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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