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**Dentistry — Dental rubber dam  
technique —**

**Part 1:  
Hole punch**

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

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## 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.

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.

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

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## 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.

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# 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

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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

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**4 Requirements**

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**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  $(165 \pm 5)$  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:  $\pm 0,1$  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.