Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 4: Balloondilatatsioonikateetrid

Sterile, single-use intravascular catheters - Part 4: Balloon dilatation catheters

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10555-4:1999 sisaldab Euroopa standardi EN ISO 10555-4:1997 + AC:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10555-4:1999 consists of the English text of the European standard EN ISO 10555-4:1997 + AC:2002. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa esitab nõuded balloondilatatsioonikateetritele, mis on hangitud steriilsetena ja ette nähtud ühekordseks kasutamiseks.	**Scope:**

ICS 11.040.20

Võtmesõnad: kateetrid, meditsiiniaparatuur, pärast kasutamist hävitatavad vahendid, soontesüsteem, steriilne varustus, teave tarbijale, tehnilised andmed, testimine, tähistus

EUROPEAN STANDARD
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EN ISO 10555-4

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Descriptors: Balloon dilatation catheters, catheters, medical equipment.

English version

Sterile, single-use intravascular catheters

Part 4: Balloon dilatation catheters
(ISO 10555-4 : 1996)

Cathéters intravasculaires stériles, non réutilisables – Partie 4: Cathéters de dilatation à ballonnets
(ISO 10555-4 : 1996)

Sterile intravaskuläre Katheter zur einmaligen Verwendung – Teil 4: Ballondilatationskatheter
(ISO 10555-4 : 1996)

This European Standard was approved by CEN on 1997-06-09.

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 10555-4 : 1996 Sterile, single-use intravascular catheters – Part 4: Balloon dilatation catheters,

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 January 1998 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 10555-4 : 1996 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 part of ISO 10555 specifies requirements for balloon dilatation catheters supplied in the sterile condition, and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 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 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definition apply.

3.1 balloon dilatation catheter: Intravascular catheter fitted with a balloon near the distal end, which is introduced into an artery or vein to dilate a part or parts of the vascular system.

4 Requirements

4.1 General

Unless otherwise specified in this part of ISO 10555, catheters shall comply with ISO 10555-1.

4.2 Radio-detectability

The position of the balloon shall be radio-detectable when the catheter has been inserted into the body.

NOTE 2 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque", provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Designation of nominal size

The nominal size of the catheter shall be designated by the following:

a) the diameter(s) of the inflated balloon(s) or, for multidiameter balloon(s), the diameter of each portion;

b) the effective length of the balloon;

c) the effective length of the catheter;

d) the diameter of the largest guidewire that can be used with the catheter, if applicable.

4.4 Physical requirements

4.4.1 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.