INTERNATIONAL STANDARD

ISO 11070

First edition
1998-05-01

Sterile single-use intravascular catheter introducers

Introducteurs de cathéters intravasculaires stériles, non réutilisables

Contents

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X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

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.

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

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

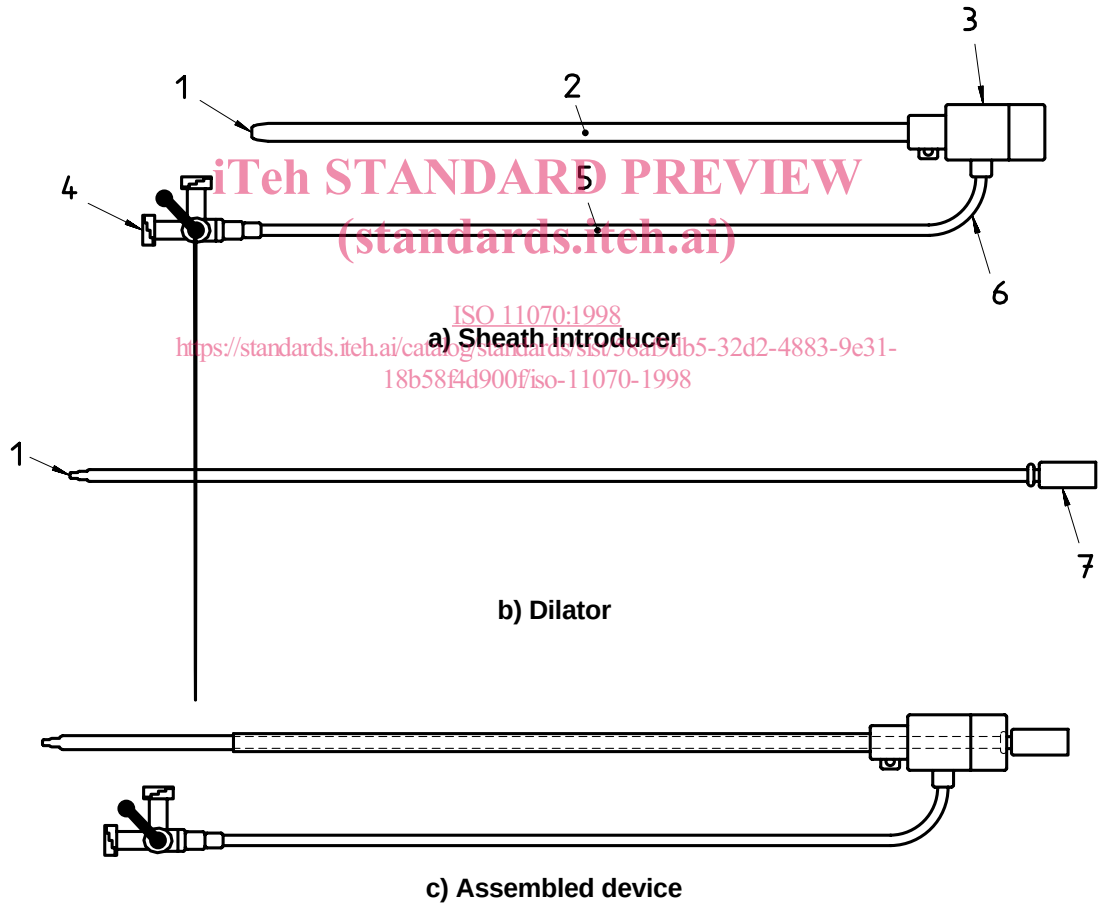
3.14
tip
extremity of the distal end of the device

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



a) Sheath introducer

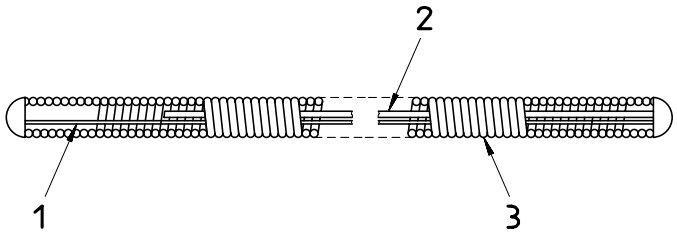
b) Dilator

c) Assembled device

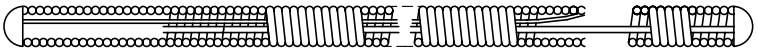
Key

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

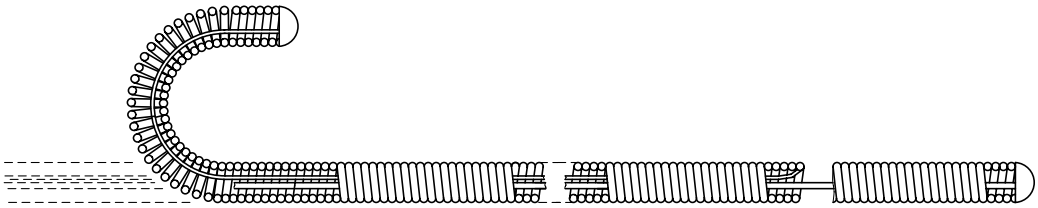
Figure 2 — Example of a sheath introducer and a dilator



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

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.

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

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

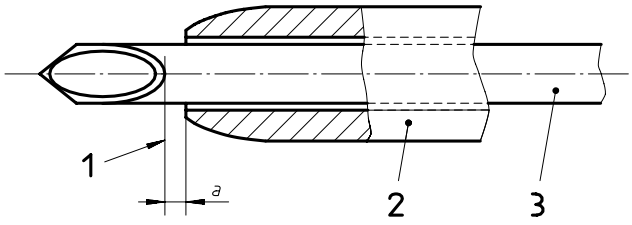
6.1 General

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.



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

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.