Mitteaktiivsed kirurgilised implantaadid. Osteosünteesiks ettenähtud implantaadid. Erinõuded

Non-active surgical implants - Implants for Osteosynthesis - Particular requirements

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14602:2010 sisaldab Euroopa standardi EN ISO 14602:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14602:2010 consists of the English text of the European standard EN ISO 14602:2010.
Standard on kinnitatud Eesti Standardikeskuse 30.06.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.04.2010.	Date of Availability of the European standard text 15.04.2010.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14602

April 2010

ICS 11.040.40

Supersedes EN ISO 14602:2009

English Version

Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010)

Implants chirurgicaux non actifs - Implants pour ostéosynthèse - Exigences particulières (ISO 14602:2010)

Nichtaktive chirurgische Implantate - Implantate zur Osteosynthese - Besondere Anforderungen (ISO 14602:2010)

This European Standard was approved by CEN on 14 April 2010.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 14602:2010: E

Foreword

This document (EN ISO 14602:2010) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by October 2010, and conflicting national standards shall be withdrawn at the latest by October 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14602:2009.

This document 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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14602:2010 has been approved by CEN as a EN ISO 14602:2010 without any modification.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC as amended by EU Directive 2007/47/EC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices as amended by Directive 2007/47/EC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC as amended by Directive 2007/47/EC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC as amended by Directive 2007/47/EC	Qualifying remarks/Notes
4	1 – 2 – 3 – 4 – 5 – 7.1	
5	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.5, 7.6, 8, 9.1, 9.2	
6	1 – 2 – 7.1 – 7.2 – 7.3 – 7.4 – 7.5 – 8.2 – 9.2	
7	1 – 2 – 3 – 4 – 6 –6.a – 7.1 – 7.2 – 7.3 – 7.5 – 7.6 – 8 – 9.1 – 9.2	
8	1 – 2 – 3 – 5 – 7.1 – 7.2	
9	1 – 2 – 7.2 – 8.1 – 8.3 – 8.4 – 8.5	
10	1 – 2 – 3 – 5 – 7.2 – 8.3 – 8.6	
11	1 – 2 – 8.7 – 13	The part of ER 13.3 a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this International Standard. ER: 13.3 f) is only partially addressed in this International Standard. The safety issue is addressed, but not the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

In general, non-active surgical implants for osteosynthesis are used in trauma treatment or corrective surgery. They maintain the reduction of fractured bones and stabilize bony (or adjacent) structures to allow bone healing or fusion and/or to provide support or correction. When they have achieved their objective, the implants are either retrieved or left *in situ*.

This International Standard, in addition to the requirements in ISO 14630, provides a method for addressing the fundamental principles in ISO/TR 14283 as they apply to non-active surgical implants for osteosynthesis. Annex A shows the correspondence between the clauses of this International Standard and those of ISO/TR 14283:2004.

This International Standard also provides a method of demonstrating compliance with the relevant essential requirements (ERs) as outlined in general terms in Annex 1 of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5 September 2007, as they apply to non-active surgical implants for osteosynthesis. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

Alternative methods of demonstrating compliance might be acceptable, in particular with respect to implants which have demonstrated satisfactory long-term clinical performance.

There are three levels of standard concerned with non-active surgical implants and related instrumentation. For the implants themselves, there are the following levels, with level 1 being the 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.

Level 1 standards contain requirements that apply to all non-active surgical implants. They also indicate that additional requirements are given in the level 2 and level 3 standards.

Level 2 standards, such as this International Standard, contain requirements that apply to a more restricted set or family of non-active surgical implants. This International Standard is a Level 2 standard that lays down particular requirements for non-active surgical implants for osteosynthesis that are in addition to those general requirements stated in ISO 14630 for non-active surgical implants. It is to be applied in conjunction with ISO 14630.

Level 3 standards, such as those listed in the annexes, apply to specific types of implant within a family of non-active surgical implants, in this case particular types of non-active surgical implant for osteosynthesis.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

Non-active surgical implants — Implants for osteosynthesis — Particular requirements

1 Scope

This International Standard specifies particular requirements for non-active surgical implants for osteosynthesis, hereafter referred to as implants.

In addition to ISO 14630, this International Standard gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14630:2008, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

3.1
non-active surgical implant for osteosynthesis
non-active implantable device intended to provide support to bony, cartilaginous, tendinous or ligamentous structures

4 Intended performance

4.1 General

The intended performance of implants shall conform to ISO 14630:2008, Clause 4, taking account of the additional aspects listed in 4.2, 4.3 and 4.4 as applicable.

NOTE Because of variations in anatomy, fracture sites and applications, it is necessary that implants for osteosynthesis be versatile. For anatomical reasons the size of the implants is necessarily restricted. The condition of the bone and the configuration of bony and other defects can affect the performance of the implants.