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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11070:2014 sisaldab Euroopa standardi EN ISO 11070:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 11070:2014 consists of the English text of the European standard EN ISO 11070:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.11.2014.	Date of Availability of the European standard is 12.11.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11070

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English Version

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

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables (ISO 11070:2014)

Sterile Einführungsinstrumente, Dilatatoren und Führungsdrähte zur einmaligen Verwendung (ISO 11070:2014)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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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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.