International

ISO 80369-6

# Small bore connectors for liquids and gases in healthcare applications —

## Part 6: Connectors for neural applications

*Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —*

*Partie 6: Raccords pour applications neurales*

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This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-6:2016), which has been technically revised.

The main changes are as follows:

— To ensure inclusive wording, the word "male" was replaced by "cone" and "female" replaced by "socket" throughout the document.

— Compared to the first edition of this document, the word "neuraxial" has been replaced with "neural" throughout the document.

— The materials requirements of Clause 5 were updated to include all applicable parts of the ISO 527 series.

— All performance requirements of the first edition of this document utilized ISO 80369-20:2015. This second edition references ISO 80369-20:2024. To retain the backward compatibility with the first edition of this document, two of the ISO 80369-20:2015 *test methods* were migrated into this document as Annex F and Annex G. Several informative passages related to these methods were similarly migrated into Annex A. Performance requirements 7.1.2 and 7.2 now reference the *test methods* of Annex F and Annex G, respectively. All other performance requirements reference the *test methods* of ISO 80369-20:2024.

— Tolerances of several *connector* dimensions in Annex B were modified. All changes are deemed backwards compatible, except for the pitch "*p*" which is now a dimensional requirement only and radius "*r*2" of Figure B.1, which is now normative. The figures were updated for clarity.

conform to the modified figures of this document. The figures were updated for clarity.

— Annexes E and F of the first edition of this document were removed as the *small-bore connectors* defined in this document have been verified against usability and design requirements.

— Annex G of the first edition of this document and all Clause 4 references to non-interconnectability, including all residual misconnections / misconnection analysis, were moved to ISO 80369-1:—,[1] Annex E.

— Annex H of the first edition of this document was removed as this content is included in ISO 80369-1:—, Annex B.

— Annex J of the first edition of this document is now Annex H.

— Remaining Annexes were renumbered accordingly.

— The bibliography was revised to cite only documents and standards that are referenced informatively in this document.

A list of all parts in the ISO and IEC 80369 series can be found on the ISO website.

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.

The *small-bore connectors* specified in this document conform with the *non-interconnectability* requirements of ISO 80369-1:—.

This document includes design and performance requirements for *small-bore connectors* for neural *applications*. Neural *applications* involve the use of *medical devices* intended to administer medications to neural sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neural *application* include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epidural, extradural, or peridural space. Neural *application* anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the brachial plexus blocks or single nerve blocks. Neural *application* procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this document, local anaesthesia injected hypodermically is not considered a neural *application*.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics.

It is possible that the *small-bore connectors* specified in this document are not suitable for some *medical devices* within this application.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” indicates a permission;

— “can” indicates a possibility or a capability**.**

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the terms in italics is given in Annex H.

Annex A contains guidance and rationale for specific clauses and subclauses in this document.