INTERNATIONAL STANDARD

ISO 10555-1

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2014-01-15

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The following part has been withdrawn and the content has been included in ISO 10555-1: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

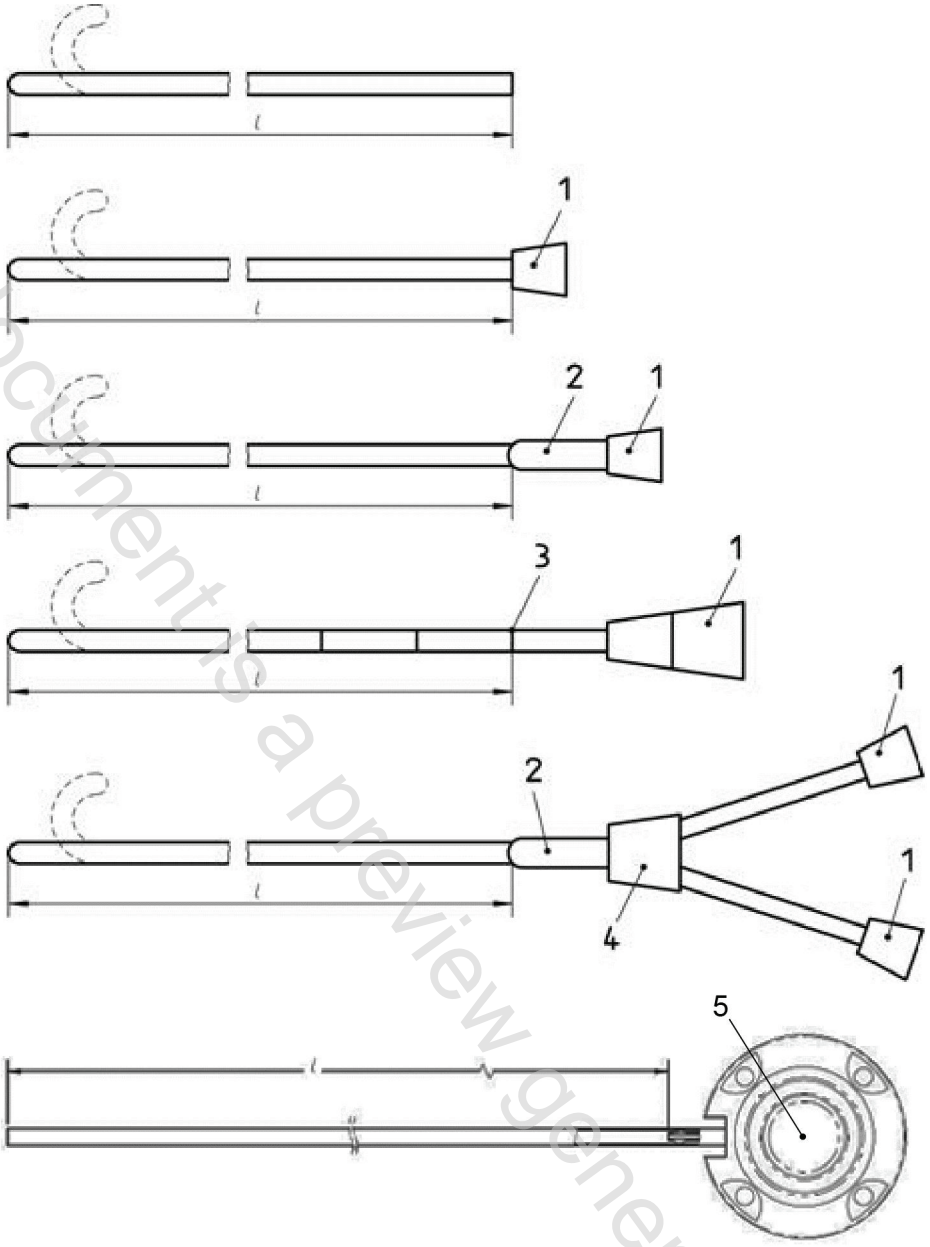
3.10
post-hydration
state of a hydratable intravascular catheter after immersion in aqueous medium at (37 ± 2) °C for a clinically appropriate period of time

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