



Lessons Learned from Cardiac Pacemakers and ICDs

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Acting Deputy Director

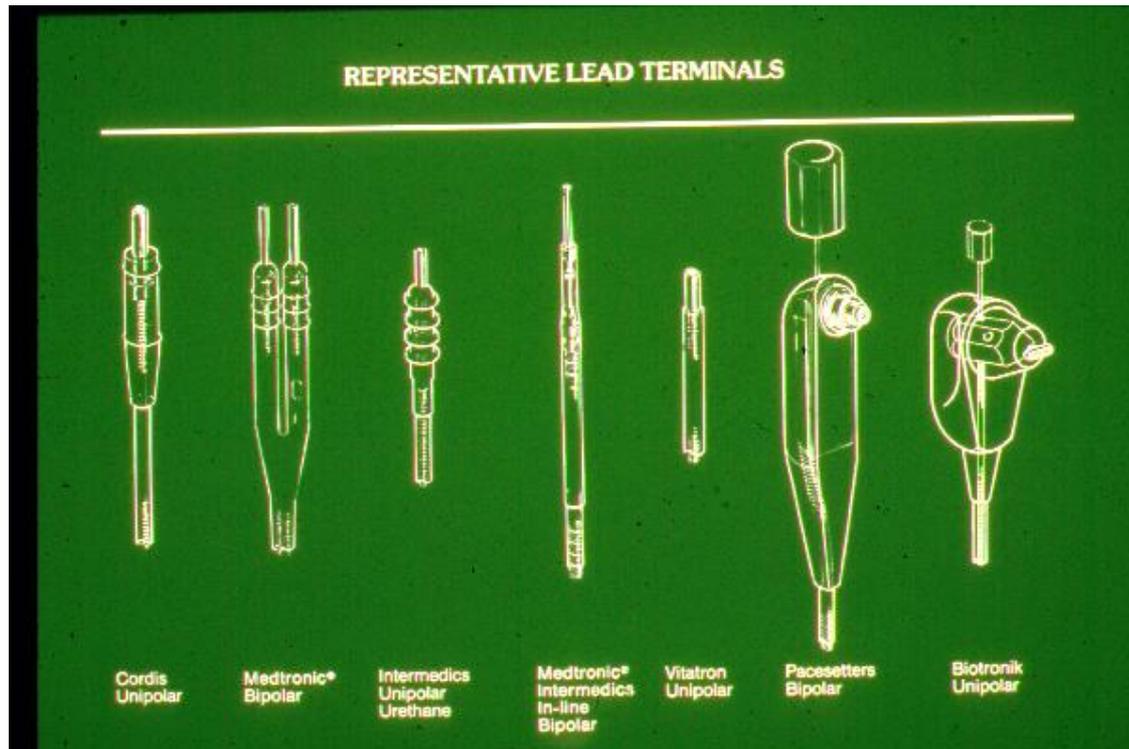
Division of Cardiovascular Devices

U.S. Food and Drug Administration

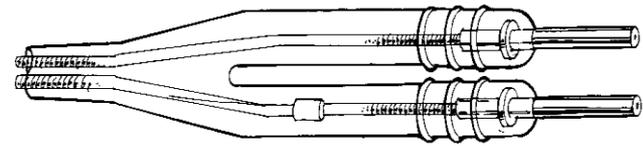
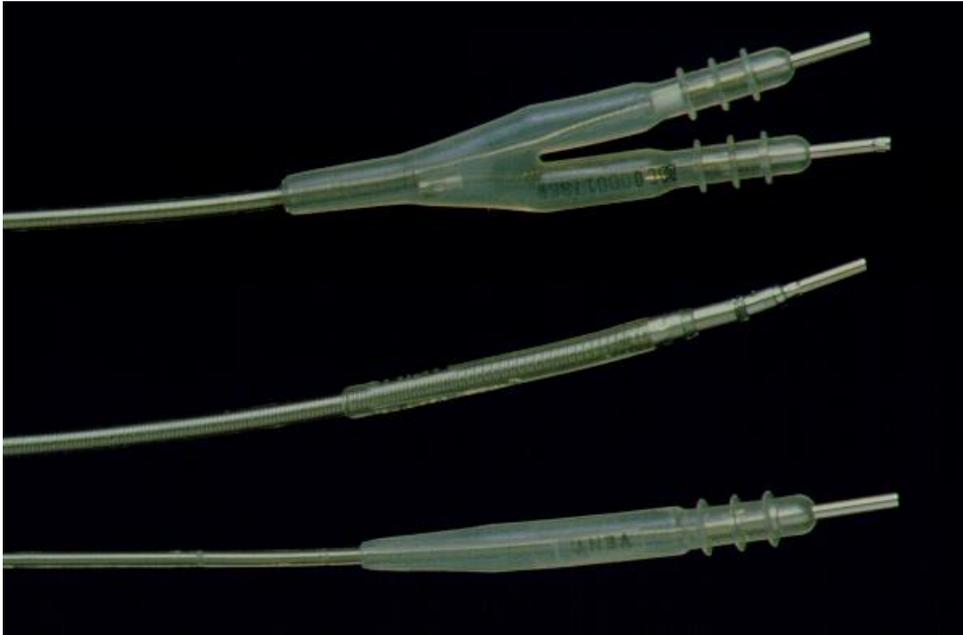
Center for Devices and Radiological Health

Office of Device Evaluation

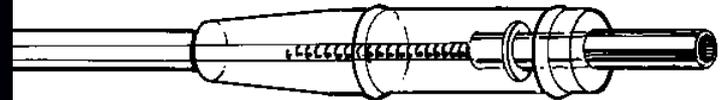
In the beginning -



Courtesy of Medtronic, Inc.



Medtronic 5mm bipolar



Cordis 6mm unipolar

Courtesy of Medtronic, Inc.

UNIVERSAL ADAPTOR	UNIPOLAR ADAPTORs				BIPOLAR ADAPTORs/EXTENSIONS			
<p>Unipolar Universal Connector</p> <p>TS-1 (Un)</p> <p>Unipolar TS-1</p> <p>VKU10V</p>	<p>Unipolar Small</p> <p>TS-1 (Un)</p> <p>Unipolar TS-1</p> <p>C/IS-10</p>	<p>Unipolar Small</p> <p>TS-1 (Un)</p> <p>Unipolar TS-1</p> <p>M/IS-10</p>	<p>Unipolar LV-1</p> <p>TS-1 (Un)</p> <p>Unipolar TS-1</p> <p>LV/IS-10</p>	<p>Unipolar LV-1</p> <p>TS-1 (Un)</p> <p>Unipolar TS-1</p> <p>IS/LV-10</p>	<p>Bipolar LV-1</p> <p>TS-1 (Un/BI)</p> <p>Bipolar TS-1</p> <p>BIS/BLV-13</p>	<p>Bipolar LV-1</p> <p>TS-1 (Un/BI)</p> <p>Bipolar TS-1</p> <p>BLV/BIS-10</p>	<p>Bipolar LV-1</p> <p>TS-1 (Un/BI)</p> <p>Bipolar TS-1</p> <p>BIS/BIS-17</p>	
<p>How do you ADAPT?</p> <p>1.800.72.OSCOR</p> <p>www.oscor.com</p> <p></p>	BIFURCATED ADAPTORs				<i>Dyad</i> BIFURCATED ADAPTORs		<i>Link</i> BIFURCATED ADAPTORs	
	<p>BIS/IS-15</p>	<p>B/IS-15</p>	<p>2-BIS/BIS-17</p>		<p><i>Dyad</i> -IS-17</p>	<p><i>Dyad</i> -LV-17</p>	<p><i>Link</i> -BIS-10</p>	<p><i>Link</i> -BLV-10</p>
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REGULATORY AFFAIRS

CARDIAC PACEMAKERS Pacemaker Leads

Part 1

IS-1, A LOW-PROFILE CONNECTOR
SAFETY AND DESIGN REQUIREMENTS

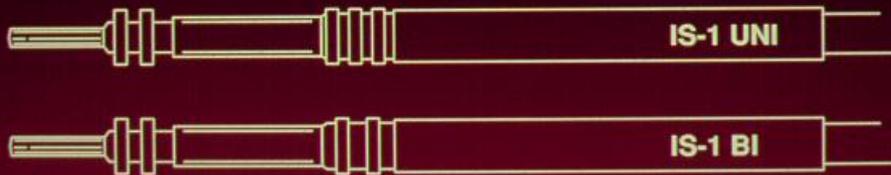
0 Introduction

The development of this standard was prompted by the concern of clinicians over the variety of apparently similar but incompatible pacing leads of the low-profile in-line type (frequently referred to as 3.2 mm leads, based on the major diameter of the lead connector area). The purpose of this document is to define a standard connector, IS-1, to provide interchangeability between lead and pulse generators from different manufacturers. The reliability and function of a particular connector part are solely the responsibility of the manufacturers.

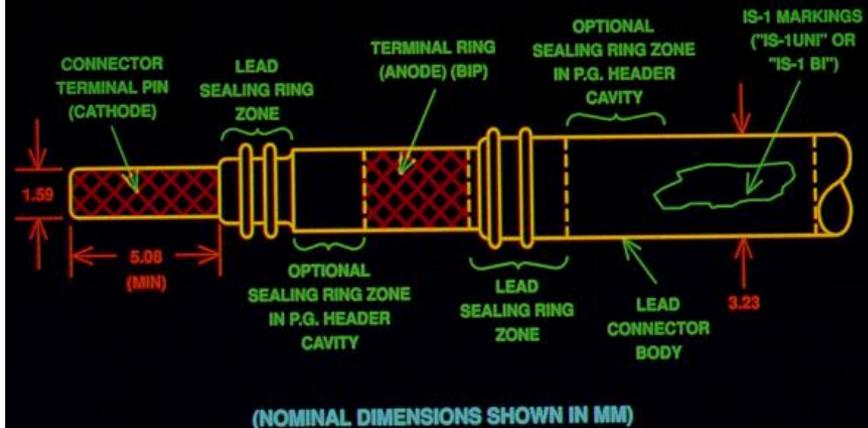
January 1989

Benefits

- Few adapters
- Less hardware
- Simplifies change-outs
- Greater patient safety
- Increased confidence

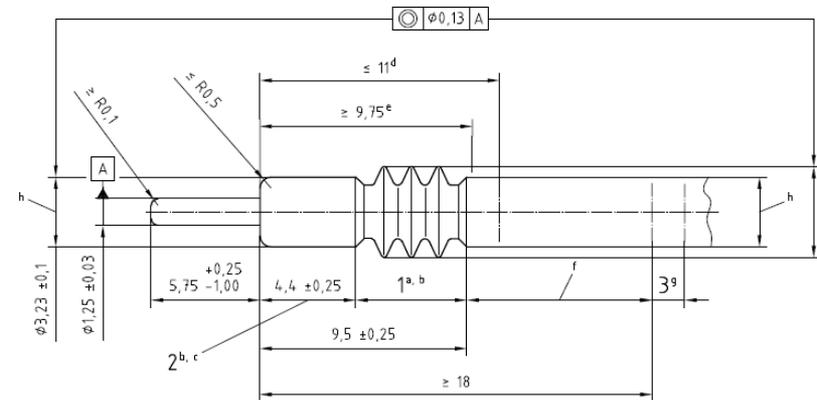


IS-1 LEAD CONNECTOR (UNIPOLAR/BIPOLAR)



ISO 11318

Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements

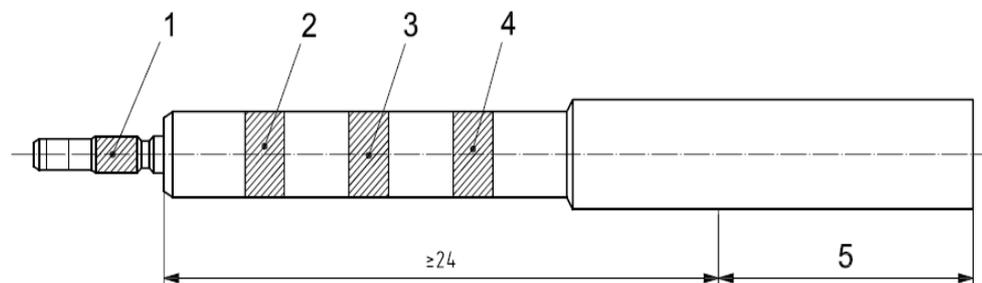


Introduction

The purpose of this International Standard is to specify a standard connector assembly, DF-1, to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

ISO 27186

Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements



Introduction

The purpose of this International Standard is to specify a four-pin connector assembly to provide interchangeability between implantable leads and pulse generators for cardiac rhythm management from different manufacturers. The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

The four-pin connector was created to allow for a reduction in the number of individual lead connectors, reduce pocket bulk associated with existing bifurcated or trifurcated leads, reduce interaction of the lead bodies in the pocket and reduce set screw connections.

This International Standard establishes two types of connector assembly: a “high voltage connector” and a “low voltage only connector”, each of which has several configurations. The high voltage connectors either have two low voltage contacts combined with one or two high voltage contacts, or they have only two high voltage contacts. The low voltage only connectors have either three or four low voltage contacts.



When things are going well, is it time to sit back and chill?



Opportunity yet unrealized.....



Opportunity yet unrealized.....

Case for a universal
programmer.

Questions?





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Center for Devices and Radiological Health

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