SLOVENSKI STANDARD
SIST EN ISO 21563:2013

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Nadomešča:
SIST EN 21563:2000
SIST EN ISO 13716:2001
SIST EN ISO 1564:2000

Zobozdravstvo - Hidrokoloidni materiali za oblikovanje (odtise) (ISO 21563:2013)

Dentistry - Hydrocolloid impression materials (ISO 21563:2013)

Zahnheilkunde - Hydrokolloidabformmassen (ISO 21563:2013)

Médecine bucco-dentaire - Matériaux d'impression hydrocolloïde (ISO 21563:2013)

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ICS:

11.060.10	Zobotehnični materiali	Dental materials

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English Version

Dentistry - Hydrocolloid impression materials (ISO 21563:2013)

Médecine bucco-dentaire - Produits pour empreintes à base d'hydrocolloïdes (ISO 21563:2013)

Zahnheilkunde - Hydrokolloidabformmassen (ISO 21563:2013)

This European Standard was approved by CEN on 22 June 2013.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 21563:2013) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.

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 21563:1991, EN ISO 13716:2000, EN ISO 1564:1998.

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Endorsement notice

The text of ISO 21563:2013 has been approved by CEN as EN ISO 21563:2013 without any modification.

INTERNATIONAL STANDARD

ISO 21563

First edition
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Dentistry — Hydrocolloid impression materials

Médecine bucco-dentaire — Produits pour empreintes à base d'hydrocolloïdes

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 21563 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition of ISO 21563 constitutes a consolidation of the three standards listed below and, as such, cancels and replaces, in whole, all three of the standards listed.

— ISO 1563:1990, *Dentistry — Alginate impression materials*

— ISO 1564:1995, *Dental aqueous impression materials based on agar*

— ISO 13716:1999, *Dentistry — Reversible/irreversible hydrocolloid impression materials systems*

Re-evaluations of all the provisions stated in the three ISO standards to be included in the consolidation led to the significant technical changes listed as follows.

— The alginate hydrocolloid impression materials (ISO 1563) are now required to be subject to the same tear strength test that has been in effect for the agar hydrocolloid impression materials (ISO 1564 and ISO 13716) instead of being subject to a compressive strength test.

— The requirement for the alginate impression material powder materials to be “free from foreign materials”, as stated in ISO 1563, has not been carried forward into the consolidation because no objective test has been specified for determining compliance with the requirement.

— The “gelation temperature” requirements in ISO 1564 and ISO 13716 have not been carried forward for the agar impression materials because results of the elastic recovery test (7.5), if conducted following the required manufacturer’s instructions for use (8.2.1 and/or 8.2.2), will indicate whether adequate gelation will take place during clinical use of the materials.

Introduction

Parties seeking clarification of any provisions of this International Standard, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting ISO/TC 106, Dentistry, whose address can be obtained through inquiry to the national standards body representing the interests of the inquiring parties.

Dentistry — Hydrocolloid impression materials

1 Scope

This International Standard specifies the requirements and tests for helping determine whether the elastic aqueous agar and alginate hydrocolloid dental impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes. It also specifies requirements for labelling and instructions for use.

NOTE This International Standard specifies no requirements or tests for freedom from unacceptable biological hazards. However, it is recommended that, to address possible biological hazards associated with the use of hydrocolloid impression materials, interested parties should refer to ISO 7405 and ISO 10993.

2 Normative references

The following referenced documents are indispensable for 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 1942, *Dentistry — Vocabulary*

ISO 6873, *Dentistry — Gypsum products*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
bonding
adherence of the reversible and non-reversible impression material components constituting a single impression after each of the separate but interfacing materials has reached the level of elasticity and effective setting required for successful removal from the mouth

3.2
bulk container
labelled consumer packaging or primary packaging container holding a greater amount of otherwise unpackaged granular, liquid, powder, or other loose substance than is usually needed for a single dental clinical or laboratory procedure

3.3
combined reversible/non-reversible impression material system
system of impression making in which a light bodied agar material is first syringed around selected teeth so that it can bond with the non-reversible alginate material that will be forced over it later during the formation of an impression

3.4
consumer packaging
retail packaging
sales packaging
packaging constituting, with its contents, a sales unit to the final user or consumer at the point of retail

[SOURCE: ISO 21067:2007, definition 2.2.5]

3.5
elastic recovery test
method of determining whether an elastic impression material will possess the elastic properties required to recover optimally from deformation occurring during removal of impressions from contact with the impressed oral or craniofacial tissues

3.6
extrusion temperature
temperature at which a liquefied Type 3 or Type 3A agar impression material is extruded from the containing cartridge or syringe onto any oral cavity tissue

3.7
impression
negative copy of oral or craniofacial tissue surfaces obtained by impressing a mouldable impression material, usually contained in an impression tray, or injected into contact with the tissue surfaces, and allowing it to harden, or to become elastic, such that the entire impression material/tray assembly can be removed from the contact without significant harm to the tissues or to the assembly

Note 1 to entry: A properly formed impression is capable of having a relatively fluid model (cast) forming material poured against the intaglio surface so that, when the modelling material sets, a positive copy of the impressed surfaces is formed.

3.8
initial setting time
time, measured from commencement of mixing components of a material, or otherwise activating the chemistry involved, and ending at a time when results of a prescribed test show that the activated material has begun to set at a rate indicating that the effective setting time will be reached at some predictable time thereafter

Note 1 to entry: Initial setting times stated in the manufacturer's instructions are useful to test operators, users and standards developers because they can be helpful:

— in determining whether quality of a product has deteriorated before or after opening of the packaging; for example, if the initial setting time found by the test operator or user corresponds closely to that stated in the manufacturer's instructions, it can be assumed that the product is of a quality suitable for testing or use;

— in the development of standards for certain materials when there is a need for a standard to identify a reference point in time that can be used as a basis for specifying a later point in time at which a subsequently specified procedure can safely begin.

EXAMPLE It is reasonable to expect that the effective setting times for certain types of gypsum product mixtures will have been reached within 45 min after the initial setting times previously recorded for the mixes.

3.9
liquefaction
process of heating an agar impression or duplicating material to change it from the elastic gel state to the mouldable or pourable sol state

3.10
non-reversible impression material
any impression material which, having been brought to the effective setting stage as required for removal from the mouth, cannot be returned to the mouldable state required for forming impressions

3.11
primary packaging
primary container
immediate container (deprecated)
packaging designed to be in direct contact with the product

Note 1 to entry: Adapted from ISO 21067:2007, definition 2.2.2.

3.12
reversible impression material
impression material such as an agar hydrocolloid which, after having been brought to the gel state for marketing purposes, can be heated so as to bring it to the relatively fluid colloid or paste-like state required for making an impression

Note 1 to entry: Whereas in past years the "gel to sol" and "sol to gel" reversibility capacities of such impression materials has allowed them to be recycled for repeated uses, modern infection control practices now discourage user recycling of the reversible impression materials for repeated uses in the mouth.

3.13
secondary packaging
over packaging (deprecated)
packaging designed to contain one or more primary packagings together with any protective materials, accessory devices that may have to be provided for use with the product

Note 1 to entry: Adapted from ISO 21067:2007, definition 2.2.3.

3.14
storing
process of holding increments of liquefied reversible agar hydrocolloid impression material at a reduced temperature pending time they will be injected or tempered for impression making purposes

3.15
strain-in-compression test
standardized test method for determining whether elastic impression materials, when formed as impressions, will have the

— flexibility required to permit removal of the impressions from the mouth without significant injury to the impressed oral tissues, and

— the stiffness to resist the deforming forces possibly occurring during the pouring of a model-forming gypsum into the impressions, or to make the material more effective for transferring implant components and securing them in desired positions in an impression

3.16
tempering
process of holding a heavy or medium bodied agar impression material in a slightly higher than mouth temperature water bath, after the material has been placed into an impression tray, so as to further reduce the sol state temperature as necessary for safe and effective seating in the mouth

3.17
unit packet
packaging containing only the amount of product usually needed for a single dental clinical or laboratory application

4 Classification of agar hydrocolloid impression materials

The agar impression materials are classified according to the consistencies they exhibit while they are ready for impressing against the oral or craniofacial tissue surfaces, and when tested according to 5.2.

Type 1 Heavy bodied, for making impressions of complete or partial dental arches, with or without the use of companion increments of lighter bodied Type 2 or Type 3 agar impression materials.

Type 2 Medium bodied, for making impressions of complete and partial dental arches, with or without the use of companion syringe-extruded increments of Type 3 agar materials.

Type 3 Light bodied, for syringe use with either the Type 1 or Type 2 agar materials.