SLOVENSKI STANDARD
oSIST prEN ISO 5840-1:2014

01-julij-2014

Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 1. del: Splošne zahteve (ISO/DIS 5840-1:2014)

Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements (ISO/DIS 5840-1:2014)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 1: Grundlegende Anforderungen

Implants cardiovasculaires - Prothèses valvulaires - Partie 1: Exigences générales (ISO/DIS 5840-1:2014)

Ta slovenski standard je istoveten z: **prEN ISO 5840-1**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

oSIST prEN ISO 5840-1:2014 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 5840-1

ISO/TC **150**/SC **2** Secretariat: **ANSI**

Voting begins on: **2014-04-10**

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Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

Implants cardiovasculaires — Prothèses valvulaires —

Partie 1: Exigences générales

ICS: 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 5840-1:2014(E)

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 5840-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems.*

Introduction

There is, as yet, no heart valve substitute which can be regarded as ideal.

This International Standard has been prepared by a group well aware of the issues associated with heart valve substitutes and their development. In several areas, the provisions of this International Standard deliberately have not been specified to encourage development and innovation. It does specify types of tests, test methods, and/or requirements for test apparatus, and requires documentation of test methods and results. The areas with which this International Standard are concerned are those which will ensure that associated risks to the patient and other users of the device have been adequately mitigated, facilitate quality assurance, aid the clinician in choosing a heart valve substitute, and ensure that the device will be presented at the operating table in convenient form. Emphasis has been placed on specifying types of *in vitro* testing, on preclinical *in vivo* and clinical evaluations, on reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations and on the labelling and packaging of the device. Such a process involving *in vitro*, preclinical *in vivo*, and clinical evaluations is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent problems.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical, and biocompatibility characteristics, this International Standard also covers important hydrodynamic and durability characteristics of heart valve substitutes.

The Standard does not specify exact test methods for hydrodynamic and durability testing but it offers guidelines for the test apparatus.

This International Standard is incomplete in several areas. It is intended to be revised, updated, and/or amended, as knowledge and techniques in heart valve substitute technology improve.

DRAFT INTERNATIONAL STANDARD **ISO/DIS 5840-1:201x**

Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements

1 Scope

1.1 This International Standard is applicable to heart valve substitutes intended for human implantation and provides general requirements. Subsequent parts of this International Standard provide specific requirements.

1.2 This International Standard is applicable to both newly developed and modified heart valve substitutes and to the accessories, packaging, and labelling required for their implantation and for determining the appropriate size of the heart valve substitute to be implanted.

1.3 This International Standard outlines an approach for qualifying the design and manufacture of a heart valve substitute through risk management. The selection of appropriate qualification tests and methods are derived from the risk assessment. The tests may include those to assess the physical, chemical, biological, and mechanical properties of heart valve substitutes and of their materials and components. The tests may also include those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

1.4 This International Standard defines operational conditions for heart valve substitutes.

1.7 This International Standard excludes homografts.

NOTE—A rationale for the provisions of this International Standard is given in Annex A.

2 Normative references

The following referenced documents are indispensable for the application 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 11135-1:2007, *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11135-2: *Sterilization of health care products -- Ethylene oxide -- Part 2: Guidance on the application of ISO 11135-1*

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 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

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 14155:2011, *Clinical investigation of medical devices for human subjects—Part 1: General requirements*

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid chemical sterilants*

ISO 14630:2012, *Non-active surgical implants—General requirements*

ISO 14937:2000, 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

ISO 14971:2007, Medical devices—Application of risk management to medical devices

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*

3 Terms and definitions

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

3.1
accessories
device-specific tools that are required to assist in the implantation of the heart valve substitute

3.2
adverse event
AE
untoward medical occurrence in a study subject which does not necessarily have to have a causal relationship with study treatment

NOTE 1 to entry: An AE can be an unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease, temporary or permanent, whether or not related to the prosthetic valve implantation or procedure.

3.3
actuarial methods
statistical technique for calculating event rates over time

NOTE 1 to entry: Standard actuarial methods calculate the probability of freedom from events within pre-specified intervals of time. When the intervals approach zero width, the methods are called Kaplan-Meier methods.

3.4
arterial end diastolic pressure
minimum value of the arterial pressure during diastole

3.5
arterial peak systolic pressure
maximum value of the arterial pressure during systole

3.6
back pressure
differential pressure applied across the valve during the closed phase

3.7
body surface area
BSA
total surface area (m^2) of the human body

NOTE 1 to entry: This can be calculated (Mosteller's formula) as the square root of the product of the weight in kg times the height in cm divided by 3600. See Mosteller, RD.

3.8

cardiac index
cardiac output (CO, lL/min) divided by the body surface area (BSA, m^2), with units Ll/min/m^2

3.9 cardiac output
stroke volume times heart rate

3.10
closing volume
portion of the regurgitant volume that is associated with the dynamics of valve closure during a single cycle

NOTE 1 to entry: See Figure 1.

3.11
coating
thin-film material that is applied to an element of a heart valve system to modify its physical or chemical properties

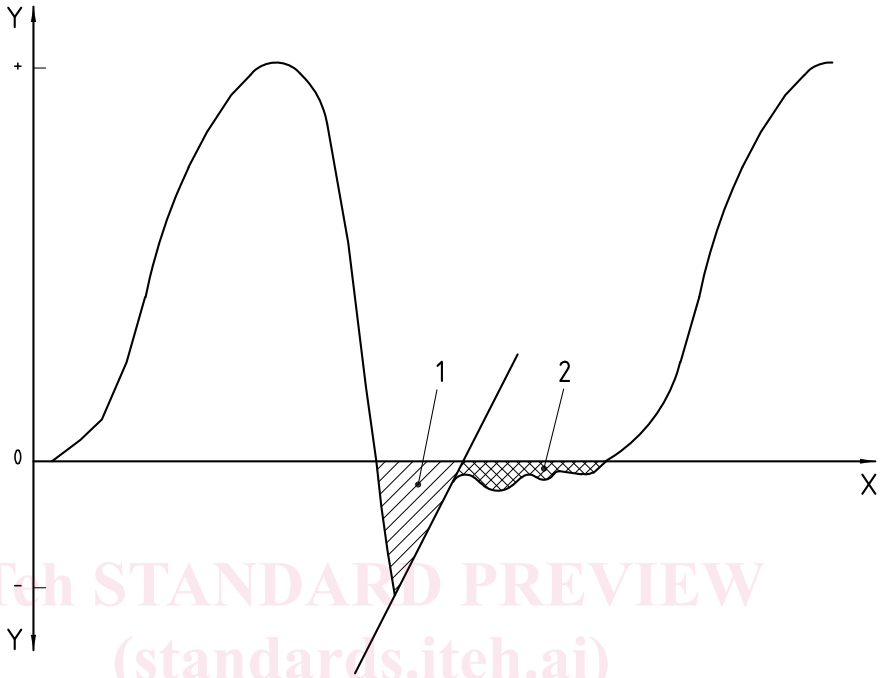
3.12
compliance
relationship between change in diameter and change in pressure of a deformable tubular structure (e.g., valve annulus, aorta, conduit), defined in this document as:

$$C = 100\% \times \frac{(r_2 - r_1) \times 100}{r_1 \times (p_2 - p_1)}$$

where

- C is the compliance in units of %radial change/100 mmHg
- p_1 is the diastolic pressure, in mmHg;
- p_2 is the systolic pressure, in mmHg;
- r_1 is the inner radius at p_1, in millimeters;
- r_2 is the inner radius at p_2, in millimeters;

NOTE Reference ISO 25539-1.



Key
X time
Y flowrate
1 closing volume
2 leakage volume

Figure 1 — Schematic representation of flow waveform and regurgitant volumes for one cycle

3.13
component-joining material
material, such as a suture, adhesive or welding compound, used to assemble the components of a heart valve system

3.14
cumulative incidence
statistical technique where events other than death can be described by the occurrence of the event over time without including death of the subjects

NOTE 1 to entry: Cumulative incidence is also known as “actual” analysis.

3.15
cycle
one complete sequence in the action of a heart valve substitute under pulsatile-flow conditions

3.16
cycle rate

number of complete cycles per unit of time, usually expressed as cycles per minute (cycles/min)

3.17
design verification
establishment by objective evidence that the design output meets the design input requirements

3.18
design validation
establishment by objective evidence that device specifications conform with user needs and intended use(s)

3.19
device failure
inability of a device to perform its intended function sufficient to cause a hazard

3.20
device migration
detectable movement or displacement of the heart valve substitute from its original position within the implant position, without device embolization

3.21
effective orifice area
EOA
orifice area that has been derived from flow and pressure or velocity data

For in-vitro testing, EOA is defined as:

$$EOA = \frac{q_{v\,RMS}}{51{,}6 * \sqrt{\frac{\Delta p}{\rho}}}$$

where

EOA is the Effective Orifice Area (cm^2);

$q_{v\,RMS}$ is the root mean square forward flow (ml/s) during the positive differential pressure period;

Δp is the mean pressure difference (measured during the positive differential pressure period) (mmHg);

ρ is the density of the test fluid (g/cm^3).

3.22
prosthetic valve endocarditis
any infection involving a valve in which an operation has been performed, based on reoperation, autopsy or the Duke Criteria for Endocarditis

NOTE 1 to entry: See Li et al (2000).

3.23
failure mode
mechanism of device failure

NOTE 1 to entry: Support structure fracture, calcification, and prolapse are examples of failure modes.

3.24
flexible surgical heart valve substitute
surgical heart valve substitute wherein the occluder is flexible under physiological conditions

NOTE 1 to entry: The orifice ring may or may not be flexible.

3.25
follow-up
continued assessment of patients who have received the heart valve substitute

3.26
forward flow volume
volume of flow ejected through the heart valve substitute in the forward direction during one cycle

3.27
fracture
disruption, under the action of applied stress or strain, of any part of the heart valve substitute that was previously intact

3.28
heart valve substitute
device used to replace the function of a natural valve of the heart

3.29
implant site/implant position
intended location of heart valve substitute implantation or deployment

3.30
intended use
use of a product or process in accordance with the specifications, instructions, and information provided by the manufacturer

3.31
leakage volume
portion of the regurgitant volume which is associated with leakage during the closed phase of a valve in a single cycle and is the sum of the transvalvular leakage volume and paravalvular leakage volume

NOTE 1 to entry: The point of separation between the closing and leakage volumes is obtained according to a defined and stated criterion (the linear extrapolation shown in Figure 1 is just an example).

3.32
linearized rate
total number of events divided by the total time under evaluation

NOTE 1 to entry: Generally, the rate is expressed in terms of percent per patient year.

3.33
major bleeding
any episode of major internal or external bleeding that causes death, hospitalization, or permanent injury (e.g. vision loss) or necessitates transfusion

3.34
mean arterial pressure
time-averaged arithmetic mean value of the arterial pressure during one cycle

3.35
mean pressure difference / mean pressure gradient
time-averaged arithmetic mean value of the pressure difference across a heart valve substitute during the forward-flow phase of the cycle

3.36
nonstructural valve dysfunction

abnormality extrinsic to the heart valve substitute that results in stenosis, regurgitation and/or haemolytic anemia

3.37
occluder/leaflet
component that inhibits backflow

3.38
outflow tract profile height
maximum distance that the heart valve substitute extends axially into the outflow tract in the open or closed position, whichever is greater, measured from the valve structure intended to mate with the top (atrial or aortic/pulmonic side) of the patient's annulus

3.39
pannus
ingrowth of tissue onto the heart valve substitute which may interfere with normal functioning

3.40
paravalvular leakage volume
portion of the leakage volume that is associated with leakage around the closed heart valve substitute during a single cycle

3.41
profile height
maximal axial dimension of a heart valve substitute in the open or closed position, whichever is greater

3.42
reference valve
heart valve substitute with a known clinical experience used for comparative preclinical and clinical evaluations

NOTE 1 to entry: The reference valve should be legally marketed and approximate the test heart valve substitute in type, configuration, and tissue annulus diameter; it may be an earlier model of the same valve, if it fulfils the necessary conditions. The characteristics of the reference valve should be well documented with clinical data.

3.43
regurgitant fraction
regurgitant volume expressed as a percentage of the forward flow volume

3.44
regurgitant volume
volume of fluid that flows through a heart valve substitute in the reverse direction during one cycle and is the sum of the closing volume and the leakage volume

NOTE 1 to entry: See Figure 1.

3.45
rigid surgical heart valve substitute
surgical heart valve substitute wherein the occluder(s) and orifice ring are non-flexible under physiological conditions

3.46
risk
combination of the probability of occurrence of harm and the severity of that harm

NOTE 1 to entry: Adapted from ISO 14971

3.47
risk analysis
systematic use of available information to identify hazards and to estimate the associated risks