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Catheter systems for neuraxial application — Sterile and single-use catheters and accessories

Systèmes de cathéters pour application neuraxiale — Cathéters et accessoires stériles et à usage unique

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Foreword

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

Introduction

International Standards covering catheter systems for neuraxial applications do not exist; nevertheless, this class of medical devices is very broad and counts several million catheters inserted or implanted per year. For many of these applications (e.g. the ones targeting the brain or the spine) there are considerable clinical risks.

Incorrect delivery route of medication and other misconnections between medical devices have resulted in a greater awareness of the potential role of incompatible connectors in reducing these incidents. Connectors for neuraxial applications are described in ISO 80369-6.

The development of a dedicated standard for neuraxial application is addressed in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Catheter systems for neuraxial application — Sterile and single-use catheters and accessories

1 Scope

This document specifies general requirements and test methods for catheter systems intended to be used in neuraxial applications.

This document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate conformity with these requirements.

Catheters for neuraxial applications are intended to administer medications directly into neuraxial sites, to deliver wound infiltration analgesia and to other regional analgesia procedures or to monitor or remove fluids from neuraxial sites for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial application include the spine, intrathecal or subarachnoid space and the epi-, extra-, or peri-dural space (applications mentioned are just examples and not an exhaustive list). In neuraxial application, anaesthetics/analgesics 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. Neuraxial application procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 Local anaesthesia/analgesia injected hypodermically and systemic injection of anaesthetics are not considered neuraxial applications.

This document is applicable to the following types of devices:

— spinal/epidural catheter systems;

— spinal/epidural port catheter systems;

— peripheral nerve block catheter systems;

— wound infusion catheter systems (also known as catheters for Surgical Site Continuous Analgesia).

This document is not applicable to:

— pumps and other devices intended to deliver medications through these catheter systems;

— catheters generically intended to administer substances into the body which are not intended to interact directly with the nervous system, but which have an indirect effect on nervous system (e.g. cannula needles);

— drainage catheters for any other application than neuraxial.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

3 Terms and definitions

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

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

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

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

3.1
catheter
tubular device designed to be partially or totally inserted or implanted into the body for administration and/or removal of fluids

3.2
distal end
end of the *catheter* (3.1) inserted furthest into the patient

3.3
hub
connector(s) at the proximal end of the *catheter* (3.1) which may either be integral with the *catheter* (3.1) or be capable of being securely fitted to the proximal end of the *catheter* (3.1)

Note 1 to entry: The proximal end is the end of the catheter to which connection can be made.

3.4
effective length
length of the *catheter* (3.1) that can be inserted into the body

Note 1 to entry: See Figures 1 and 2.

3.5
functional length
length of the *catheter* (3.1) between the tip and the most proximal hole

Note 1 to entry: Applies to catheters with side openings.

Note 2 to entry: See Figures 1 and 2.

3.6
total length
overall length of the *catheter* (3.1), including the catheter connector

Note 1 to entry: See Figures 1 and 2.

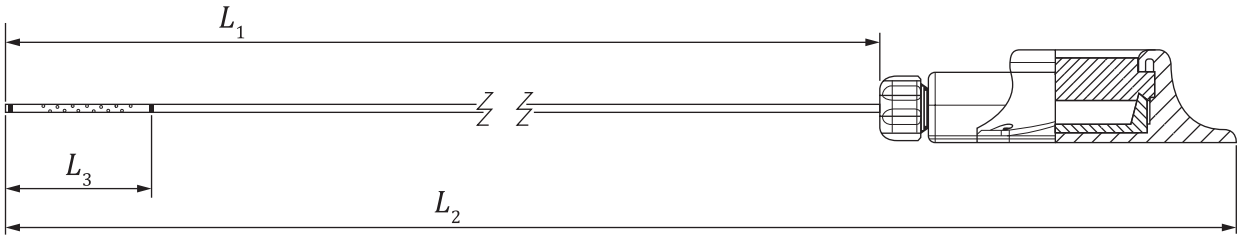
3.7
outside diameter
largest diameter of the *catheter* (3.1) along the *effective length* (3.4)

3.8
junction
joining of one or more tubes with the rest of the *catheter* (3.1)/device, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

3.9
stylet
flexible device inside the *catheter* (3.1) to assist the insertion of the *catheter* (3.1)

3.10
risk assessment
overall process comprising a risk analysis and a risk evaluation

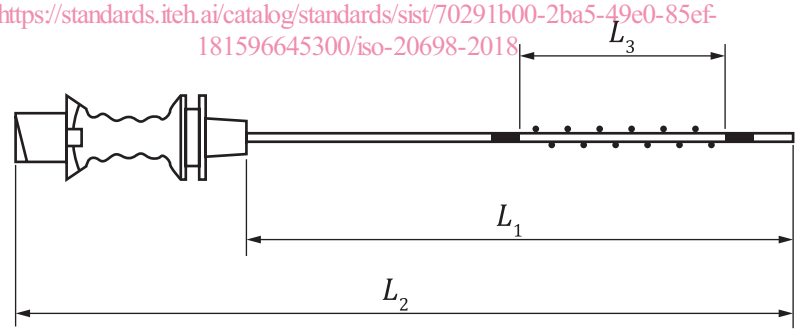
[SOURCE: ISO 14971:2007, 2.18]



Key

L_1 *effective length* (3.4)
L_2 *total length* (3.6)
L_3 *functional length* (3.5)

Figure 1 — Example of neuraxial catheter with identification of lengths and markings — Spinal/epidural port



Key

L_1 *effective length* (3.4)
L_2 *total length* (3.6)
L_3 *functional length* (3.5)

Figure 2 — Example of neuraxial catheter with identification of lengths and markings — Wound infusion catheter

4 Intended performance

The intended performance of a neuraxial catheter shall be described and documented by addressing the following, with particular regard to safety.

a) Intended purpose(s):

   In particular, it shall be clear:

   — which is the target destination of the catheter, and

   — the type of contact with the patient (e.g. totally/partially implantable, invasive).

b) Functional characteristics.

c) Intended conditions of use.

d) Intended lifetime and/or implant-time/duration time, if necessary.

The flow rate performance definition shall be given (see also 7.2.5).

5 Design attributes

5.1 Nominal size of the catheter

5.1.1 General

The nominal size of the catheter shall be designated as specified in 5.1.2 and 5.1.3.

5.1.2 Outside diameter

Unless otherwise specified in another part of this document for a particular type of catheter, the outside diameter shall be expressed as the nominal dimension in millimetres. Units of measurement systems other than those specified may additionally be used (e.g. a Gauge scale as defined in Annex E).

NOTE Designation of nominal dimension and number of significant digits after the decimal point can be provided according to risk assessment and manufacturing tolerances.

For devices that are not round by design the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

5.1.3 Catheter lengths

All catheter lengths (as defined in 3.4 to 3.6) shall be expressed in millimetres or centimetres.

NOTE This document does not specify tolerances to all lengths.

5.2 Catheter holes

The design, number and positioning of catheter holes shall be such as to minimize adverse effects on the catheter and trauma to the tissues.

5.3 Distal tip

The distal tip shall be smooth, rounded, tapered or similarly finished in order to minimize trauma to tissues during catheter insertion and use.

5.4 Surface

The external surface of the effective length of the catheter, including the distal end, shall be free from process and surface defects. The definition of the defects shall be determined by intended use requirements and risk assessment.

5.5 Hubs

If the catheter is supplied with either an integral or a separate hub it shall be a female hub that shall comply with ISO 80369-6.

The conformity of the hubs with ISO 80369-6 is also applicable to any accessories included in the device package that are intended to access the neuraxial site directly or indirectly.

5.6 Markings

Appropriate markings shall be provided on the catheter based on risk assessment and intended use.

See Figures 1 and 2 for examples of conforming catheter markings for different applications.

5.7 Filter

If a filter is included, an appropriate definition of its specification (e.g. nominal pore size) shall be defined.

5.8 Stylet

If a stylet is provided, it shall not protrude from the distal end or lateral holes of the catheter. If intended to be removable, the stylet shall be equipped with a handle allowing safe removal of the stylet from the catheter.

Removal of the stylet from the catheter shall not cause buckling by compression or tear the catheter.

5.9 Detectability

The catheter, or at least its effective length, shall be detectable by X-ray or by other means (ultra-sound, MRI, etc.), if required by the risk assessment.

5.10 Fixation devices

When a fixation device is provided, it shall not reduce the flow rate by more than 10 % in comparison with the flow rate without a fixation device.

6 Materials

6.1 General

Device materials shall be selected according to the properties required for the intended purpose. The selection shall also take into account the effects of manufacture, handling, sterilization and storage, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the device material in order to modify its properties. Possible reactions or interactions shall be considered.

If the device includes any metallic parts that could be exposed to tissues or drugs, they shall be resistant to corrosion (see 7.2.4).

When a medicinal product is an integral part of a device, the medicinal product shall be assessed according to pharmaceutical principles.