CapSureFix MRI™
ENGINEERED WITH SURESCAN MRI™ TECHNOLOGY

Active-Fixation lead
Model 5086
Modern pacing systems are not safe for MRI

- The American College of Radiology (ACR) and the Radiological Society of North America (RSNA) warn that medical devices may malfunction or cause problems during an MRI exam.
- Contraindications against MRI scans for people with implantable cardiac devices are found on the websites of all the main manufacturers of implantable cardiac devices.
- Patients are at risk of serious side effects or death in the absence of a pacing system approved for MRI use.

What are the patient risks specific from the lead?

- The lead, when exposed to the extensive radiofrequency (RF) energy and gradient magnetic field in the MRI machine, can be a source of risk to the patient.
- The pulse RF field applied on the lead can make it behave as an antenna and the energy is dissipated to the tip, heating the lead tip which can damage the tissue.

- Induced energy can also result in capture, delivering unintended pacing.

How did Medtronic counteract MRI risk with the 5086 CapSureFix MRI™ lead?

Start with a well established design

- Titanium Nitride (TiN) coated electrodes, to provide low tip-to-tissue polarization.
- MED-4719 silicone inner and outer insulation for improved crush-resistance property.
- Short 10 mm tip-to-ring spacing to reduce far-field sensing when used in the atrium.

Over 2 millions 5076 leads have been implanted worldwide with 99% long term survivability rate over the past 8 years.

Safe by design, not by chance

- Exhaustive research and rigorous testing led to a 5086 inner coil geometry redesigned to reduce transfer of induced energy.

Is there a pacing system with proven safety in the MRI environment?

- The SureScan™ pacing system, consisting of the pacemaker and leads, when used together, allows patients to safely undergo MRI scans under certain conditions.
- A clinical study of more than 450 patients confirmed the safety and performance of the SureScan pacing system.
- It’s the first pacing system to receive CE mark approval for use in MRI.
Implanting the 5086 lead

**General considerations for active leads fixation**

- Do not direct drive lead with fully seated stylet into resistive cardiac structures.
- Number of pin connector rotations for helix extension can vary based on the lead path in the body.
- Expect more rotations in tortuous anatomy.
- Fluoroscopy is the only reliable confirmation of helix extension.
- Do not give the lead body one turn post fixation.

**Consideration specific to 5086 (compared to other CapSureFix Novus® leads)**

- Handling of the 5086 is comparable to other Medtronic active leads with some differences primarily in stiffness and torque transfer due to its unique design.
- 5086 will require more pin connector rotations to extend the helix.
- On X-Ray, radiopaque icon identifies a SureScan lead.

**SureScan™. The world’s first pacing systems designed, tested and approved for MRI**

**Specifications**

<table>
<thead>
<tr>
<th>Type</th>
<th>Bipolar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixation</td>
<td>Screw-in</td>
</tr>
<tr>
<td>Materials</td>
<td>Conductor MP35N nickel alloy</td>
</tr>
<tr>
<td>Insulation</td>
<td>Treated silicone rubber</td>
</tr>
<tr>
<td>Electrode (Helix/ring) materials</td>
<td>Titanium nitride coated platinum alloy</td>
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<tr>
<td>Tip to ring spacing</td>
<td>10 mm</td>
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<tr>
<td>Diameter Lead body</td>
<td>2.3 mm</td>
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<tr>
<td>Lead introducer (recommended size)</td>
<td>without guide wire: 2.7 mm (8 French) with guide wire: 3.7 mm (11 French)</td>
</tr>
<tr>
<td>Lengths</td>
<td>45, 52, 58 cm</td>
</tr>
<tr>
<td>Connector</td>
<td>IS-1 BI</td>
</tr>
</tbody>
</table>

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**References**

6. MAUDE database.
11. EnRhythm MRI SureScan Pacing System Clinical Study.

**Brief Statement**

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

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