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10555-2

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Sterile, single-use intravascular catheters — Part 2: Angiographic catheters

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Cathéters intravasculaires stériles, non réutilisables —

Partie 2: Cathéters angiographiques

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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.

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.

International Standard ISO 10555-2 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

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

- *Part 1: General requirements*
- *Part 2: Angiographic catheters*
- *Part 3: Central venous catheters*
- *Part 4: Balloon dilatation catheters*
- *Part 5: Over-needle peripheral catheters*

Annex A forms an integral part of this part of ISO 10555. Annex B is for information only.

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Sterile, single-use intravascular catheters —

Part 2: Angiographic catheters

1 Scope

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

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

2 Normative reference

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the edition indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definitions apply.

3.1 angiographic catheter: Intravascular catheter used for the injection or infusion of contrast media and/or fluids and which may be used for pressure measurements and to obtain blood samples.

3.2 distal end configuration: Shape of the catheter which is designed to facilitate its manual manipulation through the cardiovascular system and the placement of the tip in the location chosen for the angiographic procedures.

4.1 General

Unless otherwise specified in this part of ISO 10555, catheters shall comply with ISO 10555-1.

4.2 Radio-detectability

The catheter shall be radio-detectable.

NOTE 2 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Designation of nominal size

The nominal size of the catheter shall be designated in accordance with ISO 10555-1 and also by the diameter of the largest guidewire that can be used with the catheter. If the inside diameter of the catheter is additionally designated, it shall be expressed in millimetres, rounded down to the nearest 0,1 mm.

4.4 Physical requirements

4.4.1 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.

4.4.2 Freedom from leakage and damage under high static pressure conditions

When tested as described in annex A, there shall be no liquid leakage from the catheter and no visible signs of damage. There shall be no permanent deformation of the catheter shaft sufficient to prevent the free movement of a ring gauge over the tested portion of the catheter.

4.4.3 Side holes

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

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also include the following:

- a) nominal size of the catheter, as designated in 4.3;
- b) depiction or description of the distal end configuration, if not identifiable through the package;
- c) maximum rated injection pressure, expressed in kilopascals (kPa), as determined under dynamic test conditions.

NOTES

3 The time for which the catheter can withstand the maximum rated pressure may also be given.

4 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

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Annex A (normative)

Test for freedom from leakage and damage under high static pressure conditions

A.1 Principle

The catheter is connected via its hub or proximal end to a source of hydraulic pressure. Pressure is applied for a fixed time, and the specimen examined for rupture and leakage under pressure, and for evidence of leakage, damage or distortion after the pressure is removed.

A.2 Apparatus

A.2.1 Hydraulic pressure-generating device, which uses only liquid as a pressurizing fluid and maintains its temperature at $(37 \pm 2)^\circ\text{C}$.

A.2.2 Leak-proof connector.

A.2.3 Locking device, for securing the catheter to the connector (A.2.2).

A.2.4 Means of occluding the catheter, for example a clamp.

A.2.5 Ring gauges for each size of catheter, each having an inside diameter 10 % greater than the nominal outside diameter of the catheter shaft.

NOTE 5 The general arrangement of the apparatus is shown in figure A.1. The apparatus for generating and controlling the pressure is not shown in detail, as it may vary in design, complexity and degree of automation.

A.3 Test procedure

WARNING — It is essential that precautions and safeguards be taken to protect the test operator from the consequences of failure of the pressurized system and the resulting escape of liquid under high pressure.

A.3.1 Start the filtration system (see figure A.1), if fitted.

A.3.2 Bring the pressurized liquid and the catheter to a temperature of $(37 \pm 2)^\circ\text{C}$, and maintain this temperature throughout the test.

A.3.3 Attach the free end of the hub of the catheter to the connector (A.2.2), securing it with the locking device (A.2.3).

A.3.4 Ensure the air is displaced from the catheter by the liquid, then occlude the catheter at a distance of approximately one-half its effective length from the catheter hub, using the clamp (A.2.4).

A.3.5 Check the hydraulic circuit for integrity and freedom from leaks.

A.3.6 Adjust the pressure-generating device (A.2.1) so that it will apply the maximum rated pressure stated by the manufacturer of the catheter under test for a time of 2 s or the maximum time stated by the manufacturer of the catheter under test, whichever is longer.

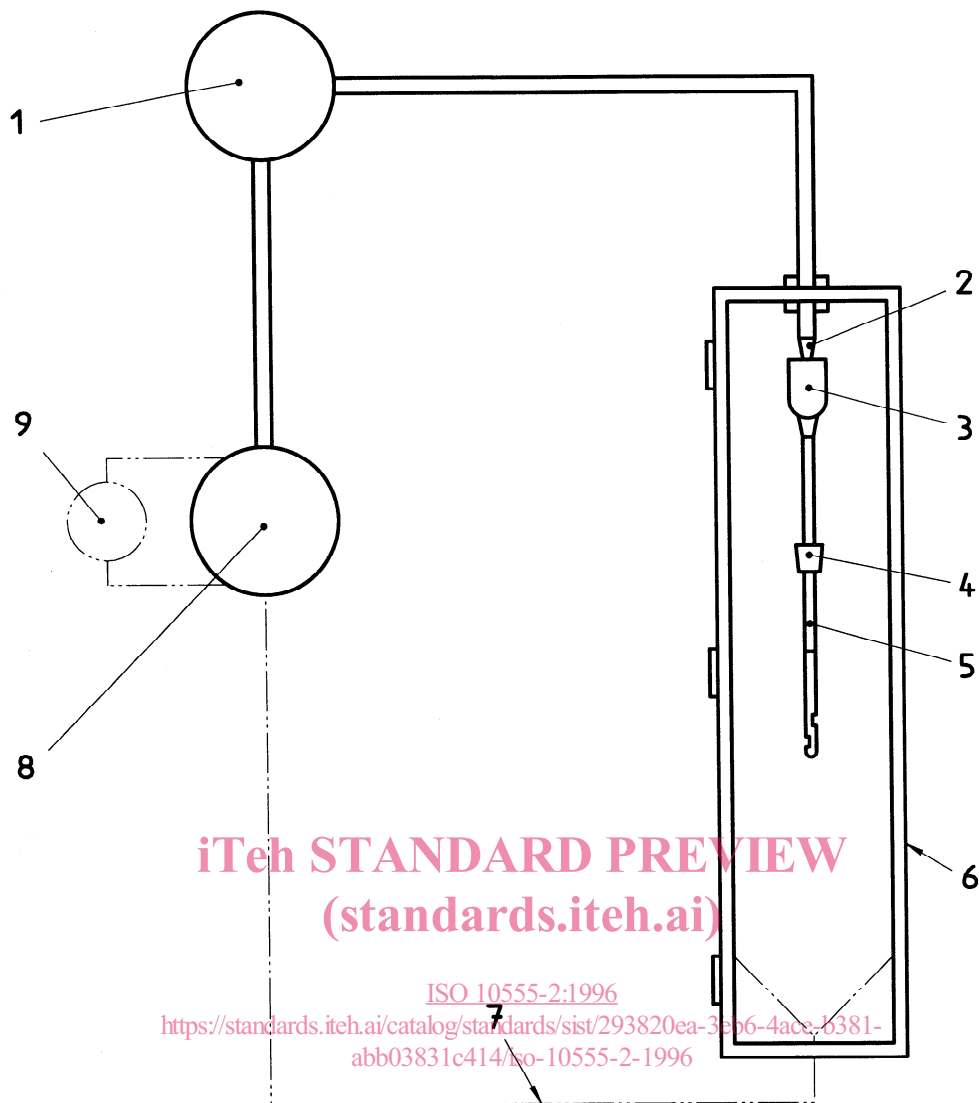
A.3.7 Apply the selected pressure for the selected time.

A.3.8 While the pressure is being applied, inspect the catheter for rupture and leakage (i.e. formation of one or more falling drops of liquid). After the pressure has been removed, disconnect the catheter from the test apparatus and examine it for damage, rupture or evidence of leakage. Attempt to pass the ring gauge freely along the test portion of the catheter shaft.

A.4 Test report

The test report shall include the following information:

- identity of the catheter;
- rated pressure and pressurization time used;
- whether leakage occurred from the test portion of the catheter;
- whether the test portion of the catheter was damaged or ruptured;
- whether the ring gauge could be passed freely along the tested portion of the catheter shaft.



Key

- 1 Hydraulic pressure generator and control system (A.2.1)
- 2 Connector (A.2.2)
- 3 Locking device (A.2.3)
- 4 Clamp or plug (A.2.4)
- 5 Catheter under test
- 6 Example of test chamber
- 7 Spent liquid return (optional)
- 8 Reservoir for pressurizing liquid
- 9 Filtration system (optional)

Figure A.1 — General arrangement of test apparatus for assessing freedom from leakage and damage under high static pressure conditions

Annex B
(informative)

Bibliography

- [1] ISO 11070:—¹⁾, *Sterile, single-use intravascular catheter introducers*.

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