



SLOVENSKI STANDARD
SIST EN 12563:2000
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Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za umetni kolk

Non-active surgical implants - Joint replacement implants - Specific requirements for hip joint replacement implants

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Hüftgelenkersatz

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Implants chirurgicaux non actifs (protheses de l'articulation de la hanche) - Exigences spécifiques relatives aux protheses de l'articulation de la hanche

[SIST EN 12563:2000](https://standards.iteh.ai/catalog/standards/sist/5e4d3c91-5e6a-4388-9001-647a661d6878/sist-en-12563-2000)

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EUROPEAN STANDARD

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English version

Non-active surgical implants - Joint replacement implants - Specific requirements for hip joint replacement implants

Implants chirurgicaux non actifs - Prothèses de l'articulation
de la hanche - Exigences spécifiques relatives aux
prothèses de l'articulation de la hanche

Nichtaktive chirurgische Implantate - Implantate zum
Gelenkersatz - Besondere Anforderungen an Implantate für
den Hüftgelenkersatz

This European Standard was approved by CEN on 2 December 1998.

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.

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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 June 1999, and conflicting national standards shall be withdrawn at the latest by June 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 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 the highest:

- level 1: General requirements for non-active surgical implants; EN ISO 14630:1997
- level 2: Particular requirements for families of non-active surgical implants (for example for joint replacement implants - EN 12010)
- level 3: Specific requirements for types of non-active surgical implants.

This standard is a level 3 standard and contains requirements applying specifically to hip joint replacements.

The level 1 standard EN ISO 14630:1997 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 more restricted sets or families of implants such as those designed for use in osteosynthesis, cardiovascular surgery or joint replacement.

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 Annex B.

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, in addition to EN ISO 14630:1997 and EN 12010:1997, 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 hip joint replacement implants.

1 Scope

This European Standard provides specific requirements for hip joint replacement implants.

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

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.

ISO 7206-1:1995	Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification, designation of dimensions and requirements.
ISO 7206-2:1996	Implants for surgery - Partial and total hip joint prostheses - Part 2: Bearing surfaces made of metallic and plastics materials
ISO 7206-4	Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties of stemmed femoral components with application of torsion
ISO 7206-6:1992	Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
ISO 7206-8	Implants for surgery - Partial and total hip joint prostheses - Part 8: Endurance performance of stemmed femoral components with the application of torsion
ISO 7206-9	Implants for surgery - Partial and total hip joint prostheses - Part 9: Determination of resistance to torque of head fixation of modular stemmed femoral components.
EN 12010:1998	Non-active surgical implants - Joint replacement implants - Particular requirements.

3 Definitions

For the purposes of this standard the definitions in EN 12010 and ISO 7206-1 apply, together with the following.

3.1 hip joint replacement (hip arthroplasty): Implant used to replace one or both of the articulating surfaces of the hip joint.

3.2 total hip joint replacement (total hip arthroplasty): Implant comprising a femoral component and an acetabular component whether monobloc or modular intended to replace both of the articulating surfaces of the hip joints.

3.3 partial hip joint replacement (hip hemiarthroplasty): Implant comprising a femoral component whether monobloc or modular intended to replace the femoral articulating surface of the hip joint.

NOTE: partial hip joint replacement implants incorporate either a bipolar or a unipolar head.

3.4 bipolar head: Component of a hip joint replacement with a concave (inner) surface intended to articulate with the spherical head of the femoral component and a convex (outer) spherical surface intended to articulate with the biological acetabulum.

3.5 unipolar head: Head of a femoral component intended to articulate with the biological acetabulum.

3.6 femoral component: Part of a total or partial hip joint replacement which is intended to be attached to the femur.

3.7 modular component: Femoral or acetabular component which is assembled by the user from a number of sub-components .

3.8 monobloc component: Femoral or acetabular component which is supplied as a single unit.

3.9 acetabular component: Implant of monobloc or modular construction intended to be fixed to the prepared biological acetabulum.

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4 Intended performance

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The requirements of clause 4 of EN 12010:1998 shall apply together with the following:

Range of angular movement SIST EN 12563:2000
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When measured in accordance with the method given in Annex A the range of movement between the femoral and acetabular components shall be at least 80° in flexion/extension, at least 60° in abduction/adduction and at least 90° in internal/external rotation.

5 Design attributes

The requirements of clause 5 of EN 12010:1998 shall apply together with the following:

5.1 Radio-opacity of acetabular components made of radiolucent materials alone

Monobloc acetabular components made of radio translucent material alone shall comply with the requirements of clause 4 of ISO 7206-1:1995.

5.2 Tolerances and dimensions

Tolerances and dimensions shall be in accordance with the following:

5.2.1 Tolerances and dimensions of taper connections.

NOTE 1: Particular attention should be paid to at least the following: diameter, taper angle, straightness, roundness, micro and macro surface texture.

NOTE 2: In the design of modular femoral components the risk of generation of wear particles at modular component interfaces should be taken into account.

5.2.2 Tolerances on diameters of articulating surfaces

NOTE 1: In this standard ultra high molecular weight polyethylene is designated UHMWPE.

The tolerances on the diameters of the articulating surfaces of metallic or ceramic femoral components intended to be used with UHMWPE acetabular components and the tolerance on the diameters of the articulating surface of UHMWPE acetabular components shall be in accordance with ISO 7206-2:1996 clauses 4.1.3 and 4.2.3 respectively.

NOTE 2: The requirements for sphericity and surface finish for UHMWPE on metal and on ceramic are prescribed in ISO 7206-2.

5.2.3 Requirements for metal-on-metal and ceramic-on-ceramic articulating surfaces

NOTE: there is not yet sufficient information on the surface roughness, tolerance on diameters and clearances to allow specification of these parameters.

5.3 Thickness of UHMWPE in acetabular components and bipolar heads

5.3.1 Acetabular components

For acetabular components of outside diameter 42mm or more the UHMWPE component shall have the following minimum thickness.

- a) 5mm for components with a metal or other backing
- b) 6mm for components without backing

5.3.2 Bipolar heads

For bipolar heads of outside diameter 44 mm or more the minimum thickness of UHMWPE liners shall be 5mm.

NOTE: Where the skeletal size of the population for which these implants are intended requires an acetabular component of less than 42 mm diameter or a bipolar component of less than 44mm diameter it may be necessary to use thickness values less than those specified.

6 Materials

The requirements of clause 6 of EN 12010:1998 shall apply together with the following:

Titanium and titanium alloys

Unalloyed titanium and titanium alloys shall not be used as the articulating surfaces of total hip joint replacements, unless an appropriate surface treatment is undertaken and demonstrated to be suitable in clinical use.

7 Design evaluation

7.1 General

The requirements of clause 7 of EN 12010:1998 shall apply together with the following:

Number of tests

One or more of the tests in 7.2 may not be required:

- a) for every component within a range of components (product family)
- b) where the required test results already exist for the same or a similar component

In these cases a justification for omitting any given test on any given component shall be documented.

7.2. Preclinical evaluation

7.2.1 Endurance testing of femoral components

Femoral components of total hip joint replacement implants shall be tested in accordance with ISO 7206-4. The performance shall conform with ISO 7206-8. The results of the test shall be recorded.

NOTE 1: ISO 7206-4 is in process of revision.

NOTE 2: The performance requirements specified in ISO 7206-8 may be amended to correspond to the revision of ISO 7206-4.

7.2.2 Endurance properties of head and neck region of stemmed femoral components

The head and neck region of stemmed femoral components shall be tested in accordance with 7.2 of ISO 7206-6:1992.

NOTE: An international standard with performance requirements is in course of preparation
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7.2.3 Resistance to torque of modular heads of femoral components

The resistance to torque of the head fixation of modular stemmed femoral components of hip joint replacements shall be determined in accordance with ISO 7206-9. The results of the test shall be recorded.

NOTE: ISO have been approached to prepare a standard for performance requirements.

7.2.4 Wear testing of total hip joint replacements

The wear characteristics of total hip joint replacement implants comprising a femoral component with an integral head or a modular head articulating on a metal, ceramic or UHMWPE acetabular component, shall be tested in accordance with a controlled, validated and documented procedure.