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Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical — Exigences et méthodes d'essai

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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 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).

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).

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 9626:1991), which has been technically revised. It also incorporates the Amendment ISO 9626:1991/Amd 1:2001.

The main changes to the previous edition of ISO 9626 introduced by this revision are the following:

a) addition of specifications for stainless steel needle tubing for metric sizes 0,18 mm, 0,2 mm 0,23 mm and 0,25 mm and to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use;

b) addition of wall thickness designations beyond regular-walled and thin-walled tubing;

c) addition of minimum inner diameters for additional items where possible;

d) revision of the means of specifying the steels to be used;

e) revision of the table of tubing dimensions and stiffness parameters.

Annex A, Annex B, Annex C, Annex D and Annex E form an integral part of this International Standard.

Introduction

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

1 Scope

This International Standard applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

This International Standard provides requirements and test methods for the tubes manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This International Standard specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (10 Gauge) to 0,18 mm (34 Gauge).

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
designated metric size
outer diameter designation of the tubing as defined in Table 1

Note 1 to entry: It is expressed in millimetres.

3.2
gauge
legacy size designation

Note 1 to entry: A particular gauge size corresponds to a designated metric size defining limits for outer diameters.

3.3
wall thickness
material thickness between the inner and outer diameter of the tube

Note 1 to entry: It is expressed as RW=Regular Wall, TW=Thin Wall, ETW= Extra Thin Wall, and UTW=Ultra Thin Wall as designated in Table 1.

4 Materials

Tubing shall be made of stainless steels listed in ISO 15510. The chosen materials shall be in accordance with the requirements indicated in this International Standard. Selection of specific stainless steel material shall be made in consideration with the intended use, e.g. long-term contact with drugs and should consider biocompatibility requirements.

NOTE Suitable biocompatibility requirements can be found in ISO 10993-1.

5 Requirements

5.1 General

For the selection of tubing for a specific application and intended use, a risk based approach shall be applied.

5.2 Surface finish and visual appearance

When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects.

Surface finish specifications may be different based on the final function of the medical device; in such cases, the medical device manufacturer should prepare specific specifications for surface finishing.

When examined by normal or corrected vision, the needle tube shall appear straight and of regular roundness.

5.3 Cleanliness

When examined by normal or corrected vision, the surfaces of the tubing shall be free from metal soil and processing agents.

Cleanliness specifications may be different based on the final function of the medical device; in such cases, the medical device manufacturer should prepare specific specifications for cleanliness.

5.4 Limits for acidity and alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one pH unit of that of the control fluid.

5.5 Size designation

Tubing size shall be designated by the nominal outer diameter, expressed in millimetres (i.e. the designated metric size), corresponding gauge size (e.g. G31 or 31G), and by wall thickness.

EXAMPLE 0,25 mm (31G) ETW.

5.6 Dimensions

The dimensions of tubing shall be as given in Table 1.

Table 1 — Dimensions of tubing

Designated metric size mm	Gauge	OD_{MIN} mm	OD_{MAX} mm	Wall	ID_{MIN} mm
0,18	34	0,178	0,191	RW	0,064
				TW	0,091
				ETW	0,105
0,20	33	0,203	0,216	RW	0,089
				TW	0,105
				ETW	0,125
0,23	32	0,229	0,241	RW	0,089
				TW	0,105
				ETW	0,125
				UTW	0,146
0,25	31	0,254	0,267	RW	0,114
				TW	0,125
				ETW	0,146
				UTW	0,176
0,30	30	0,298	0,320	RW	0,133
				TW	0,165
				ETW	0,190
				UTW	0,240
0,33	29	0,324	0,351	RW	0,133
				TW	0,190
				ETW	0,240
				UTW	0,265
0,36	28	0,349	0,370	RW	0,133
				TW	0,190
0,40	27	0,400	0,420	RW	0,184
				TW	0,241
0,45	26	0,440	0,470	RW	0,232
				TW	0,292
0,50	25	0,500	0,530	RW	0,232
				TW	0,292
0,55	24	0,550	0,580	RW	0,280
				TW	0,343
0,60	23	0,600	0,673	RW	0,317
				TW	0,370
				ETW	0,460

NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.

NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

NOTE 3 This International Standard does not specify maximum inner diameter.

NOTE 4 OD = outer diameter; ID = inner diameter.

Table 1 *(continued)*

Designated metric size mm	Gauge	OD_{MIN} mm	OD_{MAX} mm	Wall	ID_{MIN} mm
0,70	22	0,698	0,730	RW	0,390
				TW	0,440
				ETW	0,522
0,80	21	0,800	0,830	RW	0,490
				TW	0,547
				ETW	0,610
				UTW	0,645
0,90	20	0,860	0,920	RW	0,560
				TW	0,635
				ETW	0,687
				UTW	0,713
1,10	19	1,030	1,100	RW	0,648
				TW	0,750
				ETW	0,850
				UTW	0,891
1,20	18	1,200	1,300	RW	0,790
				TW	0,910
				ETW	1,041
1,40	17	1,400	1,510	RW	0,950
				TW	1,156
				ETW	1,244
				UTW	1,276
1,60	16	1,600	1,690	RW	1,100
				TW	1,283
				ETW	1,390
1,80	15	1,750	1,900	RW	1,300
				TW	1,460
				ETW	1,560
2,10	14	1,950	2,150	RW	1,500
				TW	1,600
				ETW	1,727
2,40	13	2,300	2,500	RW	1,700
				TW	1,956
2,70	12	2,650	2,850	RW	1,950
				TW	2,235

NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.

NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

NOTE 3 This International Standard does not specify maximum inner diameter.

NOTE 4 OD = outer diameter; ID = inner diameter.

Table 1 *(continued)*

Designated metric size mm	Gauge	OD_{MIN} mm	OD_{MAX} mm	Wall	ID_{MIN} mm
3,00	11	2,950	3,150	RW	2,200
				TW	2,464
3,40	10	3,300	3,500	RW	2,500
				TW	2,819
NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.					
NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.					
NOTE 3 This International Standard does not specify maximum inner diameter.					
NOTE 4 OD = outer diameter; ID = inner diameter.					

5.7 Sample size

Where sampling is applicable, the sample sizes shall be determined on the basis of risk assessment principles and be included in the tube specification and based on the intended use.

5.8 Stiffness

When tested in accordance with Annex B, the tubing shall show a deflection not greater than the relevant value given in Table 2.

For tubes where stiffness test parameters are not defined in this International Standard, the medical device manufacturer shall prepare specific stiffness requirements based on a risk assessment of the final intended use of the tube.

Consideration should be given to the final product intended use of the tube to determine if additional tests are required.

Table 2 — Conditions for stiffness test

Designated metric size	Regular-walled tubing			Thin-walled tubing			Extra-thin walled tubing			Ultra-thin walled tubing		
	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm
0,18	a	a	a	a	a	a	a	a	a	a	a	a
0,2	5,0	0,6	0,25	5,0	0,6	0,27	a	a	a	a	a	a
0,23	5,0	0,9	0,20	5,0	0,9	0,20	5,0	0,9	0,22	5,0	0,9	0,25
0,25	5,0	1,1	0,17	5,0	1,1	0,18	5,0	1,1	0,21	5,0	1,1	0,24
0,3	5,0	1,3	0,11	5,0	1,3	0,11	5,0	1,3	0,16	5,0	1,3	0,20
0,33	5,0	1,6	0,09	5,0	1,6	0,12	5,0	1,6	0,17	5,0	1,6	0,19
0,36	5,0	3,6	0,14	5,0	3,6	0,14	a	a	a	a	a	a
0,4	9,5	2,7	0,52	7,5	3,4	0,34	a	a	a	a	a	a
0,45	10,0	3,1	0,45	10,0	3,1	0,51	a	a	a	a	a	a
0,5	10,0	5,1	0,37	10,0	5,1	0,40	a	a	a	a	a	a
0,55	10,0	6,4	0,34	10,0	6,4	0,36	a	a	a	a	a	a
0,6	12,5	4,8	0,33	12,5	4,8	0,43	12,5	4,8	0,51	a	a	a
0,7	15,0	6,7	0,42	15,0	6,7	0,52	15,0	6,7	0,60	a	a	a
0,8	15,0	9,6	0,38	15,0	9,6	0,45	15,0	9,6	0,51	a	a	a
0,9	17,5	9,0	0,48	17,5	9,0	0,56	17,5	9,0	0,60	a	a	a
1,1	25,0	9,7	0,71	25,0	9,7	0,97	25,0	9,7	1,08	a	a	a
1,2	25,0	12,2	0,51	25,0	12,2	0,81	a	a	a	a	a	a
1,4	25,0	16,6	0,46	25,0	16,6	0,68	25,0	16,6	0,82	a	a	a
1,6	25,0	22,0	0,25	25,0	22,0	0,30	25,0	22,0	0,34	a	a	a
1,8	25,0	25,0	0,35	25,0	25,0	0,45	a	a	a	a	a	a
2,1	30,0	40,0	0,40	30,0	40,0	0,50	a	a	a	a	a	a
2,4	40,0	40,0	0,38	40,0	40,0	0,65	a	a	a	a	a	a
2,7	40,0	50,0	0,31	40,0	50,0	0,45	a	a	a	a	a	a
3	50,0	50,0	0,41	50,0	50,0	0,55	a	a	a	a	a	a
3,4	50,0	60,0	0,32	50,0	60,0	0,46	a	a	a	a	a	a

a No data are available; therefore, this International Standard does not specify stiffness properties for these sizes of tubing.