BS EN 1642:2011

BSI Standards Publication

Dentistry — Medical devices for dentistry — Dental implants

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 1642:2011. It supersedes BS EN 1642:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/8, Dental implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 76107 2

ICS 11.060.15

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2011.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1642

October 2011

ICS 11.060.15

Supersedes EN 1642:2009

English Version

Dentistry - Medical devices for dentistry - Dental implants

Médicine bucco-dentaire - Dispositifs médicaux pour la médicine bucco-dentaire - Implants dentaires

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Dentalimplantate

This European Standard was approved by CEN on 20 September 2011.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 1642:2011: E

Contents

Foreword

This document (EN 1642:2011) has been prepared by Technical Committee CEN/TC 55 “Dentistry”, 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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 1642:2009.

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 93/42/EEC.

For relationship with EU Directive 93/42/EEC, see informative Annex ZA, which is an integral part of this document.

The following changes were made:

a) normative references:

   1) addition of new relevant product standards, issued after 2004: EN 1641, EN ISO 11135-1, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14801, EN ISO 14971, EN ISO 22794, EN ISO 22803;

   2) deletion of the following withdrawn standards: EN 550, EN 552, EN ISO 14727;

b) 4.5 Clinical evaluation: clarification of requirement for a clinical evaluation;

c) 4.6.4 Instructions for use: clarification of requirement that information may be provided in an electronic format;

d) Annex ZA: actualisation of the annex.

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 United Kingdom.

Introduction

There are three levels of European Standards dealing with medical devices used in dentistry. These are as follows:

— Level 1: General requirements for medical devices;

— Level 2: Requirements for families of medical devices used in dentistry;

— Level 3: Specific requirements for types of medical devices used in dentistry.

There are no level 1 standards written exclusively in respect of medical devices used in dentistry.

This European Standard is a level 2 standard and details requirements that apply to dental implants (for surgically implantable dental materials included within the definition of restorative materials see EN 1641). It is also indicated that there are additional requirements in the level 3 standards. Where available, these are included as normative references. To cover all the requirements for a particular product, it is necessary to use a standard of the lowest available level.

In the bibliography a reference for guidance on the classification of dental devices and accessories [4] is given.

1 Scope

This European Standard specifies general requirements for dental implants and accessories. Surgically implantable dental materials defined as restorative materials are specifically excluded and described in EN 1641.

This European Standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, 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.

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 21942-1:1991, *Dental vocabulary — Part 1: General and clinical terms (ISO 1942-1:1989)*

EN 21942-2:1992, *Dental vocabulary — Part 2: Dental materials (ISO 1942-2:1989)*

EN ISO 1942-5:1994, *Dental vocabulary — Part 5: Terms associated with testing (ISO 1942-5:1989)*

EN ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)*

EN ISO 10451, *Dental implant systems — Contents of technical file (ISO 10451:2002)*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)*

EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)*

EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

EN ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)*

EN ISO 14801*, Dentistry — Implants — Dynamic fatigue test for endosseous dental implants (ISO 14801:2007)*

EN ISO 14971*, Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

EN ISO 22794, *Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of technical file (ISO 22794:2007)*

EN ISO 22803, *Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of technical file (ISO 22803:2004)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 21942-1:1991, EN 21942-2:1992, EN ISO 1942-5:1994 and the following apply.

3.1
dental implants
device designed to be placed surgically within or on the mandibular or maxillary bone to provide resistance to displacement of a dental prosthesis or to provide orthodontic anchorage

NOTE The term dental implant includes transendodontic implants.

4 Requirements

4.1 General

4.1.1 Dental implants shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the implant concerned. Conformity with these requirements shall be considered to be met by demonstrating compliance with the requirements of the following subclauses, if appropriate.

4.1.2 Risk management shall be carried out and documented. This shall include a risk analysis in accordance with EN ISO 14971.

4.2 Design and properties

4.2.1 Materials

Dental implants shall be manufactured from materials selected with regard to the properties required for the intended purpose.

4.2.2 Contents of technical file

The contents of the manufacturer's technical file shall be in accordance with EN ISO 10451, EN ISO 22794 and EN ISO 22803, if applicable.

4.2.3 Biocompatibility

Dental implants shall be assessed for biocompatibility. Guidance on the selection of tests is given in EN ISO 7405 and EN ISO 10993-1. EN ISO 7405 includes usage tests specific to dental materials.

Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

NOTE Further information is given in Annex I of Council Directive 67/548/EEC of 27 June 1967.

4.2.4 Biophysical properties and modelling

Dental implants, other than those designed to provide orthodontic anchorage, shall be assessed for mechanical stability by fatigue testing according to EN ISO 14801.

NOTE The stability of dental implants designed to provide orthodontic anchorage shall be assessed by mechanical tests with regard to the properties required for the intended purpose.

4.3 Control of contamination

4.3.1 General

4.3.1.1 Dental implants shall be manufactured under such conditions so as to minimize microbial or other contamination.

4.3.1.2 The condition in which dental implants are supplied shall be clearly stated, i.e. sterile, non-sterile.

4.3.2 Dental implants supplied sterile

4.3.2.1 Dental implants supplied sterile shall comply with EN 556-1.

4.3.2.2 Sterilization processes shall be validated and routinely controlled:

a) If dental implants are to be sterilized by ethylene oxide, EN ISO 11135-1 shall apply;

b) If dental implants are to be sterilized by irradiation, EN ISO 11137-1 shall apply.

4.3.2.3 Packaging systems for dental implants supplied sterile shall be such that the implants remain sterile until the package is opened.

Packaging systems for dental implants supplied sterile shall be in accordance with EN ISO 11607-1 and EN ISO 11607-2.

4.3.3 Dental implants supplied non-sterile

4.3.3.1 Packaging systems for dental implants supplied non-sterile shall maintain the level of cleanliness of the implants during transport and storage.

4.3.3.2 If dental implants are to be sterilized immediately prior to use the method of sterilization shall be given.

4.3.4 Dental implants which incorporate materials of animal origin

The tissues of animal origin shall be from an approved source and shall have undergone appropriate inactivation, conservation and test procedures.

NOTE Further information is given in EN ISO 22442-1 [5].

4.4 Dental implants used in combination

Dental implants used in combination with prefabricated components and connecting systems other than any custom made superstructure such as a denture shall not impair the specified respective performance of any of the parts.

EN ISO 10451 specifies requirements for the contents of a technical file to prefabricated parts connecting a dental suprastructure to a transgingival implant.

4.5 Clinical investigation and evaluation

A clinical investigation shall be conducted for all types of dental implants in accordance with EN ISO 14155-1 and EN ISO 14155-2, unless it is duly justified and documented to rely on existing clinical data.

A clinical evaluation shall be conducted and reported for all dental implants.

4.6 Marking, labelling and information supplied by the manufacturer

4.6.1 General

Information required for the safe use of dental implants shall be provided by the manufacturer in accordance with EN 980, EN 1041, 4.6.2, 4.6.3 and 4.6.4, and the following standards, if appropriate:

EN ISO 10451, EN ISO 22794, EN ISO 22803.

4.6.2 Symbols

Marking, labelling and instructions for use of dental implants shall, if appropriate, include information in the form of symbols as specified in EN 980.

4.6.3 Label

4.6.3.1 The label shall include the following minimum information:

a) name or trade name and address of the manufacturer. For dental implants imported into the Community the name and address of the authorized representative, if the manufacturer does not have a registered place of business in the Community;

b) description of the dental implant, including name, size and material(s);

c) the word "Sterile" or the symbol STERILE, the method of sterilization and the recommended method of opening the pack to ensure sterile presentation at time of use, if appropriate;

a) batch code, preceded by the word "LOT" or the symbol LOT, or the serial number preceded by SN, related to the records of raw materials, manufacture, packaging and, if appropriate, sterilization;

b) "use by" date expressed in accordance with ISO 8601, if appropriate;

c) indication that the dental implant is for single use;

d) the words "exclusively for clinical investigation", if the dental implant is intended for clinical investigations;

e) special storage and/or handling conditions;

f) warnings and/or precautions to take.

4.6.3.2 If it is not practicable for all the above to be included on the label of the primary container, the relevant information shall be provided on the outer packaging or included in the instructions for use.

4.6.4 Instructions for use

NOTE Additional Information for the user may be provided at the discretion of the manufacturer in an electronic format (e.g. webpage, DVD).

The instructions for use shall include at least the following information:

a) details referred to in 4.6.3.1 with the exception of d) and e);

b) intended purpose of the dental implant and any restrictions on use;

c) sufficient details of its characteristics to identify the correct equipment and procedures to be used in order to obtain a safe combination, if, for its intended purpose, the dental implant is used in combination with other restorative materials, devices or prefabricated components;

d) information to avoid risks in connection with implantation of the device;

e) action to be taken in the event of damage to the packaging of a dental implant supplied sterile;

f) details of any further treatment or handling needed before the dental implant can be used (in the case of dental implants provided non-sterile: instructions for final cleaning and sterilization, final assembly);

g) details allowing the dental personnel to brief the patient on the precautions to be taken. These details shall include in particular:

   1) precautions to be taken in the event of changes in the performance of the dental implant;

   2) information on the risk to the patient that may arise after implantation;

h) characteristics and technical factors known to the manufacturer that could pose a risk if the dental implant were to be re-used;

i) date of issue of the instructions for use;

j) should additional information be provided by the manufacturer in electronic format, then the means of accessing this information shall be given.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European 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 concerning medical devices.

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 European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2.1, 4.2.3, 4.2.4	7.1	The three indents of ER 7.1 are covered.
4.4	7.3	Dental implants intended to administer medicinal products are not covered.
4.3.2	8.4	
4.3.1, 4.3.2	8.5	
4.3.3	8.6	Only the part of ER 8.6 relating to maintaining the level of cleanliness is addressed.
4.4, 4.6.4	9.1	Only the part of ER 9.1 relating to not impairing the performance of the other parts of the combination is covered by 4.4. Only the second part of ER 9.1 is addressed in 4.6.4.

Bibliography

[1] 93/42/EEC Council Directive of 14 June 1993, amended by Directive 2007/47/EC, concerning medical devices, Official Journal of the European Union (OJEU), L. 169 from 12.07.1993, pages 1-43.

[2] MedDev 2.7.1, European Commission, Guidelines on Medical Devices (MedDev), Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies, Version 2.7.1, April 2003.

[3] CEN/TR 12401, *Dentistry — Guidance on the classification of dental devices and accessories*

[4] EN ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity (ISO 3950:1995)*

[5] EN ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007)*

[6] EN 1641, *Dentistry — Medical devices for dentistry — Materials*

This page deliberately left blank

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™