Boston Scientific

CLINICAL SUMMARY

VITALITY

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

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CLINICAL STUDY - VITALITY

CLINICAL STUDY POPULATIONS

Guidant ICDs have been demonstrated to be safe and effective in patient populations including, but not limited to, those with:

- Prior myocardial infarction and an ejection fraction (EF) ≤ 30%, based on the Guidant sponsored MADIT II clinical study. (Guidant devices were the only devices studied in the MADIT II clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT II population.)

- Prior myocardial infarction, left ventricular ejection fraction of ≤ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia, based on the Guidant sponsored MADIT clinical study. (Guidant devices were the only devices studied in the MADIT clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT population.)

CHRONIC IMPLANT STUDY - VITALITY

Summary

The purpose of this study was to evaluate the safety and effectiveness of Guidant VITALITY family devices with Automatic Intrinsic Rhythm ID. This clinical study was a single-arm, prospective, multi-center study. There were a total of 100 patients enrolled at 21 US investigational centers between December 3, 2002 and January 10, 2003.

Study Design

A prospective, multi-center, nonrandomized clinical study evaluated the safety and effectiveness of the VITALITY device in humans. Ninety-six patients selected from the investigator's general patient population who met the indications for use of the VITALITY device were followed through pre-discharge, 2-week and 1-month follow-ups and continued every 3 months thereafter until study closure.

Study Results

Demographic Data

One hundred patients were enrolled in this study and 96 patients received investigational devices. The mean age of the patients implanted with the VITALITY device was 67.3 ± 10.8 years old. The mean left ventricular ejection fraction was 30.4% (range 11.0% - 71.0%). Seventy-eight (78) patients (81.3%) were male. The primary cardiovascular disease (42.1%) was coronary artery disease (CAD) and the primary tachyarrhythmia (38.5%) was monomorphic ventricular tachycardia (MVT).

Chronic Implant Study Results

A total of 100 patients were enrolled in this study. Of these, 96 patients were successfully implanted, with 4 intents. Ninety-three (93) patients finished their 1-month follow-up per the study protocol. All primary and secondary endpoints of this study were met. The results from this study provide evidence of the safety and effectiveness of the VITALITY with Automatic Intrinsic Rhythm ID algorithm (Table 1).

Table 1. VITALITY Chronic Study Results

Safety Endpoints			
VT/VF Detection Time			3.43 seconds
Primary Endpoints			
Sensitivity			
Induced VT/VF			100%
Spontaneous VT/VF			100%
Specificity—Induced			
Rhythm	**Physician/ Annotation**	**Device Decision–SVT**	**Specificity**
Atrial Fibrillation	71	68	95.8%
Atrial Flutter	94	88	93.6%
Sinus Tachycardia	7	5	71.4%
Total Induced	172	161	93.6%

Table 1. VITALITY Chronic Study Results

Specificity–Spontaneous			
Rhythm	**Physician/ Annotation**	**Device Decision–SVT**	**Specificity**
Atrial Fibrillation	65	65	100%
Atrial Flutter	31	28	90.3%
Sinus Tachycardia	37	32	86.5%
Other	7	7	100%
Total Spontaneous	140	132	94.3%[a]
Combined Specificity[b]	312	293	93.9%
Secondary Endpoints			
Acute Automatic Rhythm ID Accuracy (2 weeks)			100%
Automatic Rhythm ID Accuracy (1 month)			97.7%
Manual Rhythm ID Accuracy (1 month)			100%

a. GEE adjusted specificity = 93.7%
b. Combined specificity includes both Induced and Spontaneous data.

ACUTE STUDY - VITALITY

Summary

The VITALITY ICD was compared to a commercially available ICD (VENTAK PRIZM, or VENTAK PRIZM 2 ICD) in an acute (nonimplant) paired study of 50 patients enrolled at nine investigating centers between March 8, 2001 and July 24, 2001. A total of 47 patients were tested with the study device, followed by a control device at the time of a Guidant commercially approved (VENTAK PRIZM, model 1851 or VENTAK PRIZM 2, model 1861) implantation.

The purpose of the acute study was to demonstrate that the addition of an SVT detection enhancement and brady features did not adversely impact normal ICD sensing and detection functionality. A total of 50 patients were tested in nine U.S. centers.

Study Design

The acute study was done in the operating room or electrophysiology laboratory without implantation of the study device. The primary endpoint was to determine that VT/VF detection time for induced episodes is within two seconds of the VENTAK PRIZM or VENTAK PRIZM 2 detection time.

Study Results

Demographic Data

The patients (38 M/9 F) had a mean age of 66 years (range 37 to 90) and a left ventricular ejection fraction of 32% (range 10% to 62%). Most (40%) presented with monomorphic ventricular tachycardia (MVT) and nonsustained VT as their primary arrhythmia. Of the patients studied, 87 percent presented with coronary artery disease or ischemic cardiomyopathy.

Acute Study Results

A total of 50 patients were enrolled in the acute study. Of those, 47 patients were successfully tested with the system per study protocol; there were two attempted procedures and one intent. There was one clinical complication and two observations reported in the acute study, all of which were non-investigational device related. No patient deaths were reported. The VT/VF detection time of the VITALITY ICD was found to be within two seconds of the VENTAK PRIZM 2 detection time, leading to the conclusion that activating the additional VITALITY features does not have a negative effect on the existing ICD sensing and detection functionality (Table 2).

Table 2. Acute study results

Study Endpoint	VITALITY (Mean ± std) N	VENTAK PRIZM 2 DR (Mean ± std) N
VT/VF Detection Time (seconds)	3.60 ± 0.60 N = 47	3.52 ± .057 N = 47
	p-value: <0.001	

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358487-009 EN US 01/11