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STN	**Stomatológia Podkladové materiály na podloženie zubných náhrad v zubnej ambulancii Časť 1: Tvrdé materiály (ISO 23401-1: 2023)**	**STN EN ISO 23401-1 85 6406**

Dentistry - Chairside denture base relining materials - Part 1: Hard type materials (ISO 23401-1:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/23

Obsahuje: EN ISO 23401-1:2023, ISO 23401-1:2023

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23401-1

March 2023

ICS 11.060.10

English Version

Dentistry - Chairside denture base relining materials - Part 1: Hard type materials (ISO 23401-1:2023)

Médecine bucco-dentaire - Matériaux de rebasage pour base de prothèses dentaires - Partie 1: Matériaux durs (ISO 23401-1:2023)

Zahnheilkunde - Unterfütterungswerkstoffe am Behandlungsstuhl - Teil 1: Harte Werkstoffe (ISO 23401-1:2023)

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European foreword

This document (EN ISO 23401-1:2023) 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of an identical text or by endorsement, at the latest by September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.

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

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Endorsement notice

The text of ISO 23401-1:2023 has been approved by CEN as EN ISO 23401-1:2023 without any modification.

INTERNATIONAL STANDARD

ISO 23401-1

First edition
2023-03

Dentistry — Chairside denture base relining materials —

Part 1: Hard type materials

Médecine bucco-dentaire — Matériaux de rebasage pour base de prothèses dentaires —

Partie 1: Matériaux durs

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 2, *Prosthodontic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 23401 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of denture base relining materials is to improve the fit of dentures to the oral mucosa. The materials can reline the denture the same day. Thus, they can be a useful material for the general denture patients and especially for bedridden patients who may have no access to dental surgery.

Requirements and test methods for the soft type materials are defined in detail by ISO 10139-1 and ISO 10139-2, but it is extremely difficult to incorporate the hard type materials in these International Standards of soft lining materials because of the differences in the main components, curing mechanisms and physical properties.

Also, chairside denture base relining materials and denture base materials covered by ISO 20795-1 and ISO 20795-2 differ in terms of polymerization method and required properties. As chairside denture base relining materials are partially or even mainly handled intraorally, properties such as consistency and exothermicity during intra-oral polymerization are quite important.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

INTERNATIONAL STANDARD **ISO 23401-1:2023(E)**

Dentistry — Chairside denture base relining materials —

Part 1:
Hard type materials

1 Scope

This document specifies the requirements for acrylic hard type materials used as chairside denture base relining materials and the test methods to determine compliance with these requirements. This document also specifies requirements for packaging and marking the products and for the instructions for use to be supplied by the manufacturer.

Dentures which are relined by chairside denture base relining materials specified by this document are limited to those of acrylic.

This document is not applicable to either denture base relining materials that are for laboratory use or soft lining materials.

NOTE 1 Acrylic hard type materials contain acrylic and methacrylic monomers such as acrylic acid esters and substituted (meth)acrylic acid esters and their polymers.

NOTE 2 Acrylic dentures are made of polymers such as poly (acrylic acid esters), poly (substituted acrylic acid esters) and rubber-modified poly (methacrylic acid esters).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4545-1, *Metallic materials — Knoop hardness test — Part 1: Test method*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*