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Dentistry — Laser welding and filler materials

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

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Foreword

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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 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:

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 7.3.

4.4 Corrosion resistance

4.4.1 Static immersion test

When pieces of a single metallic material are joined, the metal ion release shall not exceed 200 µg cm^{-2} in a time period of 7 d ± 1 h.

The metallic materials to be joined and the laser welded specimens shall conform to ISO 22674:2016, 5.7. Testing shall be carried out in accordance with 7.4.

4.4.2 Appearance after corrosion exposure

Magnified visual comparison prior to and after corrosion testing shall not reveal any visible selective corrosion in the vicinity of the laser weld.

Testing shall be carried out in accordance with 7.4.

4.5 Laser welding process

Specific information about the laser welding process is given in Annex A.

5 Sampling

The metallic filler material and the metallic material each shall be from one lot. It shall be sufficient to prepare the specimens as required in 6.1 and 6.2 including provision for a second set for tensile testing. Further samples and packaging materials shall be made available for inspection in accordance with 9.2.

If the proof strength values of 0,2 % non-proportional extension of the one or two metallic materials to be joined by laser welding are available from a test report according to ISO 22674, these data can be used. If not, perform the tests according to ISO 22674 to determine the required values of proof strength of 0,2 % non-proportional extension.

6 Preparation of specimens

6.1 General

The specimens consist of the metallic materials joined by laser welding either with or without using a filler material according to the instructions for use. For casting alloys to be tested prepare the test specimens by the “lost wax process” of investment casting. Methods other than casting may be recommended by the manufacturer for the metallic material to be tested for suitability for laser welding. Use such a method, if recommended by the manufacturer. Follow the instruction for use relating to the processing of the metallic material(s) and if applicable the filler material including the use of necessary aids and casting and welding equipment.

Specimens with visible defects shall be discarded and replaced. Specimens shall be separated from sprues, casting beads/runners, fins and other projections. Surface contaminations shall be removed.

The specimens shall be in the metallurgical state(s) appropriate to their intended application(s).

If a heat-treatment is recommended by the manufacturer, perform the tests in the heat-treated state in accordance with the instruction for use.

If laser welding is recommended following ceramic firing, the simulated ceramic firing of the specimens shall be in accordance with ISO 22674:2016, 7.2.3, and shall be applied before laser welding.

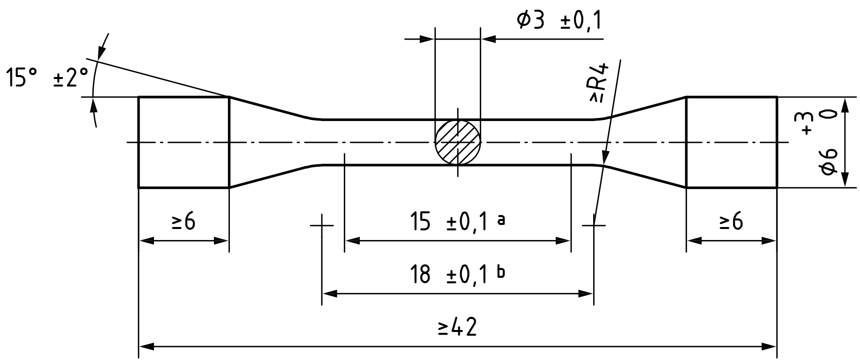
6.2 Specimens for tensile testing

6.2.1 General

Prepare six specimens of the metallic material(s) to be laser welded which conform to either Figure 1 or Figure 2. Cut the specimens of the set at right angles to its long axis at the midpoint of the gauge length using a fine saw.

Replace specimens that have visible shrinkages, defects or porosities.

Dimensions in millimetres

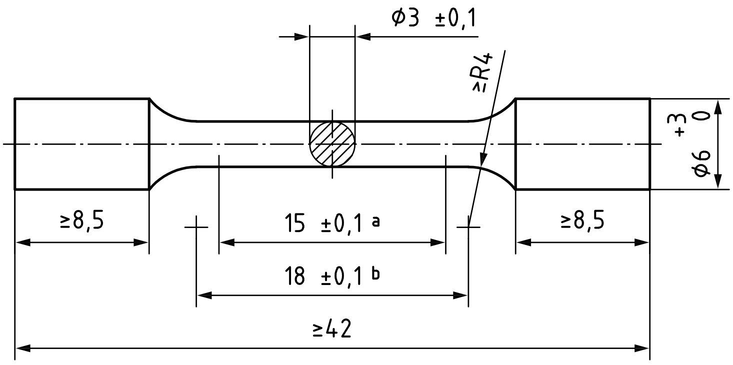


a Gauge length.

b Rotation symmetrical section of test specimen.

Figure 1 — Test specimen with conical shoulders

Dimensions in millimetres



a Gauge length.

b Parallel section of test specimen.

Figure 2 — Test specimen with radial shoulders

6.2.2 Procedure

Support the two halves of the specimens and align them in an investment or a rigid jig. If two different metallic materials are to be laser welded, use one of each for the two halves. In case the recommended filler material is used, follow the instruction for use (see Clause 8).

Weld the specimens with a laser welding unit in accordance with the instructions for use.

After laser welding, ensure that the diameter of each tensile specimen is within the tolerances given in Figure 1 or Figure 2, and does not show visual evidence of radial run-out when rotated.

6.3 Specimens for corrosion testing

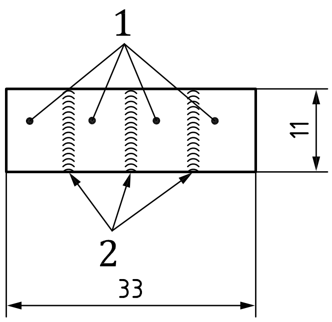
6.3.1 General

Platelets for preparation of specimens are prepared according to ISO 10271:2011, 4.1.6.

For corrosion testing of a laser-welded joint, two test specimens measuring 33 mm × 11 mm × 1 mm shall be prepared (see Figure 3).

Platelets of each metallic material to be joined are cut, to create four narrow parts (of 11 × 8,25 mm each). Once the platelets have been cut, the parts shall be laser-welded in the combination to be tested following the specifications of the manufacturer of the metallic materials (either AAAA or ABAB; A = material 1; B = material 2). Following laser welding, remove at least 0,1 mm from all surfaces of the samples using standard metallographic procedures ending with wet silicon carbide paper of grade P1200 in accordance with ISO 6344-1. Use the same piece of grinding paper solely for the preparation of specimens of the same combination.

Dimensions in millimetres
All tolerances: ± 2 mm



Key

1 metallic plate

2 laser welded seam

Figure 3 — Specimen for corrosion testing, consisting of four platelets fused by laser welding

6.3.2 Seam geometry

There are four possible and permitted seam geometries: V-seam, I-seam, X-seam and Y-seam, as shown in Figures 4 to Figure 7. The initial letters V, I, X and Y before "–seam" in the names describe these geometries.

Prepare the ends of the specimens to the recommended seam geometry.

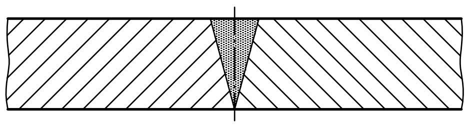


Figure 4 — V-seam

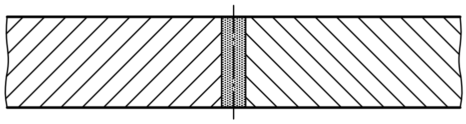


Figure 5 — I-seam

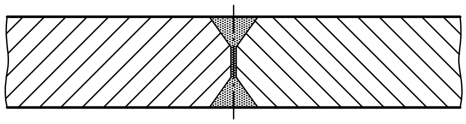


Figure 6 — X-seam

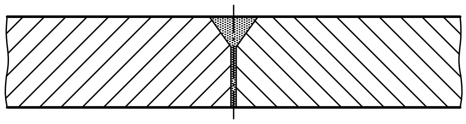


Figure 7 — Y-seam

7 Measurement and test methods

7.1 Visual inspection

Prior to testing the specimens for tensile strength or corrosion resistance visually inspect all weld seams for the presence of cracks, cavities (voids), defects regarding the lack of side wall fusion and if spots overlap adequately and evenly. Record and report these observations.

Visually inspect to check that requirements specified in Clause 8 and Clause 9 have been met.

7.2 Chemical composition

Determine the composition of the filler material using analytical procedures with sensitivities appropriate to concentration of each element and its permitted deviation from the stated value or permitted limit.

7.3 Tensile testing

7.3.1 General

Determine the tensile strength in accordance with ISO 22674 on six test specimens prepared in accordance with 6.2. Load the test specimens in tension in a mechanical testing instrument at a cross-head speed of (1,5 ± 0,5) mm/min until the specimens fracture.

Calculate the fracture stress on the basis of the original cross-sectional area, using the force for elongation at fracture derived from the force/elongation diagram.

7.3.2 Evaluation of tensile testing results

If four, five or six test specimens are found to exceed the minimum requirements given in 4.3, the laser welded joint satisfies the tensile strength requirements of this document.

If two or fewer test specimens are found to conform to the minimum requirements given in 4.3, the laser welded joint fails the tensile strength requirements of this document.

If three test specimens are found to conform to the minimum requirements given in 4.3, repeat the test with a second set of six test specimens.

If, in the second test, five or six test specimens are found to exceed the minimum requirements given in 4.3, the laser welded joint satisfies the tensile strength requirements of this document.

If four of fewer specimens in this second set exceed the minimum requirement given in 4.3 the joint fails the tensile strength requirement for this document.

7.3.3 Calculation of tensile strength

Calculate the tensile strength as the mean of the values of those four, five or six test specimens of the first test, or, if applicable, of those three test specimens of the first test plus those five or six test specimens of the second test, that are found to conform to the requirements given in 4.3, and report to the nearest 5 MPa.

7.4 Corrosion resistance by static immersion test

7.4.1 Reagents

Use reagents in accordance with ISO 10271:2011, 4.1.3.

7.4.2 Apparatus

Use apparatus according to ISO 10271:2011, 4.1.4. The sensitivity of the water-pH meter should be ±0,05 pH units.

7.4.3 Test solution

Prepare a fresh solution for each test according to ISO 10271:2011, 4.1.5.

7.4.4 Test procedure

Determine the surface area of each test specimen to the nearest 0,1 cm^2. Immerse the specimens in ethanol or methanol and clean for 2 min in an ultrasonic bath.

Rinse the specimens in water and dry them with water-free and oil-free compressed air. Place each specimen in a separate borosilicate glass container and follow the test procedure according to ISO 10271:2011, 4.1.7.

Use an additional container to hold a reference solution to be maintained in parallel with the solutions containing the specimens, as specified in ISO 10271:2011, 4.1.7.

Record the pH value of the solution. Add the solution to each container sufficient to produce a ratio of 1 ml of solution per 1 cm^2 of specimen surface area and to fully immerse it. Record the volume used, to an accuracy of 0,1 ml. Close the container to prevent evaporation. Hold at (37 ± 1) °C for 7 d ± 1 h. Remove the specimens and record the pH value of the residual solution.

7.4.5 Analysis

Analyse each test solution quantitatively for constituents of the metallic filler materials as specified in 8 a) and the constituents of the metallic material to be joined, as specified in ISO 22674:2016, 4.1.8. In addition analyse for nickel, cadmium, beryllium and lead.

7.4.6 Microscopic inspection

Perform microscopic inspection of the laser welded joints with a magnification of at least ×10 prior to and after corrosion testing in accordance with 7.4.4. Record the surface of the laser welded joints by appropriate micro-photography.

7.4.7 Report

Describe the analytical method used, and give the detection limits for the elements under investigation. For all elements found in each test solution, record the values in μg/cm^2 separately. Calculate the total amount of leached ions for each test solution and report the mean.

8 Instruction for use

The instruction for use for a metallic filler material (welding rod) for laser welding shall contain at least the following information about applications and processing of laser welding:

a) all alloying elements, present in excess of 1 % (mass fraction) shall be stated quantitatively and all other alloying elements present in concentrations between 0,1 % and 1 % (mass fraction) shall be mentioned either by name or by symbol;

b) if the metallic filler material contains nickel in excess of 0,1 % (mass fraction), adequately detailed information regarding its potential for adverse reactions and the text: “This product contains nickel.”;

c) a general warning regarding the potential health hazards associated with the inhalation of metallic dust;

d) instruction(s) for fabrication and processing;

e) metallic materials and/or the combinations, recommended for use with the filler material.

9 Marking and labelling

9.1 Marking

The direct packaging of metallic filler material shall be clearly marked to identity the manufacturer and the material.

9.2 Labelling

The label or the insert in the package shall be marked at least with the following information:

a) name of manufacturer or authorized representative and/or trademark and address;

b) trade name or brand name of the filler material;

c) lot number;

d) minimum net mass, expressed in grams;

e) all alloying elements, present in excess of 1 % (mass fraction) shall be stated quantitatively and all alloying elements present in concentrations between 0,1 % and 1 % (mass fraction) shall be mentioned either by name or by symbol;

f) if the filler material contains more than 0,1 % (mass fraction) of nickel [see 8 b)], a caution symbol in accordance with ISO 15223-1:2016, 5.4.4, Table 1 (a triangle within which there is an exclamation mark).

10 Test report

For documentation of suitability of metallic materials for laser welding in the context of this document a test report shall be prepared. The test report shall contain at least the following information:

a) batch number of fused alloys and batch number of filler material;

b) seam geometry used for testing of tensile strength and corrosion;

c) filler material, if used;

d) the laser welding equipment that was used;

e) parameter settings for laser welding (pulse energy, current, pulse length, frequency, focal settings, protection gas);

f) reported results for the tensile strength and corrosion resistance in accordance with Clause 7;

g) name of the test house.

Annex A
(informative)

Laser welding process

A.1 Work station and equipment

The laser welding unit available shall be suitable for the welding job at hand.

Welding shall be conducted with argon as shielding gas [Group I argon, Code No. 1 (purity ≥ 99,99) in accordance with ISO 14175].

Both welding energy and performance shall be controllable through appropriate settings on the laser welding unit (e.g. pulse voltage and pulse duration).

A microscope presumably with protection to prevent laser light reaching the eyes of the observer is needed and should provide for not less than 10-power magnification.

A.2 Protective device and safety measures

A.2.1 General

All prescribed protective devices shall be in place during the welding procedure, and protective measures required shall be observed.

A.2.2 Personal protection against laser radiation

Functionality and effectiveness of laser radiation shielding (e.g. shutter) shall be checked in regular intervals.

A.2.3 Personal protection against dust and fumes

An operational exhaust system shall be in place and adequately maintained.

A.3 Maintenance and operational state

A.3.1 Maintenance of welding equipment

Welding equipment shall be maintained in regular intervals in accordance with the laser manufacturers' instructions for use. Maintenance shall be documented.

A.3.2 Operational state

Prior to welding check the operational state of the laser welding unit.

A.4 Selection of materials

Select the appropriate materials. The combination of materials used, including additives, shall conform to the requirements for suitability for laser welding, as specified in this document.

A.5 Joining technique

Use the recommended joint geometry for the intended application.

A.6 Inspection of welding results

Inspect the welding result. The welding result should exhibit all quality and safety features.

A.7 Operational state of laser welding unit

A.7.1 General

Check the adjustability of the welding parameters in accordance with the laser manufacturers' instructions.

A.7.2 Visual inspection

All functional displays of the laser welding unit should signal full operational state.

Shielding gas feeding should be released and adjusted. There is a possibility that the operational pressure may have to be readjusted.

Any obstructive coating on protective glasses shall be removed by means of appropriate glass detergents.

A.7.3 Setting of working microscope

The eyepiece with cross hairs should be in sharp focus.

Move the workpiece surface into focal plane by vertical readjustment (e.g. lift the table). The eyepiece is focused onto this second plane.

A.7.4 Check of laser beam

The laser beam shall be checked, e.g. by means of blackened photographic paper. The photographic paper is placed flat on the bottom of the welding chamber. A test shot is fired, using parameters specified by manufacturer data for medium energy and time, to achieve surface burning of the photographic paper. Evaporation of the photographic layer should be circular and complete. Minor flaws in the evaporation zone are permissible.

A.7.5 Setting of shielding gas zone

Shielding gas used in equipment with variable shielding gas feeds should be directed to flow evenly across the welding area.

Shielding gas flow should be in accordance with laser manufacturers' instructions for use.

A.7.6 Setting and control of welding parameters

Once the welding parameters of the laser unit have been set, they should be documented by repetitive burning into adjacent spots in the depth of a paper block. This way controls at a later point in time with the stored values in the same paper block can be checked.

A.7.7 Optimization of welding parameters

Welding parameters should be optimized in the following way in response to change of welding conditions:

a) test welding should be precisely at focal plane (e.g. scissor table);

b) welding parameters should be determined and adjusted by preliminary tests, depending on the welding task and the materials to be bonded.

Depth of penetration and outer melting diameter of welding parameters used shall be documented, following rupture of a weld by fusion of alloy platelets with the laser welding spot. The surface of the rupture should be free of visible voids, (pipe) cavities and cracks. This visual inspection shall be conducted under the working microscope of the laser equipment.

A.8 Microscopic inspection of welding result

Check the welding result externally prior to and on completion of work, using the working microscope, to detect or rule out the following irregularities (groups in accordance with ISO 6520-1):

a) cracks;

b) cavities (voids);

c) defects regarding lack of side wall fusion;

d) form variations/geometrical errors (misalignment);

e) other irregularities.

Weld spots should be evenly overlapping, with the degree of overlapping being at least 70 %.

Weld spots should be checked for their adequate location relative to the designed bonding point.

Shortcomings should be rectified. The welding job fails to conform to requirements if rectification proves impossible.

A.9 Fit

Fit, as required for dentistry, should be checked on the model.

Bibliography

[1] ISO 6520-1, *Welding and allied processes — Classification of geometric imperfections in metallic materials — Part 1: Fusion welding*

[2] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[3] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[4] ISO 14175, *Welding consumables — Gases and gas mixtures for fusion welding and allied processes*

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