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Dentistry — Endodontic instruments —

Part 4: Auxiliary instruments

Médecine bucco-dentaire — Instruments d'endodontie —

Partie 4: Instruments auxiliaires

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Contents

Page

Foreword

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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).

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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).

This second edition cancels and replaces the first edition (ISO 3630-4:2009), which has been technically revised.

The main changes are as follows:

— rasps requirements have been removed;

— a cyclic fatigue test of paste carriers has been added;

— the term cannula has been added;

— the cannula symbol has changed;

— Annexes A and B have been added.

A list of all parts in the ISO 3630 series can be found on the ISO website.

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.

Dentistry — Endodontic instruments —

Part 4: Auxiliary instruments

1 Scope

This document specifies requirements and test methods for hand-held or mechanically operated auxiliary instruments for performing root canal procedures such as barbed broaches, paste carriers, explorers, cotton broaches and cannulae. This document specifies requirements for size, product designation, safety considerations, instructions and labelling.

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 1797, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2019, *Dentistry — Endodontic instruments — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 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
barbed broach
endodontic instrument with barbs designed for removing the pulp tissue

3.2
paste carrier
endodontic instrument designed for conveying filling material or medicaments into a root canal system

3.3
explorer
endodontic instrument designed for exploring the root canal system

3.4
cotton broach
endodontic instrument used with cotton for drying root canals or placing medicaments

3.5
instrument core
portion of endodontic instrument that is the centre of the working part

3.6
core diameter of the instrument
diameter of the solid portion of a *barbed broach* (3.1)

3.7
height of barb
height measured perpendicularly from the outside of the instrument core to the tip of the barb of a *barbed broach* (3.1)

3.8
thermoplastic delivery device
powered endodontic instrument designed for placing thermoplastic obturation material into a root canal system

3.9
cannula
tube, connected to a *thermoplastic delivery device* (3.8) to deliver the thermoplastic obturation material into a root canal system

4 Classification and symbols

4.1 Classification

For the purposes of this document, endodontic instruments are grouped according to the shape and intended endodontic application of the instrument as follows:

— type 1: barbed broaches;

— type 2: paste carriers;

— type 3: explorers and cotton broaches;

— type 4: cannulae.

4.2 Symbols

For the purposes of this document, the following symbols apply.

D core diameter of the instrument (projected core for paste carriers) measured at the tip

d_m core diameter of the instrument or working part measured from the tip at length l_m

d_n core diameter of the instrument or working part measured from the tip at length l_n

d_{op} core diameter of the instrument or operative part at length l_{op}

d_w core diameter of the instrument or working part measured from the tip at length l_w

h height of barb

l_b tip length, measured from the tip of the broach to the base of the first barb

l_m length for measuring point d_m

l_n length for measuring point d_n

l_{op} length of operative part

l_{tot} total length of instrument

l_w length of working part, measured from the tip

d_{od} outer diameter of cannula

d_{id} inner diameter of cannula

5 Requirements

5.1 Material

The material for the endodontic instrument and for the handle or shank is left to the discretion of the manufacturer.

The handle or shank security shall meet the requirement specified in ISO 3630-1:2019, 5.9.3.

5.2 Dimensions

5.2.1 General

The nominal diameters, selected by the manufacturer, represent the sizes of the instrument and shall meet the requirements included in Figures 1 to 4 and Tables 1 to 4.

The length of the operative part of the endodontic instrument shall be the nominal length, as specified by the manufacturer, with a tolerance of ±0,5 mm.

The dimensions of the shank shall meet the requirements of ISO 1797.

5.2.2 Barbed broaches — Type 1 instruments

Type 1 instruments shall meet the dimensions and tolerances specified in Figure 1 and Table 1.

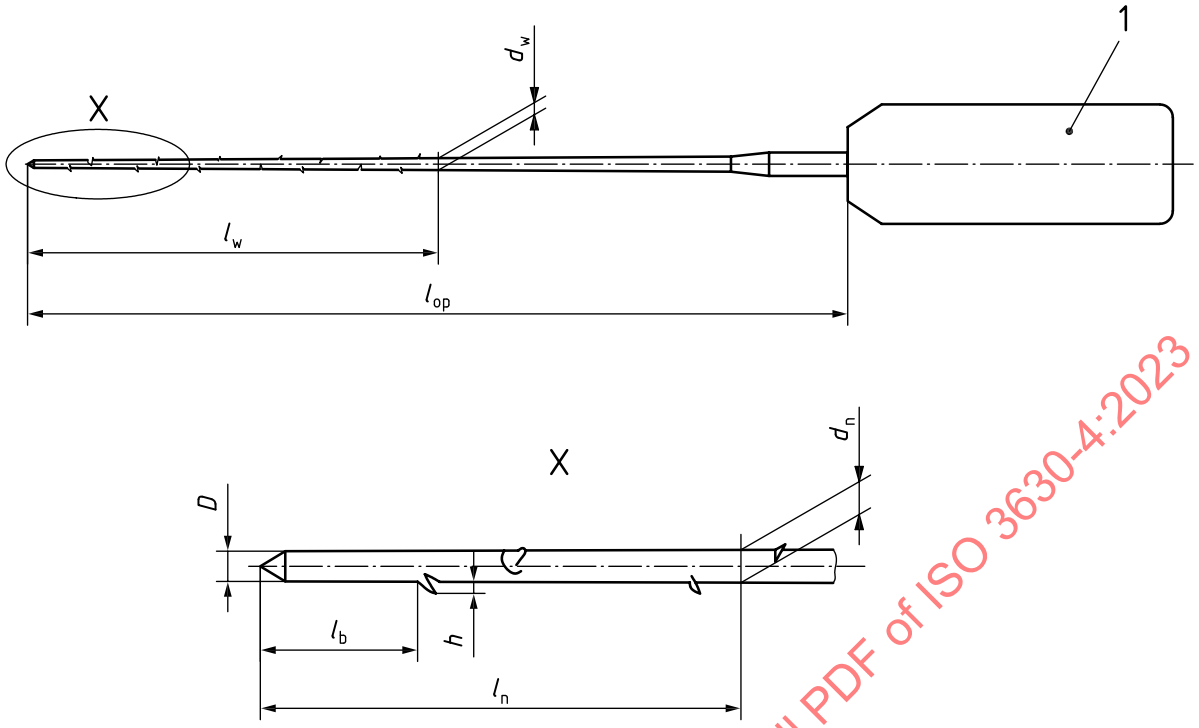
The shape of the tip and the design of the handle are at the discretion of the manufacturer.

The working length (l_w) shall be at least 8 mm.

The operative length (l_{op}) shall be at least 20 mm.

There shall be three barbs per millimetre with the first barb starting 1 mm from the tip (l_b).

Dimensions in millimetres



Key

1 handle

Figure 1 — Barbed broaches — Type 1 instruments

Table 1 — Dimensions and designations for barbed broaches — Type 1 instruments

Dimensions in millimetres

Nominal size	D	Tolerance	l_b min	d_n	Tolerance	d_w	Tolerance	h (±0,02)	Designation by	
									colour	number of rings
020	0,12	±0,02	1	0,15	±0,02	0,22	±0,02	0,075	purple	0
025	0,14			0,17		0,24		0,085	white	I
030	0,16			0,19		0,26		0,096	yellow	II
035	0,18	±0,03		0,21	±0,03	0,28	±0,03	0,105	red	III
040	0,21			0,24		0,31		0,120	blue	III I
050	0,25	±0,04		0,28	±0,04	0,35	±0,04	0,140	green	III II
060	0,29			0,32		0,39		0,160	black	III III

5.2.3 Paste carriers — Type 2 instruments

Type 2 instruments shall meet the dimensions and tolerances specified in Figure 2 and Table 2.

The minimum working length (l_w) shall be 16 mm.

The taper of the working part shall be from 0 % to 2 %.

The operative length (l_{op}) is left to the discretion of the manufacturer.

The winding of the spiral shall be such as to convey the material to the tip of the instrument when rotated clockwise as viewed from the handle or shank end.

The minimum number of spirals shall be 10 and the design of these spirals is left to the discretion of the manufacturer.

Shanks shall be designed in accordance with ISO 3630-1:2019, 5.8.3.2. Test in accordance with ISO 3630-1:2019, 7.6.

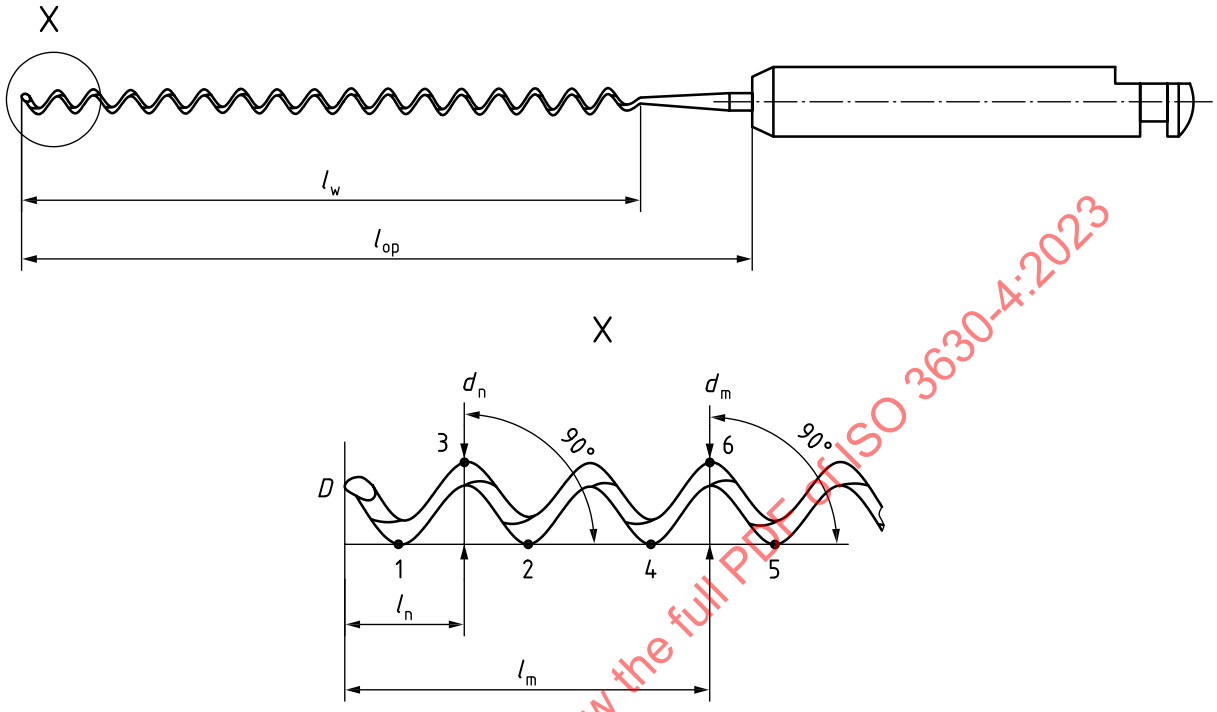


Figure 2 — Paste carriers — Type 2 instruments

Table 2 — Dimensions and designations for paste carriers — Type 2 instruments

Dimensions in millimetres

Nominal size	D	d_n	Tolerance	Colour	Rings
25	0,25	See 7.2.2	±0,05	Red	I
30	0,30			Blue	II
35	0,35			Green	III
40	0,40			Black	IIII

5.2.4 Explorers and cotton broaches — Type 3 instruments

Type 3 instruments shall meet the dimensions and tolerances specified in Figure 3 and Table 3.

The cross-section along the operative part (e.g. round or polygonal) shall be at the discretion of the manufacturer.

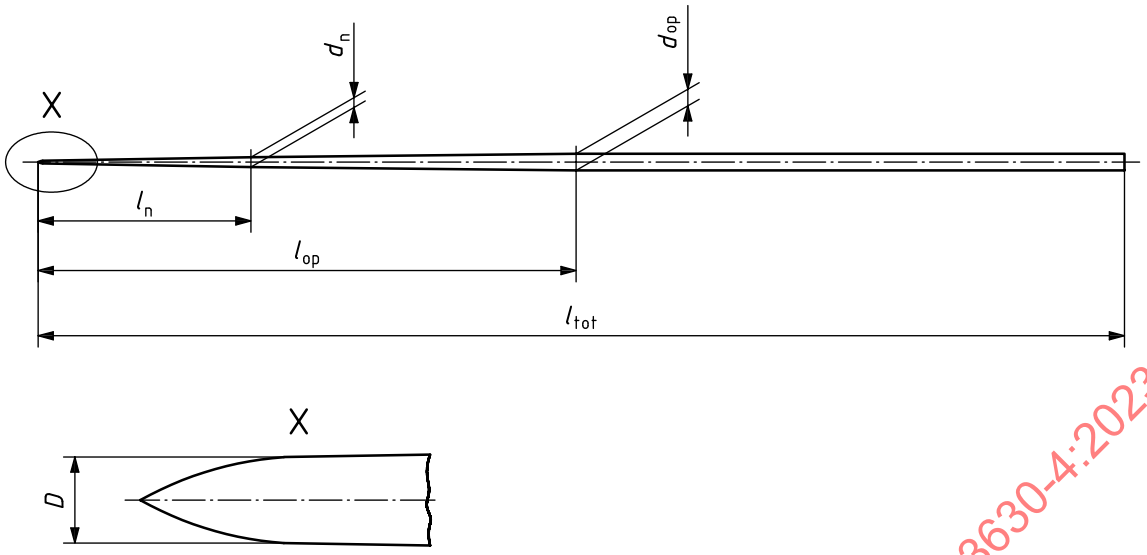


Figure 3 — Explorers and cotton broaches — Type 3 instruments

Table 3 — Dimensions and designations for explorers and cotton broaches — Type 3 instruments

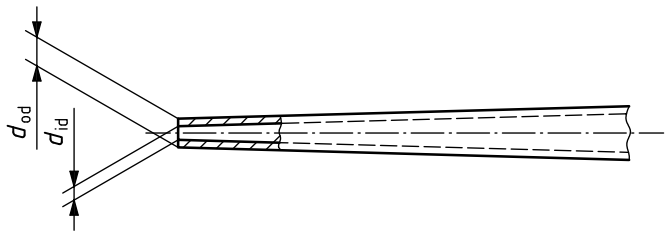
Dimensions in millimetres

Nominal size	D ±0,02	$d_{n\ at\ 3\ mm}$ ±0,02	Designation by	
			colour	number of rings
12	0,12	0,20	White	I
15	0,14	0,23	Yellow	II
17	0,16	0,25	Red	III
20	0,18	0,28	Blue	III I
25	0,21	0,33	Green	III II
30	0,25	0,38	Black	III III

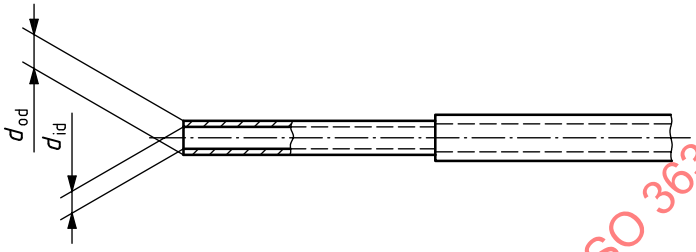
The minimum operative length (l_{op}) shall be 25 mm and the total length (l_{tot}) of the instrument shall be (50 ± 1,5) mm, the maximum operative part (d_{op}) shall be 0,8 mm, and the length for measuring point d_n (l_n) shall be 10,5 mm.

5.2.5 Cannulae — Type 4 instruments

Type 4 instruments shall meet the dimensions and tolerances specified in Figure 4 and Table 4. The shape of the cannula is at the discretion of the manufacturer.



a) Tapered



b) Staged

Figure 4 — Cannulae — Type 4 instruments

Table 4 — Dimensions and designations for cannulae — Type 4 instruments

No.	Size	d_{od} ±0,01 mm
01	30Gauge	0,311
02	28Gauge	0,362
03	25Gauge	0,514
04	24Gauge	0,565
05	23Gauge	0,641

5.3 Colour designation and size marking with rings

If the manufacturer uses colours and/or rings to identify the size of the instrument, such marking(s) shall comply with the requirements of Tables 1 to 3.

5.4 Mechanical requirements

5.4.1 Resistance to fracture by twisting (torque) and angular deflection — Types 1 and 3

When barbed broaches, explorers, and cotton broaches are tested in accordance with ISO 3630-1:2019, 7.4, the instrument shall not fracture below the value specified in Table 5.

Types 1 and 3 instruments shall not fracture at less than 90° of angular deflection.

Table 5 — Resistance to fracture by twisting — Torque

Nominal size	Minimum resistance to fracture by twisting mN·m	
	for barbed broaches	for explorers and cotton broaches
20	0,5	1,2
25	0,6	2,1
30	0,8	3,5
35	1,0	NA
40	1,2	NA
45	NA	NA
50	2,0	NA
60	3,4	NA
Key NA: not applicable; these instrument sizes are not manufactured		

5.4.2 Stiffness — Resistance to bending — Types 1 and 3

When barbed broaches, explorers and cotton broaches are tested in accordance with ISO 3630-1:2019, 7.5, the instrument shall not fracture below the value specified in Table 6.

Table 6 — Stiffness — Resistance to bending

Nominal size	Maximum bending moment mN·m	
	for barbed broaches	for explorers and cotton broaches
20	2,5	7,8
25	2,9	11,7
30	3,9	16,6
35	4,9	NA
40	7,8	NA
50	11,8	NA
60	16,7	NA
Key NA: not applicable; these instrument sizes are not manufactured		

5.4.3 Handle or shank security — Types 1, 2 and 3 instruments

The handle shall meet the requirements of ISO 3630-1:2019, 5.9.3.

5.4.4 Resistance to fatigue — Type 2

When paste carriers are tested in accordance with 7.2.3, the tested instruments shall meet the minimum number of revolutions given in Table 7.

Table 7 — Resistance to fatigue for paste carriers

Nominal size	Diameter mm	Minimum number of revolutions
025	0,25	4 000
030	0,30	2 400
035	0,35	1 500
040	0,40	1 000

5.4.5 Resistance to breakage or cracking — Type 4

When the cannulae are tested in accordance with Annex A, four out of five instrument samples shall not break or crack at less than the minimum value for the resistance to breakage or cracking by bending, as specified by the manufacturer.

5.5 Reprocessing

Explorers, cotton broaches and paste carriers shall meet the requirements of ISO 3630-1:2019, 5.10. When tested in accordance with Annex B, four out of five cannulae shall not show evidence of corrosion.

5.6 Heat effects of sterilization

5.6.1 General

Barbed broaches, explorers, cotton broaches and paste carriers, if applicable, shall meet the requirements of ISO 3630-1:2019, 5.10. This requirement does not apply to sterile-packed single-use instruments.

5.6.2 Single-use instruments (supplied non-sterile)

For barbed broaches, explorers, cotton broaches and paste carriers following one cycle of sterilization, the instrument shall comply with the requirements specified in 5.4.1, 5.4.2, 5.4.3 and 5.4.4, when tested as specified in ISO 3630-1:2019, 7.7.

For cannulae, following one cycle of sterilization, the instrument shall comply with the requirements specified in 5.4.5, when tested as specified in Annexes A and B.

5.6.3 Multi-use instruments

Following 10 cycles of sterilization as specified by manufacturer, barbed broaches, explorers, cotton broaches and paste carriers shall comply with the requirements specified in 5.4.1, 5.4.2, 5.4.3 and 5.4.4, when tested as specified in ISO 3630-1:2019, 7.7.

For cannulae, following five cycles of sterilization as specified by the manufacturer, the instrument shall comply with the requirements specified in 5.4.5, when tested as specified in Annexes A and B.

6 Sampling

Test 10 instruments of types 1 to 3 and of each size of the same lot. If all 10 samples pass, the product passes. If eight or fewer samples pass, the product fails. If nine samples pass, test 10 additional samples. When 10 additional samples are required to be tested, all 10 shall pass for the product to comply.

For cannulae (type 4), follow instructions in Annexes A and B.

7 Testing

7.1 General

For barbed broaches, explorers, cotton broaches, and paste carriers, use the test methods specified in ISO 3630-1:2019, Clause 7. For cannulae, use the test methods specified in Annexes A and B.

7.2 Dimensions

7.2.1 General

For instruments with handles, remove the handle and insert the neck into a suitable holder. For instruments with shanks, insert the shank into a suitable holder.

7.2.2 Barbed broaches

7.2.2.1 Location of barbs

Rotate the instrument to locate the position in full view of the barb closest to the tip. Measure the distance from the tip of the instrument to the base of the first barb as l_b.

Rotate the instrument to locate the position in the full view of the barb most distant from the tip. Measure the distance from the tip of the instrument to the tip of the last barb as l_w.

7.2.2.2 Height of barbs

Rotate the instrument to locate the barb nearest the tip. Measure the vertical distance from the barb base to the barb tip.

NOTE This procedure is intended as guidance for the calculation of nominal size.

7.2.2.3 Number of barbs

Count the number of barbs from the tip of the instrument to the end of the working part.

7.2.2.4 Tip

Rotate the instrument, as described in 7.2.2.1, to locate the first barb. Visually determine the point at which the barb base and instrument core surface meet and measure from this point to the tip for length as l_b.

7.2.2.5 Taper calculation

Calculate the taper by subtracting the diameter d_3 from the diameter d_{10} and dividing by 7.

EXAMPLE For a standard instrument size 10 (see Table 1), d_3 = 0,15 mm, d_{10} = 0,22 mm, the taper is calculated as: (0,22 − 0,15) / 7 = 0,01.

NOTE Taper tolerance is controlled solely by the tolerance of the specified diameters.

7.2.3 Paste carriers — Type 2 instruments

7.2.3.1 Diameters

The diameter, *D,* is calculated according to the following formula, where d_n and d_m are two diameters measured at l_n and l_m, respectively, away from the tip, as illustrated in Figure 2.

$$D = d_n - l_n * \frac{d_m - d_n}{l_m - l_n}$$

Position l_n at a distance of 3 mm from the tip, trace a tangent passing through point 1 and 2, trace a perpendicular at this tangent passing by point 3, located at the maximum distance of the spiral. Measure the diameter d_n, which is the distance between point 3 and the tangent 1-2.

Repeat the same procedure for the second diameter d_m at l_m, the distance shall be selected at 10 mm from the tip.

Measure the instrument diameters *D*, d_n, d_w and d_{op} using the procedure described in ISO 3630-1:2019, Clause 7.

7.2.3.2 Number of spirals

Count the number of spirals from the tip of the instrument to the end of working part, by counting each single "peak" on one side.

7.2.3.3 Resistance to cyclic fatigue

Grip the shaft of the instrument in the chuck of a variable-speed motor and place the head in the ball-bearing ring. Locate the centre of the ball bearing as specified in Figure 5. Deflect the ball-bearing 2 mm away from the axial alignment with the motor (see Figure 5). Rotate the motor at (4 000 ± 400) revolutions per minute. Count the total number of revolutions until failure (see Table 7).

Test 10 instruments.

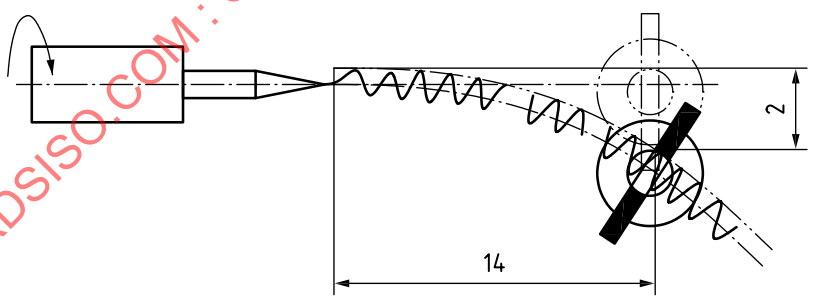


Figure 5 — Apparatus for testing resistance to fatigue — Type 2 instruments

8 Product information

8.1 Marking

The nominal size of the barbed broaches, explorers, cotton broaches and paste carriers shall be marked on the handle, shank or on the packaging (unless there are extreme space constraints). Marking symbols shall comply with ISO 3630-1:2019.

For cannulae, the identification symbol on the packaging or in manufacturer's literature shall be in accordance with Figure 6.

a) Taper b) Staged

Figure 6 — Identification symbols for cannulae

8.2 Labelling

Instruments shall comply with the labelling requirements as specified in ISO 3630-1.

8.3 Packaging

Instruments shall comply with the packaging requirements as specified in ISO 3630-1.

8.4 Instructions for use

Instruments shall comply with the instructions for use requirements as specified in ISO 3630-1.

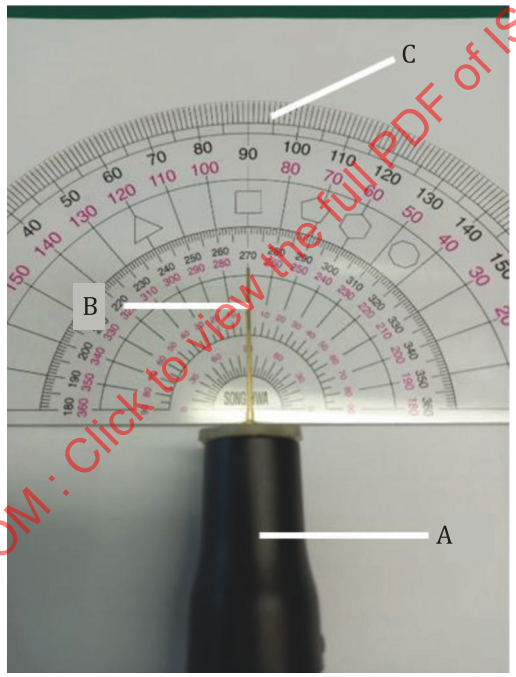
Annex A
(normative)

Test method for resistance of cannula to breakage or cracking

A.1 Principle

One end of the cannula is fixed to the thermoplastic delivery device or to a customized support. A force is applied to bend the cannula through a specified angle, first in one direction and then in the opposite direction for one cycle.

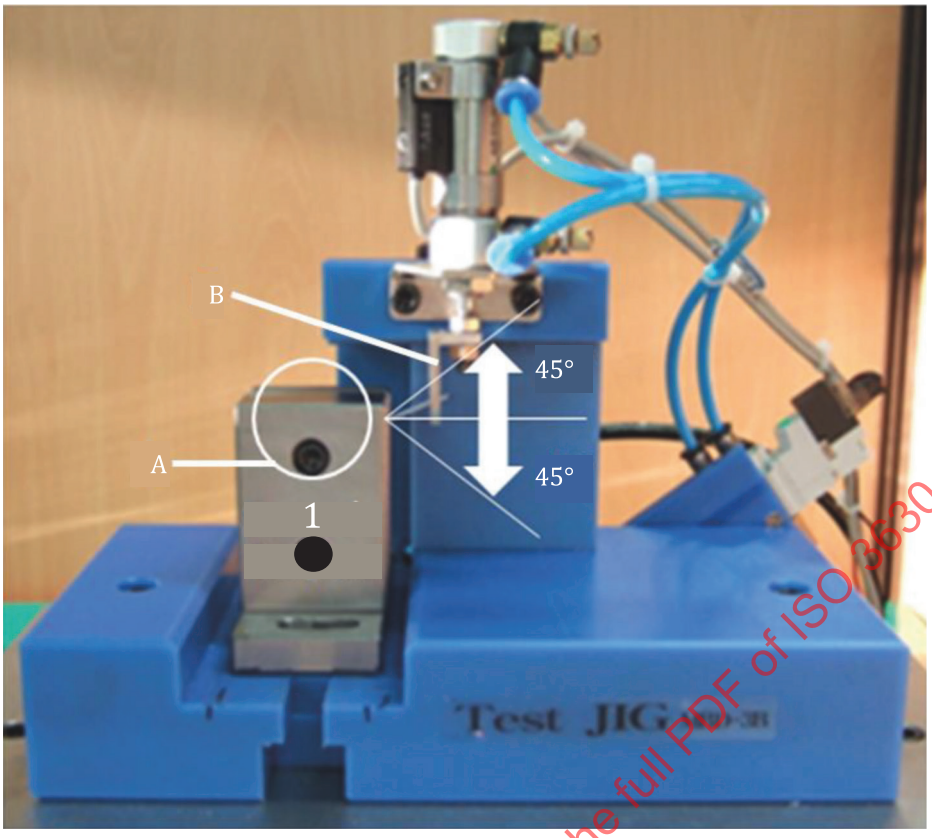
A.2 Apparatus



Key

A support/holder for fixing the cannula
B cannula
C protractor

Figure A.1 — Manual test apparatus for resistance of cannula to breakage by bending



Key

A support/holder for fixing the cannula

B bending tool

1 cannula fixation

Figure A.2 — Electronic test apparatus for resistance of cannula to breakage by bending

A.2.1 Thermoplastic delivery device or the support/holder for fixing the cannula, capable of holding and fixing the cannula (see Key A in Figure A.1 or Key A in Figure A.2 for examples).

A.2.2 Bending tool (if applicable), that would be capable of bending the cannula without damage. (See Figure A.3, Figure A.4 or Key B in Figure A.2 for examples). Manual bending can be also done by bending with hand and therefore does not require this tool. (See Figure A.5 for an example.) If applicable, the bending tool shall be supplied by the manufacturer.

Figure A.3 — Bending tool for manual test

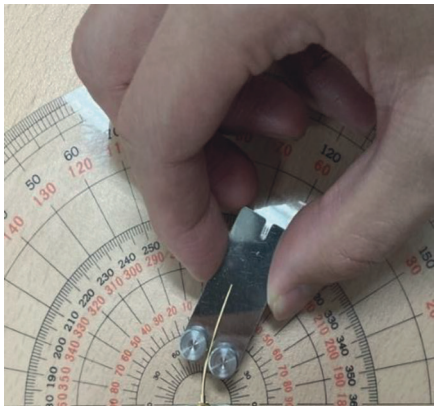


Figure A.4 — Demonstration of bending with the bending tool

Figure A.5 — Demonstration of bending by hand for manual test

A.2.3 Microscope (up to ×100), capable of examining at the bent surface of the cannula to determine if there is breakage or cracking at the bent surface.

A.2.4 Protractor, capable of measuring the angle of bending, to the nearest 1°.

A.3 Procedure

A.3.1 Manual test method

A.3.1.1 Rigidly fix one end of the cannula in the thermoplastic delivery device or support (A.2.1) and place the fixed cannula on the protractor (A.2.4) so that the cannula is in line with 90° indication of the protractor. (See Figure A.2 as an example).

A.3.1.2 Using the bending tool (A.2.2) or a hand, bend the cannula in one direction to an angle of (45 ± 5)°.

NOTE Figure A.6 shows an example using the hand.