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Dentistry — Dental rubber dam instruments —

Part 2: Clamp forceps

Médecine bucco-dentaire — Instruments de digue dentaire en caoutchouc —

Partie 2: Pinces porte-crampons

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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

— *Part 1: Hole punch*

— *Part 2: Clamp forceps*

Introduction

In order to support the increasing use of dental rubber dam the application of dental rubber dam should be supported by standardization 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.

Dentistry — Dental rubber dam instruments —

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

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

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the device manufacturer for the processing of reusable 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 elastomeric film composed of natural rubber latex or synthetic material that is used to isolate one or several teeth from the rest of the oral cavity during a dental restorative procedure

3.2
locking part
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

3.3
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 1 to entry: The working ends move diametrically opposed to the forceps handles as a result of the handles being guided in the joint.

3.4
retaining pins
pin-like ends of the clamp forceps receiver which are 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 that the working end with the retaining pins is angled against the handle and/or stepped.

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 orientated in three spatial directions while the forceps is applied to the tooth.

4.2 Total length

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

Test in accordance with 5.2.

4.3 Locking part

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.

Test in accordance with 5.2.

4.5 Retaining pins

4.5.1 Length of retaining pins

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

Test in accordance with 5.2.

4.5.2 Diameter of retaining pins

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

Test in accordance with 5.2.

4.5.3 Distance between the retaining pins

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 a closed position by means of as 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; S42020), or 4028-420-00-I (X30Cr13; S42030), 4034-420-00-I (X46Cr13, S42040) 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 (X5CrNi18-10; S30408) in accordance with ISO 15510:2010.

Same parts can be made of austenitic corrosion resistant steel having the material numbers 4301-304-00-I (X5CrNi18-10) or 4310-301-00-I (X10CrNi18-8; S30110) according to ISO 15510:2010.

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 manufacturer may choose between a brightened and a matted surface.

All surfaces of the clamp forceps shall be free of pores, cracks and all residues, including abrasives and/or polishing agents.

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 withstand 100 reprocessing cycles, as defined by the manufacturer's instructions in accordance with ISO 17664, without deterioration or showing signs of corrosion.

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

Perform visual examination with normal visual acuity without any magnification.

5.2 Dimensions

The dimensions are tested by means of appropriate length measuring devices (e.g. micrometers, callipers) with a maximum permissible error of ≤ 0,1 mm.

5.3 Reprocessing

Carry out 100 reprocessing cycles in accordance with the manufacturer's recommended methods of cleaning, disinfection and sterilization. Visually inspect the forceps for signs of corrosion or surface deterioration.