INTERNATIONAL STANDARD

ISO 10555-1

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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

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10555-1 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-1:1995), which has been technically revised. It also incorporates the amendments ISO 10555-1:1995/Amd 1:1999 and ISO 10555-1:1995/Amd 2:2004.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

— *Part 1: General requirements*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

The following part is under preparation:

— *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

— *Part 2: Angiographic catheters*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

This corrected version of ISO 10555-1:2013 incorporates an editorial correction in H.3.

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*[1)]

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

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

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular 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 cardiovascular system and the placement and anchoring of the distal tip in the chosen location

1) Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

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

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

3.6
effective length
l
length of the catheter, or pre- and post-hydration lengths of hydratable catheters that can be inserted into the body

SEE: Figure 1.

3.7
outside diameter
largest diameter of the catheter or pre- and post-hydration largest diameters of hydratable catheters that can be inserted into the vessel

3.8
junction
the joining of one tube or more tubes, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

3.9
hydratable intravascular catheter
intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium

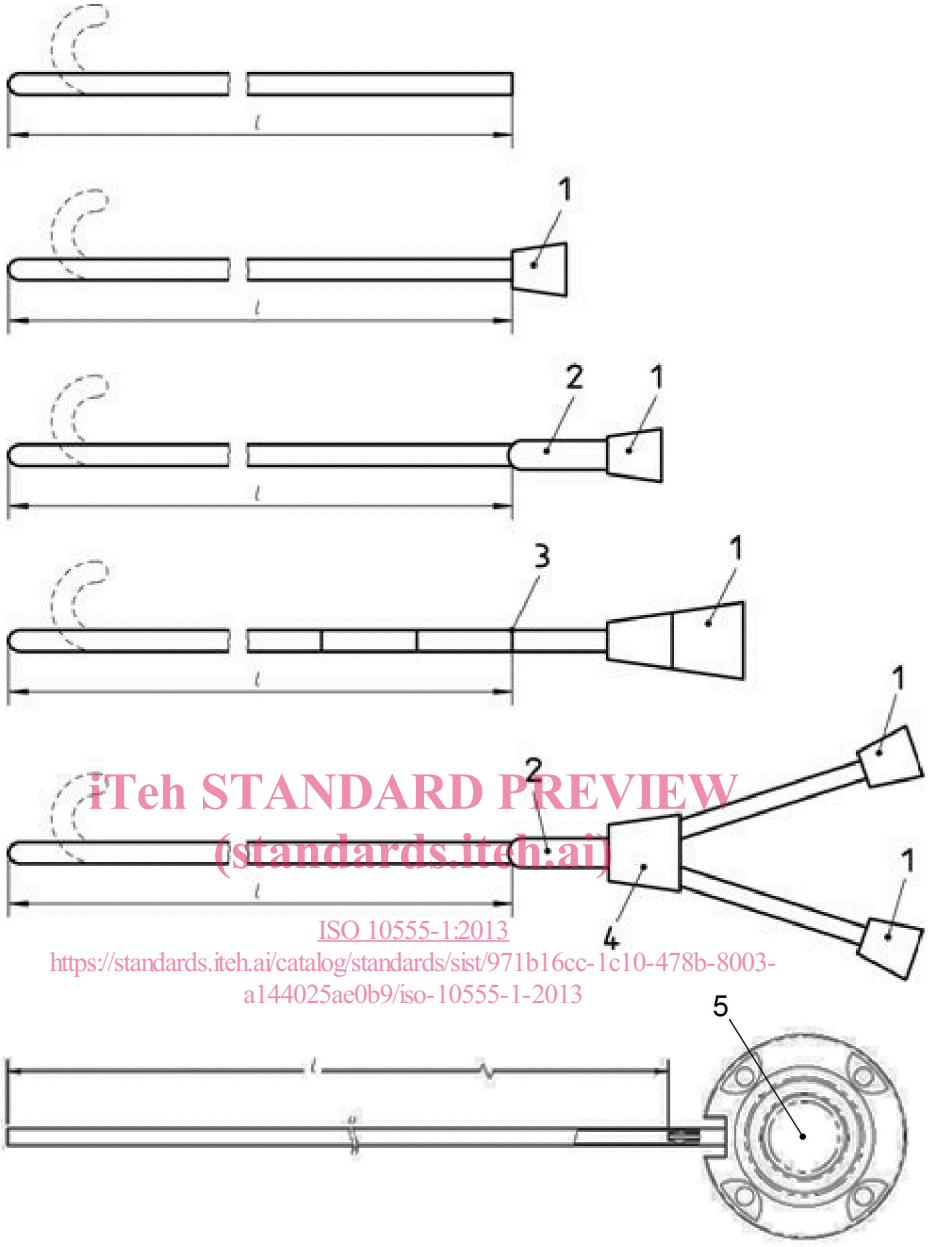
3.10
post-hydration
state of a hydratable intravascular catheter after immersion in aqueous medium at (37 ± 2) °C for a clinically appropriate period of time

3.11
clinically significant hydration
hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 1 % of the effective length, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more

3.12
power injection
rapid injection of fluid at high pressure

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

3.14
secondary packaging
packaging designed to contain one or more primary packages



Key

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

Figure 1 — Examples of effective length of catheters

3.15
angiographic catheter
intravascular catheter used for the injection of contrast media and/or fluids and which may be used for pressure measurements and to obtain blood samples or insertion of coaxial inner catheter, occlusion coils or other devices

4 Requirements

4.1 General

The catheter shall have been sterilized by an appropriate validated method, and shall comply with 4.2 to 4.8 in the sterile condition.

4.2 Radio-detectability

Parts of the catheter shall be radio-detectable if required as determined by the risk assessment.

Compliance should be demonstrated by an appropriate test method, such as ASTM F640-12 or DIN 13273-7.

4.3 Biocompatibility

The catheter shall be free from biological hazard.

NOTE See ISO 10993-1 for the selection of appropriate test methods.

4.4 Surface

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

The external surface of the effective length of the catheter, including the distal end, shall be free from process and surface defects which could cause trauma to vessels during use.

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.

4.5 Corrosion resistance

When tested in accordance with the method given in Annex A, metallic components of the catheter intended for fluid path contact shall show no signs of corrosion.

4.6 Peak tensile force

When tested in accordance with the method given in Annex B, the peak tensile force of each test piece shall be as given in Table 1.

Table 1 — Peak tensile force of catheter test pieces

Smallest outside diameter of tubular portion of test piece mm	Minimum peak tensile force *N*
≥ 0,55 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	10
≥ 1,85	15
NOTE This part of ISO 10555 does not specify requirements for peak tensile force for tubing of less than 0,55 mm outside diameter (prehydration outside diameter for hydratable intravascular catheters) or for a distal tip and its junction to the shaft tube. These values should be determined by the manufacturer based on risk assessment.	

4.7 Freedom from leakage

4.7.1 The hub or connection fitting assembly or any other part of the catheter shall not leak liquid when tested in accordance with the method given in Annex C.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.7.2 Air shall not leak into the hub assembly during aspiration when tested in accordance with the method given in Annex D.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.8 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 594-1 and ISO 594-2.

4.9 Flowrate

For devices for which flow rate is defined, when tested in accordance with Annex E, the flow rate for each lumen shall be a minimum of 80 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated by the manufacturer for catheters of nominal outside diameter equal to 1,0 mm or greater.

If the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

4.10 Power injection

If the catheter is indicated for power injection, the catheter burst pressure shall exceed the peak pressure present in the catheter at maximum flow conditions as determined by Annexes F and G.

4.11 Side holes

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

4.12 Distal tip

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

5 Designation of nominal size

The nominal size of the catheter shall be designated as specified in 5.1 and 5.2.

5.1 Outside diameter

Unless otherwise specified in one other part of this International Standard for a particular type of catheter, the outside diameter shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,01 mm or 0,1 mm.

For devices which 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.

5.2 Nominal effective length

The nominal effective length shall be expressed in millimetres for effective lengths of less than 100 mm.

The nominal effective length shall be expressed in millimetres or centimetres for effective lengths of 100 mm or more.

NOTE Tolerances to the effective length are not specified.

6 Information to be supplied by the manufacturer

6.1 General

Each device shall be accompanied by the information needed to use it safely and properly. All dimensions given shall be expressed in SI units of measurement.

Units of measurement systems other than those specified may additionally be used.

Where appropriate, ISO 15223-1 should be used.

6.2 Marking on the device and/or primary packaging

NOTE The primary packaging is often transparent. Therefore, for the purposes of this subclause, the combination of marking of the device which is visible through the package and the primary packaging itself are to be considered.

The information listed below shall be specified on the first practical level in the following order: device, primary packaging, instructions for use:

a) the name or trade name and address of the manufacturer and/or his authorized representative;

b) the details strictly necessary to identify the device (including the nominal size as designated in Clause 5) and the contents of the packaging and, if applicable, the guidewire that is intended by the manufacturer for use with the catheter;

c) the word "STERILE" or the appropriate symbol in ISO 15223-1;

d) the method of sterilization;

e) the batch code, preceded by the word 'LOT', or the serial number or the appropriate symbol in ISO 15223-1;

f) an indication of the date by which the device should be used, in safety, expressed as, at a minimum, the year and month (e.g. as YYYY-MM);

g) an indication that the device is for single use;

h) any special storage and/or handling conditions;

i) if the intended purpose of the device is not obvious to the user, the manufacturer shall clearly state it (where a device is provided with separate instructions for use, this requirement may be omitted from the primary packaging);

j) where appropriate, an indication to consult the instructions for use;

k) for angiographic catheters, a depiction or description of the distal end configuration, if not identifiable through the package.

6.3 Instructions for use

When a separate instruction for use is provided, it shall at least contain information on the following:

a) the details referred to in 6.2 with the exception of d) f), j) and k);

b) precautions to be taken and any warnings (e.g. to cleaning agents, if relevant);

c) if the device is intended to be connected to other devices or accessories in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices in order to obtain a safe combination;

d) description of additives or coatings;

e) any unique requirements for disposal of device, taking into account item d) above;

f) if applicable, special claims made because of the presence of an additive or coating, and as applicable:

— description of the additive or coating material,

— duration of effectiveness in use,

— any contra-indications, warnings and precautions based on the additive or coating material(s);

g) if applicable, known reactions between the catheter and magnetic resonance imaging (MRI);

h) date of issue or the latest revision of the instructions for use;

i) for devices indicated for power injection, the following information shall be included:

— recommended power injector pressure limit setting(s);

— maximum flow rates for a range of clinically applicable viscocities and/or specific injectates.

6.4 Marking on the secondary packaging

Where devices are provided in secondary packaging, the marking on the secondary packaging shall include the details referred to in 6.2, if appropriate.

Annex A
(normative)

Test method for corrosion resistance

A.1 Principle

The catheter is immersed in sodium chloride solution, then in boiling distilled water, and afterwards examined visually for evidence of corrosion.

A.2 Reagents

A.2.1 Saline solution, comprising a solution of analytical reagent grade sodium chloride in freshly prepared distilled water [c(NaCl) = 0,15 mol/l].

A.2.2 Distilled or deionized water.

A.3 Apparatus

A.3.1 Borosilicate glass beakers.

A.4 Procedure

Immerse the catheter in the saline solution (A.2.1) in a glass beaker (A.3.1) at room temperature for 5 h. Remove the test specimen and immerse it in boiling distilled water (A.2.2) for 30 min. Allow the water and the test specimen to cool to 37° C, and maintain them at this temperature for 48 h. Remove the test specimen and allow it to dry at room temperature. Disassemble specimens that have two or more components which are intended to be separable in use. Do not strip away or cut open any coatings on metallic components. Inspect the specimen visually for signs of corrosion.

A.5 Test report

The test report shall include the following information:

a) identity of the catheter;

b) statement as to whether corrosion occurred during the test.