SLOVENSKI STANDARD
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Neaktivni kirurġki vsadki (implantati) ï Posebne zahteve za srļ no-ġilne vsadke (kardiovaskularne implantate) ï Posebne zahteve

Non active surgical implants - Particular requirements for cardiac and vascular implants - Specific requirements for arterial stents

Nichtaktive chirurgische Implantate - Besondere Anforderungen an Herz- und Gefäßimplantate - Spezielle Anforderungen an Arterienstents

Implants chirurgicaux non actifs - Exigences particulieres s'appliquant aux implants cardiaques et vasculaires - Exigences spécifiques relatives aux endoprotheses artérielles

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Non active surgical implants - Particular requirements for cardiac and vascular implants - Specific requirements for arterial stents

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This European Standard was approved by CEN on 2 February 2004.

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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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN 14299:2004) has been prepared by the Technical Committee CEN/TC 285 “Non-active surgical implants”, the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

This document has been prepared under a mandate given to CEN by the Commission of the European Community and the European Free Trade Association, and supports Essential Requirements of EC Directive(s).

For relationship with the EC Council Directive 93/42/EEC of June 14, 1993. see informative Annex ZA, which is an integral part of this document.

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 being 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 3 standard and contains requirements that apply to specific types of implants within a family.

The level 1 standard, EN ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

The level 2 standards apply to a more restricted set or family of implants such as those designed for use in osteosynthesis, cardiovascular surgery, or joint replacement.

NOTE For cardiac and vascular implants three level 2 standards have been published:

— EN 12006-1, *Non-active surgical implants - Particular requirements for cardiac and vascular implants - Part 1: Heart valve substitutes.*

— EN 12006-2, *Non-active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits.*

— EN 12006-3, *Non-active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices.*

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

References to other European or International Standards can also be found in the Bibliography.

Annexes A and B are informative.

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

Introduction

In addition to EN ISO 14630 and EN 12006-3 this European Standard provides minimum requirements for sterile arterial stents and endovascular prostheses and the methods of test for their evaluation.

1 Scope

This European Standard specifies specific requirements for arterial stents and endovascular prostheses and their deployment intended to correct or compensate for a defect of an artery.

With regard to safety, this standard gives in addition to EN ISO 14630 and EN 12006-3 specific requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

This European Standard applies to arterial stents and endovascular prostheses used in the aorta, cervical segments of cerebral arteries, coronary arteries, intra-cerebral arteries, peripheral arteries, pulmonary arteries, supra-aortic arteries and visceral arteries. It also includes endovascular prostheses used to treat aneurysms, arterial stenoses, or other vascular abnormalities.

NOTE 1 Delivery systems are included in this standard if they comprise an integral component of the deployment of the implant.

NOTE 2 Covered stents used as occluders are included in this standard.

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 (including amendments).

EN ISO 10555-1:1996, *Sterile, single-use intravascular catheters – Part 1: General requirements (ISO 10555-1:1996).*

EN ISO 10555-4:1997, *Sterile, single-use intravascular catheters – Part 4: Balloon dilatation catheters (ISO 10555-4:1996).*

EN ISO 11070, *Sterile single-use intravascular catheter introducers (ISO 11070:1998).*

EN 12006-2:1998, *Non-active surgical implants – Particular requirements for cardiac and vascular implants – Part 2: Vascular prostheses including cardiac valve conduits.*

EN 12006-3:1998, *Non-active surgical implants – Particular requirements for cardiac and vascular implants – Part 3: Endovascular devices.*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects – Part 1: General requirements (ISO 14155-1:2003).*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans (ISO 14155-2:2003).*

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

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 12006-3:1998 and the following apply.

3.1
arterial stent
implantable tubular structure which supports an arterial conduit. This includes endovascular prostheses

3.2
bare stent
stent that is not covered or coated

3.3
cervical segments of cerebral arteries
extracranial segments of the internal carotid and vertebral arteries

3.4
crush resistance
ability of an implant to withstand load until permanent (or plastic) deformation or full collapse occurs

3.5
delivery system
system or mechanism used to deliver the implant to the targeted position which is then removed

3.6
direct stenting
placement of the implant without prior balloon dilatation

3.7
dogboning
dumbbell-shaped deformity observed during direct stenting if the proximal and distal ends of the balloon expand beyond the dilated implant diameter

3.8
endoleak
persistence of blood flow outside the lumen of an implant but within an aneurysm sac or adjacent vascular segment being treated by the graft. Endoleaks are categorized as follows:

— type I endoleak is periprosthetic and occurs at the proximal or the distal attachment zones;

— type II endoleak is caused by retrograde flow from collateral arterial branches;

— type III endoleak arises from a defect in the graft fabric, or inadequate seal or disconnection of modular graft components;

— type IV endoleak is due to graft permeability, often resulting in a generalized mild blush of contrast medium within the aneurysm sac

3.9
endovascular prosthesis
transluminally placed vascular prosthesis, e.g. a stent graft, residing partially or completely within a vascular conduit to form an internal bypass or shunt between sections of the vascular system

3.10
implant
arterial stent or endovascular prosthesis

3.11
implant free surface area
percentage of the surface area of the cylinder formed by the implant frame, which is not covered by implant material

3.12
implant recoil
amount by which the diameter of an implant changes from its initial diameter when still on its fully inflated delivery system to its relaxed final diameter after deflating the system, expressed as a percentage of the diameter measured when still on the fully inflated delivery system

3.13
MRI compatibility
the implant is MRI compatible if, when used in a specified MRI environment:

— it has been demonstrated not to significantly affect the quality of the diagnostic information; and

— the implant function is not affected by the MRI environment

3.14
nominal condition
diameter and length of the implant as stated by the manufacturer for the relaxed implant after expansion

3.15
outer package
container for the unit package(s), designed to protect from damage due to storage and/or transportation

3.16
patency
ability of an implant to maintain an open lumen following implantation

3.17
radial outward force (for self-expanding implants)
force exerted by a self-expanding implant as a function of the implant diameter

3.18
reference device
implant or delivery system chosen to compare methods and/or results for testing

3.19
self-expanding implant
implant where the diameter is increased from its pre-deployed size to its post-deployed size without requiring plastic deformation

3.20
supra-aortic arteries
supra-aortic arteries begin at the aortic arch and extend up to the bifurcation of the carotid and the take-off of the vertebral arteries. Within these boundaries are included all the arteries supplying the head and the upper extremities: innominate artery, subclavian arteries and carotid arteries

3.21
unit package
package intended to maintain sterility

3.22
visceral arteries
visceral arteries include the coeliac trunk and its branches, the renal arteries, the superior mesenteric artery, the inferior mesenteric artery and the internal iliac arteries

4 Intended performance

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

5 Design attributes

The requirements of Clause 5 of EN 12006-3:1998 apply, together with the following:

The design attributes for implants (with or without delivery system) are listed in Table A.1 (see Annex A) with reference to the test sections for the evaluation of the design (7.2. and 7.3). It is recognized that not all tests identified in a category will be necessary or practical for any given implant and/or delivery system. Furthermore, tests other than those mentioned in this standard may be applicable to prove compliance with the Essential Requirements of the European Council Directive 93/42/EEC of June 14, 1993. Therefore Table A.1 is a framework for the development of an assessment programme and not a checklist. The tests considered and the rationale for selection and/or waiving of tests shall be recorded.

6 Materials

6.1 General

The requirements of Clause 6 of EN ISO 14630:1997 apply.

NOTE 1 A stent delivery system should be considered as an external communicating device in contact with circulating blood for less than 24 hours.

NOTE 2 The series EN ISO 10993 within ISO/TC 194 "biological evaluation of medical devices" is a work in progress.

6.2 Corrosion

The susceptibility of the material(s) and the final product to corrosion shall be evaluated in an appropriate environment.

7 Design evaluation

7.1 General

This evaluation shall address the relevant design attributes as listed in Annex A.

The requirements of Clause 7 of EN 12006-3:1998 apply together with the following:

If acceptance criteria are not specified, the manufacturer shall evaluate the acceptability of the results against predetermined and justified criteria.

If no test method is described in this standard, a description of the justified test method, and sample preparation used in the evaluation shall be documented by the manufacturer. The method chosen, including the choice of the reference implant, shall be justified.

NOTE If it can be justified that sterilization has no effect on the characteristics of the implant or delivery system that are under evaluation, the required tests can be carried out on non-sterilized implant or delivery system.

7.2 Pre-clinical evaluation: Bench and analytical tests for implants

7.2.1 General

The relevant design attributes shall be tested in an environment which simulates the intended use conditions (e.g. temperature, geometry). The rationale for the test conditions and sample size selected shall be specified by the manufacturer. The assessment of the results against the acceptance criteria shall be documented by the manufacturer.

7.2.2 Simulated use / conformability to vessel wall

The design attributes as identified in Annex A shall be evaluated using a model that simulates the intended use conditions.

7.2.3 Dimensions

The requirements of Clause 7.2.1 of EN 12006-3:1998 apply, together will following:

In case of implants the length of the implant after expansion needs to be determined in nominal conditions.

NOTE The inner diameter may be calculated from the outer diameter and the implant wall thickness.

Using an adequate measurement technique measure the outer diameters of the implant at each end and in the middle in two perpendicular directions.

For each implant calculate the mean of all the diameters measured.

For a non-cylindrical implant (for example an oval or conical implant), the profile shall be described.

In the case of implant designs where the length changes as a function of the expanded diameter, the corresponding lengths and diameter shall be measured.

In the case of a self-expanding implant the expansion range (minimum and maximum diameter after expansion) shall be measured.

The working range of the implant shall be documented. The test results shall be recorded and shall be within the tolerances claimed by the manufacturer.

7.2.4 Visibility

The visibility of the implant, including under fluoroscopy, shall be determined and evaluated, and the test conditions shall be documented. The implant shall be visible under validated imaging techniques used clinically.

7.2.5 Crush resistance

For each nominal diameter and each implant configuration, the change in implant diameter shall be measured as a function of circumferential applied pressure or radial force until permanent deformation or full collapse occurs.

7.2.6 Radial outward force (for self-expanding implants)

For each nominal diameter the force exerted by the self-expanding implant shall be measured as a function of the diameter of the implant or displacement, as appropriate to test method used.

7.2.7 Recoil for balloon expandable implants

The implant recoil shall be measured and express as a percentage of the initial diameter.

NOTE This test is appropriate for implants manufactured from a material that is plastically deformed when the diameter of the implant is increased from its pre-deployed size to its post-deployed size by mechanical means.

The test shall be performed without external stress to the implant.

The implant shall be mounted onto a balloon of a nominal size for which the implant is intended to be used.

The balloon with the implant shall be inflated to the nominal pressure.

The size of the expanded implant on the inflated balloon shall be measured.

The balloon shall be deflated and the diameter of the implant shall be measured.

The measurement accuracy of the actual diameters shall be less than 1 % of the nominal diameter.

The implant recoil is given by the following expression: