YES, OUT OF SIGHT, **OUT OF MIND.**

Micra™
Transcatheter Pacing System

cardiocapsule
miniaturized | sophisticated | complete

Medtronic

MEET MICRA

The invisible cardiocapsule

Micra™ is the world's smallest pacemaker[1] – leaving no bump under the skin, no chest scar and requiring no lead. This cardiocapsule is completely self-contained within the heart and provides the therapy needed without a visible or physical reminder of a medical device.

Yes,
this is actual size

WHAT IS BRADYCARDIA?

Bradycardia is a condition in which the heart beats too slowly. A healthy heart beats 60 to 100 times per minute, pumping about 284 liters of blood every hour. When you have bradycardia, the heart beats fewer than 60 times per minute. At that rate, the heart may not be able to pump enough oxygen-rich blood to the body during activity or exercise. As a result, you might feel dizzy, tired, short of breath or have fainting spells.

DIAGNOSING BRADYCARDIA

Only a doctor can determine if you have bradycardia and, if so, how far it has progressed. To rule out or confirm the diagnosis of bradycardia, one or several diagnostic tests may be ordered, depending on the suspected heart rhythm problem.

These tests may include:

- Electrocardiogram (ECG)
- Exercise ECG, or stress test (measures your heart rhythm while you're engaged in a physical activity)
- Holter or event monitor
- Insertable cardiac monitor
- External loop recorder
- Tilt table test
- Electrophysiology study (EP Study)

TREATING BRADYCARDIA

Treatment strategies vary, depending on your bradycardia causes and symptoms. Your doctor might prescribe new medications, or adjust the doses of medications you are currently taking to restore your normal heart rate. If this fails to restore your normal heartbeat, a pacemaker can regulate your heart's rhythm. A pacemaker is designed to mimic the heart's natural rhythm. By sending an impulse when the heart's rhythm is slow or interrupted, it effectively regulates the heart rate automatically, freeing you to enjoy your regular activities.

HOW DO PACEMAKERS WORK?

A pacemaker is designed to mimic the heart's natural rhythm when there are disturbances, such as pauses, in the natural rhythm. The pacemaker has two main purposes—pacing and sensing.

- **Pacing:** A pacemaker will send an electrical impulse to the heart when the heart's own rhythm is too slow or interrupted.
- **Sensing:** A pacemaker will also "sense" (monitor) the heart's natural electrical activity. When the pacemaker senses a natural heartbeat, it will not deliver a pacing pulse.

WHY IS MICRA DIFFERENT?

TRADITIONAL PACING SYSTEM

Most pacemakers require a device (size of tea bag) to be surgically implanted under your skin in the upper chest. The system also requires a lead to be connected to the pacemaker and is threaded into the heart. The lead carries electrical signals from the pacemaker to your heart to help it beat regularly.

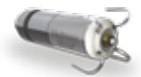
MICRA TRANSCATHETER PACING SYSTEM

Micra is 93% smaller than traditional pacemakers. It is the size of a large vitamin capsule, and has a battery that lasts as long as a traditional pacemaker.[1,2] Unlike a standard pacemaker, it is implanted into the heart through a vein in your leg and does not require a lead. Micra's miniaturized size and minimally invasive approach leaves no visible sign of a medical device under the skin. This can mean fewer post-implant activity restrictions and no obstructions to shoulder movement.

IS MICRA FOR EVERY PATIENT?

Micra is intended for patients who need a single chamber (also known as a ventricular pacemaker, or VVIR) pacemaker. Talk to your doctor about the benefits and risks of Micra.

Traditional pacemaker and lead

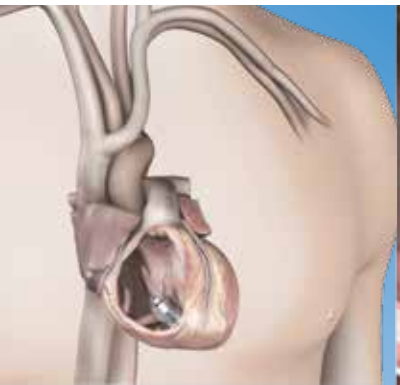


Micra cardiocapsule

Vitamin Pill

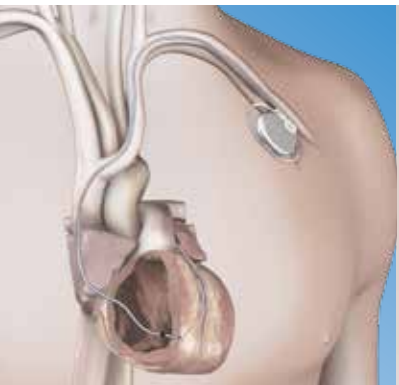
HOW IS MICRA IMPLANTED?[1]

- Your doctor will insert a "straw-like" catheter system into a vein, typically near the upper thigh area of your leg
- The catheter system moves the Micra into the right ventricle of the heart
- The Micra is placed against the heart wall and secured with flexible tines (see image at the far right below)
- Your doctor tests the Micra to ensure it is working properly
- The catheter system is then removed



HOW IS A TRADITIONAL PACEMAKER SYSTEM IMPLANTED?

- A small incision, approximately 5 cm long is made in the upper chest
- A lead (thin insulated wires, like a spaghetti noodle) is guided through the vein into the heart
- Your doctor connects the lead to the pacemaker and programs the device
- The pacemaker is then inserted beneath the skin
- Your doctor tests the pacemaker to ensure it is working properly
- The incision is then closed



"I know it's there, but it's not there."

Ron,
Medtronic Micra Patient

FREQUENTLY ASKED QUESTIONS

Many people with a pacemaker like the Micra cardiocapsule resume their normal daily activities after recovering from the implant procedure. There may be certain situations your doctor will ask you to avoid. Discuss your activity and lifestyle goals with your doctor and develop a plan that works best for you.

- **Is it safe for me to have an MRI scan?**
  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. Micra was designed, tested and approved to be used safely with MRI scanners. You can undergo an MRI scan as long as patient eligibility requirements are met. The pacemaker ID card specifies implanted device model.

Visit www.MRISureScan.com for questions about MRI scanning eligibility or about the scanning process. Heart doctors with questions should contact a Medtronic representative or Medtronic Technical Services.

- **Can I go through the airport security?**
  Given the short duration of security screening, it is unlikely that a Micra will be affected by metal detectors (walk-through archways and hand-held wands) and full body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports, courthouses and jails. However, the metal case of a pacemaker could set off a metal detector.

  To minimize the risk of temporary interference with a Micra while going through the security screening process, avoid 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 hand-held wand is used, ask the security operator not to hold it over the pacemaker and not to wave it back and forth over the pacemaker. Requesting a hand search is also an alternative.

  If you have concerns about these security screening methods, show your Micra ID card, request alternative screening and then follow the instructions of the security personnel.

- **Can I use a mobile phone?**
  Yes. When talking on a mobile phone keep the phone's antenna about 6 inches away from an implanted Micra. We also recommend avoiding placing the mobile phone in a shirt or jacket pocket of the chest.

- **Are household appliances safe to use?**
  Yes. Most household appliances are safe to use as long as they are properly maintained and in good working order. This includes microwave ovens, major appliances, electric blankets and heating pads.

- **Will magnets affect my Micra?**
  Items that contain magnets, such as magnetic therapy products, stereo speakers and hand-held massagers can temporarily affect the operation of a pacemaker. Therefore, it is recommended keeping items containing magnets at least 6 inches away from an implanted pacemaker. We do not recommend the use of magnetic mattress pads and pillows because it is difficult to maintain a 6 inch distance when using these items.

- **How long will my Micra last?**
  A new Micra is needed when battery power falls to a low level. Battery power is affected by many factors, including the nature of the heart condition. The estimated average battery life for Micra is 10-12 years after it is implanted[1]; individual patient experience may vary.

  The battery power is checked at each Micra follow-up appointment. The doctor or nurse will notify you when you need a new pacemaker.

  Micra is designed to provide options when a new device is needed. It may be turned off and a new Micra or a traditional system may be implanted or it may be retrieved and a new system implanted. Your doctor will determine what is best for you.[1,3]

- **Can I exercise? Can I go about my regular activities?**
  You should be able to return to your usual activities, as long as those activities do not exceed current fitness levels. Questions about specific exercises should be discussed with your physician.

Additional information can be found on our website:
www.medtronic.eu and **www.mrisurescan.com**

References

1 Medtronic Micra MC1VR01 Clinician Manual. November 2014.

2 Williams, Eric; Whiting Jon. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic Data on File.

3 Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. Published online November 9, 2015.

Brief Statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

www.medtronic.com/manuals

Consult instructions for use on this website. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

cardiocapsule
miniaturized | sophisticated | complete

Medtronic

Europe
Medtronic International
Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland
Medtronic Limited
Building 9
Croxley Green Business Park
Hatters Lane
Watford
Herts WD18 8WW
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

UC201505295bEE

Printed in Europe.
Not for distribution in France.

www.medtronic.eu