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ISO/TC 84~~/WG 9 N 886~~
~~Replaces N 885~~

Secretariat: DS

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Intravascular catheters — Sterile and single-use catheters —

Part 4: Balloon dilatation catheters

~~*DIS*~~*Cathéters intravasculaires — Cathéters stériles et non réutilisables —*

Partie 4: Cathéters de dilatation à ballonnets

FDIS stage

~~This document contains the result of the discussions of the comments received on ISO/DIS 10555-4.~~

~~The comments with WG observations is circulated as document N 884 and a version with traced changes of this draft is circulated as document N 885.~~

~~Project leader: Chris Burton (US)~~

~~**Next step:** After final WG 9 approval, the clean version of this draft will be sent to ISO/CS for initiation of the FDIS procedure.~~

Contents

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO ~~documents~~document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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~~Attention is drawn~~ISO draws attention to the possibility that ~~some of~~ the ~~elements~~implementation of this document may ~~be~~involve the ~~subject~~use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights~~.~~ in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights. ~~Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).~~

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see ~~www.iso.org/iso/foreword.html~~www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10555-4:2013), which has been technically revised.

The main changes are as follows:

- ~~defined Rated Burst Pressure (RBP) (see 3.2);~~
- ~~defined crossing profile~~added a definition for balloon rated burst pressure (RBP) (see 3.2);
- added a definition (see ~~3.3), added~~ 3.3), requirement (see ~~4.4.5),~~4.4.5), and created test method (see ~~Annex E);~~Annex E) for crossing profile;
- added guidance on endpoint of deflation period (see ~~Annex C);~~Annex C);
- defined effective length of the balloon (see ~~3.4);~~3.4);
- expanded radio-detectability to include detectability by x-ray or by other means (see ~~4.2);~~4.2);

— ~~—~~within designation of nominal size, added the minimum inner diameter of the introducer, guide catheter, sheath, etc. that can be used with the catheter (see ~~4.3);~~4.3);

— ~~—add~~added requirement (see ~~4.4.6)~~4.4.6) and test method (see ~~Annex F)~~Annex F) for balloon removal without damage after inflation and deflation;

— ~~—~~added annex for rationale of changes and guidance (see ~~Annex G).~~Annex G).

A list of all parts in the ISO 10555 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Field Code Changed

Intravascular catheters - — Sterile and single-use catheters —

Part 4:
Balloon dilatation catheters

1 Scope

This document specifies requirements for balloon dilatation catheters supplied sterile and intended for single use.

This document does not specify requirements for vascular stents (see ISO 25539-2).

NOTE Guidance on the selection of balloon materials is given in ~~Annex G.~~Annex G.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10555-1, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at ~~https://www.iso.org/obp~~https://www.iso.org/obp

— IEC Electropedia: available at ~~https://www.electropedia.org/~~https://www.electropedia.org/

3.1
balloon dilatation catheter
intravascular catheter fitted with a balloon, which is introduced into an artery or vein to dilate a part or parts of the vascular system

3.2
balloon rated burst pressure
RBP
pressure at which the balloon bursts or leaks with an appropriate safety margin

3.3
crossing profile
maximum outer diameter found between the proximal end of the uninflated balloon and the distal tip of the catheter

3.4
effective length of the balloon
length of the balloon intended to treat the lesion

4 Requirements

4.1 General

Unless otherwise specified in this document, balloon dilatation catheters shall conform with the requirements in ISO 10555-1.