in un defibrillatore impiantabile, impedisce l'erogazione delle terapie di trattamento delle aritmie.
È possibile che non sia sempre possibile sapere se un oggetto contenga un magnete. Tuttavia, se si utilizzano gli elettrodomestici come previsto e se questi ultimi vengono sottoposti a manutenzione adeguata, non dovrebbero avere alcun effetto su un dispositivo cardiaco. Questo vale per microonde, elettrodomestici da cucina, telefoni cordless, radio, televisori, videogiochi, lettori CD, asciugacapelli, rasoi elettrici, spazzolini da denti elettrici, termocoperte, soffiatori, tagliaerba, dispositivi per l'apertura automatica dei garage, computer e piccoli utensili.
Se si posiziona per sbaglio un magnete troppo vicino al dispositivo cardiaco, è sufficiente allontanarlo.
L'allontanamento del magnete consente di ripristinare la normale programmazione precedente del pacemaker o del defibrillatore impiantabile.
Si sconsiglia l'uso di materassi e cuscini magnetici in quanto sarebbe difficile mantenere una distanza di 15 centimetri (6 pollici) dal dispositivo cardiaco.

DISPOSITIVI PER STIMOLAZIONE CEREBRALE





Sono dispositivi sterili o non sterili, impiantati a livello profondo nella compagine dell'encefalo durante interventi neurochirurgici. Sono dei pace-maker che risultano efficaci nel controllo della sintomatologia del morbo di Parkinson, in modo molto simile ai farmaci; l'associazione con questi ultimi permette in fase avanzata di malattia una buona gestione del paziente. Sono costituiti da uno stimolatore al quale sono collegati degli elettrodi che vengono posizionati sulle aree encefaliche coinvolte dalla malattia. I dispositivi descritti possono essere monouso o riutilizzabili.

DISPOSITIVI PER STIMOLAZIONE SISTEMA NERVOSO



NEUROSTIMOLATORI
IMPIANTABILI

Sono dispositivi sterili o non sterili, utilizzati per assicurare al paziente il controllo del dolore in patologie caratterizzate da una sensazione algica elevata. Vengono in genere impiantati a livello addominale e collegati con tronchi nervosi spinali a vario livello rachideo, ai quali vengono trasmessi impulsi a radiofrequenza. I dispositivi descritti possono essere monouso o riutilizzabili.



Patient activities and environmental precautions—You should exercise reasonable caution to avoid items that generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause your neurostimulator to switch on or off. Your implanted system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, you should use caution while performing any activities that would be potentially unsafe if your symptoms unexpectedly return. Refer to "Appendix A: Electromagnetic interference" on page 71, for more information about possible sources of EMI

DBS System explant and EMI considerations—If any DBS System components (neurostimulator, lead, extension, or lead-extension fragment) remain implanted in your body after a partial system explant, the remaining components may be affected by EMI. These effects include induced current and component heating, which may result in shocking or jolting, or tissue damage resulting in serious injury or death. Therefore, if your DBS System is surgically removed, ask your doctor if any components still remain in your body. If so, be sure to always tell any medical personnel that you have an implanted DBS System so they can take the necessary precautions.

Electromagnetic interference (EMI)

Also refer to "Medical procedures that are not allowed (contraindications)" on page 27.

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various equipment found in medical, work, and home environments.

Electromagnetic interference could cause:

- **serious injury or death**, resulting from heating of the implanted system components, which can damage surrounding tissue.
- **system damage**, requiring surgical replacement; or result in a loss of, or change in, symptom control.
- **changes in your neurostimulator function**, causing it to switch on or off, or reset to factory settings, which may result in loss of stimulation, return of symptoms and require reprogramming by your doctor.
- **unexpected changes in stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as "jolting" or "shocking."

For complete information regarding EMI warnings, please see "Appendix A: Electromagnetic interference" on page 71.

EMI lookup table

Table 6.1 Potential for interference from EMI[a]

Item or procedure	Safe	Possible	Probable
Arc welding equipment			X
CAT (or CT) scan		X	
Cautery			X
Cellular phone	X	See footnote[b]	
Computer disk drive	X		
Defibrillation, external			X
Defibrillation, implanted		X	
Dental drill or ultrasonic probe		X	
Diagnostic ultrasound	X		
Diathermy treatment			

Table 6.1 Potential for interference from EMI[a] (continued)

Item or procedure	Safe	Possible	Probable
Microwave communication transmitter			X
Pacemaker		X	
Power lines			X
Power tool		X	
Psychotherapeutic procedures			X
Perfusion systems			X
Radiation therapy			X
Radios, AM and FM	X		
Refrigerator door (magnet)	X	See footnote[b]	
Resistance welder			X
Security gates		X	
Sewing machine	X		
Smooth top range	X		
Stereo speaker (magnet)	X	See footnote[b]	
Storm door	X		

Table 6.1 Potential for interference from EMI[a] (continued)

Item or procedure	Safe	Possible	Probable
Electronic power generator			X
Electric substation			X
Electrocautery			X
Electrolysis		X	
Fluoroscopy	X		
Freezer door (magnet)	X	See footnote[b]	
Furnaces, industrial			X
Hair dryers, salon		X	
Ham radio antennas			X
Induction heater, industrial			X
Induction range	X		
Lithotripsy			X
Magnets, industrial			X
Magnetic Resonance Imaging (MRI) - see page 29			X
Mammography		X	

Table 6.1 Potential for interference from EMI[a] (continued)

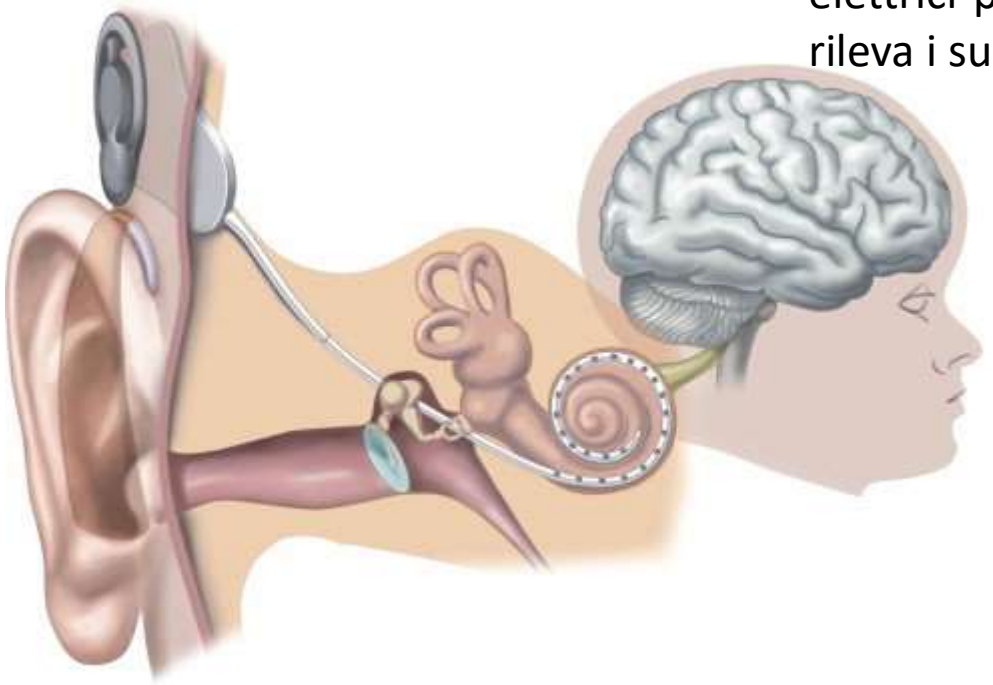
Item or procedure	Safe	Possible	Probable
Telephone (magnet)	X	See footnote[b]	
Theft detector		X	
Transmission towers for television and radio signals			X
Ultrasound, diagnostic	X		
Ultrasound, therapeutic			X
X-ray, CAT scan		X	
X-ray, diagnostic	X		

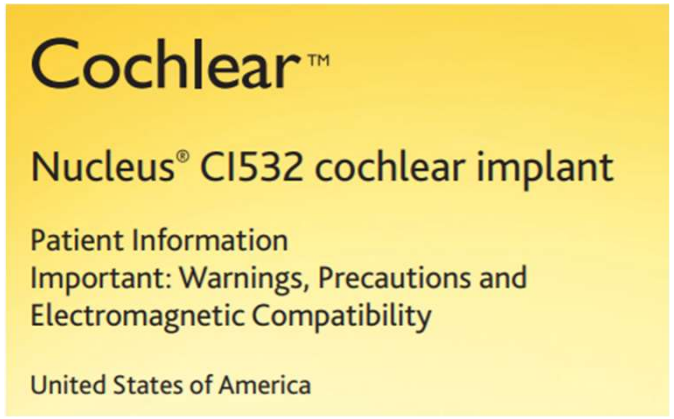
[a] Assuming equipment is in proper working order.
[b] Possible interference for Soletra DBS systems.

PROTESI ACUSTICHE

Impianti cocleari

Sono dispositivi sterili o non sterili, rappresentati da protesi impiantabili che hanno la finalità di ripristinare in parte la funzione uditiva in pazienti sordi. Consistono in un elettrodo applicato chirurgicamente a livello cocleare, collegato ad un rice-trasmettitore il quale riceve a sua volta impulsi elettrici prodotti da un microfono esterno che rileva i suoni.





POMPE ELETTRONICHE PER LA TERAPIA DEL DOLORE



Sono dispositivi sterili o non sterili, utilizzati per la somministrazione continua di farmaci (in particolare antidolorifici) in pazienti con gravi patologie. Le pompe impiantabili elettroniche sono programmate attraverso circuiti e vengono collocate a livello sottocutaneo tramite un intervento chirurgico. Da esse si diparte un catetere che scorre sotto la pelle fino al rachide, a livello del quale rilascia la sostanza medicamentosa.

Table 1. Potential effects of EMI from devices or procedures

Device or procedure	Patient injury	System damage[a]	Operational changes[a]	Change in flow rate	For guidelines
Bone growth stimulators			X		page 22
Defibrillation/ cardioversion		X			page 22
Diathermy (including therapeutic ultrasound)	X			X	page 22
Electromagnetic field devices: (eg, arc welding, power stations)			X		page 22
Lithotripsy		X			page 23
Laser procedures				X	page 23
Magnetic resonance imaging (MRI)	X	X[b]	X	X	See MRI guidelines manual
Psychotherapeutic procedures			X	X	page 23
Radiation therapy		X			page 23
Radio-frequency (RF)/ microwave ablation			X	X	page 23
Theft detector			X		page 23

[a] Applies to SynchroMed II Pumps only.

[b] Bench testing indicates that damage to SynchroMed II Pumps can occur; however, pump implantation requirements and patient orientation in a horizontal, closed-bore MRI system make this potential damage clinically unlikely. There has been no reported permanent damage to SynchroMed II Pumps due to clinical 1.5- or 3.0-Tesla (T) MRI exposure.

Electromagnetic interference

Electromagnetic interference - Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with pump function. The programmable pumps include features that provide protection from electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a pump; however, sources of strong electromagnetic interference can result in the following:

- **Patient injury,** from heating of the implanted pump resulting in damage to surrounding tissue.
- **System damage,** from electrical or mechanical effects that can cause inappropriate device responses or loss of device function, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug overdose or underdose.
- **Operational changes to the pump,** from strong magnets temporarily or permanently stopping the pump motor or electrical interference causing a pump memory error, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose. In the case of a pump memory error or a change to "safe state," reprogramming by a clinician is required.
- **Changes in flow rate,** from warming of the implanted pump, resulting in overinfusion and a clinically significant or fatal drug overdose.

Refer to Table 1 on page 14 and "Appendix: Electromagnetic interference" on page 22 for information on sources of EMI, the effect of EMI on the patient and the infusion system, and instructions on how to reduce the risk from EMI.

For information about the effects of EMI on programming, refer to "Telemetry signal disruption from EMI" on page 17.

Magnetic resonance imaging (MRI)— The SynchroMed II infusion system has been found to be MR Conditional. MR scan eligibility is based on specific settings and conditions. Scanning under different conditions may result in a life-threatening injury or device malfunction.

Do not perform an MRI examination on a patient implanted with this device until you have read and understood the full MRI eligibility information in the MRI guidelines for Medtronic implantable infusion systems manual.

PROTESI ORTOPEDICHE



Dispositivi impiantabili, sterili, utilizzati per la sostituzione delle articolazioni di anca, ginocchio, spalla, gomito, caviglia.

Costituite da: lega di titanio, lega CrCoMo, polietilene, ceramica

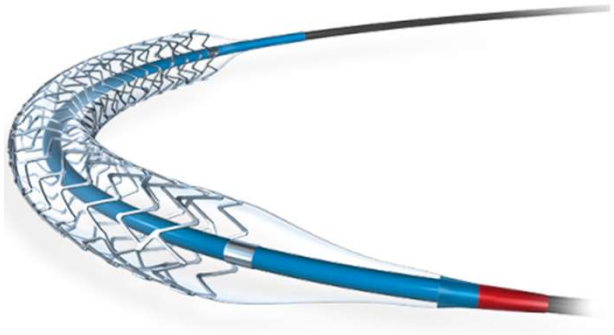






Effetti di interferenza verso sistemi di indagini diagnostiche.
Effetti di riscaldamento sotto l'effetto di campi elettromagnetici.

STENT



Stent in lega CrCo

5.11 Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated that the PROMUS stent, in single and in overlapped configurations up to 68 mm in length, is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for each duration of a sequence

The PROMUS stent should not migrate in this MRI environment. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating. MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the PROMUS stent.

Stent heating was derived by using the measured non-clinical, *in vitro* temperature rises in a GE Excite 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human heart model. The temperature rise was derived by validated calculation. At overlapped lengths up to 68 mm, the PROMUS stent produced a non-clinical maximum local temperature rise of 3ºC at a maximum whole body averaged SAR of 2.0 W/kg (normal operating mode) for one sequence of 15 minutes. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stents greater than 68 mm in length or stents with fractured struts are unknown.

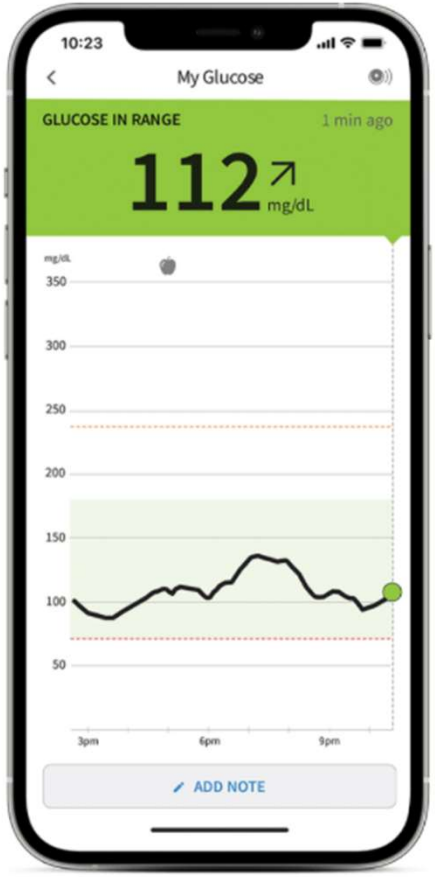
As demonstrated in non-clinical testing, an image artifact can be present when scanning the PROMUS stent. MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the PROMUS stent. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of PROMUS stents.

Stent a cessione di farmaco

Sono dispositivi sterili, utilizzati nel corso di interventi di angioplastica per mantenere la pervietà in un segmento di arteria coronaria interessato da un'ostruzione causata da una placca ateromasica. Presentano una struttura tubulare (metallica o polimerica) espandibile; si configurano in dispositivi capaci di rilasciare farmaci antiproliferazione (soprattutto sirolimus e paclitaxel), anche detti "stent medicati", o in dispositivi con rivestimento bioattivo (ad esempio in titanio e ossido nitrico). Sono disponibili in varie dimensioni (lunghezze e diametri) a seconda dell'esigenza clinica specifica. Vengono in genere posizionati attraverso l'impiego di un catetere a palloncino. I dispositivi descritti sono monouso.

Esistono oggi anche Stent completamente riassorbibili in 3-6 mesi

MONITORAGGIO CONTINUO GLIGEMIA





Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

17

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Eversense XL CGM System

Up to 180-Days of Sensor Life

Other CGM systems require a sensor removal and reinsertion every 2 weeks or more, while the Eversense XL Sensor lasts up to 180 days.

Smart Transmitter

Eversense XL offers you the flexibility and discretion to remove the transmitter without wasting a sensor.

iOS and Android App

With Eversense XL, you can see your readings directly on your compatible mobile device. And with readings every 5 minutes, you can see where you are now and where



- **Close contact with direct electromagnetic interference (EMI) may interfere with the smart transmitter's ability to send data to your mobile device. Move away from the source of EMI and check that your mobile device is connected to your smart transmitter.**

Recommended Separation Distances Between Other Portable/Mobile RF Communications Equipment and the Smartphone (Receiving Device)

Follow the smartphone (or other receiving device) manufacturer's instructions for separation distances. The customer or the user of the smartphone (or other receiving device) can help prevent electromagnetic interference by maintaining a minimum distance between other portable/mobile RF communications equipment (transmitters) and the smartphone of at least 30 cm (about 12 inches). Portable/mobile RF equipment include: baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Electrical and Safety Standards

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	Immunity Test	Tr C
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	±
Power Frequency (110VAC/60Hz, 230VAC/50 Hz) Magnetic Field IEC 61000-4-8	30 A/m	

Electrical and Safety Standards (continued)

The Eversense XL CGM System is intended to be used in the electromagnetic environment detailed in the table below. Users of the System should ensure it is used according to these specifications.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 (Smartphone only (Receiving Device))	≥ 3 Vrms (150 kHz to 80 MHz)	3 Vrms	Interference may occur in the vicinity of equipment marked with following symbol:
Radiated RF IEC 61000-4-3	≥ 10 V/m at 80 MHz to 2700 MHz (AM Modulation)	3 Vrms	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Eversense XL CGM System is used exceeds the applicable RF compliance level above, the Eversense XL CGM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eversense XL CGM System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

WEARABLE

WEARABLE MEDICAL DEVICES MARKET

Global Wearable Medical Devices Market Size (US$ Mn), 2018 to 2026



2018
$ 24,571.8 Mn

2026
$ 139,353.6 Mn

Global Wearable Medical Devices Market Share, By Product, 2018



Diagnostic & Monitoring Wearable Devices

Therapeutic Wearable Medical Devices

North America Wearable Medical Devices Market Size (US$ Mn), 2018



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SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Modena

DISPOSITIVI MEDICI IMPIANTABILI ED ESPOSIZIONE A CAMPI ELETTROMAGNETICI IN AMBITO LAVORATIVO

14 Dicembre 2021

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