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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 dispositifs implantables de gestion du rythme cardiaque — Exigences de dimensions et d'essai

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*, and Technical Committee IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 27186:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

— minor typographical errors have been corrected;

— the notch feature on lead connector pins has been made optional whereas previously it was required;

— the use of the notch feature for retention is no longer permitted;

— a clarification has been made to verify the functional sealing and functional contact zone requirements in 4.4.1.2 and 4.4.1.3.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

The intent of this document is to define a four-pole connector assembly that provides interchangeability between implantable leads and pulse generators from different manufacturers.

This document 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 document 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 document 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 document is not to be used on leads intended for low-voltage only therapy.

1 Scope

This document specifies a four-pole connector system for implantable cardiac rhythm management (CRM) devices which have pacing, electrogram sensing and/or defibrillation functions. This document 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.

NOTE The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

This document 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 document is not applicable to high-voltage systems with intended outputs greater than 1 000 V and/or 50 A. This document 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 document does not specify all connector features.

This document 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 document can be safe and reliable and can have clinical advantages.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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*