INTERNATIONAL STANDARD

ISO 4865-1

First edition
2023-10

Dentistry — General requirements of hand instruments —

Part 1: Non-hinged hand instruments

Médecine bucco-dentaire — Exigences générales relatives aux instruments à main —

Partie 1: Instruments à main non articulés

Reference number
ISO 4865-1:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Non-hinged hand instruments used in dentistry share many common characteristics including material properties and requirements for reprocessing. Despite the many common features among different categories of instruments, there is currently much variation in the published requirements and test methods. This document addresses these common characteristics and provides a normative reference to help reduce variation and to lead to a harmonization of standards for non-hinged hand instruments.

Dentistry — General requirements of hand instruments —

Part 1: Non-hinged hand instruments

1 Scope

This document specifies requirements and test methods common to all non-hinged hand instruments used in dentistry, including materials, hardness, surface finish, resistance to reprocessing and information for marking, although some can have additional specific requirements and test methods.

This document does not specify terms and definitions or classification of specific types of hand instruments.

This document excludes powered instruments. The classification and the shape of working ends of non-hinged hand instruments are excluded from this document.

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 6508-1:2016, *Metallic materials — Rockwell hardness test — Part 1: Test method*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
non-hinged hand instrument
rigid manual dental device without a hinged part (non-hinged), having a single or double working end

EXAMPLE Explorers, scalers, curettes, spoons, spatulas and mirrors.

4 Requirements

4.1 Materials

The materials used for both the handle and the working tip are at the manufacturer's discretion provided that the performance requirements are met. If stainless steel is the material of choice, examples of suitable steel types can be found in ISO 21850-1.

4.2 Handle

The shape of the handle for non-hinged hand instruments is at the manufacturer's discretion.

4.3 Surface finish

The surface finish is at the discretion of the manufacturer, but shall be visibly free from surface defects and production residues. The test shall be carried out in accordance to 5.1.

EXAMPLE 1 Surface defects are pores, crevices, grinding marks and sharp edges.

EXAMPLE 2 Production residues are residual scale, acids, grease, remaining grinding and polishing material.

4.4 Dimensions

The maximum length of non-hinged hand instruments shall be at the manufacturer's discretion but it should be noted that overall lengths in excess of 173 mm can cause difficulty in containment within a sterilization cassette. Dimensions shall be measured in accordance with 5.2.

4.5 Resistance against reprocessing

The non-hinged hand instruments to be used life-long, shall withstand 100 reprocessing cycles, as defined by the instructions for use, without deformation or showing signs of corrosion, following the test in accordance to 5.3, unless otherwise stated in a standard. Also, non-hinged hand instruments shall meet requirements stated in 4.6, 4.7 and 4.8 following the 100 reprocessing cycles and test in accordance to 5.4, 5.5 and 5.6.

4.6 Vickers and Rockwell hardness

The hardness of the working part of non-hinged hand instruments shall be stated in either Vickers or Rockwell hardness.

The hardness for the working parts of non-hinged hand instruments shall be in accordance with the requirements stated in the respective International Standard for the individual instrument.

If there is no requirement of hardness stated in the respective International Standard for the individual instrument, the hardness shall be within ±5 % of the value stated by the manufacturer.

Test in accordance to 5.4.

4.7 Tensile strength

The connection between working end and handle of the non-hinged hand instruments shall not loosen under tensile load, at the value stated in the respective International Standard for the individual instrument. Test the tensile strength in accordance with 5.5.

4.8 Torque strength

The connection between working end and handle of the non-hinged hand instruments shall not loosen when subjected to the torque value stated in the respective International Standard for the individual instrument. Test the torque in accordance with 5.6.

5 Measurements and test method

5.1 Visual inspection

Conduct visual inspection at normal visual acuity without magnification.

5.2 Dimensions

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

5.3 Resistance against reprocessing

For critical or semi-critical instruments that will be sterilized using steam and/or dry heat, carry out 100 reprocessing cycles with the non-hinged hand instruments, as defined by the instructions for use. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning, disinfection, and sterilization, in accordance with ISO 17664-1. If the manufacturer has specified a maximum number of cycles less than 100, this number shall be used for the test. Inspect all of the surfaces of the non-hinged hand instruments for any signs of corrosion/surface defect in accordance to 5.1.

The test results should include specific information regarding manual or automated cleaning methods and sterilization cycles validated according to ISO 17664-1.

For semi-critical instruments that will be reprocessed using validated high-level thermal or chemical disinfection, carry out 100 reprocessing cycles with the non-hinged hand instruments, as defined by the instructions for use. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning and disinfection in accordance with ISO 17664-1. If the manufacturer has specified a maximum number of cycles less than 100, this number shall be used for the test. Inspect all of the surfaces of the non-hinged hand instruments for any signs of corrosion/surface defect in accordance to 5.1.

For non-critical instruments that do not require sterilization or high-level disinfection, carry out 100 cleaning and disinfection cycles with the non-hinged hand instruments, as defined by the instructions for use. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning and disinfection in accordance with ISO 17664-2. If the manufacturer has specified a maximum number of cycles less than 100, this number shall be used for the test. Inspect all of the surfaces of the non-hinged hand instruments for any signs of corrosion/surface defect in accordance to 5.1.

If a manufacturer supplies a number of different dental hand instruments that share common attributes such as scalers, forceps, explorers, then resistance against reprocessing may be performed as a product family according to ISO 17664-1 and ISO 17664-2.

Carry out test stated in 5.4, 5.5 and 5.6 after the reprocessing cycles.

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

5.4 Vickers and Rockwell hardness

Test the Vickers hardness in accordance with ISO 6507-1.

Test the Rockwell hardness in accordance with ISO 6508-1:2016, Class C, respectively.

5.5 Tensile test

5.5.1 Principle

The test of tensile strength of connection between handle and the working part is performed by measuring the maximum tensile strength when pulled from each end.

5.5.2 Apparatus

Apparatus for tensile strength test, such as a universal testing machine that is capable of pulling test sample at 0,5 mm/min while measuring the applied tensile load.

5.5.3 Procedure

Connect the handle and the working end securely to each part of the jig connected to tensile strength machine, such as universal testing machine. Apply the tensile load at 0,5 mm/min until the handle has loosened from the main part. Record the tensile force at the point of maximum force recorded during the test until the point of failure.

5.5.4 Expression of results

Express the maximum tensile load in newton (N).

5.6 Torque test

5.6.1 Principle

The test of resistance to torque on connection between handle and the working part is performed by measuring the maximum torque value when handle and working part is twisted in different directions.

5.6.2 Apparatus

Apparatus for torque test, such as torque meter that is capable of twisting a sample at one rotation per minute while measuring applied torque force.

5.6.3 Procedure

Connect the handle and the working end securely to each part of the jig connected to torque control bench (torque tester). Apply the rotational force at one full turn per minute until handle is loosen from the main part. Record the maximum torque value during the test until the point of failure.

5.6.4 Expression of results

Express the maximum torque value in newton meter (N·m).

6 Marking, labelling and packaging

6.1 General

General information for marking, labelling and packaging shall be in accordance with ISO 20417.

6.2 Marking

Non-hinged hand instruments shall be marked as follows:

a) name of the manufacturer and/or trade name;

b) model number (reference number);

c) lot number (batch designation) or UDI-code (unique device identification), as required in country of sale.

For the indication, the graphical symbol for "sterilizable in a steam sterilizer" given in ISO 21531:2009, Table 4, N° 20 is recommended.

6.3 Labelling

Labelling on the package shall use graphical symbols in accordance with ISO 15223-1.

Labelling on the package shall include:

a) name and address of the manufacturer;

b) model number (reference number);

c) lot number (batch designation);

d) UDI-code (unique device identification), as required in the country of sale.

7 Instructions for use

Instructions for use shall include:

a) general information (name of the manufacturer, product description);

b) indications for use;

c) contraindications for use;

d) warnings;

e) precautions for special handling;

f) known adverse reactions;

g) reprocessing method described in accordance with ISO 17664-1 or ISO 17664-2, including cleaning, disinfection, sterilization and packaging/storage;

h) date of issue or revision version.

If graphical symbols are used which are not in accordance with ISO 15223-1, they shall be explained in the instructions for use.

Instructions for use can be made accessible in paper or electronic form on the homepage of the manufacturer.