
**Sterile single-use intravascular
introducers, dilators and guidewires**

*Introduceurs, dilatateurs et guides intravasculaires stériles non
réutilisables*

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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

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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 594-1¹⁾, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2²⁾, *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)

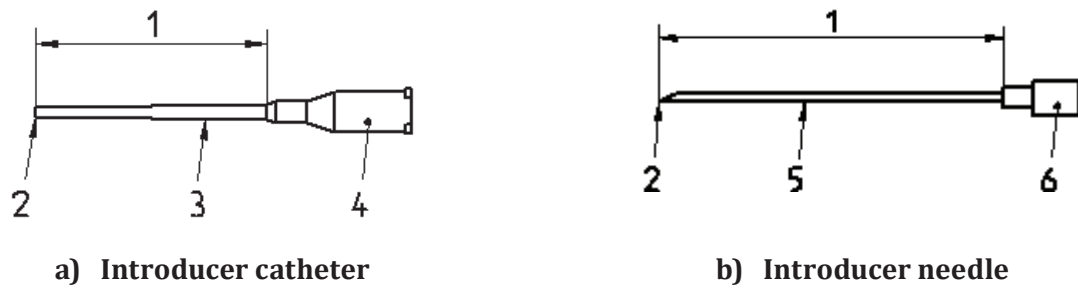
additional wire used to minimize the possibility of detachment of the tip

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

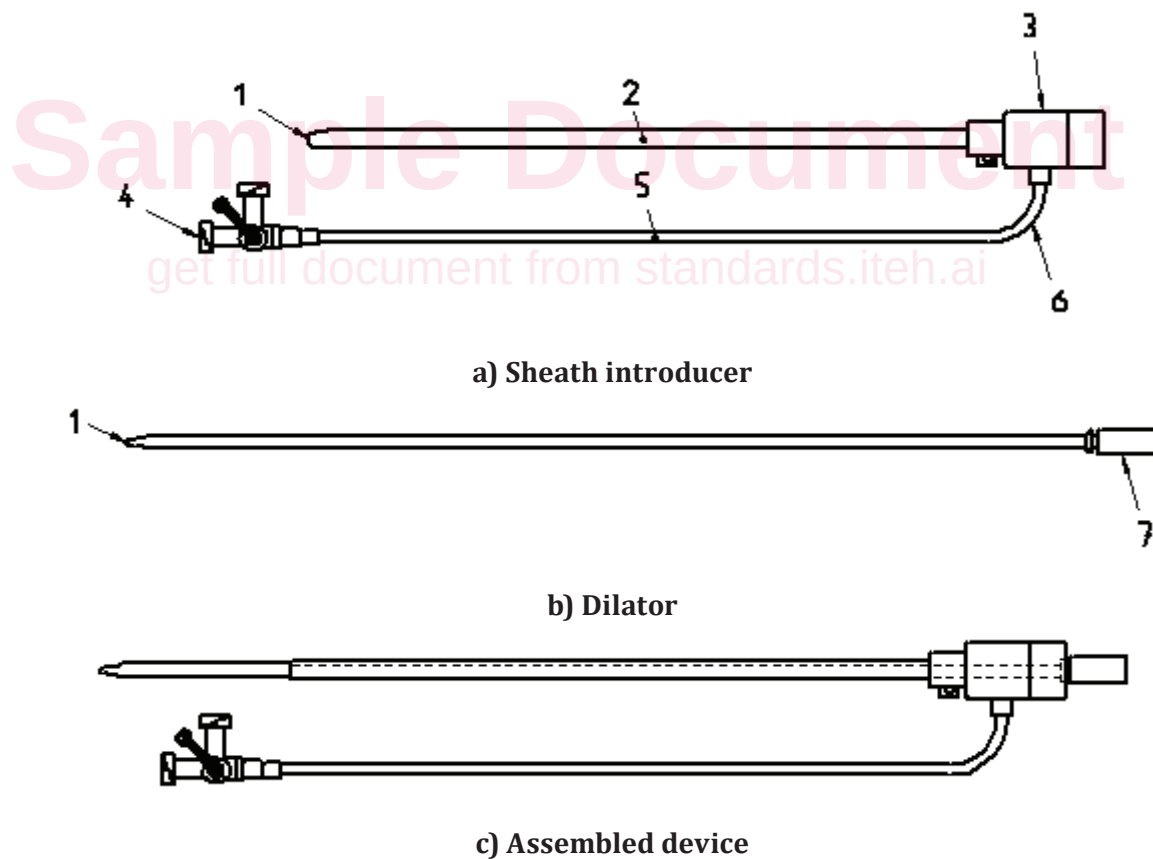
extremity of the *distal end* (3.4) of the device



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



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