SureScan™ Heart Devices — approved by the FDA for safe use in the MRI environment when specified conditions are met.
Based on your unique cardiac condition and other health needs, your doctor has made a choice to implant a Medtronic heart device system, engineered with Medtronic SureScan™ technology, and designed for safe use in the magnetic resonance imaging (MRI) environment. The designation “MR Conditional” means your implanted heart device has been shown to pose no known hazards in a specified MR environment with specified conditions of use.

This brochure will help you better understand MRI, its unique benefits and why having access to MRI capabilities is an important part of your overall healthcare both today and in the future.
WHAT IS AN MRI?

MRI stands for magnetic resonance imaging. MRI is an imaging technique that provides a visualized detail of internal body tissues. MRI provides much greater contrast and clarity between the different soft tissues of the body than other imaging technologies, making it especially valuable in diagnosing neurological (brain), musculoskeletal and cardiovascular conditions, as well as cancer.

The difference between MRI and other technologies

MRI, unlike CT scans, does not use radiation to produce an image but rather uses strong magnetic fields to create images of structures inside the body. While CT scans are great for imaging hard materials in the body like bones, MRI is used to image soft tissue.

The benefits of having a cardiac system that is approved for use with MRI

Unlike previous generations of cardiac devices, the SureScan systems are FDA approved for use in the MRI environment.

Without SureScan technology, an MRI could change the settings and/or temporarily affect the normal operation of your heart device. If you are referred for an MRI scan, your cardiologist will have further information about the steps you need to take before getting a scan.

Any of these health conditions may increase the chances of needing an MRI

- Stroke
- Headaches
- Heart Disease
- Cancer (breast, prostate, bladder)
- Existing implants (hip, knee, shoulder, stents, etc.)
- Chronic pain (back, shoulder, hip, neck)

These medical issues don’t necessarily mean you need an MRI, but they often lead to other conditions that do.

- Diabetes
- Hypertension
- Atrial Fibrillation
- Coronary Artery Disease

Annually 12–16% of device patients are likely to have an MRI ordered.¹–⁴
SURESCAN SYSTEMS

A full portfolio of heart device systems approved by the FDA for conditional use with MRI

- Pacemakers, Implantable Cardioverter Defibrillators (ICD), or Cardiac Resynchronization Therapy Devices (CRT-D) are small heart devices that are implanted under the skin, typically just below your collarbone. The device delivers therapies to treat irregular, interrupted, fast or slow heartbeats.

- Transcatheter pacemakers, also referred to as leadless pacemakers, are implanted directly in the heart and provide the same therapy options as traditional pacemakers.

- Leads are thin, soft, insulated wires; each is about the size of a spaghetti noodle. The leads carry the electrical impulse from the heart device to your heart, and send information about your heart’s natural activity back to your device. If you are a current heart device patient, ask your doctor if your leads are approved for MRI scans.

- An Insertable Cardiac Monitor (ICM) is a small insertable monitor placed just under the skin that provides continuous, long-term cardiac monitoring to help doctors with diagnosis or ongoing management. The device automatically detects and records abnormal heart rhythms.
Within a couple of weeks after your implant procedure you will receive your device identification card. The card contains important information about your SureScan heart device system.

Please carry the card with you at all times and present it, when necessary, to inform people that you have a Medtronic pacemaker, ICD, CRT-D, or ICM. Your card will indicate if you have a complete heart device system that allows you access to an MRI scan.
There may come a time when a physician, such as an orthopedic doctor, oncologist or neurologist, refers you for an MRI scan. Since some implantable cardiac devices are not considered safe for use in an MRI, there are some things you should consider while scheduling your MRI.

When a physician refers you for an MRI, make sure to tell him or her about your cardiac device. Present your device identification card to your doctor to inform the physician that you have a complete heart device system that allows you access to an MRI scan. Your identification card will help your physician understand what kind of implantable device you have. Your physicians may also need to consult with your cardiologist; his or her contact information is on the card.

You may be asked to contact your cardiologist directly. Your cardiologist may need to confirm that your device is working properly and is safe for use in the MRI environment. Your cardiologist may also work with you to locate an MRI center that is best suited to meet not only your MRI need but your cardiac needs as well.

When you call to schedule your MRI, make sure to tell them you have an implantable pacemaker, ICD, CRT-D, or ICM device designed for use with MRI. You may be asked to provide your cardiologist’s contact information, which is located on your identification card.

On the day of your scan, your heart device, except for an ICM, will be programmed into a special setting. This will help ensure that your device works properly while in the MRI environment. The programming will look and feel much like the programming that is done for your in-office check-up appointments. After the MRI, your device will be programmed back to its previous settings.

If you experience any heart issues after your MRI scan, be sure to contact your cardiologist immediately.

If you have any questions about having an MRI procedure, contact Medtronic Patient Services at 1-800-551-5544, Monday – Friday, or visit the Medtronic website at www.medtronic.com.
EDUCATIONAL SERVICES FOR PATIENTS

Medtronic understands how important it is for you to get answers to your questions. That’s why we have the educational resources on the right to help you.

Patient Services
If you have a Medtronic pacemaker, ICD, CRT-D, or ICM system and would like to learn more about your heart device or have questions about living with an implanted heart device, call our Medtronic Patient Services Team at 1-800-551-5544. Our Patient Services Specialists are available to assist you Monday – Friday.

Medtronic.com
The website includes in-depth information on heart conditions, treatment options and support networks for patients and their caregivers. Our interactive websites allow you to view video, read patients’ stories and link to other resources. Visit us online at www.medtronic.com.
Important Safety Information

SureScan™ Transvenous Pacemaker, ICD, and CRT-D Devices

An implantable pacemaker, defibrillation, or cardiac resynchronization therapy (CRT) system relieves symptoms of heart rhythm disturbances. It does this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing or for patients who may benefit from synchronizing the pumping of the heart chambers. In addition to these functions, an implantable cardioverter-defibrillator (ICD) system delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. A cardiac resynchronization therapy (CRT) implantable cardioverter-defibrillator (ICD) system delivers therapies to treat patients who may benefit from synchronizing the pumping of the heart chambers. A CRT ICD (also referred to as CRT-D) also delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. Risks associated with these implantable device systems include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable device system, you will have limitations with magnetic and electromagnetic radiation, electric or gas-powered appliances, and tools with which you are allowed to be in contact.

Your physician may prescribe an MRI scan for you. A magnetic resonance imaging (MRI) scan is a type of medical imaging that uses magnetic fields to create an internal view of the body, which doctors use for diagnostic purposes. Unlike previous generations of heart devices, your SureScan heart device system was designed and tested to be used safely with MRI scanners. The electromagnetic fields present during MRI scans have the potential to cause hazardous effects on heart devices, which can result in cardiac tissue heating, inappropriate therapy, and dangerous arrhythmias. Due to the unique design of the SureScan heart device systems, these risks are reduced to a very low level so that under specified conditions, patients may safely undergo MRI scans. You can undergo an MRI scan as long as you meet the patient eligibility requirements that Medtronic provides to your heart doctor and the scan is conducted according to Medtronic directions. For example, your heart device system must consist only of a Medtronic SureScan model heart device and the appropriate number of SureScan labeled leads visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan. The Revo MRI™ SureScan and Advisa MRI™ SureScan pacing systems; the Evera MRI™ SureScan and Visia AF MRI™ defibrillation systems; and the Amplia MRI™ SureScan and Compia MRI™ SureScan CRT ICD systems are MR Conditional. This means the system is designed to allow patients to undergo MRI when your doctor determines you meet patient eligibility requirements and the scan is conducted according to Medtronic directions. This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further questions, contact patient services at 1-800-551-5544.

Micra™ Transcatheter Pacing System VVIR Single Chamber with SureScan™ MRI

An implantable pacemaker system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing.

Risks associated with the Micra Transcatheter Pacing System (Micra) implant include, but are not limited to, complications at the surgical site, injury to the heart where the device is attached such as pericardial effusion (fluid around the heart) and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving a Micra, you will have limitations with certain magnetic and electromagnetic radiation, electric or gas powered appliances, and tools in which you are allowed to be in contact.

Once implanted, removal of the Micra after it has become encapsulated may be difficult because of the development of fibrotic tissue. At such time, your physician has the option of permanently turning off the Micra, and leaving it in the heart.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further information, please call the Medtronic toll-free number at 1-800-551-5544 (7:00 a.m. to 6:00 p.m., Monday – Friday, Central Time) or see the Medtronic website at www.medtronic.com.

References

1 Data from 2010 MarketScan® Commercial and Medicare data bases from Truven Health Analytics, Inc. were used to characterize nonpacemaker and pacemaker cohorts and utilization of radiology services. Cohorts were matched based on age, gender, and comorbidities.
2 Medtronic data on file 2015; ICD data from MarketScan® 2012 Commercial and Medicare Database, Truven Health Analytics.
4 Medtronic data on file 2015; CRT data from MarketScan® 2012 Commercial and Medicare Database, Truven Health Analytics.
Reveal LINQ™ Insertable Cardiac Monitor

The Reveal LINQ Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Possible risks associated with the implant of the Reveal LINQ Insertable Cardiac Monitor include, but are not limited to, infection at the surgical site, device migration, erosion of the device through the skin and/or sensitivity to the device material. Treatment with a Reveal LINQ Insertable Cardiac Monitor is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further information, please call the Medtronic toll-free number at 1-800-551-5544 (7:00 a.m. to 7:00 p.m., Monday – Friday, Central Time) or see the Medtronic website at www.medtronic.com.

Patient Assistant

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.