



ISO 27186

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

Third edition
2026-07

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Published in Switzerland

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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.