Sentus ProMRI®

The Smallest MRI QP Lead

QP ExCELs

BIOTRONIK
excellence for life

Clinical Safety and Performance of the Sentus OTW Quadripolar LV Lead

QP ExCELs Study Objective

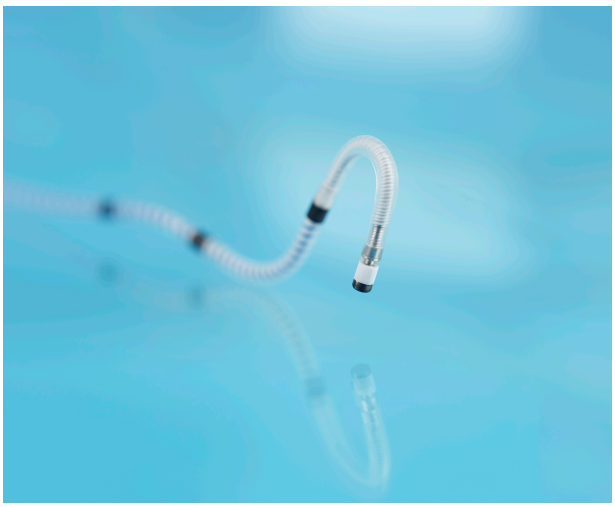
Confirm the safety and effectiveness of the BIOTRONIK Sentus QP LV lead.

Study System

- Sentus OTW QP L, Sentus OTW QP S, and Sentus OTW QP S/49 LV lead
- Sentus OTW QP S/49 LV, Sentus OTW QP L/49 and Sentus OTW QP L/49 LV leads were not implanted or analyzed as part of the pre-market study
- BIOTRONIK CRT-D system with IS4 LV port

Study Design

- Prospective, non-randomized, multi-center, international study
- Combined Pre-Market Investigational Device Exemption (IDE) and Post-Approval Study regulated by Food and Drug Administration
- Pre-Market Analyses Cohort: All subjects implanted (or implant attempt) on or before January 29, 2016 (N=299)



97.1% Sentus Complication-Free Rate Through 6 Months

Clinical Goal

Evaluate the Sentus QP related complication-free rate through 6 months post-implant.

Clinical Results

Eight of the 279 subjects included in the primary endpoint 1 analysis experienced endpoint-related events as determined by the CEC resulting in a complication-free rate of 97.1% (271/279), p<0.0001, 95% CI: (94.4, 98.8)*.

Primary Endpoint 1 Adverse Event Summary

Adverse Event Type	Subjects with AE	% with AE	Number of AEs	Rate (per subject year)
Related to Sentus QP Lead and Meets Primary Endpoint Criteria				
Lead dislodgement	4	1.43%	4	0.028
Extracardiac stimulation	3	1.08%	3	0.021
Lead impedance out of range, high	1	0.36%	1	0.007
Total	8	2.87%	8	0.055

Total number of implanted subjects = 279; subject years since successful implant = 144.7

Minimal complication rate at 3 Months.

*Compared to performance goal of 90%

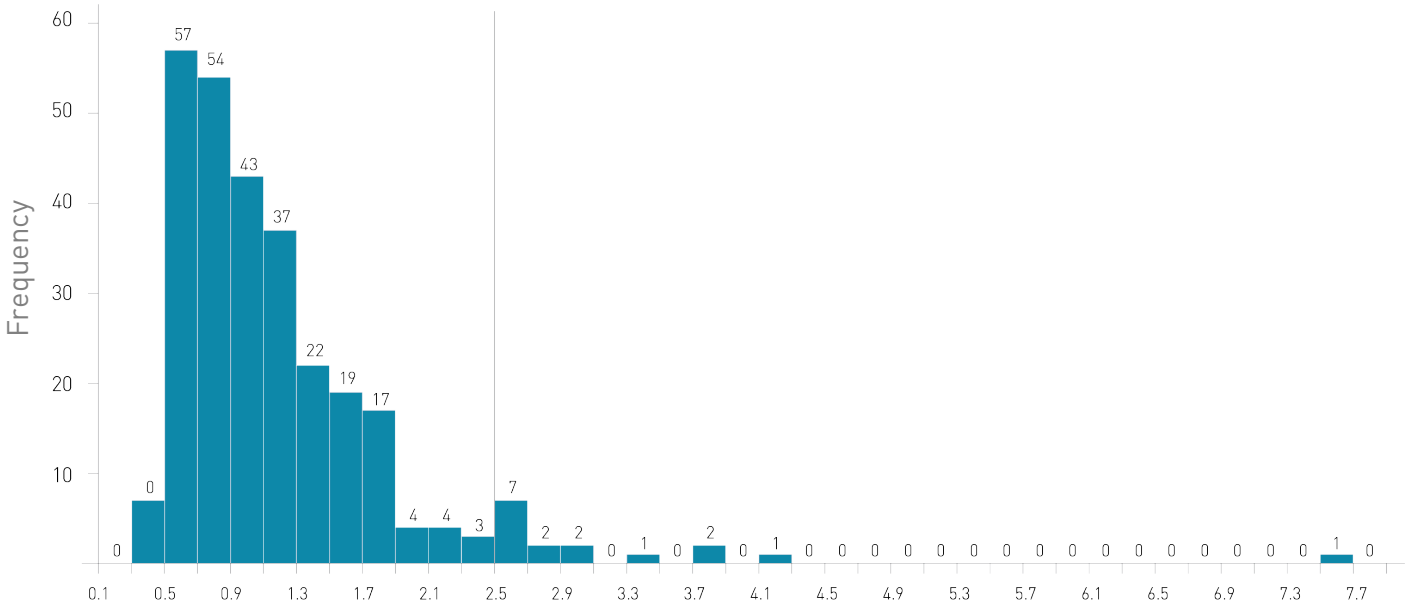
93.4% of Patients Experienced Acceptable LV Pacing Threshold (≤ 2.5V @ 0.4ms)

Clinical Goal

Evaluate the percentage of subjects with acceptable pacing threshold in permanently programmed vector at 3 months.

Clinical Results

A total of 267 of the 286 subjects included in primary endpoint 2 analysis had an acceptable LV Pacing Threshold resulting in a rate of 93.4% (267/286), p=0.002, 95% CI: (89.8, 96.0)*.



Acceptable LV Threshold at 3 Months.

*Compared to a performance goal of 88%

95.6% of Subjects Had at Least One Novel Vector with an Acceptable Threshold at 3 Months

Clinical Goal

Evaluate Sentus QP pacing threshold in novel vectors at 3 months.

Clinical Results

Number of novel vectors with acceptable threshold at 3 months.

Novel Vectors with Acceptable Threshold	Number of Subjects	% (N=155)
7 of 7 Novel Vectors	9	5.8%
6 of 7 Novel Vectors	22	14.2%
5 of 7 Novel Vectors	28	18.1%
4 of 7 Novel Vectors	16	10.3%
3 of 7 Novel Vectors	17	11.0%
2 of 7 Novel Vectors	19	12.3%
1 of 7 Novel Vectors	32	20.6%
0 of 7 Novel Vectors	12	7.7%

52.1% (147/282) entered 3M visit with a traditional vector. Of these 91.2% had one or more novel vectors with an acceptable threshold

Pacing Vector	Mean Threshold (V)+/- SD	Number of Subjects with Pacing Threshold Tests Conducted at 0.4 ms	No Capture Possible N (%)	Acceptable LV Pacing Threshold N (%)
LV1 tip to LV4 ring	1.4 +/-1.26	221	14 (6.3%)	168 (76.0%)
LV2 ring to LV4 ring	2.1 +/-1.71	197	15 (7.6%)	136 (69.0%)
LV3 ring to LV2 ring	3.0 +/-1.82	184	27 (14.7%)	73 (39.7%)
LV3 ring to LV4 ring	2.8 +/-1.85	189	46 (24.3%)	82 (43.4%)
LV3 ring to RV coil	2.2 +/-1.75	197	31 (15.7%)	121 (61.4%)
LV4 ring to LV2 ring	3.6 +/-2.04	201	37 (18.4%)	58 (28.9%)
LV4 ring to RV coil	3.3 +/-2.45	208	67 (32.2%)	72 (34.6%)

Sentus QP vs. the Competition

The Sentus QP lead demonstrates the best complication-free rate at 6 months, a very low LV lead dislodgement rate, and comparable rates of successful thresholds ≤ 2.5V.

	Primary Endpoint 1		Primary Endpoint 2
	Complication-Free Rate at 6 Months	LV Lead Dislodgement Rate	Threshold ≤ 2.5V at 3 Months
BINC – Sentus QP[1]	97.1%	1.43%	93.4%
BSX – Acuity X4[2]	96.5%	1.30%	94.0%
MDT – Attain Performa[3]	96.0%	2.05%	93.9%[4]
STJ – Quartet[5]	96.0%[6]	3.50%	90.4%

1. Sentus OTW QP Lead Family Technical Manual.

2. BSX – Acuity X4 straight model: Boston Scientific. Clinical Summary Navigate X4 Study (with the AcuityTM X4 lead family). January 2016.

3. MDT – Attain Performa model 4298: Medtronic, ATTAIN® PERFORMA® MODELS 4298, STRAIGHT 4398, AND S 4598 QUADRIPOLAR LEFT VENTRICULAR LEADS Safety and effectiveness information. December 17, 2014.

4. At 6 months.

5. STJ – Quartet model 1458Q: Tomassoni G, et al. Postoperative performance of the Quartet® left ventricular heart lead, J Cardiovasc Electrophysiol, 2013, vol. 24 (pg. 449 -56).

6. Through 3 months.

QP ExCELs Study Design

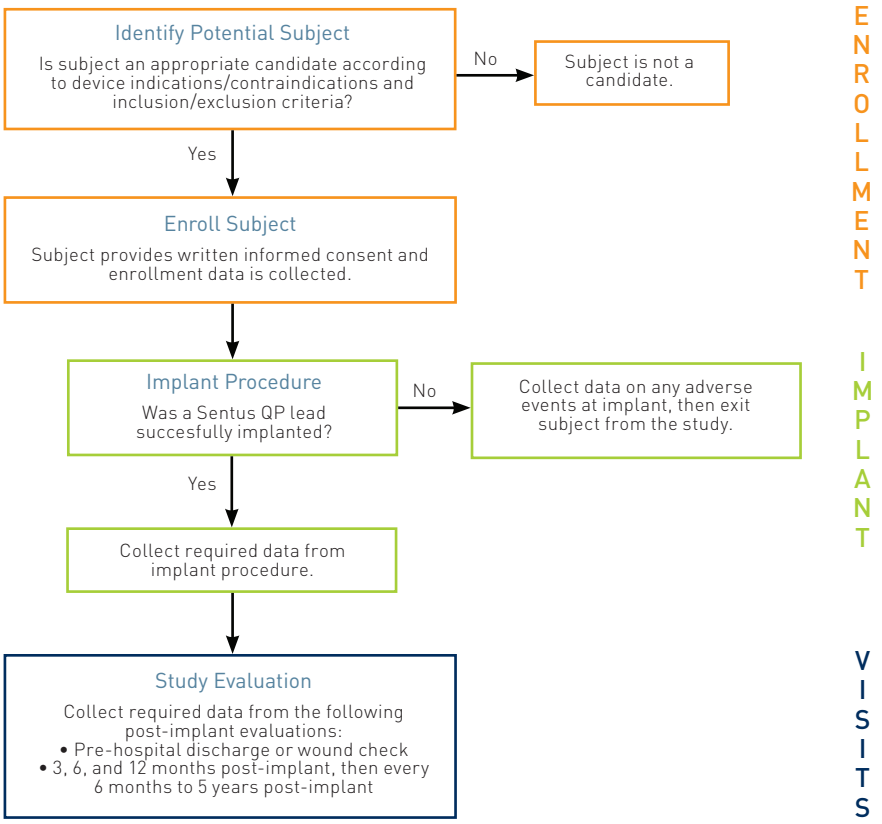
Patient Population

Key Inclusion Criteria

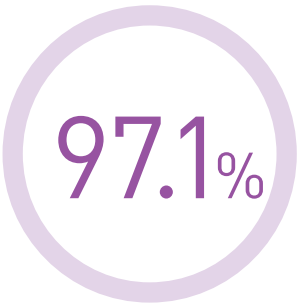
- Standard CRT-D indication according to clinical routine
- De novo implantation or upgrade from existing ICD or pacemaker implant (with no prior attempt at LV lead placement) utilizing a BIOTRONIK CRT-D system with IS4 LV port and Sentus QP LV lead

Key Exclusion Criteria

- Contraindication to CRT-D therapy
- Currently implanted with an endocardial or epicardial left ventricular lead or had prior attempt to place a left ventricular lead
- Cardiac surgical procedure, such as coronary artery bypass graft, valve surgery, or ablation that is planned to occur within 6 months after implant (ablations planned to occur prior to or at implant are not exclusionary)



Key Results



Freedom from Sentus QP complications
through 6 months post-implant

Data demonstrates

safety and effectiveness of Sentus QP lead

All pre-market study primary safety and performance endpoints were

met with statistical significance

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