INTERNATIONAL STANDARD

ISO 5841-3

Second edition
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Implants for surgery — Cardiac pacemakers —

Part 3: Low-profile connectors [IS-1] for implantable pacemakers

Implants chirurgicaux — Stimulateurs cardiaques —

Partie 3: Connecteurs à bas profil [IS-1] pour stimulateurs implantables

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 part of ISO 5841 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5841-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

This second edition cancels and replaces the first edition (ISO 5841-3:1992), which has been technically revised.

ISO 5841 consists of the following parts, under the general title *Implants for surgery — Cardiac pacemakers*:

Part 1: Implantable pacemakers

Part 2: Reporting of clinical performance of populations of pulse generators or leads

Part 3: Low-profile connectors (IS-1) for implantable pacemakers

Annex A forms a normative part of this part of ISO 5841. Annex B is for information only.

Introduction

The development of this part of ISO 5841 was prompted by the concern of clinicians over the variety of apparently similar but incompatible pacing leads of the low-profile in-line type. (Because the major diameter of such leads is 3,2 mm, these connectors were frequently referred to as “3,2 mm” leads.) The purpose of this part of ISO 5841 is to specify a standard connector assembly, IS-1, to allow leads and pulse generators from different manufacturers to be interchangeable. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

Annex A gives a test method for lead connector impedance.

Annex B provides a rationale. It is recommended that this annex be read before using this part of ISO 5841 so that the user is informed about its limited objectives.

Implants for surgery — Cardiac pacemakers —

Part 3:
Low-profile connectors [IS-1] for implantable pacemakers

WARNING — Do not use the connector cavity specified in this part of ISO 5841 if the implantable pulse generator is capable of introducing dangerous nonpacing signals (e.g. defibrillation signals) through an IS-1 connector (see 4.3.3).

1 Scope

This part of ISO 5841 specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pacemaker pulse generators. Essential dimensions and performance requirements related to connector fit are specified, together with appropriate test methods.

Other connector features such as fastening means and materials are not specified in this part of ISO 5841. This part of ISO 5841 is applicable only to the form and fit of the connector assembly, and does not address all aspects of functional compatibility, system performance or reliability of different leads and pulse generator assemblies.

This part of ISO 5841 supplements ISO 5841-1 only for those pacemaker components which are claimed by their labelling to be fitted with an IS-1 connector assembly part. It does not replace any requirements in ISO 5841-1.

NOTE Pacemaker connector assemblies not complying with this part of ISO 5841 may be safe and reliable and may have clinical advantages.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 5841. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5841 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5841-1:1989, *Cardiac pacemakers — Part 1: Implantable pacemakers.*

3 Terms and definitions

For the purposes of this part of ISO 5841, the terms and definitions given in ISO 5841-1 and the following apply.

3.1
connector assembly
assembly consisting of a lead connector and a connector cavity for the electrical and mechanical connection of a lead to a pulse generator