MEET MICRA

ACTUAL SIZE

Micra™
Transcatheter Pacing System

Medtronic

MEET MICRA™

The world's smallest pacemaker[1]

Together, we can provide new opportunities to redefine the patient experience and reduce complications associated with traditional pacing technology.[2]

> 99%
Implant Success[3,4]

63%
Fewer Major Complications[4]

Redefined Patient Experience
- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

Eliminated Pocket-related Complications[5]
- Infection
- Hematoma
- Erosion

Eliminated Lead-related Complications[5]
- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

Long-term Lead- and Pocket-related Complications with Traditional Systems
- Pocket-related complications **8% at five years**[5]
- Lead-related complications **11% at five years**[5]

MINIATURIZED.

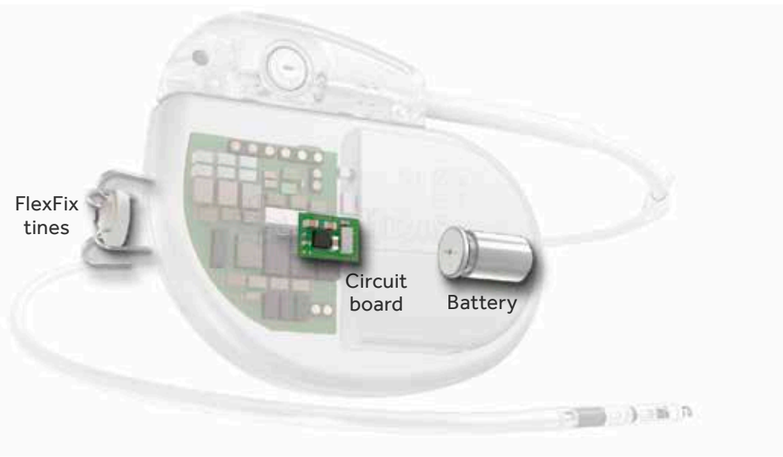
93% smaller than modern-day pacemakers[6]
- Completely self contained within the heart, no leads required
- New ultra-low power circuit design delivers a 12-year longevity[3]

SOPHISTICATED.

Engineered for a minimally invasive approach
- Atraumatic FlexFix™ nitinol tines provide secure capsule placement[7,8]
- Integrated delivery system facilitates a streamlined implant procedure via a percutaneous, femoral approach

COMPLETE.

The only transcatheter pacing system to offer a complete feature set[3,9,10]
- 12-year battery longevity[3]
- MRI SureScan™ Technology, which allows the patient to be safely scanned using either a 1.5T or 3T full body MRI[3]
- Accelerometer-based rate response
- CareLink™ 2090 and Encore™ programmer compatible, no accessories required
- Capture Management™



MINIATURIZED.
SOPHISTICATED.
COMPLETE.

PACING CAPSULE[10]

Parameter	Micra™
Pacing Mode	VVIR
Mass	1.75 g
Volume	0.8 cc
Electrode Spacing	18 mm
Programmable 3-axis Accelerometer	

Device life cycle management options

- Micra is designed to offer options
  - Micra can be programmed off at the end of service and can be differentiated from additional Micra devices, if subsequent devices are implanted
- The Micra design incorporates a proximal retrieval feature to enable acute retrieval
  - Successful retrieval demonstrated after 28 months in chronic animal models[11]

ANODE

- Bipolar pacing

PROXIMAL RETRIEVAL FEATURE

CATHODE

- Steroid-eluting electrode
- Separated from FlexFix™ tines to ensure optimal contact with myocardium

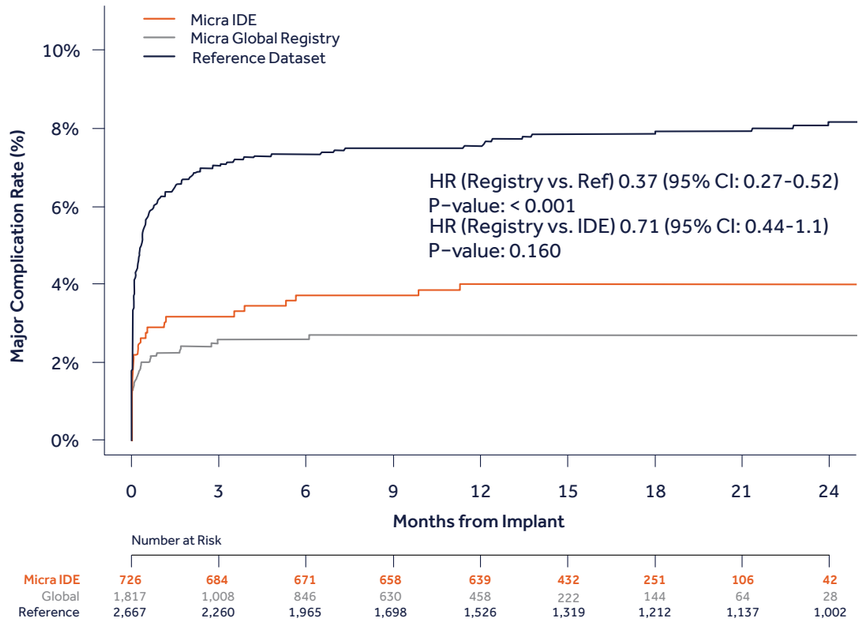
Primary prespecified safety, effectiveness, and long-term safety objectives were met (n = 726)[3,12]

- 96% of patients experienced no major complications by 12 months follow-up[12]
  - 0 dislodgements or systemic infections
  - Low (0.4%) revision rate
- Pacing thresholds remained low and stable through twelve months[3]
  - Yielding an estimated battery longevity on average of **12.1 years**

Real-world experience reinforces safety and long-term performance of Micra (n = 1,817)[4]

- High implant success rate (99.1%)
- Low major complication rate through 12 months (2.7%)
  - Low dislodgement rate (0.06%)
  - Low procedure-related infection rate (0.17%)

63% fewer major complications than traditional pacemakers*[4]



*Historical cohort comprised of 2,667 patients from six trials of commercially available technology (HR: 0.46, 95% CI: 0.30-0.72; P-value < 0.001). To adjust for difference in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra.

FlexFix Nitinol Tines

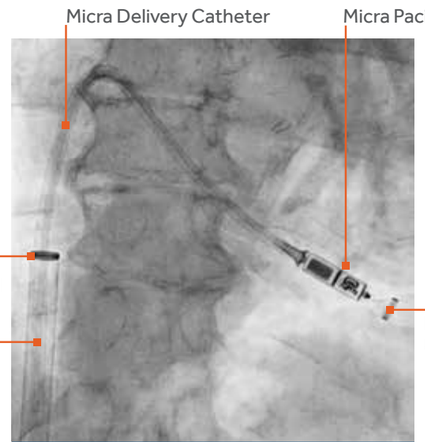
- Multidimensional redundancy: two tines have 15 times the holding force necessary to hold the device in place[8]
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval[7]
- Optimal electrode tissue interface allows for low and stable chronic thresholds[13]

> 99%
IMPLANT SUCCESS[3,4]

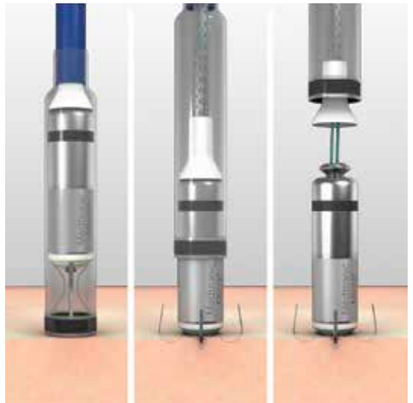
STREAMLINED IMPLANT PROCEDURE WITH INTEGRATED DELIVERY SYSTEM

Micra Delivery Catheter

- 105 cm long catheter system with a handle that controls deflection and deployment of the Micra™ pacing capsule[3]



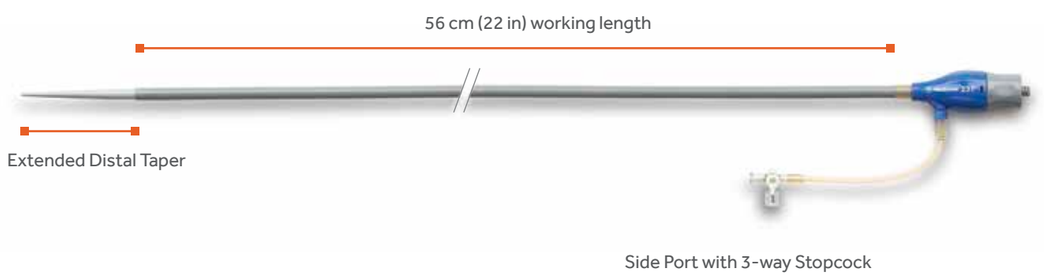
Delivery catheter provides visual feedback when adequate tip pressure has been achieved and retracts during deployment.[10]



Linear one-step deployment facilitates consistent capsule placement, no torque required.[10]

SMOOTH VESSEL NAVIGATION WITH THE MICRA™ INTRODUCER

- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip



References

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[2] Ritter P, Duray GZ, Zhang S, et al. The rationale and design of the Micra Transcatheter Pacing Study: safety and efficacy of a novel miniaturized pacemaker. *Europace*. May 2015;17(5):807-813.
[3] Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. February 11, 2016;374(6):533-541.
[4] El-Chami M, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at HRS May 2018, Boston, MA.
[5] Udo EO, Zuithoff NP, van Hemel NM, et al. Incidence and predictors of short- and long-term complications in pacemaker therapy: the FOLLOWPACE study. *Heart Rhythm*. May 2012;9(5):728-735.
[6] Williams, Eric; Whiting, Jon. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic data on file.
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[8] Eggen MD, Grubac V, Bonner MD. Design and Evaluation of a Novel Fixation Mechanism for a Transcatheter Pacemaker. *IEEE Trans Biomed Eng*. September 2015;62(9):2316-2323.
[9] St. Jude Medical Nanostim™ Leadless Pacemaker, Nanostim Delivery System Catheter Instructions for Use, January 2014.
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[11] Bonner MD, Neafus N, Byrd CL, et al. Extraction of the Micra transcatheter pacemaker system. *Heart Rhythm*. May 2014;11(5):S342.
[12] Duray GZ, Ritter P, El-Chami M, et al. Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. *Heart Rhythm*. May 2017;14(5)702-709.
[13] Bonner M, Eggen M, Haddad T, et al. Early Performance and Safety of the Micra Transcatheter Pacemaker in Pigs. *Pacing Clin Electrophysiol*. November 2015;38(11):1248-1259.

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

Indications

Micra Model MC1VR01 is indicated for patients with:

- Symptomatic paroxysmal or permanent high grade AV block in the presence of AF
- Symptomatic paroxysmal or permanent high grade AV block in the absence of AF, as an alternative to dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses), as an alternative to atrial or dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

Contraindications

Micra Model MC1VR01 is contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤ 12.5 cm (4.9 in), or known intolerance to the materials listed in the Instructions for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated.

Steroid use — Do not use in patients for whom a single dose of 1.0 mg of dexamethasone acetate cannot be tolerated.

Warnings and Precautions

End of Service (EOS) — When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use — Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. Asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end-of-device-life care for a Micra device may include the addition of a replacement device with or without explantation of the Micra device, which should be turned off.

Potential Complications

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, acceleration of tachycardia, myocardial infarction, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, death, device embolization, access site hematoma and AV fistulae, vessel spasm, infection, inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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