BRITISH STANDARD

BS EN
14299:2004

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

The European Standard EN 14299:2004 has the status of a British Standard

ICS 11.040.40

BSI
British Standards

National foreword

This British Standard is the official English language version of EN 14299:2004.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/2, Cardiovascular implants, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/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 subcommittee 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 Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 8 June 2004

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 39 and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 43859 7

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14299

May 2004

ICS 11.040.40

English version

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

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

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

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 14299:2004: E

Contents

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:

Implant recoil (%) = [(Diameter $_{inflated}$ - Diameter $_{final}$)/Diameter $_{inflated}$] $\times$ 100

where

Implant recoil = The 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.

Diameter $_{inflated}$ = The outer diameter of the implant with the balloon fully inflated.

Diameter $_{final}$ = The outer diameter of the implant in a stable condition after deflating the balloon (when demonstrated that a stable minimum diameter is reached).

The implant recoil shall be calculated for proximal, middle, and distal cross-sections for each implant. If the expanded and recoiled implants are not circular and concentric, this shall be explained with the recoil data provided. The average and standard deviation of implant recoil shall be calculated for all data for each size of implant.

7.2.8 Fatigue testing

The evaluation of the fatigue resistance of the implant shall demonstrate that the in vivo conditions to which the implant may be exposed will not result in implant failure.

The long-term dimensional and structural integrity of the implant shall be evaluated. This includes the integrity of each single part of the implant and the connections and contact areas between each other and to the regions intended to be in contact with the vessel. Tests shall be conducted under conditions simulating in vivo radial, axial and other loads as appropriate.

Fatigue testing shall include in vitro testing of at least 380 million cycles (10 years equivalent). If the intended implant life is less than 10 years, shorter duration fatigue testing may be appropriate and shall be justified.

Constant and periodic stresses equivalent to physiologic load shall be applied to at least six implants. The deformation of the implant under test shall be at least as great as under the intended implant condition, simulating the worst-case physiological load. The test frequency shall be chosen such that the diametric displacements of the implant remain within the required limits for the duration of the test. The maximum testing frequency may be limited by the effects of the strain rate on the mechanical properties of the materials. For example, at high frequency the implant may not experience the intended displacement. Additionally, the test frequency may be limited by the test equipment. Secondary harmonics may be introduced when testing at some frequencies.

The implant size(s) and configurations to be evaluated shall be selected to represent the greatest potential for fatigue failure and other failure modes being evaluated based upon appropriate engineering analysis such as a stress/strain analysis.

The test of balloon-expandable implants may be conducted at room temperature. The tests of thermo self-expanding implants shall be conducted at (37 $\pm$ 2) °C.

The implant size(s) and test frequency selected shall be justified.

7.2.9 Strength

7.2.9.1 Burst strength, longitudinal tensile strength, factory anastomotic strength and suture retention strength (when applicable) for implants

The requirements of Clause 7.4 of EN 12006-2:1998 apply together with the following:

The tests shall be conducted on the finished product and separately on graft material if appropriate.

7.2.9.2 Strength of implant/attachment system to graft bond (e.g. adhesie, sutures)

Evaluate the strength of the connection of the graft to the implant/attachment system.

7.2.9.3 Longitudinal tensile strength

The longitudinal tensile strength shall be determined to evaluate the force to separate bonded components.

7.2.10 Evaluation of MRI compatibility

The manufacturer shall evaluate the MRI compatibility of the implant when used in a specified MRI environment. The test conditions and test results shall be documented.

The manufacturer shall determine:

— the extent to which magnetic resonance imaging affects the implants, e.g. heating, movement of stents;

— whether the implant will cause artefacts with magnetic resonance imaging due to distortion of the magnetic field.

NOTE Literature references may substitute for actual data if adequately justified.

7.2.11 Implant free surface area

The manufacturer shall determine the free or open area of any uncovered region of the implant. This shall be expressed as a percentage of the total area.

7.2.12 Permeability and Porosity

The requirements of Clause 8.2 of EN 12006-2:1998 apply to finished products.

Determine the porosity, water permeability, and water entry pressure, as appropriate to the implant in accordance with EN 12006-2. Justification shall be provided for the property (or properties) selected to be measured.

7.3 Pre-clinical evaluation: Combination of implant and delivery system (for self-expanding and balloon-expandable implants)

7.3.1 General

If applicable all tests shall be performed in a model that simulates the vascular anatomy, which the delivery system is required to negotiate in its clinical application and under the intended and specified use conditions. Testing shall be performed in an atmosphere of 100 % relative humidity or water and a temperature of (37 ± 2) °C, if humidity and/or temperature have an influence on the test results.

7.3.2 Dimension

The manufacturer shall demonstrate and document that all dimensions and the profile of each component and accessory of the delivery system are compatible with safe access, deployment, and withdrawal.

7.3.3 Flexibility

The manufacturer shall demonstrate that the implant has sufficient flexibility to negotiate the vascular/arterial anatomy for which it is intended without compromising the function of the implant or causing it to kink. Also determine the minimum radius of curvature that the implant can accommodate without kinking.

7.3.4 Bond strength and torsional bond strength

7.3.4.1 General

The manufacturer shall determine the forces required to break the joints and the materials of the delivery system. The results shall be evaluated in relation to the force required to separate the delivery system from the implant and the force needed to pull back the delivery system in the guiding catheter. The test method, the results and the evaluation shall be documented.

Balloon catheters shall also comply with Clause 4.5 of EN ISO 10555-1:1996.

7.3.4.2 Torquability

Evaluate the ability of the delivery system to provide sufficient rotation to the distal end to deliver the implant within the anatomy in accordance with the design constraints of the system.

7.3.4.3 Pushability

Determine the ability of the delivery system to be pushed or positioned by an operator without bending or buckling.

7.3.4.4 Trackability

7.3.4.4.1 General

Determine the ability of the delivery system to advance over a guidewire, following the guidewire tip, along the path of the vessel, including in narrow and/or tortuous vessels. The guidewire

characteristics shall be documented. The elements of the simulated anatomy that the delivery system had difficulty negotiating shall be evaluated and documented.

7.3.4.4.2 Profile effect / flaring (for balloon-expandable implants)

For any premounted balloon-expandable implant, the manufacturer shall evaluate the possible radial detachment of the implant from its balloon at its proximal and distal ends during the passage through simulated arterial curvature and the potential for balloon damage during implant placement. The distance between the external diameter of the implant and the external diameter of the balloon shall be measured. The greater the distance, the higher the risk of the implant sticking to the arterial wall when going through the curvature.

If the results of this test are not satisfactory, the manufacturer shall exclude direct stenting with this implant.

7.3.4.4.3 Dislodgement force (for balloon-expandable implants)

For any premounted balloon-expandable implant, the manufacturer shall determine the force required to pull off the crimped implant from the non-expanded balloon. Tests shall be conducted both at the proximal and distal ends of the implant:

1) on a straight delivery system;

2) on a straight delivery system after passage through simulated arterial curvature.

7.3.4.5 Balloon tests

7.3.4.5.1 General

The requirements of EN ISO 10555-1 and EN ISO 10555-4 apply.

The following tests shall be conducted to a complete system, which simulates the in vivo conditions.

7.3.4.5.2 Balloon inflation

The minimal time required to expand the balloon to the maximum recommended inflation pressure shall be quantified.

The following equipment shall be used:

- water bath filled with water of (37 ± 2) °C;
- thermometer;
- inflation device filled with an appropriate liquid used clinically;
- stop-watch;
- appropriate environment adapted to the size of the balloon/stent combination;
- guidewire.

The test shall be performed as follows:

- position the guidewire in the catheter;
- place the catheter in the water bath. At least 80 % of the shaft and the balloon shall be soaked in the water bath;
- equilibrate for at least 2 min;
- pressurize the catheter with implant to the maximum recommended inflation pressure;
- measure the minimal time required to inflate the balloon to the maximum recommended inflation pressure;
- deflate the balloon.

7.3.4.5.3 Balloon deflating

The time required to deflate the balloon shall be measured and the ability to remove the deflated balloon shall be evaluated.

The following equipment shall be used:

- water bath filled with water of (37 ± 2) °C;
- thermometer;
- inflation device filled with an appropriate liquid used clinically;
- stop-watch;
- appropriate environment adapted to the size of the balloon/implant combination;
- guidewire.

The test shall be performed as follows:

- position the guidewire in the catheter;
- condition the catheter in the water bath. At least 80 % of the shaft and the balloon shall be soaked in the water bath;
- pressurize the catheter with implant to the maximum recommended inflation pressure;
- deflate the balloon;
- measure the time to complete the deflation;
- evaluate the ability to remove the deflated balloon from the implant.

7.3.4.5.4 Maximum recommended inflation pressure (for non-compliant balloons)

The maximum recommended inflation pressure shall be determined.

When the balloon bursts it shall be verified that the tear is longitudinal.

The following equipment shall be used:

- water bath to maintain a temperature of (37 ± 2) °C;
- thermometer;
- inflation device filled with fluid;
- appropriate environment adapted to the size of the balloon/implant combination;
- pressure monitoring device;
- guidewire.

The test shall be performed as follows:

- pressurize the catheter until burst according to normal clinical conditions (progressive pressure inflation rate);
- determine the mean burst pressure;
- determine the maximum recommended inflation pressure (mean burst pressure with an appropriate safety margin).

7.3.4.5.5 Balloon rated fatigue

The number of inflation cycles to the maximum recommended inflation pressure shall be determined (see Clause 4.4.2 and Annex A of EN ISO 10555-4:1997).

The following equipment shall be used:

- water bath filled to maintain a temperature of (37 ± 2) °C;
- thermometer;
- inflation device filled with water;
- guidewire.

The test shall be performed as follows:

- connect the inflation port of the catheter to the inflation device;
- condition the catheter in the water bath for an appropriate duration and leave the catheter in the water bath;
- pressurize the catheter to the maximum recommended inflation pressure;

- maintain the pressure for 10 s;
- deflate the balloon;
- repeat the steps, pressurizing, maintaining pressure and deflating the balloon 10 times.

If the balloon bursts or any other failure occurs the number of inflations/deflations and the failure mode shall be recorded.

7.3.4.5.6 Dogboning

NOTE Direct stenting is an implantation procedure increasingly used by clinicians. It requires the balloon to be inflated to a high pressure (up to 15 bars) in order to break the atheromatous plaque and at the same time release the implant. In this case, if the proximal and distal ends of the balloon beyond the implant tend to inflate to a diameter greater than that of the implant, it may cause injury to the artery.

For any premounted balloon-expandable implant, the manufacturer shall evaluate the difference between the diameter of the implant and those of the proximal and distal ends of the balloon when the implant is released under the maximum recommended inflation pressure.

If unacceptable dogboning occurs, the manufacturer shall exclude direct stenting with this implant.

7.3.5 Hemostasis

The requirements of EN ISO 11070 apply, together with the following. The ability of the entire system to minimize blood loss shall be considered. This should include, but not be limited to the following:

a) size mismatch;

b) seal incompetence;

c) other leakage.

7.4 Pre-clinical evaluation: animal testing

7.4.1 General

The requirements of Clause 7.6 of EN 12006-3:1998 apply.

7.4.2 Purpose

The purpose of in vivo pre-clinical testing is to evaluate the deployment of the implant and to obtain data pertaining to the performance and un-anticipated side effects of the implant in vivo. The testing shall evaluate the suitability of the implant for its intended use in clinical investigation.

7.4.3 Specific aims

The following items are specific aims of in vivo pre-clinical evaluation:

a) evaluate the ability to access the target location with the delivery system;

b) evaluate the handling and visualization of the delivery system and visualization of the implant;

c) verify the accuracy and efficacy of deployment;

d) characterize the ability to withdraw the delivery system;

e) evaluate the appropriateness of implant sizing;

f) evaluate the functional haemostasis of the delivery system and sheath introducer;

g) evaluate the position, structural and material integrity, and functionality of the implant acutely and over time and at explanation;

h) evaluate histology and pathology of explants and pertinent tissues/organs;

i) adverse events.

7.4.4 Protocol

The choice of animal model shall be justified taking account of the intended use of the implant, to ensure the highest degree of human compatibility conditions.

For coronary stents incorporating new significant characteristics or for any new intended use, a minimum of 25 stents shall be evaluated, and the majority shall be reviewed after a minimum of 6 months implantation. A shorter-term study may be performed if an acceptable justification is provided. For endovascular prostheses, a minimum of 6 prostheses shall be reviewed after at least 6 months implantation. Longer follow-up periods may be required for new materials, which do not have a history of use in vascular implants.

All implants shall be evaluated for at least 3 implants at a minimum of two interim sacrifice periods. The timing of the interim assessments shall be determined by the characteristics of the chosen animal model in order to obtain information on relevant endpoints, which will be of clinical relevance including; implant thrombogenicity, implant endothelialisation, vessel erosion, in-implant stenosis or restenosis etc. Marker or implant visibility and migration resistance shall also be documented.

All animals in the study shall be regularly examined. For ailing animals the cause of illness and the extent to which the implant was implicated shall be documented. Animals dying during the study shall be subject to early post mortem examination and the data shall be included within the final report. Histo-pathological assessment of explants and appropriate tissues and/or organs shall be provided.

7.4.5 Data acquisition

The following minimum data shall be recorded for each animal receiving an implant:

a) identification data:

   1. source of animals;
   2. animal identification;
   3. gender;
   4. date of birth;
   5. weight;

b) pre-operative data:

   1. verification of health status, including appropriate blood testing;
   2. medications (e.g., prophylactic antibiotics);

c) operative data:

   1. date of procedure;
   2. name of person performing procedure;
   3. description of the implant procedure including:
      i) implant identification number;
      ii) in situ length and diameter of implant;
      iii) amount of oversizing;
      iv) use of systemic antiplatelet / anticoagulant therapy.
   4. assessment of accuracy and efficacy of insertion of delivery system and deployment of the implant;
   5. assessment of handling and visualization of the delivery system and visualization of the implant;
   6. assessment of efficacy of withdrawal of delivery system;
   7. assessment of appropriateness of sizing and sizing scheme;
   8. amount and location of blood loss;
   9. assessment of position, structural and material integrity, and functionality of the implant;
   10. adverse peri-operative events.

d) post-operative data:

1. medications, including those that affect coagulation;
2. observation of endoleaks, structural integrity, functionality and position of implant, method of visualization, and date;
3. adverse events, date of occurrence, therapy, and outcome;
4. any major deviation from protocol.

e) termination data:

1. observation of endoleaks, structural integrity, functionality, patency and position of implant, method of visualization and date of sacrifice;
2. gross alteration in the dimensional, chemical and physical properties of the implant and components;
3. histo-pathological assessment of explants and appropriate tissues and/or organs.

7.4.6 Test report and additional information

Results of all animals enrolled in the protocol shall be recorded and reported even if excluded from the final analysis.

The test report shall include the following:

a) study protocol;

b) rationale for selection of the following:

1. animal species;
2. implantation site;
3. implantation periods;
4. methods of assessment;
5. intervals of observation;
6. sample size (i.e. number of animals and implants).

c) summary of results:

1. animal accountability, including rationale for exclusion of data;
2. success rates relative to the objectives;
3. adverse events;
4. summary of early deaths or sacrifices for cause;
5. operator opinion of ease of deployment, visualization and handling;

6. any deviations from protocol;

7. summary of pathology and histology of explants and appropriate tissues and/or organs, including representative gross photographs and micrographs and their corresponding implant durations;

8. summary of any changes in position, structural and material integrity, and function of the implant;

9. conclusions from study;

10. summary of quality assurance and data auditing procedures.

7.5 Clinical evaluation

7.5.1 General

The requirements of Clause 7.7 of EN 12006-3:1998 apply.

The requirements of EN ISO 14155-1 and EN ISO 14155-2 apply.

7.5.2 Purpose

The purpose of clinical evaluation is to evaluate the performance of the delivery system and assess the safety and performance of an implant and its delivery system. This evaluation is not intended to demonstrate the long-term performance of the implant.

An investigation shall be carried out for each new implant or new clinical application of an implant prior to market approval. Significant design changes that may impact safety and performance shall require clinical evaluation. Additional implant sizes outside the previously evaluated range shall require clinical evaluation. The implant shall have satisfied all appropriate preclinical testing requirements of this standard before starting the clinical investigation.

7.5.3 Specific aims

Specific aims of the study shall be stated and shall include the following, as appropriate (see Annex A):

a) evaluate the ability to access the target location with the delivery system;

b) evaluate the handling and visualization of the delivery system and visualization of the implant;

c) verify the accuracy and efficacy of deployment;

d) evaluate the ability to withdraw the delivery system;

e) evaluate the appropriateness of implant sizing;

f) evaluate the functional haemostasis of the delivery system and accessory devices;

g) evaluate the position, structural and material integrity, and functionality of the implant acutely and over time;

h) monitor lesion characteristics and implant positioning (over time);

i) report the early and late conversions and the cause;

j) evaluate histology and pathology of any explants and tissues and/or organs;

k) record reportable adverse events.

7.5.4 Study design, data acquisition, and final report

A method for evaluating the clinical outcomes shall be prospectively defined and justified. Consideration shall be given to use of an appropriate control. All patients implanted with either a test or reference implant/delivery systems, including those excluded from the final analysis, shall be reported. The final report shall include current follow-up data on all patients with follow-up as specified by the protocol for the last patient enrolled. Patient follow-up intervals shall include at least a baseline assessment at discharge from the institution and at the end of the trial.

The actual timing and number of patient follow-up assessments and the method of assessment shall be chosen so as to acquire optimal data on clinical endpoints relevant to the implant in question.

The clinical study for implants shall be prospective and multicentre.

A justification for the number of investigational sites shall be provided. A statistical justification for the number of patients included shall be provided based upon the clinical hypotheses. The calculation of the number of patients to be enrolled shall take account of the effect of comorbidities on the life-expectancy of the patient population.

The duration of patient follow-up shall be determined in relation to the objectives of the clinical investigation.

For endovascular prostheses and carotid stents the clinical investigation duration shall be 12 months for each patient. After completion of the study follow-up is advised for a minimum of 24 months for carotid stents and 48 months for endovascular prostheses.

7.5.5 Protocol

The requirements of EN ISO 14155-1 and EN ISO 14155-2 or an equivalent publication apply.

7.5.6 Data acquisition

At least the following data shall be recorded for each patient in the study.

NOTE Exceptions for the control population are stated below.

a) identification data:

   1. patient identification;

   2. sex;

   3. date of birth;

4. name of investigator;

5. name of institution.

b) pre-operative data:

1. risk factors, such as hypertension, diabetes, hyperlipademia, tobacco use, obesity, anesthesia risk and any other cardiovascular risk factors, with some measure of severity and current treatment;

2. summary of previous vascular interventions, including non-surgical interventions, and previous implantations;

3. urgency of intervention (i.e., emergency or elective);

4. diagnostic criteria:

i) clinical assessment;

ii) objective assessment of lesion and access vessel characteristics and other relevant factors (such as sizes, degree of calcification, and angle of attachment sites).

c) operative data:

1. name of implanting physician;

2. date of procedure;

3. identification data for the implant(s) including model number, implant traceability, size and configuration;

4. details of procedure, including any adjunctive vascular procedures performed;

5. relevant medications;

6. assessment of handling, visualization, deployment and withdrawal;

7. assessment of leaks;

8. assessment of patency, positioning, and integrity of the implant;

9. reportable clinical events (see Annex B);

10. date of hospital discharge.

d) baseline data:

1. implant location with note regarding clinical objective;

2. for exclusion of aneurysm, length of implant in contact with non-aneurismal tissue;

3. length of implant after implantation;

4. luminal diameter of the implant.

e) post-operative data:

1. date of each follow-up visit;
2. summary of any vascular interventions since last follow-up;
3. clinical investigation (assessment protocol may differ between the control group and the treatment group);
    i) clinical assessment;
    ii) objective assessment of implant function (leak, migration, patency, percentage of stenosis, component integrity);
    iii) objective assessment of targeted lesion characteristics and implant positioning;
4. implant relevant medications, such as anticoagulants or antibiotics;
5. reportable clinical events;
    i) event, date of occurrence, severity, management, outcome;
    ii) documentation of implant involvement (i.e., does the complication involve the implant?);
    iii) documentation of implant relationship (i.e., is the complication caused by implant, patient, or technical factors?).

f) patient withdrawal:

1. date;
2. months of study completed;
3. reason for withdrawal (lost to follow-up, death).

7.5.7 Final report

The final report shall include the following:

a) study protocol;

b) definitions of reportable clinical events;

c) rationale for selection of the following:

1. study size;
2. choice of control;
3. measurement methods;
4. statistical analyses employed;

5. patient follow-up intervals.

d) summary of results:

1. patient accountability, including rationale for exclusion of data;
2. significant and/or relevant deviations from protocol;
3. summary of patients not completing study (e.g., lost to follow-up or death);
4. summary of peri-procedural (less than 30 days or prior to discharge if longer than 30 days) and late reportable clinical events;
    i) by type of event;
    ii) detail of any events associated with other events in individual patients.
5. summary of delivery system performance;
6. summary of implant performance over time (e.g. leak, migration, patency, component integrity, change in shape);
7. summary of lesion characteristics over time (e.g. aneurysm size changes);
8. summary of lesion characteristics related to implant performance over time (e.g. aneurysm size changes related to leaks);
9. summary of vascular interventions;
10. summary of peri-procedural and late conversions to open surgery;
11. summary of peri-procedural and late deaths;
12. summary of pathology, if appropriate, including representative gross photographs and micrographs;
13. comparison of results for test and control groups;
14. conclusions from study.

8 Manufacturing

The requirements of Clause 8 of EN 12006-3:1998 apply.

9 Sterilization

The requirements of Clause 9 of EN 12006-3:1998 apply.

10 Packaging

The requirements of Clause 10 of EN ISO 14630:1997 apply together with the following:

Each device shall be packaged in a unit container. The contents of each unit container shall be sterile. Each unit container shall be packaged in an outer container.

11 Information supplied by the manufacturer

11.1 General

The requirements of Clause 11 of EN 12006-3:1998 apply.

11.2 Unit container

11.2.1 Implants without delivery system

Each unit container shall be marked in words, phrases, symbols or drawings with at least following:

1) description of the contents;

2) name and address of the manufacturer;

3) name and trade name of the device (if applicable);

4) model;

5) lot/serial number;

6) sterilization method and the notification “STERILE”;

7) single use;

8) use before date;

9) warnings or reference to read the manual (symbol);

10) dimensions: length and nominal relaxed outer diameter (range if applicable) after expansion;

11) water permeability, if appropriate.

11.2.2 Implants with delivery system

Each unit container shall be marked in words, phrases, symbols or drawings with at least following:

1) implant information as described in 11.2.1;

2) delivery system information, at least:

- dimensions: minimum required size of introducer, and guidewire (internal and external diameter as appropriate).

- recommended pressure for balloon catheters, if applicable.

11.3 Outer container

Each outer container shall be marked with all the information as given in 11.2 as well as any applicable storage and/or transport instructions.

11.4 Instructions for use as supplied with/within the packaging of the device

Each unit container or outer container of which the contents are identical shall be supplied with instructions for the use of the device. The instructions shall include the following:

a) indications for use;

b) contra-indications, cautions, and warnings that are applicable;

c) recommended methods for the aseptic presentation and the preparation of the device, including any pre-treatment and implementation techniques;

d) the statement “STERILE, SINGLE USE ONLY” in prominent form;

e) “DO NOT RESTERILIZE”, or resterilization information, if appropriate;

f) notification of additives and/or leachable components, if applicable;

g) recommendations for storage, if applicable;

h) water permeability, if appropriate;

i) attention shall be drawn to significant changes to any previous text of the ” instruction for use” either on the instruction for use or by other means;

j) MRI compatibility of the implant;

k) recommendations for visualization.

Annex A
(informative)

Cross reference of specific aims

Table A.1 — Cross reference of specific aims

DESIGN ATTRIBUTE	Implant integrity	Ability to accurately visualise	Ability to deploy	Ability to access lesion	Ability to re-cross the implant	Ability to withdraw	Ability to post-dilate implant	Conformability to vessel wall	Hemostasis	Fixation effectiveness	Patency	Appropriate sizing	MRI compatibility	Biocompatibility	Vessel wall coverage	Permeability and porosity
CLAUSE																
IMPLANT																
6: Materials	X													X		
7.2.3 Visibility		X	X		X		X									
7.2.4 Crush resistance								X		X	X					
7.2.5 Radial outward force								X		X	X					

7.2.6 Recoil for balloon expandable implants										X		X				
7.2.7 Fatigue testing	X															
7.2.8 Strength		X				X			X							
7.2.9 Evaluation of MRI com-patibility													X			
7.2.10 Implant free surface area															X	
7.2.11 Permeability and porosity																X

DESIGN ATTRIBUTE	**Implant integrity**	**Ability to accurately visualise**	**Ability to deploy**	**Ability to access lesion**	**Ability to re-cross the stent**	**Ability to withdraw**	**Ability to post-dilate stent**	**Conformability to vessel wall**	**Hemostasis**	**Fixation effectiveness**	**Patency**	**Appropriate sizing**	**MRI compatibility**	**Biocompatibility**	**Vessel wall coverage**	**Permeability and porosity**
DELIVERY SYSTEM																
6. Materials														X		
7.3.1 Dimensions			X	X		X			X							
7.3.2 Flexibility				X		X										
7.3.3 Bond strength & torsional bond strength						X										
7.3.3.3 Trackability			X	X		X		X								
7.3.4 Hemostasis									X							

IMPLANT AND DELIVERY SYSTEM																
7.2.1 simulated use			X	X		X		X		X	X	X				
7.4 pre-clinical evaluation: animal testing	X	X	X	X	X	X	X	X	X	X	X	X				X
7.5 clinical evaluation	X	X	X	X	X	X	X		X	X	X	X				

Annex B
(informative)

Definitions of reportable clinical events

Table B.1 — Definitions of reportable clinical events

Complication	Definition
Abrupt reclosure	Obstructed flow in a dilated lesion that was previously documented to be patent with antegrade flow.
Access failure	Failure to reach the intended site with the device (delivery system + accessory device + implant) due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.
Accessory device failure	Inability to use the accessory device as intended due to mechanical failure or patient anatomy. Whether or not the failure contributed to an unsuccessful implant deployment should be documented.
Adynamic ileus	Inability to tolerate oral intake without supplemental IV therapy developing more than 48 h after, but within 30 days of the procedure. The duration of the event should also be reported.
Aneurysm enlargement	Any enlargement of the diameter or volume of the aneurysm sac greater than documented measurement error, as determined by contrast enhanced CT or other appropriate modality.
Aneurysm rupture	The rupture of the native aneurysm sac.
Angina	Chest, neck, arm or other pain related to decreased coronary blood flow.
Arrhythmia	Development of a new atrial or ventricular arrhythmia or exacerbation of a prior arrhythmia requiring treatment (i.e. medical therapy, cardioversion, pacemaker) within 30 days of the procedure.
Atelectasis/pneu-monia	Atelectasis or pneumonia documented by chest X-ray within 30 days of the procedure and requiring treatment with antibiotics, inhalation therapy, intubation or suctioning. The type of treatment required should be reported.
Attachment site leak (Type I endoleak)	Blood flow into the aneurysm sac arising at or from the attachment site occurring at any time after endovascular repair as determined by contrast CT scan, ultrasound, angiography or direct observation at surgery or autopsy.
Branch flow (Type II endoleak)	Retrograde flow from patent branch arteries, for example, lumbar and intercostals, occurring at any time after endovascular repair as determined by contrast CT scan, ultrasound, angiography or direct observation at surgery or autopsy.
Branch vessel occlusion	Clinically significant, unplanned exclusion of a major branch vessel.

Coagulopathy	Development of a bleeding disorder documented by appropriate laboratory studies within 30 days of the procedure. The specific syndrome should also be noted.
Congestive heart failure	Development of an acute episode or exacerbation of existing low cardiac output accompanied by distal and/or pulmonary edema. The need for treatment and the type of treatment administered, as well as the duration of the episode should be reported.
Damage to implant	Damage to the implant caused by an accessory device or the delivery system.
Delivery system failure	Inability to deploy the implant at the intended site due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.
Embolization	Migration of intraluminal debris in the presence of clinical sequelae. This is a reportable category that may encompass events reported under other categories.
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.
Graft dilatation/rupture	Graft dilatation to more than 50 % of the manufacturer's labelled diameter or any graft rupture.
Hematoma	Development of a hematoma related to the endovascular procedure requiring surgical intervention, evacuation and/or transfusion. If the patient requires transfusion, the volume of replaced blood should be reported. If surgical intervention is required, this should also be reported.
Hepatic encephalopathy	Neurological dysfunction due to inadequate metabolism by the liver.
Hypotension	Low blood pressure.
Implant/attachment system fracture	Fracture or breakage of any portion of the implant or attachment system including metallic fracture or breakage of any of the suture material used to construct the implant or secure the implant or attachment system to the graft material.
Implant infection	Development of a confirmed implant infection. The etiology (i.e. implant sterility, endocarditis, etc.) should be reported if known.

Implant migration	Longitudinal movement of all or part of an implant or attachment system for a distance of greater than 1 cm relative to anatomical landmarks that were determined prior to discharge.
Implant realignment	Clinical symptoms associated with movement of the aorta relative to the implant as a result of post-implantation morphological changes. The clinical symptoms should be specified.
Implant thrombosis	Haemodynamically significant thrombus formation within the lumen of the endovascular implant. The degree of narrowing should be specified.
Impotence	Subjective report of failure to resume the degree of sexual function registered preoperatively within 6 months of the procedure.
Ischaemia	Development of the clinical picture of acute or chronic ischaemia within 30 days of the procedure. The cause of the ischaemia should be diagnosed and reported (i.e. embolism, thrombosis or dissection). Define severity and location.
Loss of integrity of the implant wall	Any hole or tear in the wall of the implant.
Lumen obstruction	Unintentional obstruction of flow through the vascular lumen due to twisting or kinking of the implant, oversizing, failure of the implant to fully open, or any other cause.
Lymphocele/lymph fistula	Cystic accumulation of lymf or groin wound drainage occurring at the incision site. Any intervention required to resolve the event should also be reported.
Myocardial infarction	Myocardial infarction documented by the presence of raised cardiac enzymes within 30 days of the procedure. Clinical symptoms, EKG changes and/or hemodynamic instability associated with the event should also be reported.
Neurological deficit	Development of a new transient or permanent neurological deficit or exacerbation of a prior deficit as determined by CT/MRI Scan and/or clinical exam that occurs within 30 days of the procedure. Whether the deficit was permanent or transient should also be reported.
Post-procedure bleeding	Procedure-related bleeding which occurs after the patient leaves the OR resulting in the need for transfusion. The volume of replaced blood, the source of the bleeding and whether or not surgical intervention was required to stop the bleeding should also be reported.
Procedural bleeding	Any blood loss requiring intervention (i.e. transfusion, medical therapy). The volume of blood lost during the procedure should be determined from the operative report. The need for transfusion and the volume and source (banked, autologous, autotransfused) of transfused blood should also be reported.
Pulmonary embolism	Clinical evidence of pulmonary embolism confirmed by high-probability VQ scan or pulmonary angiography occurring within 30 days after the procedure.
Recurrence of portal hypertension	Recurrent high blood pressure in the portal venous system.
Renal failure	A rise in creatinine greater than 50 % above the pre-procedure level resulting in a creatinine level above high normal that does not spontaneously resolve. The need for and the duration of dialysis treatment should also be reported.

Respiratory failure	The need for mechanical ventilation beyond the first 24 h after the procedure or the need for reintubation or ventilator support any time between 24 h and 30 days postoperative (unless the patient was ventilator dependent when he/she entered the study). The duration of ventilator support should be reported.
Restenosis	Reduction in diameter when compared to the reference diameter.
Spinal neurological deficit	Neurological deficit related to spinal chord ischemia developing within 30 days of the procedure.
Transgraft leak (Type IV endoleak)	The documented leakage of blood through the graft wall.
Trauma to adjacent structures	Injury to adjacent structures associated with vascular trauma (see definition below).
Vascular trauma	Injuries to vessels as a result of an endovascular procedure, including dissections or perforations, false or true aneurysms. The specific site and source of the injury as well as the clinical sequelae should be reported. All required surgical or interventional procedures required to repair the injury should also be reported.

Annex ZA
(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 93/42/EEC of 14 June 1993 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 of this standard are likely to support requirements of UE Directive 93/42/EEC of 14 June 1993 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.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clauses/sub-clauses of this European Standard	Corresponding paragraphs of Annex I: "Essential Requirements" of Directive 93.42.EEG	Comments
4	**1, 2, 4, 7.1**	
5	**1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.5, 8, 9.2**	
6	**1, 2, 7.1, 7.2, 7.3, 7.5, 8.2, 9.2**	
7	**1, 2, 3, 4, 6, 7.1, 7.2, 8, 9.2, 14**	
8	**1, 2, 3, 5, 7.1, 7.2**	
9	**1, 2, 3, 7.2, 8.1, 8.3, 8.4**	
10	**1, 2, 3, 5, 7.2, 8.3, 8.4**	
11	**1, 2, 8.7, 13.1, 13.3, 13.4, 13.6**	

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