

Sterile, single-use intravascular catheter introducers

The European Standard EN ISO 11070:1999 has the status of a
British Standard

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National foreword

This British Standard is the English language version of EN ISO 11070:1998. It is identical with ISO 11070:1998. It supersedes BS 7174-4:1990 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/27, Medical plastics tubing, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 July 1999

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Contents

	Page
National foreword	Inside front cover
Foreword	2
Foreword	iii
Text of ISO 11070	1

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 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.

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CEN

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

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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).

INTERNATIONAL STANDARD

ISO 11070

First edition
1998-05-01

Sterile single-use intravascular catheter introducers

Introduceurs de cathéters intravasculaires stériles, non réutilisables



Contents

	Page
Foreword	iii
1 Scope	1
2 Normative references	1
3 Definitions	1
4 General requirements	4
5 Additional requirements for introducer needles	5
6 Additional requirements for introducer catheters	5
7 Additional requirements for sheath introducers	6
8 Additional requirements for guide wires	7
9 Additional requirements for dilators	8
10 Additional requirements for kits containing combinations of devices specified in this International Standard	8
Annex A (informative) Guidance on materials and design	9
Annex B (normative) Test for corrosion resistance	9
Annex C (normative) Determination of force at break of introducer catheters, sheath introducers and dilators	9
Annex D (normative) Test for liquid leakage from sheath introducers under pressure	10
Annex E (normative) Test for liquid leakage through haemostasis valves of sheath introducers	11
Annex F (normative) Test for fracture of guide wires	12
Annex G (normative) Test for resistance of guide wires to damage by flexing	13
Annex H (normative) Test for strength of union of core wire and coil of guide wire and union of coil and safety wire	14
Annex J (informative) Bibliography	16
Annex ZA (normative) Normative references to international publications with their relevant European publications	Inside back cover
Figure 1 — Example of an introducer catheter and an introducer needle	2
Figure 2 — Example of a sheath introducer and a dilator	3
Figure 3 — Examples of guide wires	4
Figure 4 — Example of an introducer needle point and an introducer catheter tip	6
Figure D.1 — Apparatus for testing liquid leakage from sheath introducers	11
Figure F.1 — Apparatus for testing guide wires for fracture	13
Figure G.1 — Test rig for testing flexibility of guide wires	14
Figure H.1 — Example of a split-tapered clamp	15
Table 1 — Designation of nominal size of introducer needles and introducer catheters	5
Table 2 — Minimum force at break of introducer catheter, sheath introducer and dilator test pieces	6
Table 3 — Dimensions to be given for kits	8
Table C.1 — Examples of conditions for a 20 mm/min/mm strain rate	10
Table H.1 — Forces for testing strength of union	16

Descriptors: Medical equipment, sterile equipment, disposable equipment, vascular system, catheters, accessories, specifications, designation, size designation.

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*.

Annex B, Annex C, Annex D, Annex E, Annex F, Annex G, and Annex H form an integral part of this International Standard. Annex A and Annex J are for information only.