INTERNATIONAL STANDARD

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

Dispositifs médicaux actifs implantables — Systèmes de branchement à quatre pôles pour gérer le rhythme cardiaque — Dimensions et exigences d'essai

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 27186 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

Introduction

The purpose of this International Standard is to specify a four-pole 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-pole 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.

The high voltage and low voltage only connectors and their voltage configurations are not intended to be interchangeable. This International Standard specifies a dimensional lockout feature that prevents the low voltage contacts of the lead connectors from contacting the high voltage contacts of high voltage connector cavities.

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WARNING — The low voltage only connector cavity specified in this International Standard is not to be used if the implantable pulse generator is capable of introducing dangerous non-pacing stimuli (e.g. defibrillation shocks) through the contacts of that connector cavity. Likewise, the high voltage lead connector specified in this International Standard is not to be used on leads intended for low voltage only therapy.

1 Scope

This International Standard specifies a four-pole connector system for implantable cardiac rhythm management devices which have pacing, electrogram sensing and/or defibrillation functions. This International Standard includes requirements for the connector portion of an implantable lead as well as for the mating connector cavity attached to an implantable pulse generator. Essential dimensions and performance requirements are specified together with appropriate test methods.

This International Standard is not intended to replace or provide alternatives for unipolar or bipolar connector standards that currently exist (such as ISO 11318 and ISO 5841-3). This International Standard is not applicable to high voltage systems with intended outputs greater than 1 000 V and/or 50 A. This International Standard is not applicable to systems which include sensors or unique electrodes that are not capable of conventional pacing, electrogram sensing and/or defibrillation functions.

This International Standard does not specify all connector features. It does not address all aspects of functional compatibility, safety or reliability of leads and pulse generators assembled into a system.

NOTE Lead and pulse generator connector systems not conforming to this International Standard might be safe and reliable, and might have clinical advantages.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7436, *Slotted set screws with cup point*

ASTM A276, *Standard Specification for Stainless Steel Bars and Shapes*

ASTM B348, *Standard Specification for Titanium and Titanium Alloy Bars and Billets*

ASTM F562, *Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications*

ASTM F746-04, *Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials*

ASTM B896, *Standard Test Methods for Evaluating Connectability Characteristics of Electrical Conductor Materials*