BRITISH STANDARD

BS EN
12006-3:1999

Non-active surgical implants — Particular requirements for cardiac and vascular implants —

Part 3: Endovascular devices

The European Standard EN 12006-3:1998 has the status of a British Standard

ICS 11.040.40

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National foreword

This British Standard is the English language version of EN 12006-3:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 7 and a back cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 1999

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ISBN 0 580 30888 X

Amendments issued since publication

Amd. No.	Date	Text affected

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12006-3

November 1998

ICS 11.040.40

Descriptors: medical devices, medical equipment, surgical implants, cardiac valves, vascular stents, filters, specifications, corrosion resistance, fatigue life, dimensions, design, materials, manufacturing, sterilization, packing, instructions

English version

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

Implants chirurgicaux non-actifs — Exigences particulières relatives aux implants cardiaques et vasculaires — Partie 3: Dispositifs endovasculaires

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

This European Standard was approved by CEN on 8 November 1998.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 285, Non-active surgical implants, the Secretariat of which is held by NNI.

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 May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

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).

For relationship with EU Directive(s), see informative annex C, which is an integral part of this standard.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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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 EN ISO 14630:1997, clause **4** apply.

5 Design attributes

The requirements of EN ISO 14630:1997, clause **5** 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 clause **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 clause **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 EN ISO 14630:1997, clause **6** shall apply.

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7 Design evaluation

The requirements of EN ISO 14630:1997, clause **7** 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 ensure 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 **A.1**.

7.1.3 *Oxidation potentials*

The implant shall undergo potential measurement.

NOTE 1 Guidance can be found in **A.2**.

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 with a magnifier for process or surface defects;

NOTE 1 Magnification of ×2.5 to 5 is recommended.

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

NOTE 2 Magnification of ×20 to 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.

7.2.2 *Radial strength*

The change in outer diameter as a function of external circumferential pressure shall be determined.

7.3 Recoil testing for balloon expandable stents

The amount of elastic recoil shall be quantified 1 h after expansion for each sized stent and this variable shall be correlated with the stated dimension.

7.4 Vena cava filters

7.4.1 *Dimensions*

The geometry shall be verified against the design specification (see clause **5**). All measurements shall be done in tension free conditions.

NOTE The diameter is the distance on the filter between the vena cava fixation points.

7.4.2 *Fixation within the vena cava*

The fixation of the filter on the vena cava wall shall be evaluated and details shall be provided, including expected ingrowth, penetration and perforation.

NOTE Guidance can be found in **A.3**.

7.4.3 *Filtration*

A filtration test shall be conducted and the results shall be documented.

NOTE Guidance can be found in **A.4**.

7.5 Covered stents or stented grafts

For stents using a synthetic covering it is necessary to provide proof of their functionality in accordance with the graft related standards, but under endovascular application conditions.

7.6 Preclinical evaluation

The requirements of EN ISO 14630:1997, **7.2** shall apply. The rationale for the preclinical evaluation and the justification for carrying out or waiving of any tests shall be documented. For novel devices animal testing shall be conducted for a period of at least 6 months, in order to evaluate acute complications and clinical follow-up. The study shall include the largest and the smallest size of the device as permitted by suitable animal models.

NOTE Informative annex B provides guidance on animal studies with coronary stents.

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7.7 Clinical evaluation

The requirements of EN ISO 14630:1997, **7.3** shall apply. The rationale whether or not a clinical investigation is necessary shall be documented.

Devices for which no clinical data are available shall be subjected to clinical investigation over a period of at least 6 months.

NOTE For coronary stents recommendations as given by the European Society of Cardiology should be considered.

A clinical investigation shall also be considered for design changes intended to alter the nature of interaction of the device with the body (e.g. attachment mechanisms).

8 Manufacturing

The requirements of EN ISO 14630:1997, clause **8** shall apply.

Verification that the requirements of **7.1.5** have been met shall be demonstrated by inspection, visually and under magnification.

9 Sterilization

Endovascular devices shall be supplied sterile. The requirements of EN ISO 14630:1997, **9.1** and **9.3** apply.

10 Packaging

The requirements of EN ISO 14630:1997, clause **10** shall apply.

11 Information supplied by the manufacturer

The requirements of EN ISO 14630:1997, clause **11** shall apply together with the following:

a) for vena cava filters: recommended diameter range of the vena cava;

b) for stents: dimensions as specified in **7.2.1**;

c) for recommended balloon/catheter systems: appropriate information regarding the relationship between balloon pressure and stent diameter (see **7.2.2**);

d) for stents non pre-mounted on the delivery catheter instructions as to how the stent is to be mounted on the catheter, including use of a crimping device if appropriate;

e) if the access site is relevant for the safe implantation of the device it shall be specified in the labelling.

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Annex A (informative)
Bibliography

A.1 Fatigue analysis

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A.2 Oxidation potentials

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A.3 Fixation of the filter within the vena cava

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A.4 Filtration

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Annex B (informative)
Animal studies with stents

The purpose of animal studies is to evaluate the early and late patency rates of the stent, the biological reaction of the vessel and the performance of the delivery catheter. A minimum of 25 stents should be evaluated; however, sponsors should be aware of the risks involved in too carefully limiting the number of animal stents studied. More than one stent can be implanted in an animal. The vessels selected for testing shall have diameters similar to those proposed for stent placement in the clinical trial. The smallest and largest diameter stents shall be included in the animal studies. Although normal vessels can be stented, it does not necessarily follow that the stent will perform similarly in atherosclerotic vessels. If an atherosclerotic model is not evaluated, additional justification for the device's intended use shall be provided.

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The testing protocol(s), test results and study conclusions should be fully described in order that an independent evaluation of the conclusions can be made. In addition to documenting all complications occurring during the procedure and follow-up, the following is required.

A. Study parameters

a) Provide a clear description of the pre-stenting vessel characteristics, i.e. lumen diameter, versus post-stenting and follow-up lumen diameter as obtained from arteriography.

b) Describe the anti-coagulation therapy utilized in the animal studies with respect to its similarity to that proposed in the clinical trial.

c) Document the exact specifications of the stents used, i.e. unexpanded diameter, length, expanded diameter and inflation pressure.

d) Document the use of multiple stents at one lesion location, if this will be permitted in the clinical trial.

B. Performance of the stents/delivery system

a) Preparation — the ease with which the device can be prepared for use.

b) Introduction — the ability of the device to be loaded on to the guidewire or into a guiding catheter.

c) Pushability — the ability of the system to transmit sufficient, even force proximally allowing for equal and smooth movement distally.

d) Trackability — the ability of the system to advance distally over a guidewire, following the guidewire tip, along the path of the vessel, including in narrow, tortuous vessels.

e) Flexibility — the ability of the stent/delivery system to bend in order to accommodate a turn or angle it is required to negotiate, and the flexibility of the stent to conform to the vessel after the stent is deployed.

f) Radiopacity — the visibility of the stent and delivery system under fluoroscopy.

g) Inspection — a post-evaluation inspection to document any evidence of damage to the delivery system.

h) Accessories — a description of the performance of all accessories recommended in the labelling such as guiding catheters, haemostasis valves, sheaths, etc.

i) Investigator preference — a complete summary of comments made by investigators regarding stent performance.

C. Angiographic, haemodynamic and histological results

a) Angiographic — determine flow characteristics of the stented vessel immediately following stent deployment and immediately prior to explantation.

b) Haemodynamic — determine if ECG or blood pressure changes were noted during the implantation period. Document any cases of distal embolization.

c) Histological

1) Measure the neointimal thickness at each follow-up period throughout the stented length, including at stent/artery junctions.

2) Document any occurrences of intravascular trauma induced by stent placement in the vessel of interest.

3) Provide a pathology report including gross findings and microscopy studies involving both conventional and scanning electron microscopic techniques. The explanted vessel should be evaluated for outer diameter enlargement, lumen narrowing, filling defects, patency of side branches, protrusions of the stent into the vessel lumen and medical thinning.

4) Conduct a detailed examination of explanted stents to document integrity.

Annex C (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

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 93/42/EEC of June 14 concerning medical devices.

WARNING. Other requirements and other EU Directives *may* be applicable to the product(s) falling within the scope of this standard.

The following clauses for this standard are likely to support requirements of Council Directive 93/42/EEC of June 14 concerning medical devices.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Clauses/sub-clauses of this European Standard	Corresponding annex/paragraph of Directive (specify Directive number, e.g. 93/42/EEC)	Remarks
4, **5**, **6**, **7**, **8**, **9**, **10**, **11**	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.4, 7.5, 8, 8.1, 8.2, 8.3, 8.4, 9.1, 9.2, 13.1, 14	General: see note 2 of scope.

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