INTERNATIONAL STANDARD

ISO 11070

First edition
1998-05-01

Sterile single-use intravascular catheter introducers

Introducteurs de cathéters intravasculaires stériles, non réutilisables

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Reference number
ISO 11070:1998(E)

Contents

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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 11070 was prepared by Technical Committee ISO/TC 84, *Medical devices for injection,* Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use.*

Annexes B, C, D, E, F, G, and H form an integral part of this International Standard. Annexes A and J are for information only.

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Sterile, single-use intravascular catheter introducers

1 Scope

This International Standard specifies requirements for introducer needles, introducer catheters, sheath introducers, guide wires and dilators supplied in the sterile condition, and intended for single use in conjunction with intravascular catheters specified in ISO 10555.

NOTE - Guidance on materials and design of accessory devices is given in annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

NOTE - Schematic examples of the devices covered by this International Standard, with examples of terminology, are given for information in figures 1, 2 and 3.

3.1
coil (of a guide wire)
outer, helically wound wire

3.2
core wire (of a guide wire)
inner wire used to achieve stiffness of the guide wire

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3.3
dilator
flexible, tubular device used for dilating the percutaneous opening into a blood vessel

3.4
distal end
patient end
end of the device which is inserted into the patient

3.5
effective length
length of the device that can be inserted into the body

3.6
guide wire
spring guide
flexible device over which a catheter or dilator is passed to assist in the insertion and location of the catheter or dilator into a blood vessel

NOTE - The guide wire may be pre-formed, such as the J-type guide wire shown in figure 3, have a fixed or movable core, and may also be coated.

3.7
hub
connector(s) at the proximal end of the intravascular catheter introducer which may either be integral with the introducer or be capable of being securely fitted to the proximal end of the introducer

3.8
introducer catheter
short, flexible tube which is introduced into a blood vessel, typically over an introducer needle, and through which a catheter or guide wire can be introduced after removal of the introducer needle

3.9
intravascular catheter introducer
device designed to be used in conjunction with an intravascular catheter to facilitate introduction into the vascular system

3.10
introducer needle
pointed, rigid tube through which a guide wire or catheter can be introduced into a blood vessel

3.11
proximal end
free end
end of the device opposite the distal end

3.12
safety wire (of a guide wire)
additional wire used to minimize the possibility of detachment of the tip

3.13
sheath introducer
flexible tube which is introduced into a blood vessel, typically over a dilator, and through which a guide wire or catheter can be introduced after removal of the dilator

3.14
tip
extremity of the distal end of the device

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a) Introducer catheter b) Introducer needle

Key

1	Effective length	4	Catheter hub (optional)
2	Distal end	5	Introducer needle tube
3	Catheter	6	Needle hub

Figure 1 — Example of an introducer catheter and an introducer needle

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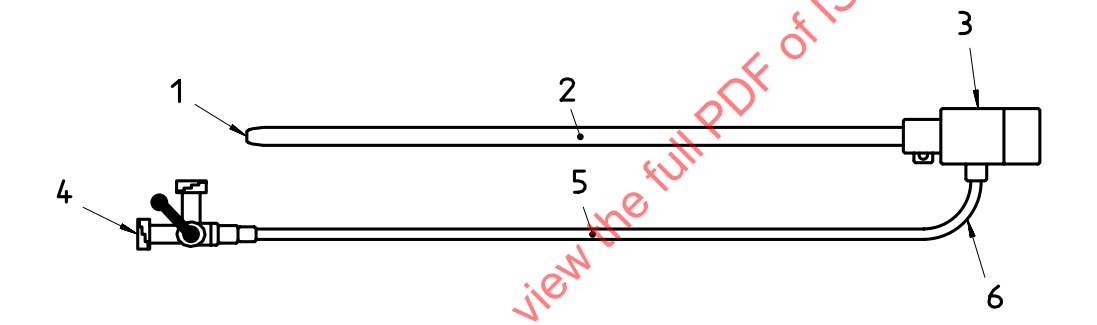
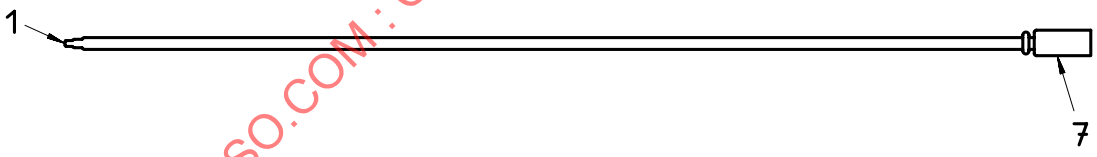
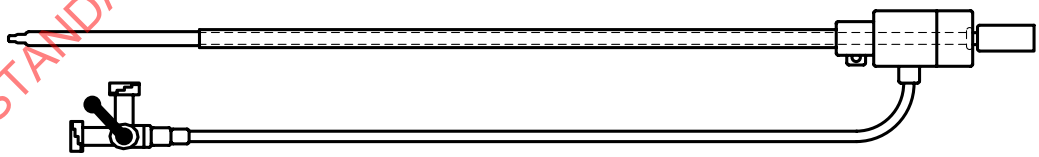


a) Sheath introducer



b) Dilator

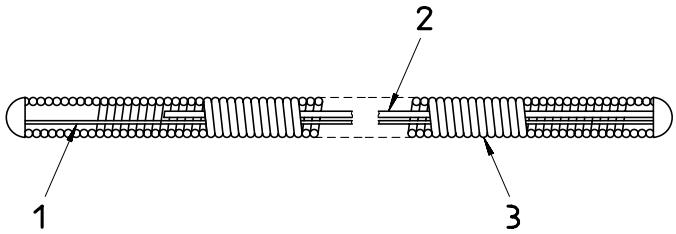


c) Assembled device

Key

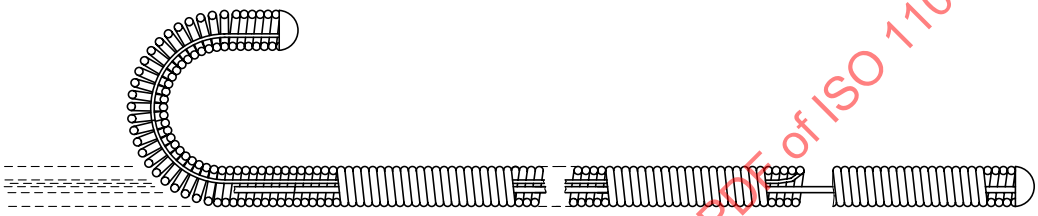
1	Distal end	4	Stopcock with Luer fitting	7	Hub
2	Sheath	5	Sidearm		
3	Haemostasis valve (optional)	6	Sidearm connection (optional)		

Figure 2 — Example of a sheath introducer and a dilator



a) Fixed core guide wire with safety wire

b) Movable core guide wire with safety wire



c) Movable core 'J' guide wire with safety wire

Key

1 Safety wire
2 Core wire
3 Spring coil

Figure 3 — Examples of guide wires

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4 General requirements

4.1 Sterilization

The device shall have been sterilized by a validated method, and shall comply with 4.2 to 4.4 in the sterile condition.

NOTE - See ISO 11134, ISO 11135 and ISO 11137 for appropriate methods of sterilization.

4.2 Biocompatibility

The device shall be free from biological hazard.

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

4.3 Surface

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

NOTE 1 - The external surface of the effective length of the device, including the distal end, should be free from process and surface defects and should cause minimum trauma to vessels during use.

NOTE 2 - If the intravascular catheter introducer is lubricated, the lubricant should not be visible as drops of fluid on the external surface of the effective length of the device when the device is examined under normal or corrected-to-normal vision..

4.4 Corrosion resistance

When tested in accordance with the method given in annex B, metallic components of the device shall show no signs of corrosion that affects functional performance or biocompatibility test results.

4.5 Radiodetectability

All intravascular catheter introducers, except dilators, shall be radiodetectable.

NOTE - At the time of publication of this International Standard, there was no acceptable, validated test method to determine radiodetectability. An approved test method for producing a value of radiodetectability will be established. Until that time, manufacturers may label their products "radio-opaque" provided they can support this claim by demonstrating that they have an appropriate method for showing radio-opacity.

4.6 Information to be supplied by the manufacturer

The manufacturer shall supply at least the information listed in a) to j). All dimensions given shall be expressed in SI units of measurement.

NOTE - Units of other measurement systems may additionally be used.

a) Description of the device;

b) name or trade name and address of manufacturer;

c) lot designation;

d) expiry date or use-by date;

e) any special storage and handling instructions;

f) indication of sterility;

g) method of sterilization;

h) indication for single use;

i) any known incompatibilities with substances likely to be used with the device;

j) instructions for use and warnings, as appropriate.

NOTE - The information may include an indication of radiodetectability.

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5 Additional requirements for introducer needles

5.1 General

The introducer needle shall comply with clause 4.

5.2 Size designation

The nominal size of the introducer needle shall be designated by the outside diameter, inside diameter and the effective length as shown in table 1.

Table 1 — Designation of nominal size of introducer needles and introducer catheters

Dimensions in millimetres

Device diameter	Outside diameter rounded up to nearest:	Inside diameter rounded down to nearest:	Effective length rounded to nearest:
⩾ 0,6 < 0,6	0,1 0,05	0,1 0,05	1,0 1,0

5.3 Needle point

The needle point shall be free from feather edges, burrs, hooks, and shall have a means of protection from damage.

5.4 Hub

5.4.1 Conical fitting

If a hub is provided, the hub shall have a female 6 % (Luer) taper conical fitting complying with ISO 594-1.

5.4.2 Strength of union of needle tube and needle hub

The union of the needle tube and the needle hub shall not be loosened by a force of 10 N for needles of nominal outside diameter of less than 0,6 mm or of 20 N for needles of nominal outside diameter of 0,6 mm or greater.

5.5 Information to be supplied by the manufacturer

The manufacturer shall give the nominal size of the introducer needle as designated in 5.2.

6 Additional requirements for introducer catheters

6.1 General

The introducer catheter shall comply with clause 4.

6.2 Tip

If supplied with an introducer needle, when the needle is fully inserted into the introducer catheter, the catheter shall neither extend beyond the heel of the needle bevel nor be more than 1 mm from it (see figure 4, dimension a).

NOTE - The distal end of the introducer catheter should be designed for ease of insertion and minimum trauma, and should fit closely to the needle.

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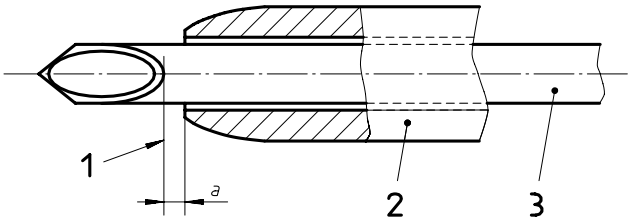

Key

1 Heel of bevel
2 Introducer catheter
3 Introducer needle

Figure 4 — Example of an introducer needle point and an introducer catheter tip

6.3 Force at break

When tested in accordance with the method given in annex C, the minimum force at break of the introducer catheter and the junction between the introducer catheter and the hub shall be as given in table 2.

Table 2 — Minimum force at break of introducer catheter, sheath introducer and dilator test pieces

Smallest outside diameter mm	Minimum force at break N
⩾ 0,550 and < 0,750	3
⩾ 0,750 and < 1,150	5
⩾ 1,150 and < 1,850	10
⩾ 1,850	15

6.4 Hub

If a hub is provided, the hub shall have a female 6 % (Luer) taper conical fitting complying with ISO 594-1.

6.5 Size designation

The nominal size of the introducer catheter shall be designated by the outside diameter, inside diameter and the effective length as shown in table 1.

6.6 Information to be supplied by the manufacturer

If the introducer catheter is supplied with a needle, the manufacturer shall give a statement warning against attempting to re-insert a partially or completely withdrawn needle.

7 Additional requirements for sheath introducers

7.1 General

Sheath introducers shall comply with clause 4.

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7.2 Size designation

The nominal size of the sheath introducer shall be designated by the following:

a) the minimum inside diameter of the sheath expressed in millimetres, rounded down to the nearest 0,1 mm;

b) the effective length expressed in millimetres or centimetres to an accuracy of ± 5 %.

7.3 Freedom from leakage from sheath introducer

When tested as described in annex D, using a test pressure of 300 kPa[1)], there shall be no leakage sufficient to form a falling drop.

7.4 Freedom from leakage through haemostasis valve

If the sheath introducer has an integral haemostasis valve, when tested as described in annex E there shall be no leakage past the haemostasis valve.

7.5 Hub

If a hub or hubs are provided, hubs shall have a female 6 % (Luer) taper lock fitting complying with ISO 594-2.

7.6 Force at break

When tested by the method given in annex C, the minimum force at break of the sheath introducer and the junction between the sheath introducer and the hub shall be as given in table 2.

7.7 Information to be supplied by the manufacturer

The manufacturer shall give the nominal size of the sheath introducer as designated in 7.2.

8 Additional requirements for guide wires

8.1 General

Guide wires shall comply with clause 4.

8.2 Size designation

The nominal size of the guide wire shall be designated by the following:

a) the maximum outside diameter, expressed in millimetres, rounded up to the nearest 0,01 mm;

b) the length, expressed in millimetres or centimetres, to an accuracy of ± 5 %.

8.3 Safety wire

A safety wire shall be provided unless the core wire is attached to the tip.

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[1)] 300 kPa = 3 bar

8.4 Fracture test

When tested in accordance with annex F, the guide wire, excluding the region of fixation and the first turn, shall show no signs of fracture, and coated guide wires shall show no flaking of the coating.

8.5 Flexing test

When tested in accordance with annex G, neither the distal end of the guide wire nor the remaining portion of the guide wire shall show signs of defects or damage, and coated guide wires shall show no flaking of the coating.

8.6 Strength of union of safety wire and coil

When tested in accordance with annex H, the unions of the safety wire at the tip and at the proximal end shall not be loosened.

8.7 Strength of union of core wire and coil

When tested in accordance with annex H, the unions of the core wire and the coil of the guide wire at both the tip and the proximal end of guide wires which are not fitted with a safety wire shall not be loosened.

8.8 Information to be supplied by the manufacturer

The manufacturer shall give the following information:

a) the nominal size of the guide, as designated in 8.2;

b) the nominal type of distal end, e.g. straight, J (including radius of curve) or other form;

c) if the core wire is moveable, a statement to that effect.

9 Additional requirements for dilators

9.1 General

Dilators shall comply with clause 4.

9.2 Size designation

The nominal size of the dilator shall be designated by:

a) the maximum outside diameter, in millimetres, rounded up to the nearest 0,1 mm;

b) the minimum internal diameter, expressed in millimetres, rounded down to the nearest 0,1 mm;

c) the effective length, expressed in centimetres, to an accuracy of ± 5 %.

9.3 Hub

9.3.1 General

A hub shall be provided.

9.3.2 Conical fitting

If the hub includes a female 6 % (Luer) fitting, the fitting shall comply with ISO 594-1.

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9.3.3 Strength of union between hub and dilator

When tested by the method given in annex C, the minimum force at break of the dilator and the junction between the dilator and the hub shall be as given in table 2.

9.4 Information to be supplied by the manufacturer

The manufacturer shall give the nominal size of the dilator as designated in 9.2.

10 Additional requirements for kits containing combinations of devices specified in this International Standard

For kits of combinations of two or more different devices specified in this International Standard, the manufacturer shall give the appropriate dimensions listed in table 3.

Sizes shall be designated as specified in the relevant clauses of this International Standard.

NOTE - Many devices covered by this International Standard are commonly packaged in kits, thus all the dimensions specified for individual devices in this International Standard may not be necessary because the manufacturer will have ensured that the components of the kit will mate together properly.

Table 3 — Dimensions to be given for kits

Kit contents	Dimensions to be given
Introducer catheter	Catheter outside diameter Catheter length
Sheath introducer	Sheath inside diameter Sheath length
Guide wire	Guide wire outside diameter Guide wire length
Dilator	Dilator outside diameter Dilator inside diameter

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Annex A
(informative)

Guidance on materials and design

A.1 Sheath introducers

The tip of the sheath introducer should be designed so as to minimize rollback of the sheath when entering the body tissues.

The tip of the sheath introducer should fit closely to the dilator and remain free from cracks during normal use.

The radial rigidity of the sheath introducer should be such that the introducer remains patent upon removal of the dilator. The sheath introducer should be sufficiently flexible to permit manipulation but should not kink under conditions of normal use.

A.2 Guide wires

Heparin and/or other coatings may be applied. Any coating processes, for example «curing», should not affect the physical characteristics of the guide wire.

A.3 Dilators

The dilator should have a certain flexibility, but sufficient rigidity to dilate the opening of the blood vessel into which it is percutaneously inserted. The tip should be designed so as to minimize rollback when entering body tissues.

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Annex B
(normative)

Test for corrosion resistance

B.1 Principle

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

B.2 Reagents

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

B.2.2 Distilled or deionized water.

B.3 Apparatus

B.3.1 Borosilicate glass beakers.

B.4 Procedure

Immerse the device in the saline solution (B.2.1) in a glass beaker (B.3) at (22 ± 5) °C for 5 h. Remove the test specimen and immerse it in boiling distilled or deionized water (B.2.2) for 30 min. Allow the water and the test specimen to cool to (37 ± 2) °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.

B.5 Test report

The test report shall include the following information:

a) identity of the device;

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

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Annex C
(normative)

Determination of force at break of introducer catheters, sheath introducers and dilators

C.1 Principle

Test pieces of an introducer catheter are chosen so that the tubular portion and the junction between hub and tubing is tested. A tensile force is applied to each test piece until the tubing breaks or the junction separates.

C.2 Apparatus

C.2.1 Tensile testing apparatus, capable of exerting a force of greater than 15 N.

C.3 Procedure

C.3.1 Select a test piece from the introducer catheter to be tested. Include in the test piece the hub, if present.

C.3.2 Condition the test piece in an atmosphere of 100% relative humidity or water and a temperature of (37 ± 2) °C for 2 h. Test immediately after conditioning.

C.3.3 Fix the test piece in the tensile testing apparatus. If a hub is present, use an appropriate fixture to avoid deforming the hub.

C.3.4 Measure the gauge length of the test piece (i.e. the distance between the jaws of the tensile testing apparatus or the distance between the hub and the jaw holding the other end of the test piece, as appropriate).

C.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/mm of gauge length (see table C.1) until the test piece separates into two or more pieces.

Note the value of the applied tensile force, in newtons, at which separation occurs, and record this value as the force at break.

Table C.1 — Examples of conditions for a 20 mm/min/mm strain rate

Gauge length mm	**Testing speed** mm/min
10	200
20	400
25	500

C.4 Test report

The test report shall include the following information:

a) identity of the introducer catheter;

b) the force at break, in newtons, and outside diameter of each test piece.

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Annex D
(normative)

Test for liquid leakage from sheath introducers under pressure

D.1 Principle

The sheath introducer is connected, via a leak-proof connection, to a syringe. A hydraulic pressure is applied to the sheath introducer and the test specimen inspected for leakage.

D.2 Reagent

D.2.1 Distilled or deionized water.

D.3 Apparatus

D.3.1 Leakproof connector, to connect tip of sheath introducer to syringe (D.3.2), fitted with gauge capable of measuring up to 350 kPa pressure and having a small internal volume.

D.3.2 10 ml syringe, which has passed the tests for leakage past the piston and nozzle as specified in ISO 7886-1.

D.3.3 Means for occluding the outlet(s) of test specimen, (e.g. clamp(s), plug(s)).

D.4 Procedure

D.4.1 Connect the tip of the sheath introducer (see figure D.1) to the syringe (D.3.2), via the leak-proof connector (D.3.1).

D.4.2 Fill the syringe with water (D.2) at (22 ± 2) °C and expel the air. Adjust the volume of water in the syringe to the nominal graduated capacity. Occlude (D.3.3) all outlets of the device, including the outlet(s) of integral haemostasis valve(s), sidearm(s) etc., if present.

D.4.3 Position the apparatus so that the axis of the connection between syringe and sheath introducer is horizontal. Apply an axial force to the syringe so that a pressure of 300 kPa to 320 kPa is generated by the relative action of the piston and barrel. Maintain the pressure for 30 s. Examine the test specimen for liquid leakage (i.e. the formation of one or more falling drops of water) and record whether or not leakage occurs.

D.5 Test report

The test report shall include the following information:

a) identity of the sheath introducer;

b) statement as to whether leakage occurred.

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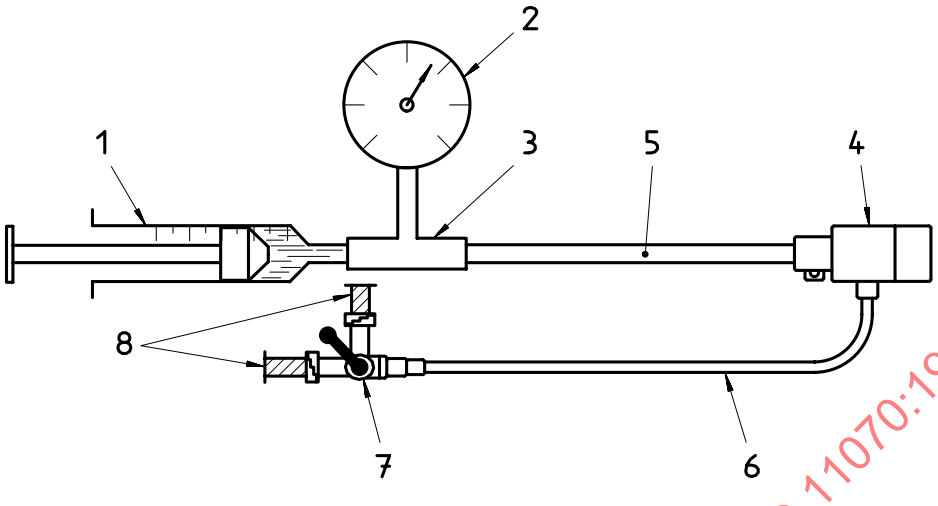

Key

1	10 ml syringe (D.3.2)	5	Sheath introducer
2	Pressure gauge (D.3.2)	6	Sidearm
3	Leakproof connector (D.3.3)	7	Stopcock
4	Haemostasis valve [outlet occluded (D.3.3)]	8	Outlet(s) occluded (D.3.3)

Figure D.1 — Apparatus for testing liquid leakage from sheath introducers

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Annex E
(normative)

Test for liquid leakage through haemostasis valves of sheath introducers

E.1 Principle

The sheath introducer is connected, via a leak-proof connector, to a syringe. A hydraulic pressure is applied to the sheath introducer and the test specimen inspected for leakage.

E.2 Reagent and apparatus

Use the reagent and apparatus described in D.2 and D.3.

E.3 Procedure

Follow the procedure described in D.4, except:

a) in D.4.2, do not occlude the outlet(s) of the haemostasis valve; for compression valves, insert the appropriate catheter and actuate the valve in accordance with its operating instructions;

b) in D.4.3, generate a pressure of 38 kPa to 42 kPa and examine the outlet(s) of the haemostasis valve or compression valve for liquid leakage.

E.4 Test report

The test report shall include the following information:

a) identity of the sheath introducer;

b) statement as to whether leakage occurred from outlet of haemostasis valve.

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Annex F
(normative)

Test for fracture of guide wires

F.1 Principle

The guide wire is wound around a cylindrical former, then unwound and examined for fractures.

F.2 Apparatus

F.2.1 Cylindrical former, of diameter equal to ten times the maximum outside diameter of the guide wire (see 8.2).

F.2.2 Support, for both ends of the cylindrical former.

F.2.3 Clamp, for restraining and retaining the distal end of the guide wire.

NOTE - Typical apparatus is shown in figure F.1.

F.3 Procedure

Fix the former (F.2.1) into the supports (F.2.2). Fix the distal end of the guide wire into the clamp (F.2.3) at a point 10 mm from the former. Wind the guide wire tightly around the former for at least eight complete turns. Unwrap the guide wire and examine it for fracture caused by the procedure. Disregard any fracture occurring in the region of fixation and the first turn. When testing coated guide wires, additionally examine the coating for signs of flaking, disregarding any such signs in the region of fixation and the first turn.

F.4 Test report

The test report shall include the following information:

a) Identity of the guide wire.

b) A statement as to whether fracture of the guide wire occurred, and whether there was any flaking of the coating of coated guide wires in the test region.

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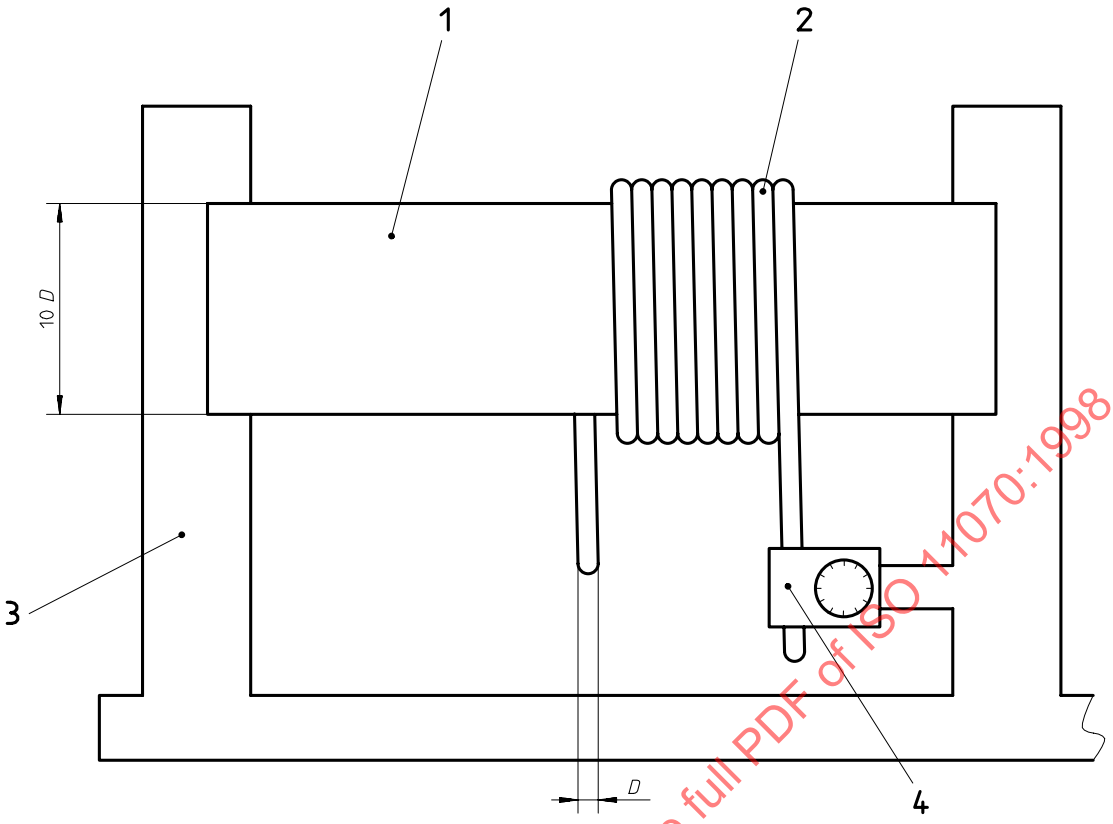

Key

1	Cylindrical former	3	Support
2	Guide wire	4	Clamp

Figure F.1 — Apparatus for testing guide wires for fracture

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