Micra™ Transcatheter pacing system

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Current Pacemaker System: Device and Leads
Clinical Need

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

<table>
<thead>
<tr>
<th>Lead Complications</th>
<th>Pocket Complications</th>
<th>Other Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dislodgement</td>
<td>• Infection</td>
<td>• Pneumothorax</td>
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<tr>
<td>• Insulation/conductor break</td>
<td>• Erosion</td>
<td>• Twiddler syndrome</td>
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<tr>
<td>• Connector issues</td>
<td>• Pocket Hematoma</td>
<td>• Aesthetic concerns</td>
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<tr>
<td>• Venous Thrombosis</td>
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<td>and discomfort of the patient</td>
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</tbody>
</table>

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

¹For reference.
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


93% smaller than other modern-day pacemakers\(^1\), 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

$^1$ Udo et al. FOLLOWPACE. Heart Rhythm 2012;9:728–735.
$^2$ Historical Control for Micra Study (6 pacemaker studies)
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

¹ Omdahl, P., et al. Right Ventricular Anatomy Can Accommodate Multiple Micra Transcatheter Pacemakers. PACE. 2016;00:1-5
² Medtronic Micra MC1VR01 Clinician Manual, November 2014
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 Design\(^1\)

**Study Design:**

- Prospective, non-randomized, single-arm, multi-site, FDA IDE study\(^2\)
- Pre-defined historical control group for comparison\(^\dagger\)
  - 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)


\(^\dagger\) 3830, 5076, EnRhythm, EnRhythm MRI, Advisa MRI, and SAVEPACe. Events related only to right atrial lead were excluded.
Thank you very much
For your time.