OptiSense®
Atrial Pacing Lead with 1.1 mm Tip-to-Ring Spacing

**Clinical Data Summary: IDE Study**
A Multi-Center, Randomized, Controlled Clinical Study Designed to Evaluate the OptiSense® 1699T Lead
Clinical Data Summary: IDE Study

Introduction

The OptiSense® lead technology IDE study was conducted as a multi-center, randomized, controlled clinical study designed to evaluate the safety and effectiveness of the OptiSense® 1699T lead. The study enrolled 122 patients from 17 medical centers across the United States. This clinical summary covers the design, key findings, and clinical indications of the study.

Lead Overview

For physicians who want the assurance that the atrial lead can sense fine atrial arrhythmias without inappropriately sensing extra-atrial signals, the unique 1.1 mm tip-to-ring spacing of the OptiSense® lead offers a more precise measurement of atrial signals when compared with other atrial leads, which have a spacing of 10 mm or more. The OptiSense® lead is compatible with a 7 F introducer.

Study Objectives

The objectives of the OptiSense® lead IDE study were to evaluate:

- Safety – Freedom from system-related complications through three months.
- Effectiveness – The amplitudes of the paced and intrinsic far-field R waves of the OptiSense® (1699T) lead versus the control (Tendril® 1688T) lead at three months.
- Electrical Performance – Sensing and capture thresholds at three months as compared to the control lead.

Patient Demographics

A total of 122 patients from 17 centers across the United States were enrolled in the study. The average age was 73.7±11.5, which represents a typical pacemaker population. The most common indication for pacemaker implant was sinus bradycardia (60% of patients), followed by sick sinus syndrome (43%).

Study Results

Safety — At three months, the survival from system-related complications was 98.8% (with a 95% lower confidence bound of 94.1%). This was greater than the performance criterion of 85%.

Effectiveness — Paced far-field R waves

The paced far-field R-wave amplitudes were significantly reduced by the OptiSense® 1699T lead compared to the standard lead. In the OptiSense® lead group, 89.7% of patients had no far-field R waves that could be seen at the most sensitive setting of 0.1 mV. In contrast, only 33.3% of patients in the control group could be maintained at a sensitivity setting of 0.1 mV without far-field oversensing (Figure 1).

Additionally, 100% of patients in the OptiSense® lead group could be programmed to a sensitivity of 0.3 mV without sensing paced far-field R waves. Thus, OptiSense® lead technology was shown to be very effective in reducing the amplitude of paced far-field R waves and allowing more sensitive atrial sensing (Figures 1 and 2).

Figure 1

<table>
<thead>
<tr>
<th>FFRW (mV)</th>
<th>OptiSense® 1699T Lead % (N=78)</th>
<th>1688T Lead % (N=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.1</td>
<td>89.7%</td>
<td>33.3%</td>
</tr>
<tr>
<td>0.1</td>
<td>6.4%</td>
<td>27.3%</td>
</tr>
<tr>
<td>0.2</td>
<td>3.9%</td>
<td>9.1%</td>
</tr>
<tr>
<td>0.3</td>
<td>0%</td>
<td>18.2%</td>
</tr>
<tr>
<td>0.4</td>
<td>0%</td>
<td>6.1%</td>
</tr>
<tr>
<td>0.5</td>
<td>0%</td>
<td>3.0%</td>
</tr>
<tr>
<td>0.75</td>
<td>0%</td>
<td>3.0%</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
</tbody>
</table>

Paced Far-Field R-Wave Amplitudes by Treatment Group

Figure 2

Source: Tendril® FSR Model 1699T Lead Study PMA and Final Report (IDE#G050207).
Effectiveness — Intrinsic far-field R waves
Furthermore, 97% of the OptiSense® (1699T) lead patients had no evidence of intrinsic far-field R waves. Statistical significance, however, was not achieved due to a low incidence of far-field R-wave signals seen in the 1688T lead group.

Reduction in Inappropriate Mode Switching
The percentage of inappropriate mode switching was dramatically lower in the 1699T lead group than in the 1688T lead group at each follow-up visit. Thus, the design of the 1699T lead resulted in a highly statistically significant reduction in inappropriate mode switching (P=0.03) (Figures 3 and 4).

Figure 3

<table>
<thead>
<tr>
<th>VISIT</th>
<th>N=35</th>
<th>% of Patients with Mode Switch IEGMs</th>
<th>% of Patients with Inappropriate Mode Switches</th>
<th>% of Patients with Mode Switch IEGMs</th>
<th>% of Patients with Inappropriate Mode Switches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Discharge</td>
<td>63</td>
<td>11.1%</td>
<td>0%</td>
<td>17.1%</td>
<td>5.7%</td>
</tr>
<tr>
<td>1 Month</td>
<td>61</td>
<td>26.2%</td>
<td>1.6%</td>
<td>25.7%</td>
<td>14.3%</td>
</tr>
<tr>
<td>3 Month</td>
<td>58</td>
<td>19.0%</td>
<td>0%</td>
<td>28.6%</td>
<td>14.3%</td>
</tr>
<tr>
<td>All Visits†</td>
<td>58</td>
<td>31.0%</td>
<td>0%</td>
<td>45.7%</td>
<td>25.7%</td>
</tr>
</tbody>
</table>

Inappropriate Mode Switching Data
†Only patients who had visits through three months were included in this row.

Figure 4

IDE Study Conclusions
- The primary safety endpoint of system-related complications was met in all analyses performed. OptiSense® lead technology was free from system-related complications through three months.
- OptiSense® lead technology was shown to reduce the amplitude of paced far-field R waves by 94%.
- OptiSense® lead technology eliminated inappropriate mode switches compared to the control atrial lead.
- There was a low incidence of intrinsic far-field R-wave sensing.
- Chronic electrical performance (capture thresholds, sensing amplitude, and pacing impedance) was comparable to, if not better than, the control lead.

Electrical Measurements
Despite the design changes in the OptiSense® (1699T) lead, the capture thresholds, sensing thresholds, and impedances were all within clinically acceptable ranges, and were similar to or better than the 1688T lead (Figures 5, 6, and 7).
St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.