Quadripolar Pacing Technology

Clinical Compendium

The first-to-market quadripolar technology from St. Jude Medical provides more options to manage common pacing complications such as PNS or high-pacing thresholds. Uniquely designed with 4 electrodes, the Quartet™ LV lead enables pacing from any of ten pacing configurations to help improve CRT efficiency during implant and follow-up.
Greater CRT Implant Efficiency

Quadripolar pacing provides more pacing options to manage common intra-operative pacing complications such as phrenic nerve stimulation (PNS) and high pacing thresholds. Published studies have shown reduced need for lead repositioning at implant. 1-5, 9,11

Left Ventricular Pacing with a New Quadripolar Transvenous Lead for CRT: Early Results of Prospective Comparison with Conventional Outcomes 4

- This study compared implant efficiency (and post-operative efficiency, discussed later) between quadripolar (n=22, quadripolar group) and conventional bipolar (n=23, bipolar group) LV leads.
- Implant success rate was 100% in both groups.
- Five patients (21.7%) in the bipolar group presented with significant PNS requiring a retraction or a repositioning of the lead to a different vein.
- Seven patients in the quadripolar group presented with significant PNS during pacing from the distal bipolar configuration that probably would have required lead retraction or a repositioning if a bipolar designed LV lead was implanted instead of a quadripolar one. Six of those patients were successfully managed by pacing from proximal electrodes (without lead reposition), available only on the quadripolar lead. The seventh patient (1/22, 4.5%) required lead repositioning to a different vein.

Initial Clinical Experience with a Novel Left Ventricular Quadripolar Lead 2

- The aim of this study was to evaluate the acute performance of the Quartet™ 1458 quadripolar LV lead in 73 patients.
- The Quartet lead was associated with a 93% implant success rate and low incidence of PNS at 7.5V.
- In 69% (47/68), LV pacing was programmed using the two standard electrodes that are also available on a traditional bipolar lead.
- In the remaining 31% of cases (21/68), lead repositioning was averted by reprogramming LV pacing to utilize the two additional electrodes available only on the quadripolar lead.

Electrode Selection to Avoid Phrenic Nerve Stimulation with a Quadripolar Left Heart Lead 3

- In this study, the quadripolar LV lead was implanted, tested for PNS occurrence and avoidance, and removed immediately prior to CRT-D implant in 18 patients.
- 4/18 patients exhibited PNS from at least one electrode on the Quartet™ lead. However, in all 4 cases, PNS was resolved by reprogramming pacing to a different configuration.
- In these patients, the quadripolar lead allowed for non-invasive reprogramming and biventricular pacing without repositioning the lead.

Acute Performance of a Quadripolar Left Ventricular Lead 4

- In this study, the Quartet™ lead was implanted and acutely evaluated for handling, implant location, diastolic myocardial capture threshold, and occurrence of PNS in 17 patients.
- Lead handling was reported to be similar to that of a conventional LV lead. However, in 3/17 patients, the Quartet™ lead had an added advantage: the lead was able to reach a more apical location—providing lead stability and the option to pace more proximally.
- In 10/17 patients, the quadripolar lead provided options to lower pacing output or avoid PNS without repositioning the lead.
Pacing Electrode Selection in a Quadripolar Left Heart Lead Determines Presence or Absence of Phrenic Nerve Stimulation

- Benefits of the quadripolar lead were highlighted in this single patient case study.
- When a quadripolar LV lead was positioned in the preferred posterolateral vein, PNS was observed and resolved by programming to another pacing configuration.
- However, when a bipolar LV lead was placed in the same location, PNS was observed and could only be resolved by repositioning the lead to a different vein.
- The Quartet™ lead’s relatively small diameter and electrode choices made it possible to advance the distal tip close to the apex to ensure lead stability while retaining the ability to pace in more locations than a traditional bipolar lead.

Electrode Selection to Avoid Phrenic Stimulation with a Quadripolar Left Heart Lead

- In this study, the Quartet™ quadripolar lead was implanted, tested using an external stimulator, and removed immediately prior to implantation of device and permanent LV lead in 33 patients.
- In 100% (9/9) of patients experiencing PNS during implant, the additional pacing electrodes available on the Quartet lead allowed for resolution of PNS without the need to reposition the lead.

Use of a Quadripolar Left Ventricular Lead to Achieve Successful Implantation in Patients with Previous Failed Attempts at Cardiac Resynchronization Therapy

- In this report, four patients with previous failed attempts at LV lead implantation due to high pacing thresholds underwent a further attempt at CRT using a Quartet™ lead.
- The Quartet lead was implanted successfully in all four patients. Problems with PNS or high capture thresholds were seen in all four patients but were successfully overcome.

Initial Single-Center Experience of a Quadripolar Pacing Lead for Cardiac Resynchronization Therapy

- In this study, 28 CRT patients were implanted with the Quartet™ quadripolar lead. Data on lead position, pacing parameters, stability, complications, and presence of PNS data were collected at implant, predischarge and 15 ± 8 weeks post-implant.
- In 8 of 11 patients with PNS at implant, the quadripolar electrodes were utilized to prevent PNS and high pacing thresholds without lead repositioning. The lead was repositioned in the remaining 3 patients.
**GREATER CRT POST-OPERATIVE EFFICIENCY**

Quadripolar pacing provides more options to manage common pacing complications (e.g., PNS and high pacing thresholds) post implant. Published studies have shown reduced need for surgical revision with quadripolar leads.1,6,7

---

**Left Ventricular Pacing with a New Quadripolar Transvenous Lead for CRT: Early Results of Prospective Comparison with Conventional Outcomes**1

- This study compared post-operative efficiency (and implant efficiency, discussed earlier) between quadripolar (n=22, quadripolar group) and conventional bipolar (n=23, bipolar group) LV leads.
- By Kaplan Meier analysis, event free survival for the combined primary outcome of LV lead failure (defined as the need for lead revision or reprogramming) during the 3 months post implant was significantly higher in patients with quadripolar leads when compared with those with bipolar leads (p=0.037) [Figure 1].

---

**Initial Clinical Experience with a Novel Left Ventricular Quadripolar Lead**6

- This multicenter prospective study evaluated the performance of the quadripolar left ventricular pacing lead at implantation and over a 1-month follow-up (75 patients were included).
- The Quartet™ lead had stable electrical performance throughout the 1-month follow-up period.
- At 1-month follow-up, a pacing configuration involving the additional proximal electrodes on the quadripolar lead was used in 24% of cases to optimize electrical parameters and prevent cases of phrenic nerve stimulation.

---

**Post operative performance of a novel left ventricular quadripolar electrode lead**7

- These data are early findings from a prospective, non-randomized, multi-center IDE study evaluating post-operative performance of the Quartet™ quadripolar lead.
- In 100% (23/23) of patients encountering PNS post-operatively, PNS was resolved noninvasively with the quadripolar lead.
- PNS was resolved in 17 of the 23 patients by reprogramming to pace from the additional Quartet lead pacing vectors and the remaining patients by reprogramming pacing output.

---

Figure 1: A Kaplan-Meier estimate of the rate of left ventricular (LV) lead failure (revision or reprogramming). After 3 months, freedom from LV lead failure was significantly higher in the quadripolar group.

For more information please visit the Clinical Discoveries Portal at https://clinical.sjmprofessional.com
Greater Opportunities to Improve CRT Efficacy

The additional electrode choices with quadripolar technology make it possible to advance the distal tip close to the apex of the heart to ensure lead stability while retaining the ability to pace more basally. The following studies show that pacing more basally is associated with improved clinical outcomes.\textsuperscript{10, 13}

Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes\textsuperscript{10}

- This study assessed the impact of segmental LV lead position on CRT outcomes (n = 155).
- In comparison to apical LV pacing, mid-ventricle/basal LV pacing was associated with significantly higher event free survival during a mean follow-up of 15.1 ± 9 months (p = 0.03) [Figure 2].
- Patients with apical LV pacing showed less improvement in NYHA class (p = 0.035) and less LV reverse remodeling (as assessed by change in % LV EDD) during the 6 month follow-up compared to those with mid-ventricle/basal pacing [Figure 3].

Left ventricular lead position and clinical outcome: Findings from MADIT – CRT\textsuperscript{13}

- This study analyzed the impact of LV lead position on outcome in patients randomized to cardiac resynchronization-defibrillation in the MADIT-CRT study (n=799).
- Leads located in an apical lead position were associated with a significantly higher rate of HF-related hospitalization or death compared to leads located in a mid-ventricular or basal location (21.8% versus 14% and 10%, respectively; p = 0.014).
- Compared to patients with basal LV pacing, patients with apical LV pacing are 2.38 times more likely to experience heart failure hospitalization or death (p = 0.005) and 5.27 times more likely to experience death (p = 0.005).
References


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.

ATRIAL FIBRILLATION • CARDIAC RHYTHM MANAGEMENT • CARDIOVASCULAR • NEUROMODULATION

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6802
+1 818 364 5814 Fax

St. Jude Medical Sweden AB
Värdshällsparken 19
SE-175 84 Järfälla
Sweden
+46 8 474 40 00
+46 8 760 95 42 Fax

St. Jude Medical Brasil Ltda.
Rua Frei Caneca, 1380
7º ao 9º andares
01307-002 - São Paulo (SP)
Brasil
+55 11 5080-5400
+55 11 5080-5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2996 0627 Fax

St. Jude Medical Japan Co., Ltd.
Shiodome City Center 35F
1-5-2, Higashimarunouchi,
Minato-ku,
Tokyo 105-7115
Japan
+81 3 6255 6370
+81 3 6255 6371 Fax

SJMprofessional.com/clinical

 Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted,™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All Rights Reserved.