INTERNATIONAL STANDARD

ISO 28319

Second edition 2018-04

Dentistry — Laser welding and filler materials

Médecine bucco-dentaire — Soudage par laser et matériaux d'apport

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO 28319:2018

https://standards.iteh.ai/catalog/standards/iso/51ac0346-3381-46a6-970f-hf76c3092heb/iso-28319-2018



iTeh Standards (https://standards.iteh.ai) Document Preview

ISO 28319:2018

https://standards.iteh.ai/catalog/standards/iso/51ac0346-3381-46a6-970f-bi76c3092beb/iso-28319-2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Fax: +41 22 749 09 47 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Contents				
Fore	word		iv	
1	Scop	De	1	
2	-	mative references		
3		ns and definitions		
4	Requ 4.1	uirements		
	4.1	Chemical composition		
		4.1.2 Filler material		
		4.1.3 Hazardous elements in filler material		
	4.2	Biocompatibility		
	4.3	Mechanical strength of laser welded joint (tensile strength	1)2	
	4.4	Corrosion resistance	3	
		4.4.1 Static immersion test		
		4.4.2 Appearance after corrosion exposure		
	4.5	Laser welding process	3	
5	Sam	pling	3	
6	Prep	paration of specimens	3	
	6.1	General	3	
	6.2	Specimens for tensile testing	4	
		6.2.1 General	4	
	6.0	6.2.2 Procedure		
	6.3	Specimens for corrosion testing		
		6.3.1 General 6.3.2 Seam geometry	5	
7	Measurement and test methods			
	7.1	Visual inspection	6	
	7.2	Chemical composition Tensile testing Chemical Composition Tensile testing Chemical Chemical Chemical Composition Chemical Composition Chemical Chemical Composition Chemical C	6	
	7.3		oc3092beb/iso-28319-2018 6	
		7.3.1 General		
		7.3.2 Evaluation of tensile testing results		
	7.4	7.3.3 Calculation of tensile strength		
	7.4	Corrosion resistance by static immersion test		
		7.4.1 Reagents 7.4.2 Apparatus		
		7.4.3 Test solution		
		7.4.4 Test procedure		
		7.4.5 Analysis		
		7.4.6 Microscopic inspection		
		7.4.7 Report	8	
8	Insti	ruction for use	8	
9	Mar	8		
	9.1	Marking		
	9.2	Labelling	8	
10	Test	Test report		
Ann	ex A (in	nformative) Laser welding process	10	
Bibli	iogranl	hv	13	

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 28319:2010), which has been technically revised.

The main changes compared to the previous edition are as follows: 6-970f-bl76c3092beb/so-28319-2018

- a) reference to the corrosion standard ISO 10271:2011, for corrosion test methods and measurements has been added;
- b) a corrosion limit for the static corrosion test has been specified;
- c) Annex A has been revised in order to describe the laser welding process.

Dentistry — Laser welding and filler materials

1 Scope

This document specifies requirements and test methods for laser welding and the filler materials thereto used in the dental laboratory for welding of metallic restorations and appliances.

For filler materials used in laser welding, this document also specifies the information given in the instructions for use, marking and labelling.

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 6344-1, Coated abrasives — Grain size analysis — Part 1: Grain size distribution test

ISO 10271:2011, Dentistry — Corrosion test methods for metallic materials

ISO 15223-1:2016, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ISO 22674:2016, Dentistry — Metallic materials for fixed and removable restorations and appliances

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 22674 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1

laser welding

method for joining similar or dissimilar metallic materials, using a laser beam as the heat source, with or without a metallic filler material (welding rod), which produces coalescence by melting abutting zones of metallic material components thereby creating a common fusion zone

3.2

filler material

<laser welding> metallic filling material used for laser welding (3.1)

4 Requirements

4.1 Chemical composition

4.1.1 Metallic materials to be joined

The metallic materials to be joined shall conform to ISO 22674:2016, 5.1 and 5.2.

4.1.2 Filler material

4.1.2.1 Chemical composition

For all elements that are present in excess of 1,0 % (mass fraction), the percentage by mass of each of the constituent elements shall be declared by the manufacturer and shall be reported to a precision of 0,1 % (mass fraction).

Any element that is present in a concentration in excess of 0,1 % (mass fraction), but not in excess of 1,0 % (mass fraction), shall be identified either by name or symbol.

4.1.2.2 Permitted deviation from the reported composition

For silver or noble-metal elements in filler materials, the percentage shall not deviate by more than 0,5 % (mass fraction) from the values stated in the instructions for use.

For base-metal elements in filler materials, all elements, present with more than 20 % (mass fraction) shall not deviate from the value stated in the instructions for use by more than 2 % (mass fraction). Those present in excess of 1 % (mass fraction) but not in excess of 20 % (mass fraction) shall not deviate from the value stated in the instructions for use by more than 1 % (mass fraction).

4.1.3 Hazardous elements in filler material

4.1.3.1 Recognized hazardous elements

For the purposes of this document the elements nickel, cadmium, beryllium and lead are designated to be hazardous elements.

4.1.3.2 Permitted limits for hazardous elements

The filler material shall contain no more than 0,02 % (mass fraction) of cadmium or beryllium or lead. If the filler material contains more than 0,1 % (mass fraction) of nickel, the percentage shall not exceed the amount indicated on the package or label or insert.

4.2 Biocompatibility

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 hazards, reference should be made to ISO 10993-1 and ISO 7405.

4.3 Mechanical strength of laser welded joint (tensile strength)

If the 0,2 % proof strength of both of the metallic materials to be joined by laser welding is more than 350 MPa, the tensile strength of laser-welded specimens shall be at least 350 MPa.

If the 0.2% proof strength of either one or both of the metallic materials to be joined by laser welding is below 350 MPa, the tensile strength shall exceed the lower 0.2% proof strength of the two.

Testing shall be carried out in accordance with <u>7.3</u>.