SLOVENSKI STANDARD
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Instrumenti, ki se uporabljajo pri neaktivnih kirurških vsadkih (implantati) - Splošne zahteve

Instrumentation to be used in association with non-active surgical implants - General requirements

Instrumente die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen

L'instrumentation devant etre utilisée en association avec les implants chirurgicaux non actifs - Exigences générales

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English version

Instrumentation to be used in association with non-active surgical implants - General requirements

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

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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of an identical text or by endorsement, at the latest by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.

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).

This standard contains requirements that apply to instruments to be used in association with non-active surgical implants.

References can be found in Annex A (informative) "Bibliography".

For relationship with EU Directive(s), see informative Annex C, which is an integral part 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.

Introduction

This European Standard provides a method to demonstrate compliance with the relevant Essential Requirements (ERs) 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 instrumentation which is to be used in association with non-active surgical implants, hereafter referred to as instruments.

1 Scope

This European Standard specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

This standard applies to instruments which may be connected to powered driven systems, but does not apply to the powered driven system itself.

This standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

With regard to safety this standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer.

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 addition of the publication referred to applies.

EN 540	Clinical investigations of medical devices for human subjects.
EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices - Validation and routine control of sterilization by irradiation.
EN 554	Sterilization of medical devices - Validation and routine control of sterilization by moist heat.
EN 556	Sterilization of medical devices - Sterility assurance level for medical devices labelled "Sterile" - Requirements.
EN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
EN 980	Graphical symbols for use in the labelling of medical devices
EN 1041:1998	Information supplied by the manufacturer with medical devices
EN 1441	Medical devices - Risk analysis

NOTE: Annex A summarizes informative references to standards for "non active" surgical implants and to informative referenced harmonized European Standards. These informative references are cited at the appropriate places in the text.

3 Definitions

For the purposes of this European Standard the following definitions apply:

3.1 associated instrument (instrument): Non-active medical device intended for use during surgical procedures related to a specific non active surgical implant.

3.2 re-supplied instrument: Instrument or set of instruments that has been returned to the manufacturer and has been re-issued.

4 Intended performance

The intended performance of an instrument shall be described and documented by addressing the following:

a) functional characteristics;
b) intended conditions of use.

NOTE: Account should be taken of:
- published standards;
- published clinical and scientific literature;
- validated test results.

The extent to which the intended performance has been achieved shall be determined (see clause 7).

5 Design attributes

The development of the design attributes to meet the performance intended by the manufacturer shall take into account at least the following:

a) physical, mechanical and chemical properties of the instrument materials (see clauses 6 and 7);
b) microbiological and particulate contamination levels (see clauses 7, 9 and 10);
c) the ease of use, cleaning and maintenance (see clause 7);
d) the potential deterioration of the material characteristics due to sterilization and storage (see clauses 6, 7 and 8);
e) the effects of contact between the instrument and body, the implant and other instruments (see clause 7);
f) shape and dimensions including their possible effects on the body (see clause 7);
g) wear characteristics of materials and the effect of wear and wear products on the instrument and the body (see clauses 6 and 7);
h) insertion, removal and interconnecting parts (see clause 7);
i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see clauses 6 and 7);
j) the accuracy and stability of instruments with a measuring function (see clauses 7 and 8);
k) the ability of the instrument or fragment of an instrument to be located by means of an external imaging device (see 11.5)

6 Materials

6.1 Selection of materials

Materials for the manufacture of instruments shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage (see clause 7).

The suitability of a given material for a particular application shall be demonstrated by either:

a) evaluating in accordance with clause 7; or

b) by selection from the materials found suitable by proven clinical use in similar applications.

NOTE: Annex B lists some of the materials that have been found acceptable in certain applications.

7 Design evaluation

7.1 General

Instruments shall be evaluated in association with the implant they are designed for to demonstrate that the intended performance (see clause 4) is achieved. Safety shall be demonstrated by pre-clinical evaluation and by carrying out a risk analysis in accordance with EN 1441.

NOTE: In certain circumstances a clinical evaluation can also be required.

7.2 Pre-clinical evaluation

If pre-clinical testing of instruments is required it shall simulate conditions of intended use.

NOTE: Test methods for specific types of instruments are referenced in A.4.

7.3 Clinical evaluation

If a clinical evaluation is required it shall be conducted using the associated implant under the intended conditions of use. Where a clinical investigation is carried out it shall be managed in accordance with the requirements of EN 540.

8 Manufacture

Instruments shall be manufactured specified in accordance with the specified design attributes (see clause 5).

NOTE 1: The application of quality systems as described in EN 46001 and EN 46002 may be appropriate.

NOTE 2: The design specification for re-supplied instruments need not necessarily be the same as the original provided that the requirements of this standard are met.

9 Sterilization

9.1 Products supplied sterile

Instruments which are labelled "STERILE" shall comply with EN 556.

Sterilization processes shall be validated and routinely controlled.
If instruments are to be sterilized by ethylene oxide, EN 550 applies,
If instruments are to be sterilized by irradiation, EN 552 applies,
If instruments are to be sterilized by steam, EN 554 applies.

9.2 Products provided non-sterile

For instruments which are supplied non-sterile, the manufacturer shall specify at least one appropriate sterilization method such that the functional safety of the product is not adversely affected. If multiple sterilizations are not allowed this shall be stated (see 11.5).

10 Packaging

10.1 Protection from damage in storage and transport

For each instrument, the packaging shall be designed so that, under conditions specified by the manufacturer of storage, transport and handling (including control of temperature, humidity and ambient pressure, if applicable), it protects against damage and deterioration and does not adversely affect the intended performance of the instrument.

NOTE: Possible test methods are specified in EN 60068-2-27, EN 60068-2-32 and/or EN 60068-2-47.

10.2 Maintenance of sterility in transit

Instruments labelled "STERILE" shall be packed in such a way that they remain sterile under normal storage, transport and handling conditions, unless the protective package is damaged or opened.

The packaging shall conform to EN 868-1.

11 Information supplied by the manufacturer

11.1 General

Information supplied with instruments by manufacturers shall be in accordance with EN 1041:1998 with the exception of 4.3. All packages shall bear a label which indicates the full contents. If the label does not list the full contents of the package a contents list shall be enclosed. If symbols are to be used, they shall be in accordance with EN 980.

11.2 Instruments with measuring function

The limits of accuracy of instruments having a measuring function shall be indicated by a marking on the device and/or label, instruction leaflet or manual.

NOTE: This requirement does not apply to gauges used for component size selection and 'go' / 'no go' determination.

11.3 Restrictions in combinations

If the instrument is intended to be used in combination with other instruments, devices or equipment, restrictions in the use of the combination shall be indicated on the label or in the instruction leaflet or the manual.

11.4 Marking on instruments

Instruments shall be marked with the following:
- manufacturer's name or trademark;
- batch code or serial number, where appropriate;
- catalogue / article number, where appropriate and/or size indication if needed for safe selection or use.

If the marking would affect the intended performance, or the instrument is too small to be legibly marked, the information required shall be given on the label.

11.5 Instructions for use

If the instrument cannot be used safely without instructions for use, these shall be provided. It shall be indicated whether the instrument or any fragment thereof may be located by means of an external imaging device, and with what kind of such device".

11.6 Instruments intended for single use

Instruments intended for single use only shall be labelled either "for single use only" or by a symbol called up in EN 980.