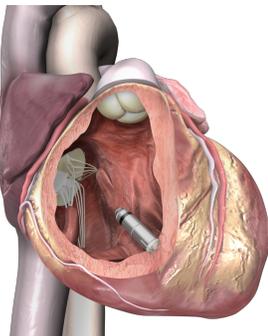


**FACT SHEET**

**Medtronic Micra® Transcatheter Pacing System (TPS):  
The World’s Smallest, Minimally Invasive Cardiac Pacemaker**

<p><b>Disease Overview: Bradycardia</b></p>	<p>Bradycardia is a condition characterized by a slow or irregular heart rhythm, usually fewer than 60 beats per minute (normal heart rate is 60 – 100 bpm). At this rate, the heart is unable to pump enough oxygen-rich blood to the body during normal activity or exercise, causing dizziness, fatigue, shortness of breath or fainting spells.</p> <p>Pacemakers, the most common way to treat bradycardia, help restore the heart's normal rhythm and relieve symptoms by sending electrical impulses to the heart to increase the heart rate.</p>
<p><b>Micra TPS Technology Overview</b></p>	<p>Unlike traditional pacemakers, the Micra® Transcatheter Pacing System (TPS) is a miniaturized, fully self-contained pacemaker that delivers the most advanced pacing technology available to patients via a minimally invasive approach.</p> <ul style="list-style-type: none"> <li>• <b>World’s Smallest Pacemaker</b> <ul style="list-style-type: none"> <li>○ Less than one-tenth the size of traditional pacemakers (~1cc)</li> <li>○ Cosmetically invisible to the patient after implantation</li> <li>○ Comparable in size to a large vitamin</li> <li>○ Weighs the same as a penny (2 g)</li> </ul> </li> <li>• <b>Advanced Pacing Technology</b> <ul style="list-style-type: none"> <li>○ Is attached to the heart via small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device</li> <li>○ Does not require the use of wires, known as “leads,” to deliver pacing therapy</li> <li>○ Has an estimated average 12-year battery life</li> <li>○ Is approved for full body MRI scans</li> <li>○ Responds to patients’ activity levels by automatically adjusting therapy</li> </ul> </li> <li>• <b>Minimally Invasive Procedure</b> <ul style="list-style-type: none"> <li>○ Delivered directly into the heart through a catheter inserted in the femoral vein</li> <li>○ Does not require a surgical incision or creation of a “pocket” under the skin, which eliminates any visible sign of the device and a potential source of complications</li> <li>○ The Micra design incorporates a retrieval feature to enable retrieval when possible; however, the device is designed to be left in the body</li> </ul> </li> </ul> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p><b>Traditional Pacemaker</b></p> </div> <div style="text-align: center;">  <p><b>Micra TPS Pacemaker</b></p> </div> </div> <div style="text-align: right; margin-top: 20px;">  </div>
<p><b>Regulatory Status</b></p>	<p>The device received U.S. Food and Drug Administration (FDA) approval in April 2016 and was awarded CE (Conformité Européenne) Mark in April 2015 based on results from the Medtronic Micra® TPS Global Clinical Trial.</p> <p>The trial enrolled 744 patients and evaluated the safety and efficacy of the device through a single-arm, multi-center study at 56 centers in 19 countries on 5 continents.</p>

**Medtronic Micra  
TPS Global  
Clinical Trial  
Results**

In August 2016, long-term results from the largest clinical evaluation of leadless pacing patients with the Micra TPS were revealed at the European Society of Cardiology Congress. In November 2015, the *New England Journal of Medicine* published 6-month results from the Micra Global Clinical Trial.

**Long-term data underscore the safety and efficacy of the Micra TPS in diverse patient groups:**

- All pre-specified safety and effectiveness objectives were met, with consistent findings from early performance, six month, and 12-month follow-up.
- At 12 months, major complication rates remained consistently low: 96 percent of patients experienced no major complications (95 percent CI, 94.2 percent-97.2 percent,  $P < 0.0001$ ).
  - The risk for major complications with the Micra TPS was nearly half of that (48 percent) seen with conventional pacemaker systems.
- There were no (0) dislodgements and no (0) systemic infections observed during the clinical study at 12 months.
- At 12 months, the risk for major complications was lower for the Micra TPS relative to conventional systems across all patient sub-groups, whether measured by age, sex or comorbidity.
- Through 12-month follow-up on 644 patients, the Micra TPS continued to provide low and stable pacing thresholds, yielding an average longevity for the device of more than 12 years based on device use conditions.

**The patients from the trial spanned a wide variety of patient profiles:**

- High-risk: including patients with lung disease such as chronic obstructive pulmonary disease (COPD) and pulmonary hypertension
- Age: from 21 to 94 years
- Weight: ranging from 41 to 148 kilograms, or 90 to 326 pounds
- Residence: including, but not limited to, Asia-Pacific, Europe and the United States

**Substantial reductions in healthcare utilization compared to conventional pacing systems:**

- The overall reduction in major complications with the Micra TPS was associated with a 47 percent decrease ( $p = 0.017$ ) in the risk of hospitalization and 82 percent ( $p < 0.001$ ) reduction in risk of system revisions (meaning extraction, repositioning or replacement) compared to conventional pacing systems.

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