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ISO/TC 84/~~WG 9 N 883~~
~~Replaces N 882~~

Secretariat: DS

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Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

~~*DIS*~~*Cathéters intravasculaires — Cathéters stériles et non réutilisables —*

Partie 1: Exigences générales

FDIS stage

~~This document contains the result of the discussions of the comments received on ISO/DIS 10555-1.~~

~~The comments with WG observations is circulated as document N 881 and a version with tracked changes of this draft is circulated as document N 882.~~

~~Project leader: Yiping Ma (US)~~

~~**Next step:** After final WG 9 approval, the clean version of this draft will be sent to ISO/CS for initiation of the FDIS procedure.~~

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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~~document 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).

Field Code Changed

~~Attention is drawn~~ISO draws attention to the possibility that ~~some of~~ the ~~elements~~implementation of this document may ~~be~~involve the ~~subject~~use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights~~.~~ in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. 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).~~

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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~~www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

The main changes are as follows:

— ~~—~~added definitions ~~on~~for "inside diameter", "gauge length", and "coating" ~~to Clause 3;~~in Clause 3;

— ~~—~~added clarification on requirements ~~(Clause 4)~~(Clause 4) related to:

  — ~~—~~peak tensile force (~~made~~revised the NOTE in ~~Table 1 of 2013 edition normative);~~Table 1);

  — ~~—~~leakage during pressurization: option for air pressure test ~~(Annex I);~~(Annex I);

  — ~~—~~power injection burst pressure.

—

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—

— added new requirements ~~(Clause 4)~~(Clause 4) related to:

  — risk approach;

  — usability engineering;

  — shelf life;

  — packaging system;

  — simulated use, kink and torque;

  — coating integrity, particulate;

  — distal tip stiffness.

— removed the requirements on side holes and distal tip;

— added text on “Nominal inside diameter for some applications” ~~(Clause 5);~~(Clause 5);

— added test details in the instructions for use for power injection ~~(Clause 6);~~(Clause 6);

— added reporting of maximum, minimum, standard deviation for variable data analysis ~~(several Annex Test Reports);~~in test reports;

— clarified “conditioning time” and “gauge length” ~~(Annex B);~~(Annex B);

— clarified “minimum outside pressure requirement” ~~(Annex D);~~(Annex D);

— introduced alternative test method using constant flowrate source ~~(Annex G);~~(Annex G);

— ~~added Table H.1 to replace figure~~ replaced Figure H.1 in previous version~~;~~ with the new Table H.1;

— added new ~~Annex I~~Annex I for alternative leakage under pressurization using air pressure;

— added new ~~Annex J~~Annex J for rationale.

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~~.

www.iso.org/members.html.

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 does not apply 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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*

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 terminology databases for use in standardization at the following addresses:

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

— IEC Electropedia: available at https://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

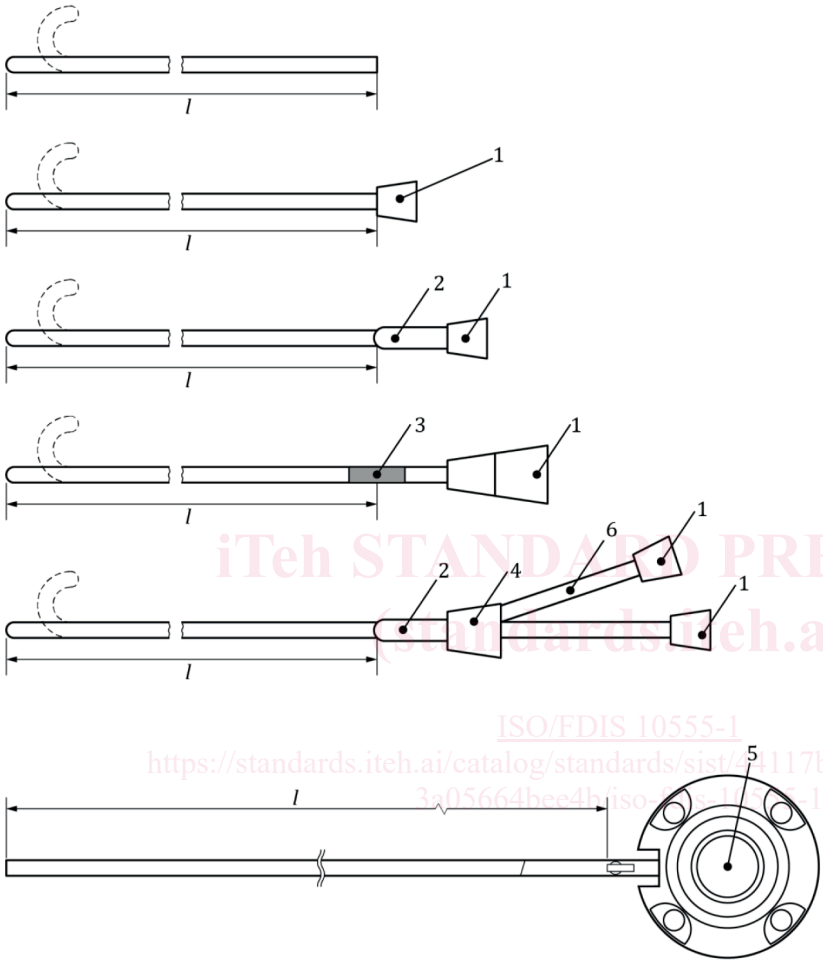
3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the vascular system and the placement and anchoring of the distal tip in the chosen location

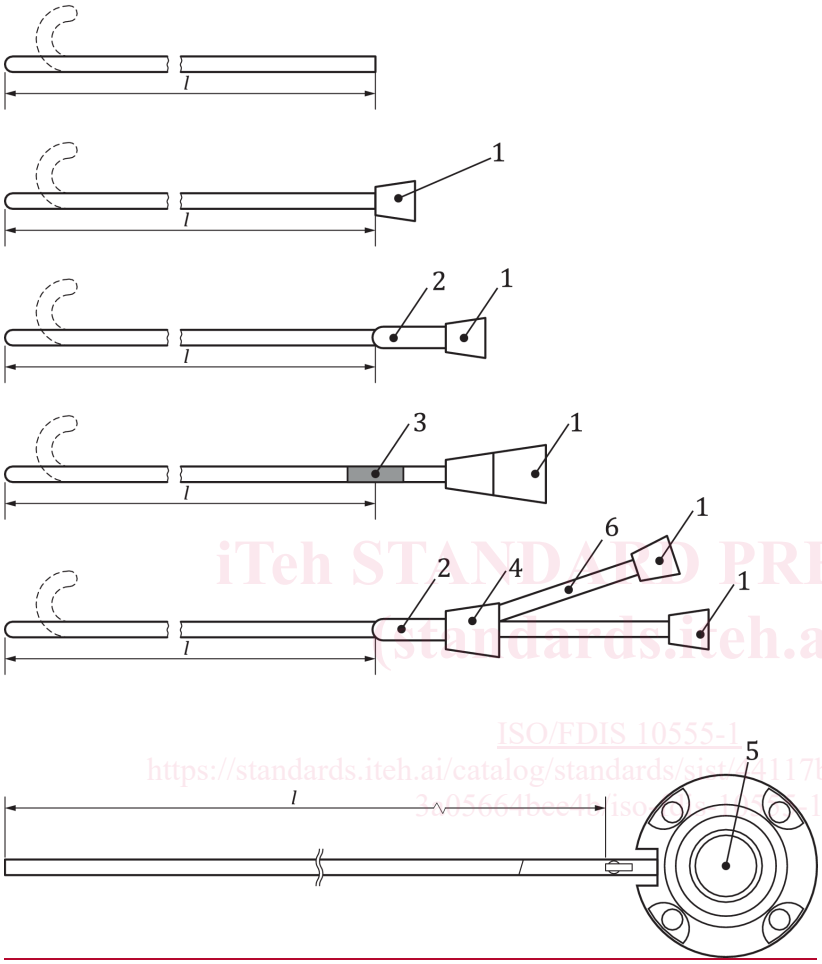
3.4
proximal end
access end
end of the catheter to which connection to another device can be made

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

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

Note 1 to entry: See ~~Figure 1~~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)~~(3.11) largest diameters of hydratable catheters over the *effective length* ~~(3.6)~~(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~~Annex J for additional 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)~~(3.7) of the effective length in *post-hydration* ~~(3.11)~~(3.11) state compared to pre-hydration

3.11
post-hydration
state of a *hydratable intravascular catheter* ~~(3.10)~~(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 constant-pressure source or constant-flowrate source capable of generating pressures greater than or equal to 689 kPa

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)~~(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~~Figure B.1.

Note 2 to entry: See ~~Annex J~~Annex J for additional information.