BS EN ISO 11070:2014

Sterile single-use intravascular introducers, dilators and guidewires
This British Standard is the UK implementation of EN ISO 11070:2014. It supersedes BS EN ISO 11070:1999 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 81677 2

ICS 11.040.25

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2014.

Amendments issued since publication
Date Text affected
EN ISO 11070

Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014)

This European Standard was approved by CEN on 30 August 2014.

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Foreword

This document (EN ISO 11070:2014) has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and catheters” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11070:1999.

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Endorsement notice

The text of ISO 11070:2014 has been approved by CEN as EN ISO 11070:2014 without any modification.
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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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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, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements

ISO 594-2, 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.