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## Dentistry — Filling instrument with contra angle

*Médecine bucco-dentaire — Instrument d'obturation à double  
angulation*

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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.

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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

## Introduction

In dentistry, corresponding to their intended use, filling instruments come into contact with the patient. Consequently, special attention is to be given in respect to (re)processing.

Consideration of ergonomic aspects is also required. This is supported by the specific contra angle design.

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# Dentistry — Filling instrument with contra angle

## 1 Scope

This document specifies requirements and test methods for a filling instrument with contra angle, which is used for the restoration of teeth via the application of polymer-based restorative materials and cements. It also specifies requirements for the design, dimensions and marking.

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

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method*

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 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 <http://www.iso.org/obp>

### 3.1

#### **filling instrument**

non-active hand-guided dental instrument for applying and modelling polymer-based restorative materials and cements during dental restoration procedures

### 3.2

#### **contra angle**

angle of the second bend of the shank that connects the handle to the *working end* (3.4) and that compensates the first bend so that the working end is in line with the axis of the shank

EXAMPLE See [Figure 1](#).

### 3.3

#### **filling instrument with contra angle**

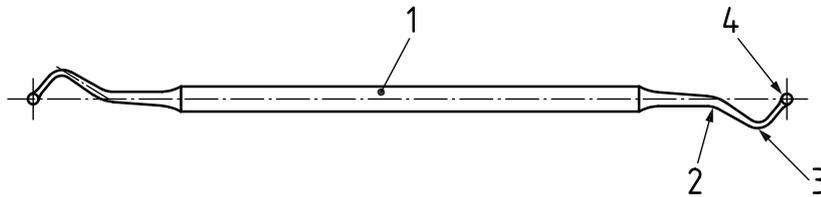
*filling instrument* (3.1), in which the *working end* (3.4) and the handle axis are on one axis and the shank forms a *contra angle* (3.2)

EXAMPLE See [Figure 1](#).

**3.4 working end**

most frontal area of the *filling instrument* (3.1) which is used for working

EXAMPLE See [Figure 1](#).



**Key**

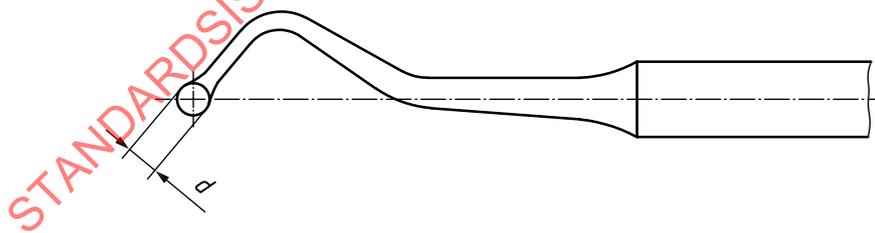
- 1 handle
- 2 first bend of the shank
- 3 second bend of the shank
- 4 working end

**Figure 1 — Design of filling instrument with contra angle**

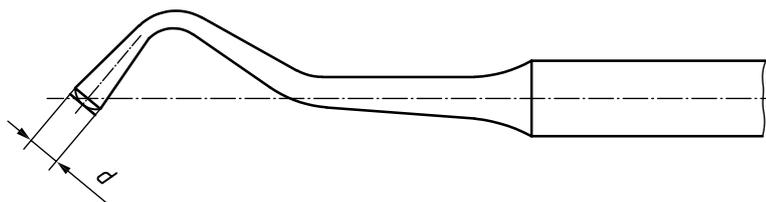
**4 Classification**

Filling instruments with contra angles are classified into the following types according to the design of the working end:

- Type A: Ball corresponding to [Figure 2](#);
- Type B: Pear corresponding to [Figure 3](#);
- Type C: Plane pluggers corresponding to [Figure 4](#) or [Figure 5](#);
- Type D: Spatula, curved over edge corresponding to [Figure 6](#);
- Type E: Spatula, curved over surface (beaver tail) corresponding to [Figure 7](#).



**Figure 2 — Type A: Ball**



**Figure 3 — Type B: Pear**

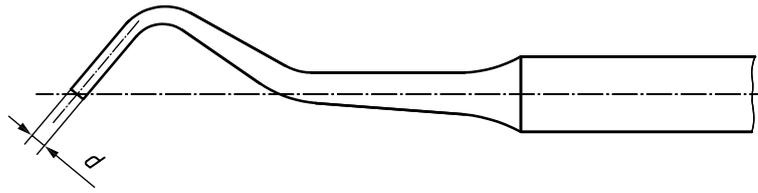


Figure 4 — Type C: Plane plugger, cylindrical

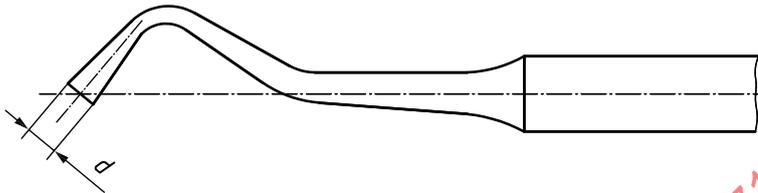


Figure 5 — Type C: Plane plugger, tapered

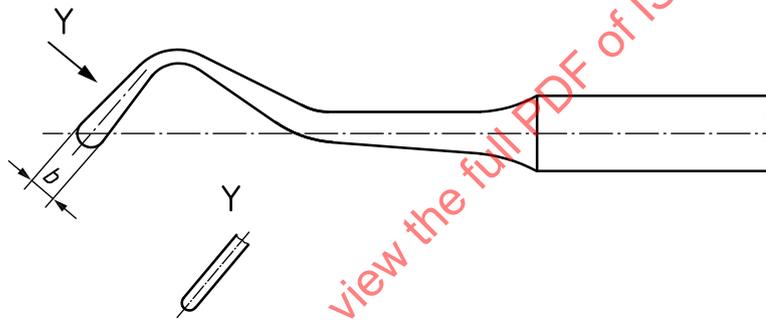
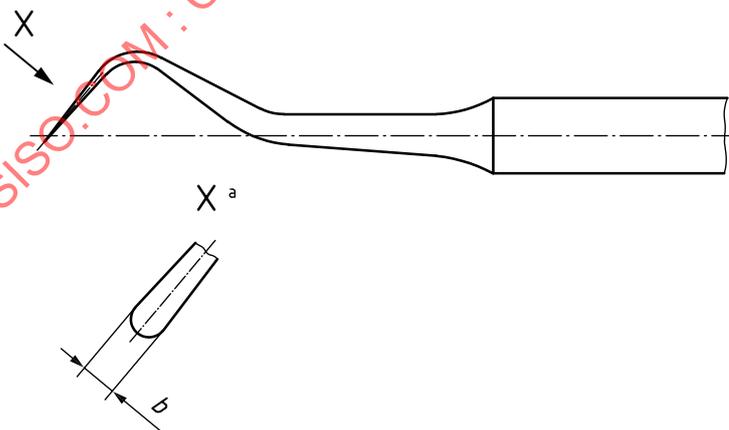


Figure 6 — Type D: Spatula, bended over edge



a Frontal view of enlargement X.

Figure 7 — Type E: Spatula, bended over surface (beaver tail)

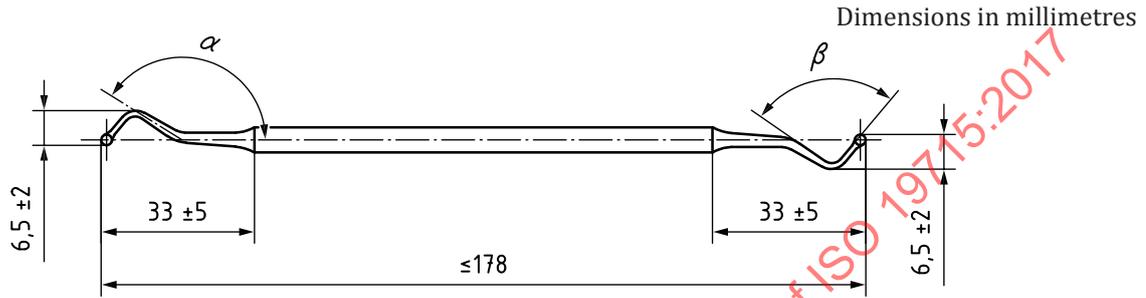
## 5 Requirements

### 5.1 Dimensions

The dimensions shown in [Figure 8](#) are recommended dimensions for filling instruments with contra angle. Other dimensions may be used at the manufacturer’s discretion.

Single-ended filling instruments are also possible.

Test in accordance with [6.1](#).



#### Key

$\alpha$  first bend angle, 135°

$\beta$  contra angle, 90°

NOTE This example shows the combination of working ends Type A — Type A.

**Figure 8 — Dimensions for filling instruments with contra angle**

### 5.2 Dimensions of working end

Working ends of filling instruments with contra angles shall satisfy the dimensions indicated in [Table 1](#) and [Table 2](#).

The diameter for Type A shall be: min. 0,8 mm, max. 3,5 mm.

The diameter for Type B shall be: min. 0,8 mm, max. 2,5 mm.

The diameter for Type C shall be: min. 0,8 mm, max. 2,5 mm.

The diameter for Type D shall be: min 1,0 mm, max. 3,2 mm.

The diameter for Type E shall be: min. 1,0 mm, max. 3,2 mm.

**Table 1 — Examples for dimensions for working end of type A, type B and type C**

| Type   | Designation   | Diameter, $d$<br>$\pm 0,1$<br>mm |     |     |     |     |     |     |     |
|--------|---------------|----------------------------------|-----|-----|-----|-----|-----|-----|-----|
|        |               | 0,8                              | 1,0 | 1,2 | 1,6 | 2,0 | 2,5 | 3,2 | 3,5 |
| Type A | Ball          | 0,8                              | 1,0 | 1,2 | 1,6 | 2,0 | 2,5 | 3,2 | 3,5 |
| Type B | Pear          | 0,8                              | 1,0 | 1,2 | 1,6 | 2,0 | 2,5 | —   | —   |
| Type C | Plane plugger | 0,8                              | 1,0 | 1,2 | 1,6 | 2,0 | 2,5 | —   | —   |

**Table 2 — Examples for dimensions for working end of type D and type E**

| Type   | Designation                    | Width, <i>b</i><br>±0,1<br>mm |     |     |     |     |
|--------|--------------------------------|-------------------------------|-----|-----|-----|-----|
|        |                                | 1,0                           | 1,5 | 2,0 | 2,5 | 3,2 |
| Type D | Spatula, edge                  | 1,0                           | 1,5 | 2,0 | 2,5 | 3,2 |
| Type E | Spatula, surface (beaver tail) | 1,0                           | 1,5 | 2,0 | 2,5 | 3,2 |

Test in accordance with [6.1](#).

### 5.3 Materials

The material of both the handle and the working tip is at the manufacturer's discretion provided that the requirements of this document are met. If stainless steel is the material of choice, examples of suitable steel types can be found in ISO 7153-1.

The stainless steel of the filling instrument shall have a hardness of 42 HRC to 60 HRC.

Test in accordance with [6.2](#).

### 5.4 Surface finish

The working ends of the filling instrument shall be polished with a surface roughness,  $R_a$ , not exceeding 0,4  $\mu\text{m}$ , except where otherwise designed. The surface can be gloss or matte, at the manufacturer's discretion. All surfaces of the filling instrument shall be free of any surface defects and residues.

Coatings may be added to the working tip of metal filling instruments to increase lubricity and provide contrast in the oral cavity.

Test in accordance with [6.3](#).

### 5.5 Handle

The shape of the handle (e.g. circular, octagonal) is left to the discretion of the manufacturer.

### 5.6 Designation and combination of working ends

The designation and combination of the working ends is described in [Annex A](#).

### 5.7 Resistance to reprocessing

The filling instrument shall withstand 100 reprocessing cycles, as defined by the manufacturer's instructions, in accordance with ISO 17664 without visible signs of distortion, deterioration in performance, or signs of corrosion.

Non-metallic filling instruments shall withstand the same reprocessing materials as metallic filling instruments, unless:

- a) the filling instrument is designated as single-use disposable item;
- b) the manufacturer has specified a maximum number of cycles less than 100. This number shall be used for the test.

The reprocessing cycle shall include the recommended methods of cleaning, disinfection and, if recommended by the manufacturer, sterilization.

Test in accordance with [6.4](#).

## 6 Measurement and test methods

### 6.1 Dimensions

Measure the dimensions using a device that is accurate to 1/10 of the tolerance to be measured.

NOTE Example of suitable measuring devices are vernier calipers and micrometers in accordance with ISO 3611.

### 6.2 Hardness testing

Carry out hardness testing in accordance with ISO 6508-1, scale C or ISO 6507-1.

### 6.3 Surface roughness inspection

Measure the surface roughness,  $R_a$ , by using a profilometer or calibrated reference plates by probing at the central point that is 1 mm in linear distance from the working end of the instrument.

### 6.4 Resistance to reprocessing test

Carry out 100 reprocessing cycles with the filling instrument, as defined by the manufacturer's instructions, in accordance with ISO 17664.

If the manufacturer has specified a maximum number of cycles less than 100, this number shall be used for the test.

Inspect the filling instrument for signs of deterioration, distortion or corrosion.

NOTE Discolorations due to water stains are not signs of corrosion.

## 7 Marking

Filling instruments with contra angle shall be indelibly marked with the following information:

- a) name of the manufacturer and/or trade name;
- b) model number (reference number);
- c) lot number (batch designation).