

ICD Lead Design

CHAPTER 12

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Introduction

The implantable cardioverter defibrillator (ICD) lead is a remarkable medical device that is as critical to the function of the ICD system as the ICD itself. High-voltage leads are required to withstand multiple chronic stresses: mechanical, thermal, electrical, chemical, and oxidative. The purpose of this chapter is not to provide an exhaustive review of ICD lead design principles, suitable for biomedical engineers. Rather, the goal is to explain the design concepts and characteristics of ICD leads and to highlight the relevant differences among current designs in order to provide the implanting physician with the knowledge needed to obtain the safest and most reliable outcomes for their patients. As is true for the ICD itself, it can be argued that any of the current generation of ICD leads is a suit-

able choice for most patients. However, some lead designs may be a more optimal choice for a specific patient.

The mortality reduction associated with ICDs implanted for primary prevention indications has been made possible by the development of effective and reliable transvenous ICD leads. Mortality rates for implantation of transvenous ICD lead systems is currently < 0.5%. By comparison, mortality rates for epicardial systems requiring thoracotomy were up to 5 times higher.¹

Since their introduction in 1993, transvenous leads have undergone rapid evolution (Box 12.1). In addition to improvements in reliability, the next generations of leads may offer the ability to monitor hemodynamics and to detect ischemia. Despite advances in design, the high-voltage lead remains the “weakest” component of the ICD system. Long-term data from a prospective registry, published in 2007, showed an overall lead survival rate of 85% at 5 years and as low as 60% at 8 years.² Although

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this study included older leads that are no longer in use (eg, Medtronic 6936), it highlights the importance and limitations of ICD lead design.

1. 1993 First transvenous lead (Guidant ENDOTAK)
2. 1993 First active fixation ICD lead (Medtronic Transvene)
3. 1995 First steroid eluting ICD lead (Guidant ENDOTAK DSP)
4. 1997 First dedicated bipolar lead (Medtronic Sprint)
5. 1997 First dual coil, integrated bipolar lead (Medtronic Sprint)
6. 1997 First silicone backfill of shock coil (Ventritex SPL)
7. 1997 First use of cable conductors (Medtronic Sprint)
8. 2000 First dual coil, dedicated bipolar lead (Medtronic Sprint Quattro)
9. 2002 First 8 Fr ICD lead (St. Jude Medical Riata)
10. 2004 First 7 Fr ICD lead (Medtronic Sprint Fidelis)

Box 12.1 Important Developments in ICD Lead Design

Despite extensive bench, preclinical, and clinical testing, the true reliability and functional characteristics of a lead are often not known until it has been in widespread use. Lead recalls are an unfortunate reality of clinical practice and an understanding of the mechanism of lead failure is essential to proper patient management. Critical appraisal of the literature requires an understanding of lead design.

Basic Concepts

The components of a transvenous ICD lead include the conductors, insulation materials, defibrillation coils, lead electrodes, the fixation mechanism, the yoke, and lead connectors. An example of a dual coil, true bipolar lead is shown in Fig 12.1. The conductor is a composite metal that connects the pin (beyond the yoke) to each of the pace/sense electrodes and to each of the coils. A bipolar ICD lead is similar to a bipolar pacing lead in that there is a tip (cathode)

electrode and a ring (anode) electrode. Conductors also connect the DF-1 pin to defibrillation coil or coils. All conductors are arranged in parallel within the lead body until they reach the yoke where the pace/sense conductors and high-voltage conductors separate and terminate in the IS-1 pin or DF-1 pin(s). The yoke is trifurcated in the case of a dual coil lead and is bifurcated in a single coil lead. The length of the distal (right ventricular [RV]) coil is limited by the size of the RV. The proximal coil (superior vena cava [SVC]), if present, is generally longer. Before the development of dual coil leads, a second coil electrode was placed in the SVC in patients with high defibrillation thresholds. Defibrillation efficiency is in part related to the total surface area of the coils. Equal length coils on a smaller diameter lead have less active electrical surface area than ones on a larger diameter lead. Like pacing leads, ICD leads are made in passive fixation and active fixation versions.

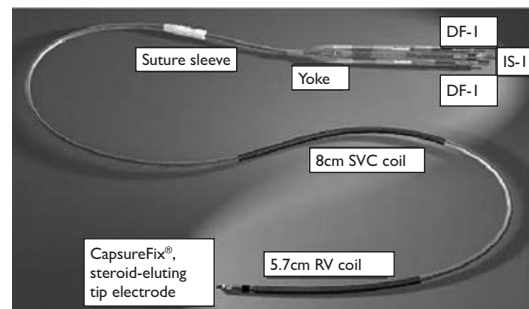


Fig 12.1 Medtronic Sprint Quattro Secure ICD lead. (Reproduced with permission of Medtronic, Inc.)

Active epicardial ICD/patch systems are rarely encountered in clinical practice today. Fig 12.2 shows a schematic of an epicardial patch. Two patches were directly applied to the epicardial surface of the heart with the ICD functioning as an inactive “can.” There are two types of patches: titanium mesh patch and a multicoil, platinum-iridium patch. Patch systems have usually been abandoned and replaced with transvenous, nonthoracotomy systems. The patch leads can cover much of the heart surface

and may unavoidably reduce the effectiveness of transthoracic defibrillation. Patch lead systems have a high failure rate and the merits of abandoning functioning epicardial patch system (in favor of a new transvenous system), at the time of ICD generator replacement should be weighed.³ Lead fracture and fluid accumulation in the insulation are among the mechanisms of failure. Constrictive pericarditis due to bacterial infection has also been reported.^{4,5}

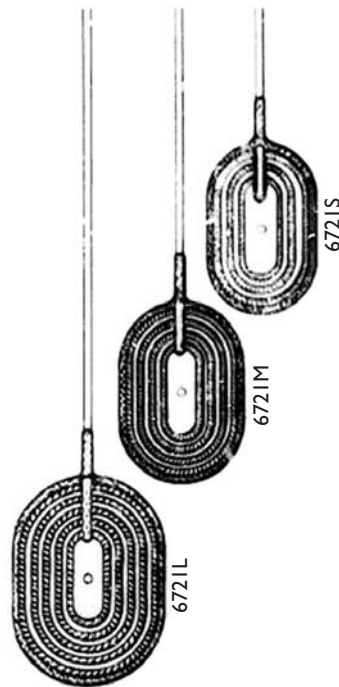


Fig 12.2 Drawings of small, medium, and large unipolar, epicardial patch leads. (Models 6721S, 6721M, and 6721L, Courtesy of Medtronic, Inc.) The lead is made of platinum alloy electrode coils and a low-resistance conductor combined with a polyester outer mesh. The lead is connected to the ICD by a 3.2-mm pin.

Of historical interest is the combination of a nonthoracotomy electrode in the form of a right ventricular catheter (cathode) and a chest wall subcutaneous patch (anode). With a monophasic shock waveform, the epicardial patch system resulted in lower defibrillation thresholds (DFTs) than a nonthoracotomy electrode system. The opposite is true when

biphasic waveforms are used.^{6,7} The subcutaneous patch was sometimes used in patients with transvenous ICD systems when high thresholds were encountered. The subcutaneous array has an equivalent effect on DFTs and offers greater ease of implant and reliability.⁸ Subcutaneous patches are also known to fracture.⁹

Although there are many similarities, each manufacturer has offered a variety of leads with unique specifications and features. Data about older leads that are not currently being marketed, but that may still be in active service, can be found in lead “encyclopedias” published by each manufacturer or other textbooks. Tables 12.1, 12.2, and 12.3 (see pages 242–44) summarize key features and specifications for the most current lead models from each major U.S. manufacturer. Some recent, but not the most current, leads may still be offered by a manufacturer to address specific patient needs or physician preference. For example, the Durata series of leads is the newest ICD lead offered by St. Jude Medical, Inc. The preceding generation (Riata series) of leads is still available for implant.

Materials

The materials used in the construction of ICD leads and lead components are manufactured to very high standards. Although the materials used by each of the major lead manufacturers are similar, there are some differences in how these materials are applied. Some materials, such as copolymer insulation, are unique to a manufacturer. The materials used in the conductor, insulation, shock coil, pace/sense electrode, and connector pin are discussed later. The application of these materials for the construction of leads is also discussed.

Conductors

The primary conductor used in most pacing and ICD leads is MP35N and silver. MP35N (Fort Wayne Metals, Fort Wayne, Indiana) is a superalloy that is double melted to remove

	ENDOTAK RELIANCE G		ENDOTAK RELIANCE SG	
Model/length (cm)	0184/59	0174/59	0180/59	0170/59
	0185/64	0175/64	0181/64	0171/64
	0186/70	0176/70	0182/70	0172/70
	0187/90	0177/90		
Fixation	Active	Passive	Active	Passive
Coils	Dual	Dual	Single	Single
Terminals	IS-I	IS-I	IS-I	IS-I
	DF-I (2)	DF-I (2)	DF-I	DF-I
Tip to proximal coil (cm)	18	18	N/A	N/A
Proximal coil Active electrode surface area (mm ²)	660	660	N/A	N/A
Tip electrode surface area (mm ²)	5.7	2.0	5.7	2.0
Isodiametric lead diameter (mm)/(Fr)	2.7/8.1			
Coil electrode diameter (mm)/(Fr)	2.7/8.1			
Distal coil active electrode surface area (mm ²)	450			
Tip-RV coil (mm)	12			
Insulation/external overlay	Silicone rubber/proprietary lubricious coating			
DF-I pin	Titanium			
IS-I pin	Stainless steel			
Pace/sense conductor	MP35N, PTFE coated			
Coil material	Platinum clad tantalum with titanium core			
Coil conductor	Drawn brazed stand (DBS) 316L bifilar cable, PTFE coated			
Tip electrode cover	Platinum iridium			
Coil electrode cover	Gore ePTFE			
Multilumen design	Asymmetric			
Sensing	Integrated bipolar			

Table 12.1 Current Boston Scientific (Guidant) ICD Leads