

Sterile single-use intravascular catheter introducers

Sterile single-use intravascular catheter introducers

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 11070:2001 sisaldab Euroopa standardi EN ISO 11070:1999 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.06.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 11070:2001 consists of the English text of the European standard EN ISO 11070:1999.</p> <p>This document is endorsed on 18.06.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p>Käsitlusala:</p> <p>This Standard specifies requirements for introducers 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.</p>	<p>Scope:</p> <p>This Standard specifies requirements for introducers 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.</p>
---	---

ICS 11.040.20

Võtmesõnad:

ICS 11.040.20

English version

**Sterile single-use intravascular catheter introducers
(ISO 11070 : 1998)**

Introduceurs de cathéters
intravasculaires stériles, non
réutilisables (ISO 11070 : 1998)

Einführinstrumente für intravaskuläre
Katheter zur einmaligen Verwendung
(ISO 11070 : 1998)

This European Standard was approved by CEN on 1999-03-22.

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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 11070 : 1998 Sterile single-use intravascular catheter introducers, which was prepared by ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by October 1999 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11070 : 1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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