INTERNATIONAL STANDARD

ISO 11070

Second edition
2014-11-01

Sterile single-use intravascular introducers, dilators and guidewires

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables

Reference number
ISO 11070:2014(E)

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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.

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 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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 11070:1998), which has been technically revised.

Introduction

The purpose of this International Standard is to

— update requirements and test methods to support the function of the guidewire, and

— update size designation.

Sterile single-use intravascular introducers, dilators and guidewires

1 Scope

This International Standard specifies requirements for introducer needles, introducer catheters, sheath introducers, guidewires, and dilators supplied in the sterile condition, and intended for single use in conjunction with intravascular catheters specified in ISO 10555-1.

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

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

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

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

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

NOTE Schematic examples of the devices covered by this International Standard, with examples of terminology, are given for information in Figure 1, Figure 2, Figure 3, and Figure 4.

3.1
coil (of a guidewire)
helically wound wire

3.2
core wire (of a guidewire)
wire used to achieve stiffness of the *guidewire* (3.6)

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

1) Upon its publication, ISO 80369-7 will replace ISO 594-1:1986.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2:1998.

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
guidewire
flexible device over which a catheter or *dilator* (3.3) is passed to assist in the insertion and location of the catheter or dilator into a blood vessel

Note 1 to entry: Examples of guidewire types are shown in Figure 3.

3.7
hub
connector(s) at the proximal end of the intravascular catheter introducer, which can 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 guidewire 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

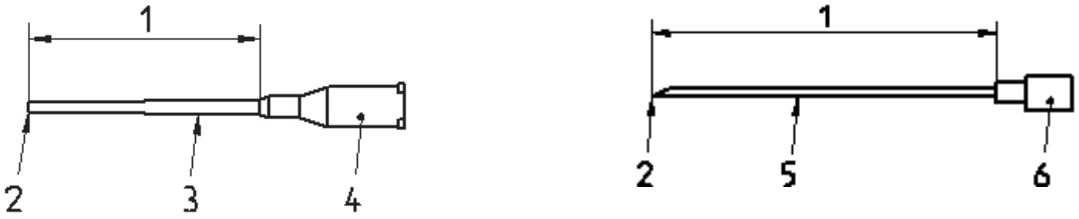
3.10
introducer needle
pointed, rigid tube through which a *guidewire* (3.6) or catheter can be introduced into a blood vessel

3.11
proximal end
free end
end of the device opposite the *distal end* (3.4)

3.12
safety wire (of a guidewire)
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* (3.3), and through which a guidewire or catheter can be introduced after removal of the dilator

3.14
tip
extremity of the *distal end* (3.4) of the device

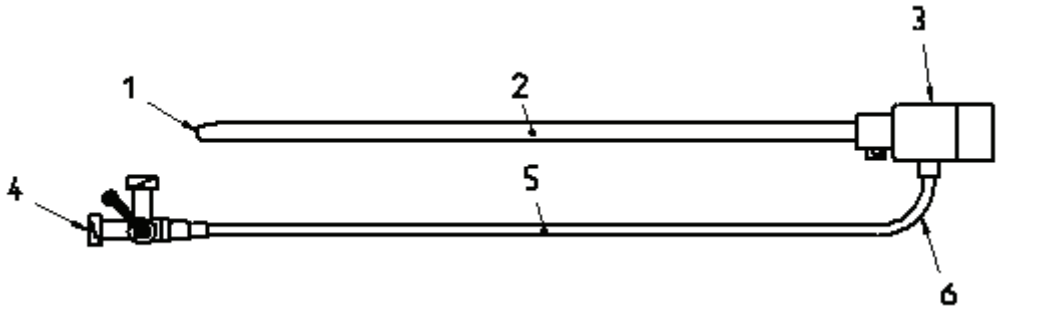


a) Introducer catheter **b) Introducer needle**

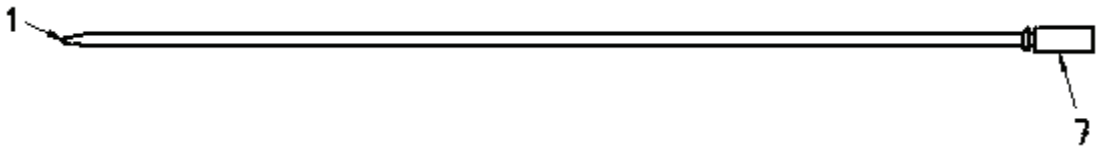
Key

1 effective length
2 distal end
3 catheter
4 catheter hub (optional)
5 introducer needle tube
6 needle hub

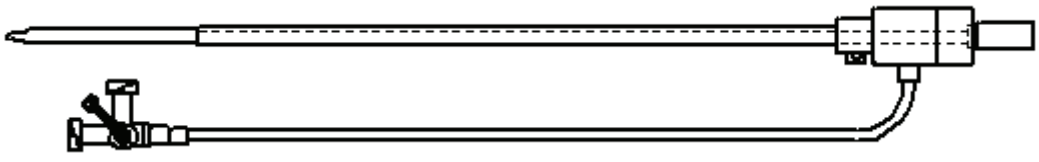
Figure 1 — Example of an introducer catheter and an introducer needle



a) Sheath introducer



b) Dilator

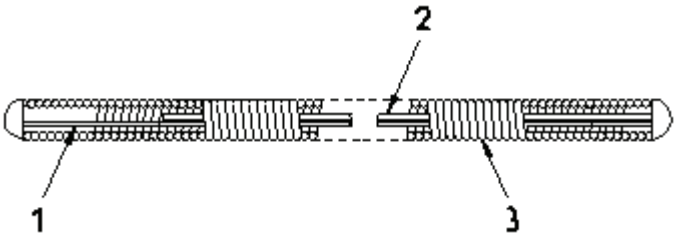


c) Assembled device

Key

1 distal end
2 sheath
3 haemostasis valve (optional)
4 stopcock with Luer fitting
5 sidearm
6 sidearm connection (optional)
7 hub

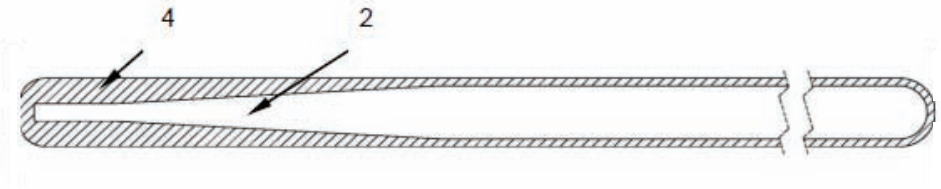
Figure 2 — Example of a sheath introducer and a dilator



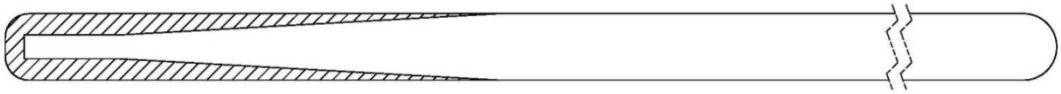
a) Fixed core guidewire with safety wire

b) Movable core guidewire with safety wire

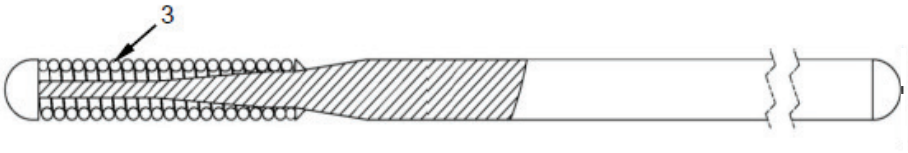
c) Movable core 'J' guidewire with safety wire



d) Guidewire with full length polymer jacket



e) Mandrel guidewire with distal polymer jacket



f) Mandrel guidewire with distal coils

Key

1 safety wire
2 core wire
3 spring coil
4 polymer jacket

Figure 3 — Examples of guidewires

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 applicable part(s) of ISO 17665, ISO 11135, and ISO 11137 for appropriate methods of sterilization.

4.2 Biocompatibility

The device shall be free from biological hazard in accordance with appropriate testing under ISO 10993-1.

4.3 Surface

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

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

If the intravascular catheter introducer is lubricated, the lubricant shall 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, if metallic components of the device show visible signs of corrosion that can affect functional performance, the level of corrosion shall be evaluated with respect to intended use and risk assessment.

4.5 Radio-detectability

Parts of the device 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.

4.6 Information to be supplied by the manufacturer

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

Units of other measurement systems can additionally be used.

Where appropriate, ISO 15223-1 should be used.

The following are the descriptions of the device:

a) name or trade name and address of the manufacturer;

b) batch code, preceded by the word LOT, or the serial number or the appropriate symbol;

c) expiry date or use-by date expressed according to ISO 8601;

d) any special storage and/or handling conditions;

e) the word STERILE or the appropriate symbol;

f) method of sterilization;

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

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

i) instructions for use and warnings, as appropriate.

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	0,1	0,1	1,0
<0,6	0,05	0,05	1,0

5.3 Needle point

When examined under 2,5x magnification, the needle point shall appear sharp and free from feather edges, burrs, and hooks (see ISO 7864).

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 and/or ISO 594-2.

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

5.4.2 Strength of union of needle tube and needle hub

When tested by the method given in Annex I, 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

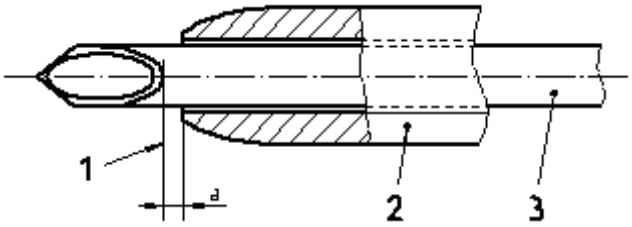
6.1 General

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).

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



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 Peak tensile force

When tested in accordance with the method given in Annex C, the peak tensile force of the introducer catheter and the junction between the introducer catheter and the hub shall be as given in Table 2.

Table 2 — Peak tensile force of introducer catheter, sheath introducer, and dilator test pieces

Smallest outside diameter mm	Minimum peak tensile force N
≥0,550 and <0,750	3
≥0,750 and <1,150	5
≥1,150 and <1,850	10
≥1,850	15
NOTE ISO 11070 does not specify requirements for peak tensile force for introducer catheter, sheath introducer, and dilator test pieces of less than 0,55 mm outside diameter. These values are determined by the manufacturer based on risk assessment.	

6.4 Hub

If a hub is provided, the hub shall have a female 6 % (Luer) taper conical fitting complying with ISO 594-1 and/or ISO 594-2.

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

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.

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;

NOTE The recommended compatible-sized device that can be accepted throughout the sheath, including fittings, and valves, can also be expressed.

b) the nominal effective length expressed in millimetres or centimetres.

7.3 Freedom from leakage from sheath introducer

When tested as described in Annex D, using a minimum test pressure of 300 kPa (300 kPa = 3 bar), 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 Peak tensile force

When tested by the method given in Annex C, the minimum peak tensile force 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 guidewires

8.1 General

Guidewires shall comply with Clause 4.

8.2 Size designation

The nominal size of the guidewire shall be designated by the following:

a) the maximum outside diameter, expressed in millimetres, rounded up to the nearest 0,01 mm. Additionally, the diameter can be expressed in 1/1 000 inches;

b) the nominal length, expressed in millimetres or centimetres.

8.3 Safety wire

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

8.4 Fracture test

When tested in accordance with Annex F, the guidewire shall not fracture, loosen, or fail in such a manner that

a) any section of coil is left free to stretch,

b) a sharp, or potentially traumatic fracture surface is exposed, or

c) any part of the device becomes separated such that it would not be removable by withdrawing the device from use.

8.5 Flexing test

When tested in accordance with Annex G, the guidewire shall not fracture, loosen, or fail in such a manner that

a) any section of coil is left free to stretch,

b) a sharp, or potentially traumatic fracture surface is exposed,

c) any part of the device becomes separated such that it would not be removable by withdrawing the device from use, or

d) coated guidewires show flaking of the coating.

8.6 Peak tensile force of guidewire

When tested in accordance with the method given in Annex H, the peak tensile force of the guidewire and any critical junctions shall be as given in Table 3.

NOTE Any connection external to the body is not subject to the tensile requirements of Annex H.

Table 3 — Peak Tensile Force of guidewires

Diameter of guidewire mm	**Peak tensile force** N
≥0,55 and <0,75	5
≥0,75	10
NOTE ISO 11070 does not specify requirements for peak tensile force for guidewires of less than 0,55 mm outside diameter. These values are determined by the manufacturer based on risk assessment.	

8.7 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, and

c) the effective length, expressed in centimetres.

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 and/or ISO 594-2.

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 4.

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 might not be necessary because the manufacturer will have ensured that the components of the kit will mate together properly.

Table 4 — 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
Guidewire	Guidewire outside diameter Guidewire length
Dilator	Dilator outside diameter Dilator inside diameter

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 Guidewires

Surface coatings can be applied. If coating is applied, the guidewire shall meet all applicable requirements of this International Standard.

Guidewire tip should be designed to minimize trauma; clinical risk assessment can be applied.

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.

Annex B
(normative)

Test method 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

B.4.1 Immerse the device in the saline solution (B.2.1) in a glass beaker (B.3) at (22 ± 5) °C for 5 h.

B.4.2 Remove the test specimen and immerse it in boiling distilled or deionized water (B.2.2) for 30 min.

B.4.3 Allow the water and the test specimen to cool to (37 ± 2) °C, and maintain them at this temperature for 48 h.

B.4.4 Remove the test specimen and allow it to dry at room temperature.

B.4.5 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.

Additional testing can be performed using alternate durations and temperatures using appropriate risk-based clinical justification.

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.

Annex C
(normative)

Method for determining peak tensile force of introducer catheters, sheath introducers, and dilators

C.1 Principle

Test pieces or the entire length of a device are chosen so that each tubular portion, each junction between hub or connector and tubing, and each junction between tubular portions 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 device to be tested. Include in the test piece the hub or connector, if present, and the junctions between the segments.

C.3.2 Place the test pieces to be conditioned (see C.3.1) in an appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time. Test in accordance with C.3.3 to C.3.8 immediately after conditioning.

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

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 or connector 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 catheter test piece separates into two or more pieces. Record the peak tensile force in newtons.

C.3.6 If testing a device that consists of a single tubular portion having regions of different outside diameter, the test piece should include the smallest diameter.

C.3.7 If testing a device that has a sidearm or sidearms,

a) repeat C.3.2 to C.3.5 on each sidearm,

b) repeat C.3.2 to C.3.5 on a test piece that includes the joint between a sidearm and the adjacent part of that portion of the device intended to be introduced into the body, and

c) repeat C.3.7 item b) for each joint.

C.3.8 Do not perform more than one test on any test piece.

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 device;

b) the peak tensile force, in newtons;

c) the location of the failure.

Annex D
(normative)

Test method 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 the tip of the sheath introducer to syringe (D.3.2), fitted with gauge capable of measuring at least 300 kPa pressure and having a small internal volume.

D.3.2 Syringe of suitable size, which has passed the tests for leakage past the piston and nozzle as specified in ISO 7886-1 or equivalent equipment.

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 sheath introducer (see Figure D.1 as an example) to the syringe (D.3.2), via the leak-proof connector (D.3.1).

D.4.2 Fill the syringe with water (D.2.1) 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.

NOTE The device can be pressurized through the stopcock and occluded at the distal end.

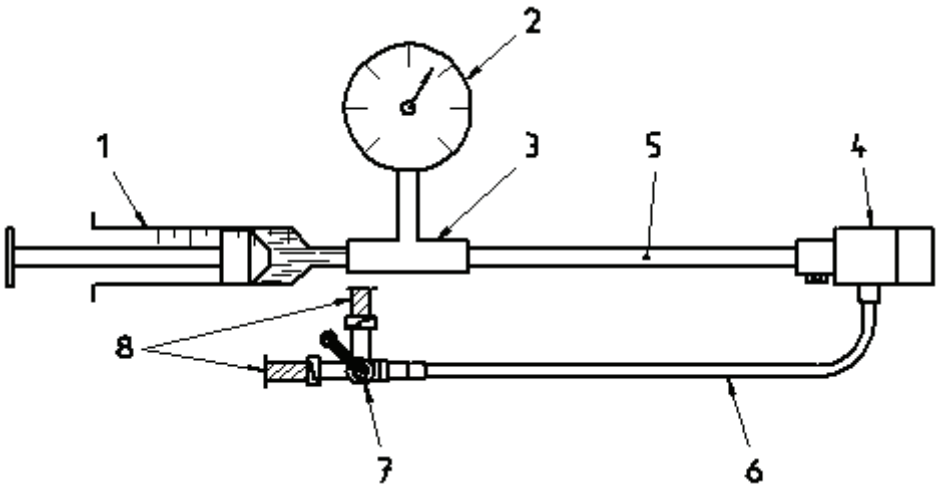
D.4.3 Position the apparatus so that the axis of the connection between syringe and sheath introducer is horizontal. Apply an axial force to the syringe so that a minimum pressure of 300 kPa is generated by the relative action of the piston and barrel. Maintain the pressure for 30 s. Examine the test 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.



Key

1 syringe
2 pressure gauge
3 leakproof connector (D.3.1)
4 haemostasis valve (outlet occluded)
5 sheath introducer
6 sidearm
7 stopcock
8 outlet(s) occluded

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

Annex E
(normative)

Test method 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 minimum pressure of 38 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.

Annex F
(normative)

Test method for fracture of guidewires

F.1 Principle

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

F.2 Apparatus

F.2.1 Cylindrical former, of diameter equal to 10 times the maximum outside diameter of the guidewire (see 8.2). A different diameter cylindrical former can be used with appropriate risk-based clinical justification (see key 1 in Figure F.1).

F.2.2 Support, for both ends of the cylindrical former (see key 3 in Figure F.1).

F.2.3 Securement, hole in the former (see key 4 in Figure F.1) for guidewire (see key 2 in Figure F.1).

NOTE Typical apparatus is shown in Figure F.1.

F.3 Procedure

F.3.1 Fix the former (F.2.1) into the supports (F.2.2).

F.3.2 Fix the distal end of the guidewire by inserting into the hole in the former (F.2.3). Secure by holding while doing the first turn.

F.3.3 Wind the guidewire tightly around the former by turning the handle and holding the guidewire tight. Wind at least eight complete turns. A reduced number of turns can be used with appropriate risk-based clinical justification.

F.3.4 Unwrap the guidewire and examine it for fracture caused by the procedure. Disregard any fracture occurring in the region of fixation and the first turn.

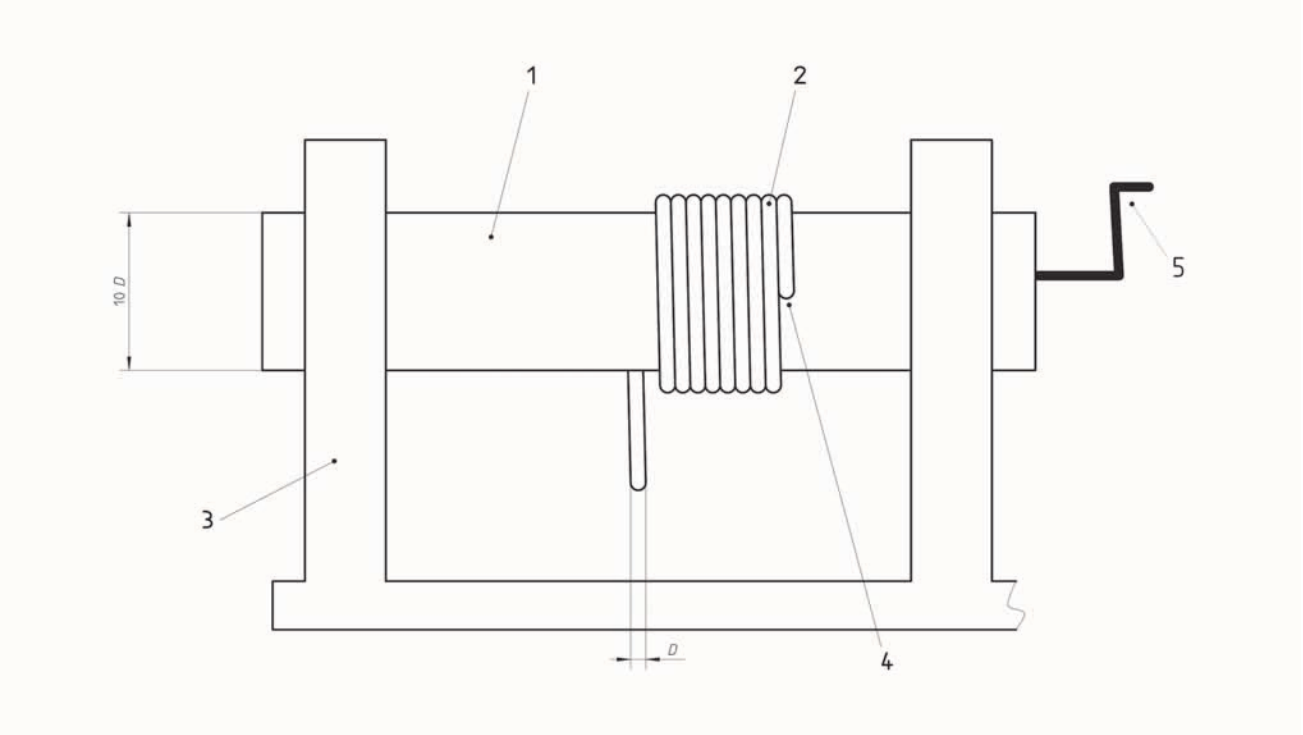
F.4 Test report

The test report shall include the following information:

a) identity of the guidewire;

b) a statement as to whether fracture of the guidewire occurred;

c) an appropriate risk-based clinical justification if deviations in diameter or numbers of turns are made.



Key

1 cylindrical former
2 guidewire
3 support for rotating former
4 hole through cylindrical former
5 handle rotating the former

NOTE The apparatus in the figure is an example that has been found to be suitable, but is not intended to preclude other designs or sizes of apparatus from being used.

Figure F.1 — Apparatus for testing guidewires for fracture

Annex G
(normative)

Test method for resistance of guidewires to damage by flexing

G.1 Principle

The portion of the guidewire under test is subjected to repeated reverse bending and straightening, then examined for damage and flaking of the coating.

G.2 Apparatus

G.2.1 Test rig, comprising two rigid cylindrical formers, each of diameter equal to 20 times the maximum outside diameter of the guidewire (see 8.2), and positioned so that there is a gap of one to three times the maximum outside diameter of the guidewire between them. See Figure G.1. Different diameter cylindrical formers can be used when testing each portion of the device with appropriate risk-based clinical justification.

G.3 Procedure

G.3.1 Test for the distal end.

G.3.1.1 Select a portion of the distal end of the guidewire in a region that includes the core wire approximately 5 mm from the end of the core wire.

G.3.1.2 Bend this portion of the distal end around one former of the test rig (G.2) and in the opposite direction around the second former. (See Figure G.1.)

G.3.1.3 Remove the guidewire from the formers, straighten it, and repeat the bending and straightening procedure for a total of 20 cycles. Examine the guidewire for defects and damage caused by the bending procedure. Additionally, examine the coating of coated guidewires for signs of flaking.

G.3.2 Test for guidewire, excluding distal end.

Select a portion of the guidewire that does not include the proximal end or the distal end. Carry out the procedure described in G.3.1.2 and G.3.1.3.

G.4 Test report

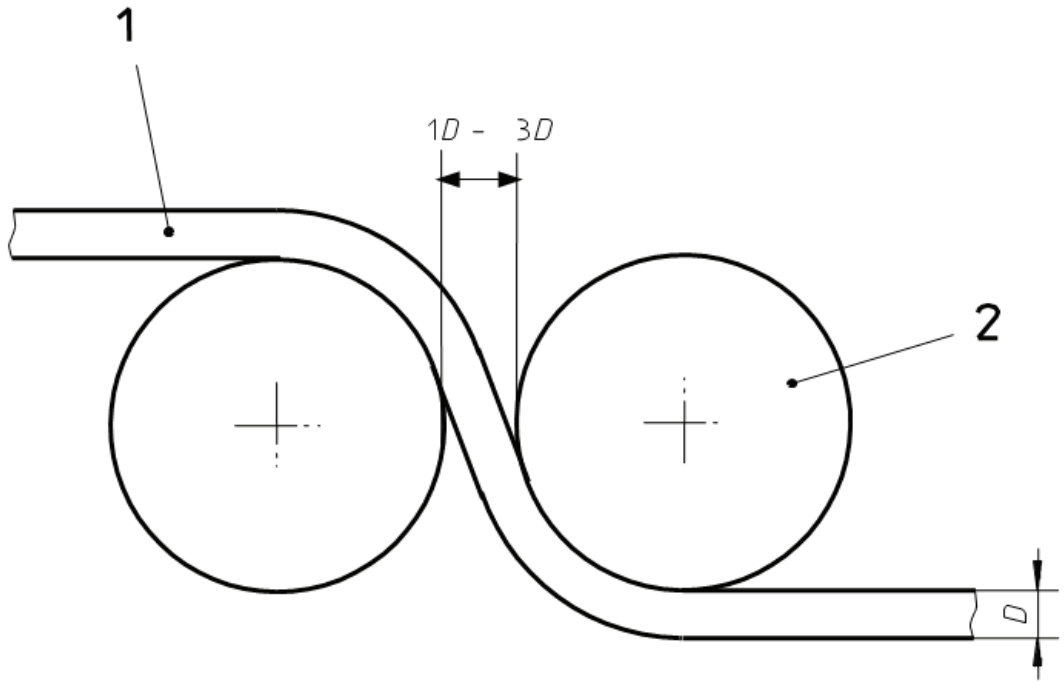
The test report shall include the following information:

a) identity of the guidewire;

b) a statement as to whether there was any damage to the point where any section of coil is left free to stretch or any section of the guidewire separates into two or more pieces;

c) a statement as to whether there was any flaking of the coating of coated guidewires;

d) an appropriate risk-based clinical justification if deviations in diameter are made.



Key

1 guidewire

2 former

Figure G.1 — Test rig for testing flexibility of guidewires

Annex H
(normative)

Method for determining peak tensile force of guidewires

H.1 Principle

Peak tensile force for critical junctions that can result in failure shall be evaluated. Any connection external to the body is not subject to the tensile requirements listed. A tensile force is applied to each test piece until failure occurs.

H.2 Apparatus

H.2.1 **Tensile testing apparatus**, capable of exerting a force of 10 N.

H.2.2 **Split-tapered clamp**, of general arrangement shown in Figure H.1, or alternative arrangement.

H.2.3 **Rubber-faced pneumatic grips**, or alternative gripping arrangement.

H.3 Procedure

H.3.1 Select a test piece from the device to be tested. Include in the test piece the critical junctions.

H.3.2 Attach the selected split-tapered clamp (H.2.2) to the moving crosshead of the tensile testing apparatus (H.2.1) and attach the pneumatic grips (H.2.3) to the fixed head.

H.3.3 Secure one end of the guidewire to the split-tapered clamp, ensuring that the clamp bears only on the end piece, and grip the guidewire at approximately its central point in the pneumatic grips, ensuring that the point of application of the grips is at least 150 mm from the split-tapered clamp.

H.3.4 Apply a tensile force at a rate of 10 mm/min until failure occurs.

H.4 Test report

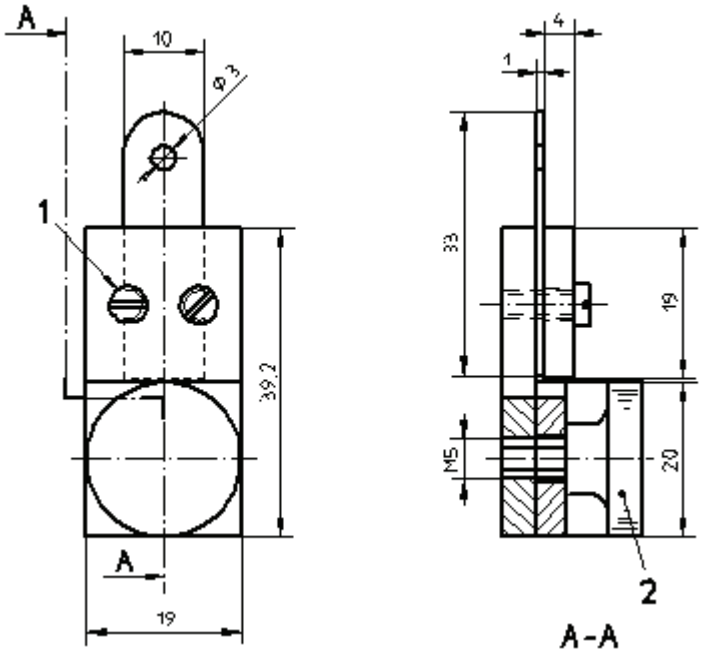
The test report shall include the following information:

a) the identity of the guidewire;

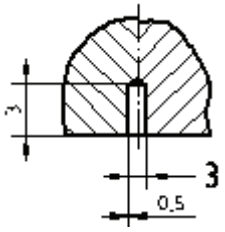
b) the peak tensile force, in newtons.

c) the location of the failure

Dimensions in millimetres



a) Clamp



b) Enlarged view of guidewire location

Key

1 M3,0 × 8,0 lg typ.2 posn.

2 M5,0 knurled knob

3 dimension *a* (0,02 mm less than minimum diameter of guidewire to be tested)

NOTE With the exception of dimension *a* which is critical, the dimensions in Figure H.1 are examples that have been found suitable, but are not intended to preclude other designs or sizes of clamps being used.

Figure H.1 — Example of a split-tapered clamp

Annex I
(normative)

Determination of strength of union of needle hub and needle

I.1 Principle

A force is applied (successively tensile and compressive) to the needle tube and needle hub and the tube-hub union is then examined for loosening.

I.2 Apparatus

I.2.1 **Tensile-testing apparatus**, capable of exerting forces of up to 20 N with an accuracy of ±1 %.

I.3 Test procedure

I.3.1 Condition the needle in an atmosphere of 40 % to 60 % relative humidity and a temperature of (22 ± 2) °C for 2 h immediately before the test.

I.3.2 Clamp the needle tube and the needle hub in the jaws of the tensile-testing apparatus and apply successively, once each, at a rate of 100 mm/min, a tensile and a compressive force of

— 10 N when testing needles of nominal outside diameter less than 0,6 mm, and

— 20 N when testing needles of nominal outside diameter 0,6 mm or greater.

I.3.3 Examine the union of needle tube and needle hub and record whether the needle tube has been loosened.

I.4 Test report

The test report shall include the following information:

a) identity of the needle;

b) outside diameter of the needle, expressed in millimetres;

c) load applied (i.e. 10 N or 20 N);

d) whether or not the needle tube was loosened in the hub.

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