INTERNATIONAL STANDARD

ISO 16635-1

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Dentistry — Dental rubber dam technique —

Part 1: Hole punch

Médecine bucco-dentaire — Technique de la digue dentaire en caoutchouc —

Partie 1: Pinces à percer la digue

Reference number
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Foreword

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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 16635-1 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*

Introduction

In order to facilitate the use of dental rubber dam, standardization of the required instruments and materials is necessary.

In dental practice hole punches do not come into direct contact with the patient, provided they are used as intended.

Dentistry — Dental rubber dam technique —

Part 1: Hole punch

1 Scope

This part of ISO 16635 specifies requirements and test methods for hole punches for dental rubber dam.

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 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

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

3.1
dental rubber dam
dental dam
rubber dam
sheet of elastic material used for the isolation of one tooth or several teeth from the rest of the oral cavity

3.2
dental rubber dam clamp
fixation aid adapted to the form of the respective tooth, usually made of spring steel and consisting of two clamp jaws closely fitting the contour of the tooth and linked with each other by means of one or two bow(s)

Note 1 to entry: Usually, the clamp jaws have one hole each through which they can be grasped and fixed by means of a clamp forceps.

3.3
clamp forceps
forceps used for the placement and removal of dental rubber dam clamps

Note 1 to entry: For this purpose, a clamp is grasped by inserting the two retaining pins of the clamp forceps into the holes of the clamp jaws; the clamp is then tensioned and fitted to the tooth in the desired position.

3.4
hole punch
forceps used to punch holes of different diameters in the dental rubber dam

3.5
punch handle
gripping end for grasping and operating the hole punch

3.6
die plate
rotary plate engaging in defined positions and having holes of different sizes

3.7
die plate engagement mechanism
mechanism at the die plate ensuring the engagement of that plate in defined positions

3.8
punch
tapered working end of the hole punch designed to perforate the dental rubber dam by penetrating into the holes of the die plate

3.9
perforation point
point where the punch makes contact with the dental rubber dam on the die plate

3.10
insertion opening
opening between the punch and the die plate

3.11
insertion depth
distance between the punch and the hinge assembly, where the dental rubber dam can be inserted into the punch forceps

4 Requirements

4.1 General

The purpose of the hole punch for dental rubber dam is the exact punching of holes of different sizes in dental rubber dam of different types and thicknesses.

A mechanical arrangement shall be provided which ensures: a) automatic opening of the hole punch (e.g. by a spring); b) exact positioning of the holes of the die plate below the punch.

Test in accordance with 5.1.

4.2 Total length

The total length of the hole punch for dental rubber dam shall be (165 ± 5) mm.

Test in accordance with 5.2.

4.3 Distance between the forceps handles in the open passive state

The distance between the punch handles in the open passive state shall not exceed 95 mm.

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

Test in accordance with 5.2.

4.4 Characteristics of the die plate

The die plate shall have six holes ranging in size from 0,8 mm to 2,3 mm in diameter or eight holes ranging in size from 0,5 mm to 2,6 mm in diameter, with approximately the same increments (see Table 1 and Figure 1).

Test in accordance with 5.2.

Table 1 — Hole sizes for die plates

Dimensions in millimetres
Tolerances: ± 0,1 mm

Die plate with 6 holes	Die plate with 8 holes
—	0,5
0,8	0,8
1,1	1,1
1,4	1,4
1,7	1,7
2,0	2,0
2,3	2,3
—	2,6

Figure 1 — Die plates and hole sizes

4.5 Distances

The insertion depth shall be in the range from 20 mm to 70 mm.

NOTE This allows the dental rubber dam or a special dental rubber dam frame combination to be inserted deep enough in order to punch holes at any desired position.

Test in accordance with 5.2.

4.6 Spring type mechanism

4.6.1 Spring type mechanism for holding the hole punch open

In its passive state, the hole punch for dental rubber dam shall be opened, by means of a spring type mechanism, wide enough to ensure a distance of at least 2,5 mm between the tip of the punch and the face of the die plate.

Test in accordance with 5.2.

4.6.2 Die plate mechanism for the engagement of the die plate

The die plate shall be provided with a mechanism which ensures its engagement in defined positions in order that the punch always makes contact with the holes at their centres.

NOTE This is usually achieved by means of a spring mechanism.

Test in accordance with 5.1.

4.7 Materials

The hole punch shall be made of corrosion resistant martensitic stainless steel 4021-420-00-I (X20Cr13) and 4034-420-00-I (X46Cr13) in accordance with ISO 15510.

The die plate shall have a hardness of 48 HRC to 55 HRC or a Vickers hardness of 600 HV1 to 720 HV1.

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 profile and finish

The surface profile is at the discretion of the manufacturer.

The surfaces of the hole punch for dental rubber dam shall be free of pores, cracks, scale residues, acidic fats and residues of abrasives and polishing agents.

The surfaces of the working ends and the shafts shall be polished. A possible gloss is at the discretion of the manufacturer.

Test in accordance with 5.1.

5 Test methods

5.1 Visual examination

Perform the examination of the hole punch with normal visual acuity without any magnification.

5.2 Dimensions

Test the dimensions with usual length measuring devices with a maximum permissible error of ≤ 0,1 mm.

NOTE Usual length measuring devices include external micrometers and callipers.

The applied measuring force shall not exceed 1,5 N.

6 Marking

The hole punch shall be marked as follows:

a) name of the manufacturer and/or brand;

b) model number (reference number);

c) lot number.

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