INTERNATIONAL STANDARD

ISO 15676

Second edition
2016-08-15

Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

Implants cardiovasculaires et organes artificiels — Exigences pour les paquets de tubes à usage unique pour pontage cardiopulmonaire et oxygénation des membranes extracorporelles

Reference number
ISO 15676:2016(E)

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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.

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 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 15676:2005), which has been technically revised.

Introduction

The intent of this document is to ensure that medical grade tubing in single-use tubing packs for the transfer of blood and fluid during the period of cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) is adequately tested for both safety and function. The user commonly provides the specifications for the tubing pack. Furthermore, the purpose of this document is to ensure that the tubing pack characteristics be appropriately disclosed in the labelling and manufacturing information package. Tubing performance characteristics are specifically addressed within the context of this document as a component part of a single-use tubing pack.

This document therefore contains recommended procedures to evaluate such medical grade tubing intended for use during CPB procedures and ECMO. Test procedures to determine the material characteristics, the useful life of the tubing when used in a roller pump, and cleanliness are described. The limits for these characteristics are not specified.

This document also includes minimum reporting requirements. Ready identification of the performance characteristics should assist the user in the selection of such medical grade tubing for the procedure appropriate to the patient and procedure. This information may be useful in a clinic's quality control process that aims to improve the safety of CPB and ECMO procedures.

This document makes reference to other International Standards, which references methods for the determination of characteristics common to medical devices.

Requirements for animal and clinical studies are not included in this document. Such studies, however, may be part of a manufacturer's quality system.

This document contains only those requirements that are specific to such medical grade tubing for use during CPB and ECMO. Non-specific requirements are covered by reference to other International Standards listed in the Normative References section.

Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

1 Scope

This document specifies requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO). This document is applicable to all medical tubing intended for cardiopulmonary bypass (CPB) and/or extracorporeal membrane oxygenation (ECMO), but specific requirements and tests are included for tubing intended for use with peristaltic pumps during (short-term, i.e. <6 h duration) CPB surgery or (long-term, i.e. >24 h) ECMO procedures. The sterility and non-pyrogenicity provisions of this document are applicable to tubing packs labelled as "sterile".

This document is applicable only to the tubing aspects for multifunctional systems that may have integral components such as blood gas exchangers (oxygenators), reservoirs, blood filters, defoamers, blood pumps, etc.

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 34-1, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 9352, *Plastics — Determination of resistance to wear by abrasive wheels*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ASTM D792-00, *Standard test methods for density and specific gravity (relatively density) of plastics by displacement*

ASTM D2240-04, *Standard test method for rubber property — Durometer hardness*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
durometer hardness
measure of hardness of elastic materials by Shore A range

3.2
elongation
increase in linear dimension

3.3
tensile strength
force per unit of original cross section on *elongation* (3.2) to rupture

3.4
tear strength
measure of stress needed to continue rupturing a sheet of rubber or plastic, usually after an initial cut

3.5
tubing pack
consists of tubing sections joined by extracorporeal connectors and/or connected to extracorporeal devices intended for CPB or ECMO applications

3.6
specific gravity
ratio of the mass of a body to the mass of an equal volume of water at 4 °C

3.7
spallation
phenomenon whereby particles dislodge from a surface under cyclical stress

3.8
brittle point
temperature at which 50 % of test samples exhibit cracking or breakage after linear impact at a specified speed

3.9
blood analogue
test solution which simulates blood viscosity between $2{,}0 \times 10^{-3}$ Pa·s (2,0 cP) to $5{,}0 \times 10^{-3}$ Pa·s (5,0 cP)

Note 1 to entry: The higher viscosity specified addresses conditions encountered during a range of clinical procedures specific to the tubing pack.

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic. Compliance shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

All parts of the tubing pack that may come in direct contact with the patient's blood pathway shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 General

When tested in accordance with 5.3.1, the blood pathway shall not leak.

4.2.2 Dimensions

The dimensions of the tubing (e.g. inner diameter, wall thickness, segment lengths) shall conform to the specifications of the user.

4.2.3 Material properties

The tubing material shall be tested or specified by the manufacturer or extruder to determine that the material properties listed in this subclause conform to the manufacturer's specifications as reported in 6.4 b). Upon request, the manufacturer should make them available in a technical data sheet. The material properties include the following:

a) durometer hardness;

b) ultimate elongation;

c) tensile strength;

d) brittle point;

e) specific gravity;

f) tear strength.

4.3 Performance characteristics

4.3.1 Priming volume

The priming volume shall be measured or calculated and reported in 6.2 e). Results shall indicate the priming volume over the entire range of tubing size provided by the manufacturer. Testing shall be performed according to the manufacturer's protocol.

Some of these tests may be combined and performed at the same time.