The first-to-market quadripolar technology from St. Jude Medical provides more options to manage common pacing complications such as phrenic nerve stimulation (PNS) or high pacing thresholds. Uniquely designed with 4 electrodes, the Quartet quadripolar left ventricular lead enables pacing from any of 10 pacing configurations to help improve CRT efficiency and efficacy.
Greater CRT Implant Efficiency

Pacing with the Quartet™ quadripolar left ventricular (LV) lead provides more pacing options to manage common intra-operative pacing complications (e.g. phrenic nerve stimulation [PNS] and high pacing thresholds), reducing the need for lead repositioning at implant.1-6

New Onset of Phrenic Nerve Stimulation by Left Ventricular Pacing at Mid-term Follow-up1

- This study evaluated the prevalence of PNS in patients with a Quartet LV lead and its elimination by appropriate programming at the time of lead implantation and mid-term (5 months ± 2) follow-up (n=23).
- PNS was observed in 39% (9/23) of patients at implantation and all (100%) cases of PNS were eliminated by programming a different pacing configuration without lead repositioning.
- PNS recurred in 22% (5/23) of patients at mid-term follow-up when the mean LV pacing threshold was 1.37 ± 0.95 V at 0.5 ms.
- All cases (100%) of PNS were eliminated by programming a different pacing configuration without surgical revision of the lead.

Use of a Quadripolar Left Ventricular Lead in Patients with Phrenic Nerve Stimulation and/or High Pacing Thresholds at Cardiac Resynchronization Therapy with Conventional Bipolar LV Leads2

- This study aimed to compare the short-term effectiveness of the Quartet lead in patients with PNS and/or high pacing thresholds (HPT) with conventional bipolar LV leads (n=24).
- In 92% (22/24) of patients, PNS and high pacing thresholds were overcome using the Quartet lead.

Success in CRT with a New Quadripolar LV Lead Electrical Options3

- The purpose of this study (Quartet lead And Resynchronization Therapy Options—QUARTO) was to evaluate capture and PNS thresholds observed using LV pacing vectors unique to the Quartet lead and those available on a bipolar lead (n=51).
- In 57% (29/51) of patients, a better capture threshold was achieved by using a non-traditional configuration.

New Generation of Transvenous Left Ventricular Leads - First Experience with Implantation of Multipolar Left Ventricular Leads4

- This study evaluated the ability to resolve PNS and high pacing thresholds with the Quartet quadripolar lead during implant (n=30).
- In 57% (17/30) of patients, pacing vectors only available with the quadripolar lead were programmed to manage PNS and high pacing thresholds.

Reduction of Phrenic Stimulation and Improving Pacing Thresholds with a New Quadripolar Cable for Left Ventricular Stimulation5

- The purpose of this study was to evaluate the Quartet quadripolar LV lead (n=27, quadripolar group) and compare its performance with bipolar or unipolar (n=126, conventional group) leads.
- Implant success rate was 100% for the quadripolar group.
- The quadripolar group had significantly lower left ventricular pacing thresholds (LVPT) (p=0.03) and a lower percentage of patients with high LVPT (p=0.2) compared to the conventional group.
- PNS was resolved through reprogramming in 100% of patients in the quadripolar group compared to only 86% in the conventional group.
- After 110 days the quadripolar group had no dislodgements, no incidence of PNS and no significant variations in electrical parameters.
Greater CRT Post-Operative Efficiency

Quadripolar pacing with the Quartet LV lead provides more options to manage common pacing complications (e.g. PNS and high pacing thresholds) post-implant, reducing the need for surgical revision.\textsuperscript{7,15}

Initial Single Center Clinical Procedural Experience with a Novel Left Ventricular Lead\textsuperscript{6}
- This study compared procedural time and electrical performance (LV pacing threshold, presence of PNS) at hospital discharge between patients implanted with the Quartet LV lead (n=109, quadripolar group) and standard bipolar lead (n=21, bipolar group).
- The implant success rate for the quadripolar and bipolar leads were 95% and 90%, respectively.
- For optimal pacing threshold and to avoid PNS, pacing vectors unique to the Quartet lead were programmed in 34% of patients in the quadripolar group.

Decreased Risk of Left Ventricular Lead Deactivation and Replacement Associated with Use of Quadripolar Leads\textsuperscript{7}
- This study compared outcomes of LV lead deactivation and replacement among patients receiving new cardiac resynchronization therapy (CRT) devices with either quadripolar (n=4,379) or bipolar LV (n=19,914) leads between November 2007 and April 2013.
  - Patients were followed for up to 1 year.
- At 3-month follow-up, patients with a quadripolar lead had a significantly lower rate of lead deactivation (1.2% for quadripolar vs. 2.7% for bipolar, p<0.001) and replacement (0.08% for quadripolar vs. 0.24% for bipolar, p<0.001) than those with bipolar leads.
- As presented at Europace, after 1 year, patients with the quadripolar lead had a significantly lower rate of lead deactivation (1.91% for quadripolar vs. 4.19% for bipolar, p<0.001) and replacement (0.43% for quadripolar vs. 0.98% for bipolar, p=0.02) than those with bipolar leads.

Quadripolar Left Ventricular Leads Yield Lower Capture Thresholds with Expected Increase in Battery Longevity\textsuperscript{8}
- This single-center, retrospective analysis studied the differences in capture threshold and estimated battery longevity when pacing with the Quartet lead (n=18) and with non-quadripolar leads (n=72).
- Battery longevity for each case was determined from industry estimation using the final LV parameters and presumed 100% dual-chamber biventricular pacing.
- Capture thresholds were significantly lower in quadripolar LV leads in comparison to unipolar and bipolar leads (0.82 ± 0.32 V vs. 1.25 ± 0.78 V, p<0.024).
- In patients with high capture thresholds, the use of a quadripolar lead would have extended battery life by up to 17 months.

Pacing Threshold and Site of Steroid Elution in Left Ventricular Leads\textsuperscript{9}
- Cao and colleagues compared chronic pacing thresholds in bipolar LV leads that elute steroid near the tip only and near both tip and ring electrodes (n=3,267).
- Findings from the study showed that there are no significant differences in threshold voltage and energy between the group with leads that elute steroid only at the tip electrode and those with leads eluting steroid at both tip and ring electrodes.

Use of a Quadripolar Left Ventricular Lead to Achieve Successful Implantation in Patients with Previous Failed Attempts at Cardiac Resynchronization Therapy\textsuperscript{10}
- 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 quadripolar 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.
Greater CRT Post-Operative Efficiency

Left Ventricular Pacing with a New Quadripolar Transvenous Lead for CRT: Early Results of a Prospective Comparison with Conventional Implant Outcomes¹¹

- This study compared post-operative efficiency (and implant efficiency, discussed earlier) between Quartet quadripolar (n=22) and conventional bipolar (n=23) 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).

A New Quadripolar Lead for Left Ventricular Pacing: Short Term Reliability and Future Opportunities¹²

- This study compared implant and post-operative efficiency between the Quartet (n=18) and conventional bipolar (n=12) leads.
- Implant success rate was 100% in both groups.
- At 3 months, 0% of patients required LV lead revision in the quadripolar group compared to 16% (2/12) of patients in the bipolar group. LV lead revision was required in these patients due to dislodgement and PNS not managed by reprogramming pacing vectors.
- 1 patient in the quadripolar group required reprogramming of pacing configuration at 1-month follow-up due to PNS.

Elimination of Phrenic Nerve Stimulation Occurring During CRT: Follow-up in Patients Implanted with a Novel Quadripolar Pacing Lead¹³

- This study evaluated pacing parameters, lead position, complications and presence of PNS in CRT-D patients with a Quartet lead at implant, pre-discharge and at 3 and 6 months follow-up (n=40).
- 100% (5/5) of patients who experienced PNS during the 6 months of follow-up were successfully treated by reprogramming to a different vector.
- No cases required reintervention, surgical epicardial lead placement or turning CRT pacing off.

Chronic Performance of the Quartet Left Ventricular Lead¹⁴

- These data are early findings from a prospective, non-randomized, multicenter IDE study evaluating post-operative performance of the Quartet quadripolar lead (n=170).
- After 18 months, in 100% (23/23) of patients who encountered PNS post-operatively, PNS was resolved noninvasively with the quadripolar lead.
**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. Studies by Merchant\textsuperscript{16} and Singh\textsuperscript{17} show that pacing more basally is associated with improved clinical outcomes.

**First Prospective, Multi-Centre Clinical Experience with a Novel Left Ventricular Quadripolar Lead**\textsuperscript{15}
- This multicenter prospective study evaluated the performance of the quadripolar left ventricular pacing lead at implantation and over a 1-month follow-up (n=75, 66 patients had complete data sets at the 1-month follow-up).
- Implant success rate was 95%.
- At 1-month, 97% (64/66) of patients had one or more usable pacing configuration, whereas only 86% (57/66) of patients had usable conventional configurations.
- At 1-month follow-up, a pacing configuration involving the additional proximal electrodes on the quadripolar lead was used in 24% (16/66) of cases to optimize electrical parameters and prevent cases of PNS.

**Reduced Mortality with Quadripolar Versus Bipolar Left Ventricular Leads in Cardiac Resynchronization Therapy**\textsuperscript{18}
- This analysis of 23,178 St. Jude Medical de novo CRT-D device registration records was to evaluate survival with the Quartet LV lead (n=18,026) in comparison with bipolar LV leads (n=5,152).
- The Quartet lead was associated with a lower risk of death after multivariate adjustment (HR 0.794, 95% CI [0.696, 0.906], p < 0.001).

**Hospitalization Rates and Associated Cost Analysis of Quadripolar Versus Bipolar CRT-D: A Comparative Analysis of a Single-Center Prospective Italian Registry**\textsuperscript{19}
- This study evaluated hospitalization rates and costs of 198 CRT-D patients (117 patients with Quartet leads, 81 patients with non-quadripolar leads).
- Each patient receiving a quadripolar lead had a 77.3% lower chance of hospitalization than the bipolar group, with an average reduction of 6.2 hospitalizations per 100 patient-years.
- Quartet lead patients had a 69.5% probability of having lower costs than bipolar patients.

**Reduced Costs Post CRT with Quadripolar LV Leads Compared to Bipolar LV Leads**\textsuperscript{20}
- The objective of this study was to assess hospitalization rates and costs for CRT patients receiving a Quartet quadripolar LV lead (n=41) versus a bipolar LV lead (n=38).
- CRT-D patients with the Quartet lead exhibited 87% lower hospitalization costs in the first 100 days post-implant ($3,804) compared to patients with bipolar LV leads ($30,378).
- Total events occurred more frequently in the bipolar group than in the Quartet group (5 vs. 1 patients) and were more costly in the bipolar group ($741/patient versus $100/patient).
- All events occurred in patients whose LV pacing vector was programmed to a traditional bipolar configuration rather than with a Quartet lead-specific vector.

**Acute echocardiographic optimization of multiple stimulation configurations of cardiac resynchronization therapy through quadripolar left ventricular pacing: A tailored approach**\textsuperscript{21}
- The goal of this study was to evaluate the patient response after 6 months when the optimal LV pacing configuration for CRT was determined by echocardiographic measures, QRS duration and pacing capture thresholds.
- Pacing configurations utilizing a proximal electrode (P4 or M3) generally had higher acute VTI, MR and MPI improvements than traditional bipolar vectors.
- Conventional bipolar vectors were rarely associated with the best echocardiographic improvements and for every patient provided significantly worse VTI, MR, MPI, and QRSd values than the best configuration.
- There was a significant improvement in New York Heart Association class (81%), LV ejection fraction (76%), end-diastolic and end-systolic volumes after 6 months.
Clinical and Procedural Outcome of Patients Implanted with a Quadripolar Left Ventricular Lead: Early Results of a Prospective Multicenter Study

**Forleo GB, et al. Heart Rhythm. 2012.**

- The objective of this study was to evaluate the long-term procedural and clinical outcomes of CRT patients (n=154) implanted with the Quartet LV lead.
- 71.3% were deemed as CRT responders as assessed by 6-month echocardiography (≥10% improvement in LV end systolic volume) and 66% improved at least 1 NYHA class.
- Vectors unique to the Quartet LV lead were used in 45% of patients at pre-discharge; this increased to 73% of patients at 18-month follow-up.
- 21.3% (32/150) of patients had PNS at implant and 6% (9/150) of patients developed PNS during follow-up; PNS was resolved in 100% of these patients by reprogramming the LV pacing vectors.

Left Ventricular Pacing from a Site of Late Electrical Activation Improves Acute Hemodynamic Response to Biventricular Pacing in Patients with Conduction Delay Greater Than Ten Milliseconds in a Quadripolar Left Ventricular Lead

**Zarko C, et al. Heart Rhythm. 2013.**

- This study assessed whether selecting an LV pacing site based on electrical activation time during right ventricular pacing could improve acute hemodynamic response (n=41).
- Patients with change in delay > 10 ms received significant dP/dt(max) benefit from pacing at the site of late activation (10.7 ± 9.8% vs. 13.5 ± 9.5%, p=0.017).
- There was no difference in change in dP/dt(max) relative to baseline with distal vs. proximal or with early site vs. late site pacing in patients with change in delay < 10 ms (12.3 ± 8.8% vs. 11.6 ± 8.6%, p=0.3).
- BiV pacing with LV pacing at the site of relatively later electrical activation along the Quartet LV lead significantly improves acute hemodynamic response to CRT and offers a simple way to optimize the LV pacing site for multipolar LV leads.

Vector Selection of a Quadripolar Left Ventricular Pacing Lead Affects Acute Hemodynamic Response to Cardiac Resynchronization Therapy: A Randomized Cross-Over Trial


- This study evaluated differences in acute hemodynamic response based on left ventricular pacing configurations (LVPC, n=20 patients).
- Evaluations were done by invasive measurements of LV +dP/dt(max) in all possible pacing configurations and by calculating the % change in mean LV +dP/dt(max) compared to the preceding baseline (%ΔLV +dP/dt(max)).
- LV+dP/dt(max) significantly increased in all 145 LVPCs (p<0.0001 compared to baseline) with significant intraindividual between LVPCs (p<0.0001).
- Pacing in an individually optimized configuration resulted in an additional 10% increase in %ΔLV +dP/dt(max) when comparing optimal and worst vectors.

Timing of Local Sensed Intracardiac Unipolar Electrograms from the Left Ventricular Lead Predicts Optimal Site of Pacing Patients Undergoing Cardiac Resynchronization Therapy

**Diab IG, et al. Heart Rhythm. 2012.**

- This study aimed to predict the LV pacing site that results in optimal hemodynamic effect. The authors surmised that this site could be predicted by pacing at the site of latest local sensed activation.
- The timing of the main deflection of the sensed local intracardiac electrograms (IEGMs) recorded from each LV lead electrode was used to identify which shows the latest (A) and the earliest (B) sensed IEGMs. The % increase in dP/dt(max) and the highest obtained aortic VTI were compared in A and B electrodes.
- Biventricular stimulation through A resulted in an acute hemodynamic benefit when assessed by dP/dt(max) and aortic VTI compared to B (p=0.028, p=0.07, respectively).
Greater Opportunities to Improve CRT Efficacy

Improvement in Hemodynamic Response Using a New Quadripolar LV Lead: Initial Results of the QUARTO Study
□ The Quartet lead And Resynchronization Therapy Options (QUARTO) study evaluated differences in hemodynamic response between quadripolar-specific (non-traditional) and traditional LV pacing vectors (n=51).
□ In 52.94% (27/51) of patients, the best cardiac output (CO) obtained during pacing from a non-traditional vector unique to the Quartet lead was greater than the best CO obtained during pacing from a traditional vector (mean difference was 11.69% ± 11.2% STD).

The Inter- and Intra-Vein Range of Cardiac Outputs at CRT Implantation, Measured Non-Invasively with NICOM
□ This study examined whether the range of cardiac outputs achievable within a single vein is more or less than that seen between different veins (n=10).
□ In 80% (8/10) of patients, the range of cardiac index (CI) was greater between poles within the one vein, rather than between different veins.
□ These data suggest that a greater range of CIs is likely to be found within a single vein (i.e. between basal and apical sites), rather than between two different LV epicardial veins.

Using a Quadripolar Lead in Cardiac Resynchronization: Is There a Hemodynamic Impact of Different Stimulation Vectors
Puetz V. Europace. 2012.
□ The aim of this study was to verify the benefits derived from multiple pacing configurations in order to obtain the best hemodynamic response to the different pacing sites.
□ Mean cardiac index varied between 2.025 l/min/m² and 2.75 l/min/m² and stroke volume could be increased from 59.75 ml to 81.75 ml.
□ Use of quadripolar leads and the ability to program different pacing configurations improved the hemodynamic response to CRT therapy at optimized atrioventricular delay and ventriculoventricular delay.

Quadripolar Left Ventricular Pacing for Cardiac Resynchronization Therapy: Acute Echocardiographic Evaluation
□ The purpose of this study was two-fold: 1.) To assess the acute echocardiographic response to different Quartet LV lead pacing configurations and 2.) To compare clinical outcome between CRT performed with a Quartet and bipolar LV leads (n=22).
□ Of the Quartet lead pacing configurations, the best pacing configurations for:
  – QRS-duration: D1-M2
  – VTI: M3-RVc
  – MPI: M3-M2
  – MR: M3-P4
  – Dyssynchrony: M2-P4
□ The cohort of patients with a bipolar lead had devices that were conventionally programmed. The NYHA class improved in both groups (quadripolar and bipolar).
□ LV reverse remodelling was present in 71.4% and 44.4% of patients in the quadripolar and bipolar groups, respectively.
Greater Opportunities to Improve CRT Efficacy

A Novel Quadripolar LV Lead Offers Pacing Options to Improve LV Circumferential Strain in CRT Patients


- The aim of this study was to compare the effects of pacing from traditional vectors to vectors unique to the Quartet lead on resynchronization at discharge (24 hrs) (n=8), 3 months (n=6), 6 months (n=5) and 12 months (n=1) post-implant.
- Resynchronization was achieved in all patients at each visit by pacing from at least one pacing vector. However, if only traditional vectors were used, LV resynchronization would not have occurred in 3 patients.
- Pacing with nonconventional vectors resulted in the greatest reduction in dyssynchrony in 63%, 83%, 80% and 100% of patients at 24 hours, 3, 6 and 12 months, respectively.

LV-Pacing: Vector Optimization Using a Novel Quadripolar Electrode Acutely Improves Cardiac Output in Cardiac Resynchronization Therapy Patients


- This study evaluated the hemodynamic impact of the LV pacing vectors (VSQ) only available on the quadripolar lead compared to traditional LV pacing vectors (Trad) (n= 61).
- The implant success rate was 98% (60/61) for the Quartet LV lead.
- Aortic velocity time integral (AVTI) was measured during pacing from two LV vectors at pre-discharge and at 1-month follow-up. The percentage of patients whose AVTI increased during LV pacing from VSQ relative to Trad was determined and the mean increase was calculated.
- VSQ increased AVTI over Trad in 53% of patients by an average of 1.9 cm at pre-discharge; and in 41% of patients by an average of 23 cm at 1-month follow-up.

The Use of a New Quadripolar Left Ventricular Pacing Lead Improves the Hemodynamic Response to Cardiac Resynchronization Therapy


- This study compared the effects of pacing from traditional vectors to vectors unique to the Quartet LV lead related to stroke volume (n=15).
- In 53% of all patients, the best stroke volume was obtained from pacing from one of the two proximal electrodes only available on the quadripolar lead. All of these patients were responders as they had a 10% increase in cardiac output.
References

2. Ohlow MA, et al. Use of a quadripolar left ventricular lead in patients with phrenic nerve stimulation and/or high pacing thresholds at cardiac resynchronization therapy with conventional bipolar LV leads. Europace. 2012; 14 (suppl1), Abstract 176P_18.

For a listing of additional publications, please visit sjmprofessional.com/quadripolartechnology
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.

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