


## **Boston Scientific**

### **20 Years of Landmark Clinical Leadership**

**Boston Scientific's commitment to helping ensure more patients can access the life-enhancing and life-saving benefits of device therapy is evident in our sponsorship of more than two decades of landmark clinical trials that have expanded therapy indications to more patients.**

- 1980**      **First Implanted Defibrillator**  
Michel Mirowski, MD, revolutionized cardiovascular care with lifesaving implantable defibrillator technology for patients threatened by sudden cardiac death (SCD).
- 1985**      **World's First Commercially Available ICD**  
The Company introduced the world's first commercially available implantable cardioverter defibrillator (ICD), making Dr. Mirowski's lifesaving invention available to physicians and patients around the world.
- 1993**      **First FDA Approved Transvenous Defibrillator Lead**  
The ENDOTAK lead marked a new era in cardiac therapy by eliminating the need for open-chest lead implant surgery for patients at risk of sudden cardiac death.
- 1996**      **MADIT—*opening the door earlier***  
The Multicenter Automatic Defibrillator Implantation Trial (MADIT) established for the first time that prophylactic ICD therapy used in conjunction with conventional medical therapy can dramatically improve survival (showing a 54% relative reduction in the risk of mortality) in high-risk patients versus conventional medical therapy alone. As a result of MADIT, high-risk patients



no longer have to experience a life-threatening arrhythmia to qualify for and receive the lifesaving benefits of ICD therapy.

**2001      **MADIT II – A Landmark Study in SCD—*making it easier to qualify*****

The landmark MADIT II trial proved for the first time that heart attack survivors with impaired heart function (EF  $\leq$  30%) and no other risk stratification benefit from ICD therapy with conventional treatment versus conventional therapy alone. As a result of MADIT II, patients no longer have to undergo invasive electrophysiological testing to receive the lifesaving benefits of ICD therapy.

**2001      **CONTAK CD trial****

The CONTAK CD trial was designed to determine if cardiac resynchronization therapy (CRT) slows the progression of heart failure when compared to no CRT in a patient population with symptomatic heart failure, wide QRS, and low EF. The study found that patients receiving CRT therapy had a 21 percent non-significant slowing in the progression of heart failure, as measured by a composite index that included death, heart failure hospitalization, worsening of heart failure requiring other interventions, and the occurrence of malignant arrhythmias requiring intervention from a CRT-D device. These patients also showed a significant improvement in exercise capacity, quality of life, and NYHA class.

**2002      **First FDA Approved CRT-D****

The CONTAK CD is the first cardiac resynchronization therapy defibrillator available in the U.S., enabling physicians to treat heart failure and protect against sudden cardiac death.

**2002      **COMPANION – A Landmark Study in Heart Failure—*providing new access*****

The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial proved for the first time that CRT-D therapy, used in combination with optimal pharmacologic therapy, can significantly improve both the quality and duration of life for patients with late-stage symptomatic heart failure versus using optimal pharmacologic therapy alone. As a result of COMPANION, the benefits of CRT-D therapy are available to heart failure patients who otherwise do not have an ICD indication.

**2003      **ADVANCENT Registry****

ADVANCENT is a landmark registry that included 100,000 patients with left ventricular dysfunction (LVD). It studied LVD patients in real-world settings, providing a mechanism to evaluate and improve the application of therapies supported by evidence-based medicine. Therapies of study included beta-blockers, ACE inhibitors, lipid-lowering agents, ICDs and CRT-D therapy.

**2008      **MADIT-CRT—investigating if earlier intervention slows disease progression****

The landmark MADIT-CRT trial, sponsored by Boston Scientific, is the world's largest randomized NYHA Class I/II CRT-D trial which may prove that early intervention with CRT-D versus defibrillation alone can slow the progression of heart failure. Boston Scientific has a proven track record of rigorously designed and conducted clinical trials with clinically relevant and actionable endpoints. MADIT-CRT is another testament to Boston Scientific's commitment to the advancement of heart failure treatment.