SLOVENSKI STANDARD
SIST EN ISO 11070:2000

01-januar-2000

Vodila sterilnih žilnih katetrov za enkratno uporabo (ISO 11070:1998)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 11070:1999**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 11070:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11070

April 1999

ICS 11.040.20

English version

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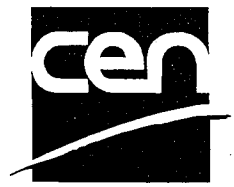
This European Standard was approved by CEN on 22 March 1999.

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.

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 Central Secretariat has the same status as the official versions.

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



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

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

Foreword

The text of the International Standard from Technical Committee ISO/TC 84 "Medical devices for injections" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

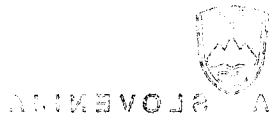
This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 1999, and conflicting national standards shall be withdrawn at the latest by October 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11070:1999 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).



Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993
ISO 7886-1	1993	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (including Technical Corrigendum 1:1995)	EN ISO 7886-1	1997

INTERNATIONAL STANDARD

ISO 11070

First edition
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Sterile single-use intravascular catheter introducers

Introducteurs de cathéters intravasculaires stériles, non réutilisables

Reference number
ISO 11070:1998(E)

Contents

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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.

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