SLOVENSKI STANDARD
SIST EN 12006-3:2000+A1:2009

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Neaktivni kirurġki vsadki (implantati) - Posebne zahteve za srļ noģilne vsadke (kardiovaskularni implantati) - 3. del: Znotrajģilni pripomoļ ki

Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices

Nichtaktive chirurgische Implantate - Besondere Anforderungen an Herz- und Gefäßimplantate - Teil 3: Endovaskuläre Implantate

Implants chirurgicaux non-actifs - Exigences particulières pour les implants cardio-vasculaires - Partie 3: Dispositifs endovasculaires

Ta slovenski standard je istoveten z: **EN 12006-3:1998+A1:2009**

ICS:

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

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English Version

Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices

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Nichtaktive chirurgische Implantate - Besondere Anforderungen an Herz- und Gefäßimplantate - Teil 3: Endovaskuläre Implantate

This European Standard was approved by CEN on 8 November 1998 and includes Amendment 1 approved by CEN on 5 April 2009.

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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 CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN 12006-3:1998+A1:2009) has been prepared by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-04-05.

This document supersedes EN 12006-3:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

⟨A1⟩ For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard. ⟨A1⟩

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 being the highest:

Level 1: General requirements for non-active surgical implants.

Level 2: Particular requirements for families of non-active surgical implants.

Level 3: Specific requirements for types of non-active surgical implants.

This standard is a level 2 standard and contains requirements that apply to all non-active surgical implants in the family of vena cava filters and vascular stents.

The level 1 standard contains requirements that apply to all non-active surgical implants.

Level 3 standards contain requirements that apply to specific types of implants within a family.

To address all requirements, it is necessary to start with a standard of the lowest available level.

References can also be found in Annex A of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This European Standard in addition to EN ISO 14630 provides a method to demonstrate compliance with the relevant Essential Requirements as outlined in general terms in Annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to endovascular devices.

1 Scope

This European Standard specifies particular requirements for endovascular devices.

With regard to safety, this standard gives in addition to EN ISO 14630, requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

NOTE 1 Vascular occluders are not addressed in this standard. For the time being the requirements as stated in EN ISO 14630:1997 apply for these products.

NOTE 2 Due to the variations in the design of the implants covered by this standard and in some cases due to the relatively recent development of some of these implants, acceptable standardized in vitro tests and long term results of clinical trials are not always available.

Where no test method is described in this standard a complete description of the validated test method and sample preparation procedure used should be documented by the manufacturer. With regard to design evaluation, where a specific standardized test is not described, guidance is given by referring to current scientific literature (see Annex A). This standard aims to ensure that manufacturers will address all aspects of design evaluation that relate to the safety of the product. As further scientific and clinical data become available, appropriate revision of the standard will be necessary.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 14630:1997, *Non-active surgical implants - General requirements (ISO 14630:1997)*

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

3 Definitions

For the purpose of this standard the definitions of EN ISO 14630 apply together with the following:

3.1
vascular stent
implantable expandable tubular structure supporting a vascular conduit

3.2
vena cava filter
implantable expanding filtering device to be inserted into the vena cava

3.3
stented graft
a combination of one or more stents and a tubular graft

4 Intended performance

The requirements of clause 4 of EN ISO 14630:1997 apply.

5 Design attributes

The requirements of clause 5 of EN ISO 14630:1997 apply together with the following:

a) oxidation-potential, the possibility of crevice corrosion, passivation level (see 7.1.3) over the relevant parts;

b) with regard to wear: fretting corrosion (see 7.1.2);

c) interface between implant and body (see 7):

   1) fixation hooks if present;

   2) relative movement between implant and tissue;

   3) forces exerted by the device on the surrounding tissue;

   4) forces required to deform the device if the deformation is permanent;

d) expected ingrowth, penetration, perforation, tilting and migration (see 7);

e) effects by flow pattern and release of ions (see 7.1.3);

f) introduction and delivery systems (see 7.1.4);

g) geometry (see clause 7).

6 Materials

The requirements of clause 6 of EN ISO 14630:1997 shall apply.

7 Design evaluation

The requirements of clause 7 of EN ISO 14630:1997 shall apply together with the following:

NOTE The effects of MRI on the implant should be evaluated during the risk analysis.

7.1 General

Where no test method is described in this standard, description of the validated test method and sample preparation used in the study shall be documented by the manufacturer. The need for a reference device shall be considered. The method chosen including the choice of the reference device shall be justified.

Data are required for a finite element or other stress analysis that identifies the peak stresses in the device when subjected to a worst-case physiological load. The amounts of residual stress shall be determined and accounted for when calculating safety factors.

7.1.1 Structural integrity testing

The anticipated deformation profile shall be determined. For self expanding stents the forces exerted by the device on the arterial wall shall be determined.

7.1.2 Fatigue analysis

An in-depth analysis of the implant's fatigue resistance shall be performed to assure that the arterial/venous implant conditions to which the device will be subjected will not result in device failure.

When in vitro-testing is used as the primary method to evaluate fatigue, analysis to determine the device fatigue at 10 years equivalent real time should be conducted on a statistically significant sample of devices and dynamically cycled over simulated vessel conditions.

NOTE Guidance can be found in Annex A1.

7.1.3 Oxidation potentials

The implant shall undergo potential measurement.

NOTE 1 Guidance can be found in Annex A2.

NOTE 2 Where several materials are used the manufacturer should provide proof of their compatibility in terms of oxidation potential.

7.1.4 Device/catheter system

The device/catheter system shall be tested to demonstrate that it can deliver the device to the intended location and that the device is not adversely affected by the catheter. Where a balloon catheter is used it shall comply with ISO 10555-4.

7.1.5 Surface

The implant shall be free from defects when examined as follows:

a) examine the implant visually with normal sight for process or surface defects;

b) examine the surface, hooks and other appropriate aspects of the stent in a magnifier for process or surface defect;

NOTE 1 Magnification of x 2.5 - 5 is recommended.

c) examine particularly exposed areas of the implant under magnification greater than used in b).

NOTE 2 Magnification of x 20 - 50 is recommended.

7.2 Stents (self expandable and balloon expandable)

7.2.1 Dimensions

At least the following dimensions shall be measured:

a) inner diameter after expansion in nominal conditions. The measured values for internal measurements shall be rounded down to the next 0.1 mm (see clause 11);

b) outer diameter after expansion in nominal conditions. The measured values for external measurements shall be rounded up to the next 0.1 mm (see clause 11);

c) length of the stent after expansion (see clause 11). The length is the distance between the two ends. The measured values for lengths shall be rounded up to the next 1 mm.

NOTE Means for hooks and fixation mounted on the stent should not be included when the outer diameter is measured.