SLOVENSKI STANDARD
oSIST prEN ISO 10555-1:2023

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Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO/DIS 10555-1:2022)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO/DIS 10555-1:2022)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO/DIS 10555-1:2022)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales (ISO/DIS 10555-1:2022)

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11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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Intravascular catheters — Sterile and single-use catheters —

Part 1:
General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

ICS: 11.040.25

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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.

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 of 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 www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 10555-1:2013), which has been technically revised. It also incorporates amendment ISO 10555-1:2013/Amd 1:2017.

The main changes compared to the previous edition are as follows:

— Added definitions on “inside diameter”, “gauge length”, and “coating” (Clause 3)

— Added clarification on requirements (Clause 4) related to the following aspects:

  — Peak tensile force

  — Leakage during pressurization: option for air pressure test (Annex I)

  — Power injection burst pressure

— Added new requirements (Clause 4) related to the following aspects:

  — Risk approach

  — Usability engineering

  — Shelf life

  — Removal of side holes and distal tip

  — Packaging system

  — Simulated use, kink and torque

  — Coating integrity, particulate

  - Distal tip stiffness
- Added text on “Nominal inside diameter for some applications” (Clause 5)
- Added test details in the instructions for use for power injection (Clause 6)
- Clarified “conditioning time” and “gauge length” (Annex B)
- Clarified “minimum outside pressure requirement” (Annex D)
- Introduced alternative test method using constant flowrate source (Annex G)
- Added new Annex I for alternative leakage under pressurization using air pressure.
- Added new Annex J Rationale section

A list of all parts in the ISO 10555 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.

Introduction

To be developed, if necessary (not mandatory).

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This document specifies general requirements for intravascular catheters, supplied sterile and intended for single use, for any application.

This document is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

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 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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:

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

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

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the vascular system for diagnostic and/or therapeutic purposes

3.2
distal end
end of the catheter inserted furthest into the patient

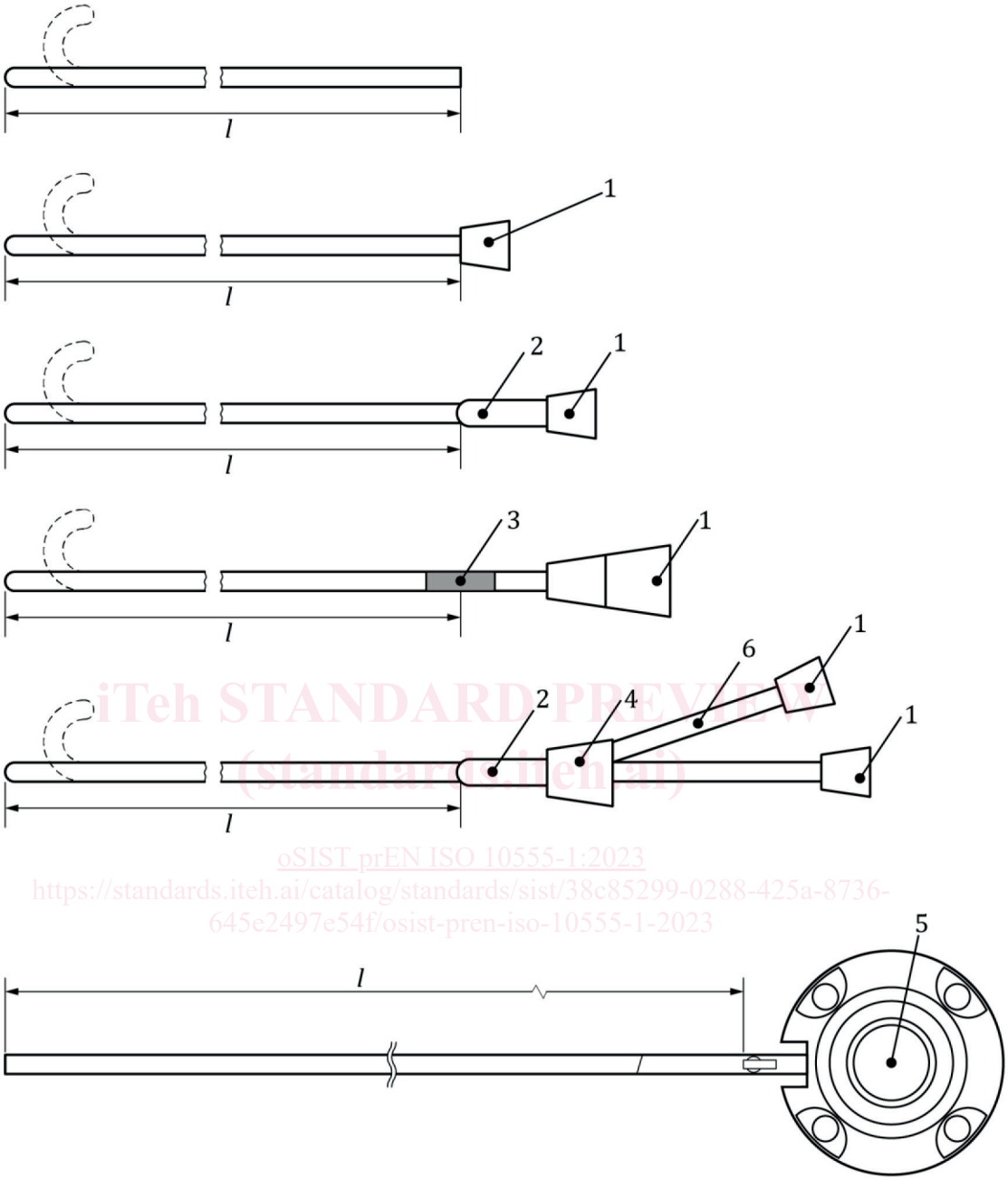
3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the vascular system and the placement and anchoring of the distal tip in the chosen location

3.4
proximal end
access end
end of the catheter to which connection to another device can be made

3.5
hub
connector(s) at the *proximal end* (3.4) of the catheter which may either be integral with the catheter or be capable of being securely fitted to the *proximal end* (3.4) of the catheter

3.6
effective length
working length
usable length
length of the catheter, or pre- and *post-hydration* (3.11) lengths of hydratable catheters, that can be inserted into the body

Note 1 to entry: See Figure 1 where "*l*" is denoted as effective length.



Key

l effective length
1 catheter hub
2 catheter strain reinforcement
3 length mark
4 junction
5 pre-connected port
6 sidearm

Figure 1 — Examples of effective length of catheters

3.7
outside diameter
largest diameter of the catheter or pre- and *post-hydration* (3.11) largest diameters of hydratable catheters over the *effective length* (3.6)

3.8
inside diameter
for a lumen intended to deliver other devices, the largest diameter that can pass through a catheter

Note 1 to entry: See Annex J for supplementary information.

3.9
junction
joint
fixed connection
joining of one tube or more tubes with another tube or component where the assembly provides mechanical support in tension/compression during clinical use

3.10
hydratable intravascular catheter
intravascular catheter consisting of a material which, when subjected to an aqueous medium, results in an increase of more than 1 % of the effective length or 10 % or more of the *outside diameter* (3.7) of the effective length in *post-hydration* (3.11) state compared to pre-hydration

3.11
post-hydration
state of a *hydratable intravascular catheter* (3.10) after immersion in aqueous medium at (37 ± 2) °C for a minimum of 2 h or a shorter time upon appropriate clinical justification

3.12
power injection
injection of an imaging contrast agent with a pump capable of generating pressures greater than or equal to 689 kPa (100 psi)

3.13
primary packaging
packaging, which has direct contact with the device and/or maintains sterility

3.14
secondary packaging
packaging designed to contain one or more *primary packages* (3.13) and/or accessories

3.15
gauge length
length of the test piece between the grips of the tensile testing apparatus that elongates significantly during testing

Note 1 to entry: See Figure B.1.

Note 2 to entry: See Annex J for supplementary information.

3.16
coating
layer of material with any different property (e.g. antimicrobial, lubricity, antithrombogenicity) than the natural surface of the substrate that is intentionally added to the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface. Liquid lubricant is not considered as coating.

4 Requirements

4.1 Risk approach

Risk analysis, risk evaluation, risk control, evaluation of residual risk acceptability shall be performed in accordance with ISO 14971.

NOTE See Annex J for supplementary information.

4.2 Usability engineering

A usability engineering program shall be developed and implemented in accordance with IEC 62366-1, which shall include addressing use risks and tests and/or assessments as part of the design verification and validation.

NOTE See Annex J for supplementary information.

4.3 Sterilization

The devices shall be sterilized by a validated method.

The devices shall fulfil the requirements specified in 4.4 to 4.18 after being sterilized by a sterilization cycle representative of the final manufacturing process.

NOTE See applicable part(s) of ISO 17665, ISO 11135, and ISO 11137 for appropriate methods of sterilization.

4.4 Shelf life

The impact of aging on product performance shall be considered based on risk assessment in order to support the shelf life.

4.5 Detectability

Parts of the catheter shall be detectable by X-ray or by other means (e.g. ultra-sound, MRI, etc.) if required as determined by the risk assessment.

Detectability shall be demonstrated by an appropriate test method (see e.g. ASTM F640-20 or DIN 13273-7).

4.6 Biocompatibility

The catheter shall be free from biological hazard in accordance with appropriate testing according to ISO 10993-1.

4.7 Surface

When examined by normal or corrected to normal vision and with a minimum x 2,5 magnification the external surface of the catheter shall appear free from foreign matter.

The external surface of the effective length of the catheter, including the distal end, shall be free from surface defects which could cause embolic risks or trauma to vessels.

If the catheter is lubricated, the lubricant shall not be visible as drops of fluid on the external surface when the catheter is examined under normal or corrected to normal vision.