

Micra[™] Transcatheter pacing system

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Medtronic
Further, Together

Current Pacemaker System: Device and Leads



Clinical Need

With traditional transvenous pacing systems the following clinical complications may occur:

Lead Complications

- Dislodgement
- Insulation/conductor break
- Connector issues
- Venous Thrombosis

Pocket Complications

- Infection
- Erosion
- Pocket Hematoma

Other Complications

- Pneumothorax
- Twiddler syndrome
- Aesthetic concerns and discomfort of the patient

Patients with the following conditions may be prevented from receiving traditional transvenous pacemakers such as:¹

- Compromised venous access
- History of infection
- Need to preserve veins for hemodialysis

New opportunities to:

REDEFINE THE PATIENT EXPERIENCE

- Potential to increase pacemaker patient satisfaction
- No chest scar, bump, and no visible or physical reminder
- Minimally-invasive procedure
- Potential for fewer post-implant activity restrictions



MEET MiCRA

Engineered for a minimally invasive approach

- Integrated delivery system facilitates a streamlined implant procedure via a percutaneous, femoral approach



Navigation to Target Location

Minimally invasive, integrated delivery system facilitates a streamlined implant procedure.



Device Deployment

Linear, one-step deployment ensures controlled capsule placement, no torque required.¹

Catheter is designed to minimize tip force

- Femoral approach and flexible distal catheter design result in an 11% push efficiency²



Miniaturized

93% smaller than other modern-day pacemakers¹, Micra™ is the **world's smallest pacemaker**², yet it offers a complete set of features.



New opportunities to

REDUCE COMPLICATIONS ASSOCIATED WITH TRADITIONAL PACING TECHNOLOGY

Pocket Related Complications

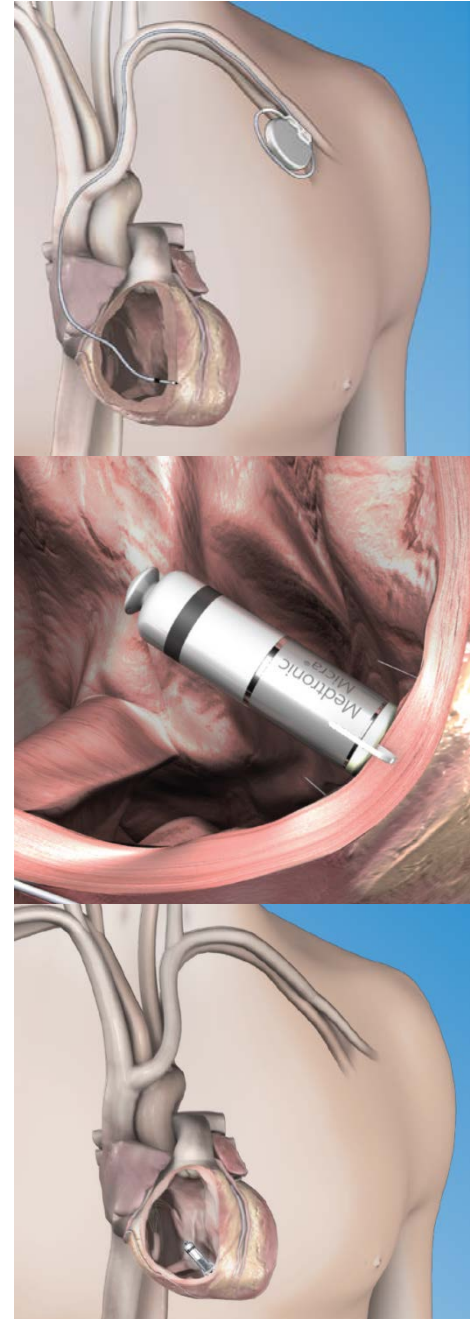
8% at 5 years with traditional technology ^{1,2}

- Infection
- Hematoma
- Erosion

Lead Related Complications

11% at 5 years with traditional technology ^{1,2}

- Lead dislodgements
- Insulation breaches/ fracture
- Venous thrombosis and obstruction
- Tricuspid regurgitation



Device life cycle management options

Options:

- Micra can be turned OFF and an additional Micra can be added
 - Micra takes up <1% of the volume of a normal right ventricle. ¹
- Micra can be turned OFF and a traditional system or upgrade can be implanted
- The Micra design incorporates a proximal retrieval feature to enable acute retrieval. ²



Proximal
Retrieval
Feature

Evidence



Complete

LARGEST TRANSCATHETER PACING DATASET (N=725) ¹

Micra Transcatheter Pacing Study

- Single-arm, global multi-center clinical trial
- 94 implanters, 56 centers, 19 countries, 5 continents

Met performance and safety objectives with wide margins

- **96%** of patients experienced no major complications at 6 months
- **51%** lower complication rate than traditional pacing systems
- **0** dislodgements
- **0** systemic infections

Globally Diverse Patient Population with Robust Trial Design¹

Study Design:

- Prospective, non-randomized, single-arm, multi-site, FDA IDE study²
- Pre-defined historical control group for comparison[†]
 - 2667 patients from 6 trials of commercially available technology
- 725 patients, 94 implanters, 56 centers, 19 countries, 5 continents
 - North America, Europe, Asia, Australia, Africa
- VVIR patients: Class I or II guideline indication* for de novo ventricular pacing with no restriction by comorbidity (e.g. COPD)

Thank you very much
For your time.