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Aktivt implantabelt medicinsk udstyr – Firepolet stikforbindelsessystem til implantabelt udstyr til hjerterytmeovervågning – Dimensions- og prøvningskrav

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

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International

ISO 27186

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

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

This third edition cancels and replaces the second edition (ISO 27186:2020), which has been technically revised.

The main changes are as follows:

— the requirement in 4.3.10 and the test method in Annex Q for lead insertion force have been added and the rationale for both has been added in Annex R;

— the requirement in 4.5.1 for connector cavity insertion and withdrawal force have been revised to improve accuracy and reproducibility, the test method for these has added in Annex S, and the rationale for both has been added in Annex T;

— the heading of 4.3.1 has been revised to distinguish this requirement from the lead insertion force requirement;

— the clause headings within Annex O have been aligned with those in the main text;

— annex titles have been aligned to better reflect content;

— editorial changes have been made to the main text and annexes have referred to in the main text where relevant.

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The four-pole connector system was created to reduce:

— the number of individual lead connectors,

— pocket bulk associated with existing bifurcated or trifurcated leads,

— interaction of lead bodies in the pocket, and

— set screw connections.

The four-pole connector system is intended to provide interchangeability between implantable leads and pulse generators from different manufacturers.

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

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 that have electrogram sensing and pacing functions with or without defibrillation capability. This document includes requirements for the connector portion of an implantable lead and for the mating connector cavity attached to an implantable pulse generator. Key dimensions and performance requirements are specified together with appropriate test methods.

This document establishes two types of connector assembly with their configurations, which are not intended to be interchangeable:

— a high-voltage connector: a connector that can have either

  — two low-voltage contacts combined with one or two high-voltage contacts, or

  — only two high-voltage contacts;

— a “low-voltage only connector”: a connector that has either three or four low-voltage contacts.

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.

This document does not replace or provide alternatives for unipolar or bipolar connector International Standards that currently exist (such as ISO 11318[2] and ISO 5841-3[1]).

This document is not applicable to high-voltage systems with intended outputs greater than 1 000 V or systems with an electric flow greater than 50 A.

This document is not applicable to systems which include sensors or unique electrodes that are not capable of conventional pacing electrogram sensing or defibrillation functions.

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

This document does not include requirements for accessories or adaptors used with four-pole connectors. Refer to Annex P for more information on connector-related products.

NOTE 1 The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

NOTE 2 Lead and pulse generator connector systems not conforming to this document can be safe and reliable and can have clinical advantages.

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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, *Fasteners — 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, *Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
axial pin movement
M
axial movement of a *lead connector pin* (3.18) with reference to the *lead connector* (3.16) body as present in some designs, particularly those with a rotating connector pin

3.2
bipolar
having two poles or electrodes

3.3
connector system
assembly consisting of a *lead connector* (3.16) and a *connector cavity* (3.4) that are electrically and mechanically joined

3.4
connector cavity
cavity within the *pulse generator* (3.27) which is intended to receive a *lead connector* (3.16)

3.5
contact mechanism
conductive hardware within the *connector cavity* (3.4) provided for making electrical connection to corresponding contacts on a *lead connector* (3.16)

3.6
distal
farthest from a point of reference

Note 1 to entry: The point of reference for a lead is the *lead connector pin* (3.18). Therefore, the most distal electrode of a lead is the electrode that is farthest from the lead connector pin.

3.7
fixation zone
specified area on the *lead connector pin* (3.18) and within the *connector cavity* (3.4) where the *lead connector* (3.16) is mechanically secured within the connector cavity

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having four poles or electrodes

Note 1 to entry: Generally, a four-pole implantable cardiac defibrillator (ICD) lead has two *low-voltage* (3.21) electrodes and two *high-voltage* (3.12) electrodes. A four-pole low-voltage only lead has four low-voltage electrodes.

3.9
functional contact zone
area within the *connector cavity* (3.4) where electrical contact with a *lead connector* (3.16) occurs

3.10
functional seal zone
area within the *connector cavity* (3.4) where sealing contact with a *lead connector* (3.16) occurs

3.11
grip zone
area of the *lead connector* (3.16) which is provided for grasping during insertion and withdrawal of the lead connector from the *connector cavity* (3.4)

3.12
high voltage
electrical potential greater than 20 V and that can go up to 1 000 V

Note 1 to entry: High voltages are generally used for defibrillating the heart.

3.13
high-voltage connector
lead connector (3.16) or *connector cavity* (3.4) that has at least one *high-voltage* (3.12)

Note 1 to entry: A high-voltage connector can also contain *low-voltage* (3.21) contacts.

3.14
insertion indicator zone
area on the pin of the *lead connector* (3.16) allocated for manufacturers to provide a visual indicator for use in verifying full insertion of a lead connector into a *connector cavity* (3.4)

3.15
integrated bipolar
two lead poles or *lead electrodes* (3.20) that are electrically common

Note 1 to entry: A typical integrated bipolar ICD lead has a *distal* (3.6) shock electrode that doubles as a *proximal* (3.26) pace or sense ring electrode and is electrically attached to two separate *lead connector contacts* (3.17).

3.16
lead connector
part of a lead that is intended for insertion into the *connector cavity* (3.4) of a *pulse generator* (3.27)

3.17
lead connector contact
conductive element on the *lead connector* (3.16) which include the *lead connector pin* (3.18) and *lead connector rings* (3.19)

3.18
lead connector pin
most *proximal* (3.26) conductive element of a *lead connector* (3.16) provided for making electrical contact as well as for securing the lead connector within the *connector cavity* (3.4)

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annular conductive element on the *lead connector* (3.16) intended for making electrical contact within the *connector cavity* (3.4)

Note 1 to entry: The *four-pole* (3.8) connector has three lead connector rings and a *lead connector pin* (3.18).

3.20
lead electrode
distal (3.6) part of a lead through which electrical impulses are transmitted to or from cardiac tissue

Note 1 to entry: *High-voltage* (3.12) electrodes are capable of delivering high-voltage electrical impulses. *Low-voltage* (3.21) electrodes are used for transmitting and sensing low-voltage impulses and are generally not suitable for delivering high-voltage.

3.21
low-voltage
electrical potential less than or equal to 20 V

Note 1 to entry: Low voltage is generally used for pacing and sensing the heart.

3.22
low-voltage only connector
lead connector (3.16) or *connector cavity* (3.4) that has only *low voltage* (3.21) contacts

3.23
pin visibility zone
area within the *connector cavity* (3.4) which is allocated for visual verification that the *lead connector* (3.16) is fully inserted

Note 1 to entry: The pin visibility zone corresponds to the *insertion indicator zone* (3.14) of the lead connector.

3.24
pristine contact zone
area on the *lead connector* (3.16) intended for making electrical contact with the mating contact in the *connector cavity* (3.4)

Note 1 to entry: The pristine contact zones of the lead connector align with the *functional contact zones* (3.9) of the connector cavity when the connectors are mated.

3.25
pristine seal zone
area on the *lead connector* (3.16) intended for sealing with the mating seals in the *connector cavity* (3.4)

Note 1 to entry: The pristine seal zones of the lead connector align with the *functional seal zones* (3.10) of the connector cavity when the connectors are mated.

3.26
proximal
nearest to a point of reference

Note 1 to entry: The point of reference for a lead is the *lead connector pin* (3.18). Therefore, the most proximal electrode of a lead is the electrode closest to the lead connector pin.

3.27
pulse generator
device that delivers electrical energy to affect cardiac rhythms

3.28
sealing mechanism
circumferential barriers within the *connector cavity* (3.4) intended to maintain electrical isolation between electrically insulated parts of an assembled and implanted *connector system* (3.3)

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mechanism within the *connector cavity* (3.4) intended for mechanically securing the *lead connector* (3.16)

EXAMPLE Set screw.

3.30
strain relief zone
area on the *lead connector* (3.16) provided for making a gradual transition from a more rigid section to a more flexible section

Note 1 to entry: The gradual transition results in an area over which strain is distributed so that concentrated mechanical forces do not occur when the lead is flexed.

3.31
tripolar
having three poles or electrodes

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