

**Boston
Scientific**

CLINICAL SUMMARY

VENTAK AV II

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 - VENTAK AV II

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.)

VENTAK AV II DR ACUTE STUDY

Summary

The purpose of the acute study was to demonstrate the performance of the VENTAK AV II DR system in detecting ventricular arrhythmias in the presence of high-rate pacing. A total of 27 patients were tested in 5 U.S. centers.

Demographic Data

The patients (21 M / 6 F) had a mean age of 69 years (range 50 to 83) and a left ventricular ejection fraction of 34% (range 15% to 60%). Most (66%) presented with monomorphic ventricular tachycardia (MVT) and nonsustained VT as their primary arrhythmia and about one quarter (24%) presented with coronary artery disease or ischemic cardiomyopathy.

Study Design

The acute study was done in the operating room or electrophysiology laboratory without implantation of the study device. The primary endpoint was VF detection time for induced episodes.

Study Results

For the 27 patients tested with the VENTAK AV II DR, 26 had inducible VF and one was not inducible into VF. The mean detection time for those 26 patients was 2.86 seconds (CI = 2.14 to 3.58). There were no patient deaths or other complications reported in the acute study for either device. The VF detection time of the VENTAK AV II DR was found not to be different from that of the VENTAK AV (Table 1).

Table 1. Acute Study Results

Study Endpoint	VENTAK AV II DR (Mean ± std) N [95% CI]	VENTAK AV (Mean ± std) N [95% CI]	Difference (Mean ± std) [95% CI]
VF detection time (seconds)	2.86 ± 1.87 n = 26 [2.14, 3.58]	2.35 ± 1.03 n = 26 [1.95, 2.75]	0.51 ± 2.06 [-0.28, 1.30]

VENTAK AV II DR IMPLANT STUDY

Summary

Since the VITALITY ICD system has many of the same therapies, diagnostics, and electrophysiology testing features as the VENTAK AV III DR system, the VENTAK AV II DR implant study, which was used to support the VENTAK AV III DR system, was used also to support the VITALITY system.

The purpose of the implant study was to confirm that the VENTAK AV II DR could sense, detect, and deliver ventricular tachyarrhythmia therapy. In addition, the adaptive-rate pacing function was evaluated by exercise testing. Fifty-two patients were enrolled and implanted in 18 centers outside the U.S. between June 27 and October 21, 1997. A total of 53 devices were used throughout the duration of the study and consisted of VENTAK AV II DR, models 1821 and 1826. The VENTAK AV II was approved for commercial distribution in the U.S. on March 13, 1998.

This clinical data remains applicable to the VITALITY devices since there are no significant differences between tachyarrhythmia therapy and adaptive-rate pacing capabilities between VENTAK AV II DR and the VITALITY VR/DR/DR+ devices.

Demographic Data

The patients (46 M / 6 F) had a mean age of 60 years (range 30 to 78) and a left ventricular ejection fraction of 36% (14% to 76%). Most (86%) presented with

coronary artery disease or ischemic cardiomyopathy and 53% presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Study Design

This was an observational study. No control group was used. Patients underwent standard ICD implant procedure and were evaluated at pre-discharge, 1 month, and 3 months postimplant. At the one-month follow-up, an exercise test consisting of a 6 minute brisk walk or 6 minutes of stair climbing was required for all patients included in the study if the accelerometer sensor was programmed on. The purpose of the exercise test was to verify if there was an adequate rate response of the sensor under exercise conditions. After the test, the device was interrogated to verify if the rate response during activity functioned according to patient need. If the rate response was insufficient, the trending function was used to optimize the sensor settings.

Study Results

The mean implant duration was 3.03 months (range 0.23 to 3.8) with a cumulative implant duration of 157.4 months. All patients were implanted in a lead alone configuration. Two patients were later revised to add SQ arrays. The mean DFT for 26 patients who were tested under a step down to failure protocol was 10.3 J stored energy. A total of 432 episodes of ventricular arrhythmias (VF/PVT and MVT) were treated including spontaneous (N = 112) and induced (N = 320). Three patients had episodes that were not converted by the device. One patient had 4 VF episodes during DFT testing at implant that were not converted by the device and were converted externally. A second patient had an electrical storm directly postimplant in which two episodes of MVT were converted externally; the device detected all episodes appropriately and used multiple attempts to deliver therapy for all episodes in the storm. A third patient's MVT accelerated to VF and was successfully terminated by the device. All other episodes of ventricular arrhythmias were converted by device therapy. There were two patient deaths: one was classified witnessed, noncardiac, nonsudden, and the other was classified unwitnessed, assumed sudden.

Forty patients had the sensor programmed "ON" and performed an exercise test. The remaining patients were not tested for the following reasons: patient had sinus rhythm and did not require adaptive-rate pacing, patient could not tolerate exercise testing, and patient death. Nominal settings were appropriate for 80% of patients

tested; in all cases, the physician was able to program appropriate adaptive-rate settings to accommodate patient need (Table 2).

Table 2. Implant study results

Effectiveness Measure	VENTAK AV II DR Mean + SD [95% CI] N
Defibrillation threshold (J) stored energy	10.3 + 3.7 [8.8, 11.8] N = 26
Safety Measure	Rate (%)
Operative mortality	1/52 (1.9%)
Conversion efficacy for all ventricular arrhythmias	425/432 (98.4%)

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