SLOVENSKI STANDARD

SIST EN 12564:2000

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Neaktivni kirurški vsadki (implantati) - Kolenske proteze - Posebne zahteve za kolensko protezo

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

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

Implants chirurgicaux non actifs - Protheses de l'articulation du genou - Exigences spécifiques relatives aux protheses de l'articulation du genou

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English version

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

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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.

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

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Contents

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of an identical text or by endorsement, at the latest by June 1999, and conflicting national standards shall be withdrawn at the latest by June 1999.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;
- level 2: Particular requirements for families of non-active surgical implants (for example 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 knee joint replacements.

The level 1 standard 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 and EN 12010, 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 knee joint replacement implants.

1 Scope

This European Standard provides specific requirements for knee 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 7207-1	Implants for surgery - Components for partial and total knee joint prostheses - Part 1: Classification, definitions and designation of dimensions
EN 12010:1998	Non-active surgical implants - Joint replacement implants - Particular requirements

3 Definitions

For the purposes of this standard the definitions of EN 12010 and ISO 7207-1 apply, together with the following:

3.1 femoral component: Component of a total knee joint replacement intended to be secured to the femur to replace its articulating surfaces. These implants may be manufactured as one component or a set of components to be assembled by the user.

3.2 tibial component: Component of a total knee joint replacement intended to be secured to the tibia to replace its articulating surfaces. These implants may be manufactured as one component or a set of components to be assembled by the user.

3.3 tibial tray: Sub-component used to support and secure the articulating sub-component of a tibial component of a unicompartmental or total knee joint prosthesis.

3.4 patella component: Component of a total or partial knee joint replacement which is used to replace the articulating surface of the patella.

3.5 patella tray: Sub-component used to support and secure the articulating sub-component of a patella component.

3.6 unicompartmental knee joint prosthesis[1]**:** Knee joint prosthesis designed to replace the femoral and tibial bearing surfaces in one compartment of the knee.

3.7 meniscal component: Component of certain total knee joint prostheses which is intended to transmit tibio-femoral load and which moves relative to both the tibial and femoral components.

4 Intended performance

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

Range of angular movment
The intended range of movement between the skeletal parts referred to in 4.1(a) of EN 12010:1998 shall be determined. Annex A indicates a suitable method. This measurement shall be limited to fully constrained knee joints.

5 Design attributes

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

5.1 Thickness of UHMWPE in tibial components and meniscal components

NOTE: In this standard ultra high molecular weight polyethylene is referred to as UHMWPE.

For tibial components and meniscal components made of UHMWPE the UHMWPE component or sub-component shall have the following minimum thickness in the load bearing area:

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[1] This definition supersedes the one presented in ISO 7207-1

a) 6mm for components having a tibial tray of metal or other material
b) 8mm for components without tibial tray

5.2 Finish of non-articulating regions of metallic knee joint components
The surface of the non-articulating regions of metallic knee joint components intended to be exposed to soft tissue shall be smooth and non abrasive.

NOTE: A roughness value Ra of 1,5µm has been found to be satisfactory.

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 knee joint replacement components 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:

7.1.1 Number of tests
One or more of the tests in clause 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 of tibial trays of knee joint components - cemented and non-cemented
The tibial trays of knee joint components intended for use with or without bone cement shall be tested to determine their endurance under cyclic load.

NOTE: ISO have been approached to prepare a standard which will enable the specification of performance requirements based on the test method given in ISO/CD14879-1

7.2.2 Wear testing of total knee joint replacements.
The wear characteristics of total knee joint replacements comprising a metallic or ceramic femoral component articulating on a tibial component shall be tested in accordance with a controlled, validated and documented procedure.

NOTE: ISO has been approached to prepare a standard which will enable the specification of performance requirements based on the test method given in ISO/CD14243 parts 1 and 2.

8 Manufacture

The requirements of clause 8 of EN 12010:1998 shall apply together with the following:

NOTE: Implants or implant components manufactured from cast cobalt-chromium based alloys should be solution heat treated if appropriate. Any solution heat treatment undertaken should be recorded and documented.

9 Sterilization

The requirements of clause 9 of EN 12010:1998 shall apply.

10 Packaging

The requirements of clause 10 of EN 12010:1998 shall apply.

11 Information to be supplied by the manufacturer

The requirements of clause 11 of EN 12010:1998 shall apply together with the following:

11.1 Information supplied on the label

The following shall be stated:

a) Product type

b) Nominal width and depth of the knee joint femoral component and (if a stem is incorporated) its stem length and diameter (see ISO 7207-1) or other indicator such as 'small, medium or large'.

c) nominal width and depth of the tibial component and its stem length and cross-sectional dimensions (see ISO 7207-1), or other indicators such as "small, medium or large.

d) The nominal diameter of the patella component (if it is to be used in the system).

11.2 Constructional compatibility of components

The following shall be stated:

For femoral, tibial, meniscal or patella components which are intended to be structurally and/or functionally compatible with each other, the instructions for use or manual shall indicate which other components are to be used.

NOTE: In general, components manufactured by one company may not be compatible with components manufactured by any other company.

11.3 Information to the patient

The manufacturer shall include in the instructions leaflet or manual at least the following statement or equivalent:

'Patients receiving knee joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity'.