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Dentistry — Dental rubber dam technique —

Part 2: Clamp forceps

Médecine bucco-dentaire — Technique à digue en caoutchouc —

Partie 2: Pinces porte-crampons

ICS 11.060.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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Contents

Page

Foreword	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements.....	2
4.1 General	2
4.2 Total length	2
4.3 Locking	2
4.4 Distance between the forceps handles in the closed, passive state	2
4.5 Retaining pins	2
4.5.1 Length of the retaining pins	2
4.5.2 Diameter of the retaining pins.....	3
4.5.3 Distance between the retaining pins when the forceps is opened to the maximum degree.....	3
4.6 Spring and ability to return to the original state	3
4.7 Materials	3
4.8 Surface finish	3
4.9 Corrosion resistance and resistance to reprocessing.....	3
5 Test methods	3
5.1 Visual examination	3
5.2 Dimensions	4
5.3 Reprocessing.....	4
6 Marking	4

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.

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ISO 16635-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 16635 consists of the following parts, under the general title *Dentistry* — *Dental rubber dam technique*:

- *Part 1: Hole punch*
- *Part 2: Clamp forceps*

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Introduction

In order to support the increasing use of dental rubber dam the application of dental rubber dam should be supported by standardisation of the required instruments and materials.

In dental practice and when used as intended, clamp forceps for dental rubber dam clamps come into contact with the patient.

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Dentistry — Dental rubber dam technique — Part 2: Clamp forceps

1 Scope

This part of ISO 16635 specifies requirements and test methods for clamp forceps intended for the application of dental rubber dam clamps to teeth.

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.

ISO 1942, *Dentistry — Vocabulary*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method (scales A, B, C, D, E, F, G, H, K, N, T)*

ISO 16635-1, *Dentistry — Dental dam technique — Part 1: Hole punch*

ISO 15510:2010-12, *Stainless steels — Chemical composition*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilisable medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 16635-1 and the following apply.

3.1

dental rubber dam

rubber dam
dental dam

sheet of elastic material used for the isolation of one tooth or several teeth from the rest of the oral cavity

3.1

locking

device located around the parts of the forceps handles near the joint, which locks automatically when the clamp forceps opens, thus fixating the forceps after it has picked up the dental dam clamp

3.2

clamp receiver

working end of the clamp forceps which serves for the picking up and bringing into position of the dental rubber dam clamp and is linked with the forceps joint by means of a connecting piece

NOTE The working ends move diametrically opposed to the forceps handles as a result of the handles being guided in the joint.

3.3

retaining pins

pin-like end of the clamp forceps receiver which is inserted into the holes of the clamp jaws of the dental rubber dam clamps

4 Requirements

4.1 General

In accordance with its intended use, a clamp forceps shall be designed such that it can be used to apply the dental rubber dam clamp across the row of teeth without the forceps coming into contact with the teeth. This requires a distinct level difference between the forceps handle and the retaining pins. The retaining pins shall be provided with a depth-control stop to ensure that they can only be inserted to a certain depth into the hole in the clamp and that the clamp can be safely oriented in the three spatial directions while the forceps is applied to the tooth.

The dimensions for clamp forceps are given in Table 1.

4.2 Total length

The total length of the clamp forceps shall be ≤ 175 mm.

Test in accordance with 5.2.

4.3 Locking

The clamp forceps shall be provided with a mechanism which locks and unlocks when the forceps is used, so that the clamp forceps holds the clamps in the tensioned state and releases them again following their application to the tooth.

Test in accordance with 5.1.

4.4 Distance between the forceps handles in the closed, passive state

The distance between the forceps handles in the closed, passive state shall not exceed 95 mm.

NOTE This ensures safe handling also by people with small hands.

Test in accordance with 5.2.

4.5 Retaining pins

4.5.1 Length of the retaining pins

The length of the retaining pins for the depth control stop shall be $(3,5 \pm 0,5)$ mm.

Test in accordance with 5.2.

4.5.2 Diameter of the retaining pins

The diameter of the retaining pins shall be $(1,5 \pm 0,2)$ mm.

Test in accordance with 5.2.

4.5.3 Distance between the retaining pins when the forceps is opened to the maximum degree

The distance between the retaining pins when the forceps is opened to the maximum degree shall be at least 20 mm (when measured at the outside).

Test in accordance with 5.2.

4.6 Spring and ability to return to the original state

The clamp forceps shall be returned to the passive state by means of a spring.

Test in accordance with 5.1.

4.7 Materials

Clamp forceps shall be made of martensitic hardening corrosion-resistant stainless steel having the material numbers 4021-420-00-I (name of the steel designation: X20Cr13) or 4034-420-00-I (X46Cr13) with a hardness of 42 HRC to 55 HRC or a Vickers hardness of 500 HV1 to 700 HV1, or of austenitic corrosion-resistant steel with the material number 4301-304-00-I (X5CrNi8-10) in accordance with ISO 15510:2010-12.

Test the Rockwell hardness in accordance with ISO 6508-1, scale C, or test the Vickers hardness in accordance with ISO 6507-1.

4.8 Surface finish

The clamp forceps shall be polished; the manufacturer may choose between a brightened and a matted surface.

All surfaces of the clamp forceps shall be free of pores, cracks, scale residues and acidic fats. Any residues of abrasives and/or polishing agents shall be removed.

Test in accordance with 5.1.

4.9 Corrosion resistance and resistance to reprocessing

The clamp forceps shall not show any signs of corrosion.

The clamp forceps shall not exhibit any changes in hardness or mechanical strength, or a permanent deformation exceeding 0,2 mm.

Test in accordance with 5.3.

NOTE Discolorations due to water spots are not regarded signs of corrosion.

5 Test methods

5.1 Visual examination

The visual examination shall be performed with normal visual acuity without any magnification.