

**Boston  
Scientific**

CLINICAL SUMMARY

**VITALITY DS**

**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 SUMMARY - VITALITY DS

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### 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)  $\leq 30\%$ , 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  $\leq 35\%$ , 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.)

### SUMMARY

The VITALITY DS US Field Following was a prospective, nonrandomized, multi-center study of 75 patients at 9 sites in the United States. The purpose of this US Field Following was to collect all observations, complications and atrial and ventricular lead measurements for the VITALITY DS ICD.

### STUDY DESIGN

#### Methods

Seventy-five patients were successfully implanted with the VITALITY DS ICD. Pacing voltage threshold, pacing impedance, shock impedance, P-wave sensing, and R-wave sensing were measured at implant, and 1-month follow-up visits.

### STUDY RESULTS

#### Demographic Data

Seventy-five patients were enrolled in the study from July 22, 2003 through September 12, 2003. The mean age was  $67.2 \pm 11.6$  years. The mean left

ventricular ejection fraction (LVEF) was  $29.2 \pm 11.7\%$ . Coronary Artery Disease (CAD) was the primary cardiac disease reported (38.1%). The most common arrhythmias was monomorphic VT (40%).

### **Vitality DS US Field Following Results**

The number of observations and complications were minimal and none were related to the VITALITY DS ICD. Pacing impedance, pacing threshold, R-wave amplitude, and P-wave results for the VITALITY DS ICD were clinically acceptable. There were no reported unanticipated adverse events related to the testing and/or implantation of the VITALITY DS ICD.



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