SLOVENSKI STANDARD
SIST EN 12180:2000

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Neaktivni kirurški vsadki (implantati) - Vsadki za oblikovanje telesa - Posebne zahteve za prsne vsadke

Non-active surgical implants - Body contouring implants - Specific requirements for mammary implants

Nichtaktive chirurgische Implantate - Weichteilimplantate - Besondere Anforderungen an Mammaimplantate

Implants chirurgicaux non actifs - Implants morphologiques - Exigences spécifiques relatives aux implants mammaires

Ta slovenski standard je istoveten z: **EN 12180:2000**

ICS:

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

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EUROPEAN STANDARD
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English version

Non-active surgical implants – Body contouring implants – Specific requirements for mammary implants

Implants chirurgicaux non actifs – Implants morphologiques – Exigences spécifiques relatives aux implants mammaires

Nichtaktive chirurgische Implantate – Weichteilimplantate – Besondere Anforderungen an Mammaimplantate

This European Standard was approved by CEN on 29 October 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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 ZA, 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 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 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.
Level 2 standards contain requirements that apply to all non-active surgical implants in particular families of implants.

NOTE: A Level 2 standard on body contouring implants is currently in preparation.

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

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, in addition to the requirements in the Level 1 and Level 2 standards, a method to demonstrate compliance with the relevant Essential Requirements (ERs) as outlined in general terms in Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to body contouring implants, specifically mammary implants for use in clinical practice.

1 Scope

This standard describes specific requirements for mammary implants for clinical practice.

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

NOTE: At the time of publication of this document for enquiry several test methods specified in the annexes were being validated. For the time being, where appropriate, disclosure statements are included in these annexes.

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)
NF T 46-002	Vulcanized or thermoplastic rubber - Tensile test
NF T 46-007	Vulcanized rubbers - Determination of tear strength (angle tear test piece with or without nick and crescent test piece)
NF S 99-401	Medical devices - Silicone elastomer of medical grade

NOTE: The Bibliography gives informative references to other useful standards.

3 Definitions

For the purposes of this standard the definitions in EN ISO 14630:1997 apply together with the following:

3.1 mammary implant: Implant designed to add to or replace volume of the breast.

3.2 shell: Envelope of the implant.

3.3 seams or seals: Junction of materials fused or adhered together.

3.4 valve: Component into which an accessory is inserted to inflate variable volume implants.

3.5 injection site: Component designed to be penetrated by a needle to alter the volume of the implant.

3.6 diffusion: Movement of material out of an implant through an intact shell.

3.7 base dimensions: Length of the major axis and the length of the minor axis when the implant is placed with its base on a flat horizontal surface at its nominal volume.

3.8 anterior projection: Maximum height of the implant when placed with its base on a flat horizontal surface at its nominal volume.

3.9 orientation means: Mark in or on the implant to assist the surgeon to position the implant.

4 Intended performance

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

5 Design attributes

The requirements of clause 5 of EN ISO 14630:1997 apply.

6 Materials

The requirements of clause 6 of EN ISO 14630:1997 apply. In addition, if silicone elastomer is used, NF S 99-401 applies.

Special attention shall be given to the biological evaluation of the device and its components following implant failure.

NOTE: The biological evaluation should be in accordance with the principles set out in EN ISO 10993-1.

7 Design evaluation

The requirements of clause 7 of EN ISO 14630:1997 apply.

7.1 Pre-clinical evaluation

The pre-clinical evaluation of mammary implants shall conform to 7.2 of EN ISO 14630:1997.

NOTE 1: With regard to validated test methods available for the pre-clinical evaluation this standard reflects the present state of the art. Tests for the evaluation of abrasion of mammary implants and for the evaluation of gel bleeding of mammary implants in vitro are currently under development. As soon as acceptable and validated test methods are available these will be considered for inclusion in this standard by an amendment or revision.

The sample size selected shall be based on a statistical rationale which shall be justified and documented. In addition the following shall be addressed (where applicable):

NOTE 2: Where appropriate, for materials other than silicone the manufacturer should consider and develop tests as indicated in 7.1.

7.1.1 Shell integrity

The integrity of the shell shall be evaluated.

The integrity of the silicone elastomer shall be tested in accordance with Annex B and shall comply with the stated requirements.

NOTE: For other materials, it is recommended that tests with similar conditions are developed.

7.1.2 Valve or injection site competence

The competence of the valve or injection site shall be tested in accordance with Annex C and shall comply with the stated requirements.

7.1.3 Silicone gel

The cohesion of silicone gel shall be tested in accordance with Annex D and shall comply with the stated requirements.

7.1.4 Mechanical tests

Mechanical tests shall be conducted in accordance with Annex E and shall comply with the stated requirements.

7.1.4.1 Fatigue test The fatigue test shall be conducted in accordance with Annex E.1. After testing, the shell of the implant shall not present any tears, cracks or cuts when examined under x10 magnification.

7.1.4.2 Impact resistance test Impact resistance test shall be conducted in accordance with Annex E.2 and shall comply with the stated requirements.

7.1.4.3 Diffusion test Gel diffusion shall be evaluated.

NOTE 1: No validated test method is currently available. The test method and requirements for this clause are under consideration.

NOTE 2: Where no test method is described in this standard, description of the validated test method and sample preparation used should be documented by the manufacturer.

7.1.4.4 Abrasion test
The abrasion properties shall be evaluated.

NOTE: No validated test method is currently available. The methodology outlined in ASTM D3389-87 is recommended as a guide. This method applies to all implants with the exclusion of implants with a silicone elastomer shell filled with silicone gel.

7.1.5 Volume
The volume of prefilled implants shall be within ±2,5 % of the volume stated on the packaging (see11.2). Volume shall be expressed in SI units or equivalent.

7.1.6. Dimensions
The intended design base dimensions and anterior projection and their tolerances shall be considered and recorded.

7.1.7 Surface
If the surface is specially treated or processed in order to form a specific texture, the surface characteristics shall be tested in accordance with Annex A and test results shall be recorded.

7.1.8 Biological evaluation, toxicokinetics and degradation studies
The implant shall be evaluated for reproductive toxicity and mutagenicity.

NOTE: Evaluation may include a study of relevant experience and/or actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design (clause 6 of EN ISO 10993-1:1997).

7.2 Clinical evaluation
The requirements of clause 7.3 of EN ISO 14630:1997 apply.

8 Manufacturing

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

9 Sterilization

Implants shall be supplied sterile. The requirements of 9.1 and 9.3 of EN ISO 14630:1997 apply.

10 Packaging

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

11 Information supplied by the manufacturer

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

11.1 Resterilization
If resterilization is not allowed, this shall be stated in the information provided by the manufacturer.

If resterilization is allowed, the requirements of 9.2 of EN ISO 14630:1997 shall apply.

NOTE: A device to be resterilized is considered a non-sterile device.

11.2 Dimensions
Base dimensions, anterior projection or nominal volume shall be indicated on the label.

11.3 Effects on diagnostic techniques
The effect of the implant on diagnostic techniques such as mammography shall be stated.

11.4 Filling materials
For inflatable implants the manufacturer shall indicate the recommended filling material and the filling instructions.

11.5 Marking on implants
The nominal volume or size shall be indicated.

11.6 Information on expected lifetime
The manufacturer shall provide relevant information on the expected duration of performance of the device as intended. Such relevant information includes the indication of factors which could have a significant influence on the actual lifetime of an individual implant.

NOTE 1: In practice it is not possible to predict accurately the actual lifetime of an individual implant.

It is well understood that several factors are out of the control of the manufacturer. These factors may have a significant effect on the lifetime of an individual device. The factors include the actual implantation procedure, the anatomy and state of health of the patient, the behaviour and activities (e.g. sporting activities), as well as predictable and unpredictable external mechanical influences.

NOTE 2: The manufacturer may select his preferred method of indicating information relating to expected lifetime under defined conditions. This includes information based on statistics.

Examples of possible methods are:
- by indicating a probability of lifetime reaching an expected value;
- by indicating a range within which such lifetime is anticipated to lie;
- by indicating statistical information derived from data obtained with similar devices already implanted.

NOTE 3: The results of tests indicated within this standard provide useful data for the manufacturer in his assessment process to provide information on anticipated lifetime.

11.7 Labelling: additional labels
The package shall include at least two additional labels.
The labels shall list the following:

a) name or trade name of the manufacturer;

b) details necessary for identification;

NOTE: these might include:
- commercial reference of the prosthesis;
- prosthesis description;
- filling volume;
- patient name;
- left or right (tick as appropriate);

c) the serial number or batch code.

Annex A
(normative)

Surface characteristics

The characteristics of the surface shall be examined by SEM (Scanning Electron Microscopy) and documented in order to present the average surface characteristics (± Standard Deviation).

The surface characteristics (e.g. pore size, peaks and valleys) shall be measured over an area of approximately 4 mm^2.

The samples shall include at least three samples taken from the base, the radius and the apex of the implant (total of nine). They shall be representative for the surface as a whole. The average measurements and standard deviation of the characteristics shall be recorded.

NOTE 1: The data resulting from the test at this point in time cannot be related to the performance or safety of the device. The data are meant to generate information to improve knowledge on the correlation of texture and performance.

NOTE 2: For manufacturing control (QA), other methods (stylus, laser etc.) calibrated against the SEM, are allowed.