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Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

AMENDMENT 1: Connectors

Implants cardiovasculaires et organes artificiels — Échangeurs gaz/sang extracorporels (oxygénateurs)

AMENDEMENT 1: Raccords

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

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Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

AMENDMENT 1: Connectors

4.2.4 Connectors

Replace the text of 4.2.4 with the following text:

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.4, allow a secure connection.

When tested in accordance with 5.3.4, the gas connection to the gas pathway shall not separate.

NOTE 1 Connectors of a type that allows connection of tubes with an inner diameter of 4,8 mm, 6,3 mm, 9,5 mm or 12,7 mm, a type that complies with ISO 8637-1:2017, Figure 1, or a type that complies with ISO 80369-7 have been found satisfactory.

NOTE 2 Connectors with dimensions as given in Annex A and fitting to functional gauges and reference steel fittings is a way to comply with this requirement.

Performance testing of the connectors shall be performed according to ISO 80369-7:2016, Clause 6. The reference fittings given in Annex A can be used in the performance testing of the connectors.

Connectors for the heat exchanger fluid pathway shall be capable of being connected to female fast couplings.

NOTE 3 Connectors corresponding to ISO 8637-1:2017, Figure 2 are considered as one way to comply with this requirement.

Clause 2

Add:

> ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

Annex A

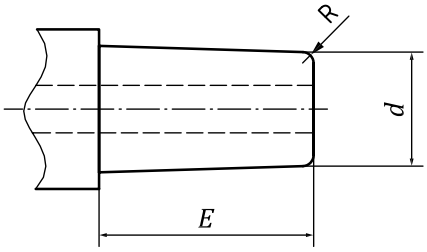
Add the following annex, before the Bibliography:

Annex A
(informative)

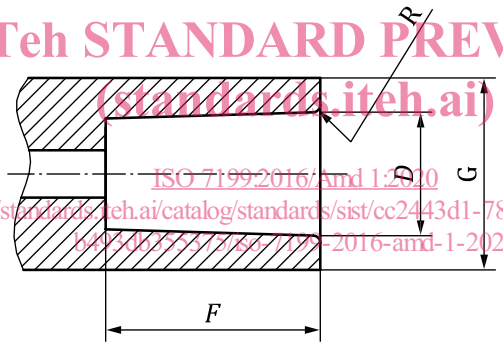
Examples of connectors

A.1 Luer Slip Fittings

A.1.1 Figures A.1 and A.2 depict Luer slip fittings. For corresponding dimensions, see Table A.1.



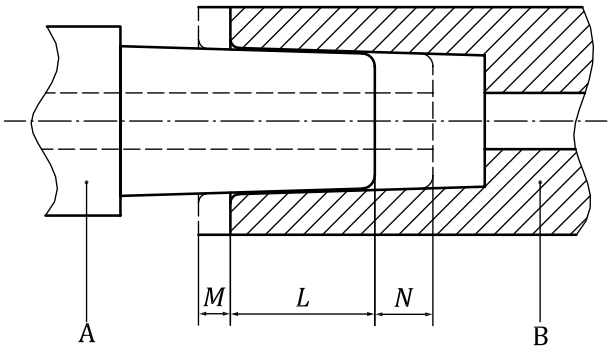
a) Male 6 % (Luer) conical fitting ("male fitting")



b) Female 6 % (Luer) conical fitting ("female fitting")

NOTE See Key and dimensions given in Table A.1.

Figure A.1 — Typical 6 % (Luer) conical fittings



NOTE See Key and dimensions given in Table A.1.

Figure A.2 — Typical assembly of 6 % (Luer) conical fittings

Table A.1 — Dimensions of 6 % (Luer) conical fittings

Reference			Designation	Dimensions (mm)	
				Rigid material	Semi-rigid material
A			Male fitting	N/A	N/A
B			Female fitting	N/A	N/A
Basic dimensions	*d*	min.	Minimum diameter of the end of the male conical fitting (reference diameter)	3,925	3,925
		max.	Maximum diameter at the end of the male conical fitting	3,990	4,027
	D	min.	Minimum diameter at the opening of the female conical fitting	4,270	4,270
		max.	Maximum diameter at the opening of the female conical fitting	4,315	4,315
	E		Minimum length of the male conical fitting	7,500	7,500
	F		Minimum depth of the female conical fitting	7,500	7,500
	G		Maximum outside diameter of female conical fitting	6,730	6,730
Other dimensions	*L*[a]		Minimum length of engagement	4,665	4,050
	M[a]		Tolerance for length of engagement of the female conical fitting	0,750	0,750
	N[a]		Tolerance for length of engagement of the male conical fitting	1,083	1,700
	R[b]		Radius of curvature (maximum)	0,5	0,5

[a] Dimensions *L*, *M* and *N* are derived from the basic dimensions.

[b] Or equivalent entry chamfer without any sharp corners.

A.1.2 Gauging test

A.1.2.1 When tested in accordance with A.1.2.4, the conical fitting should satisfy the requirements specified in A.1.2.2 and A.1.2.3.

A.1.2.2 The small end of the male conical fitting should lie between the two limit planes of the gauge and the larger end of the tapered portion should extend beyond the datum plane of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

NOTE The test for freedom from rocking may be found useful for evaluating semi-rigid fittings.

A.1.2.3 The plane of the maximum diameter at the opening of the female conical fitting should lie between the two limit planes of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

A.1.2.4 The procedure should be carried out as specified in A.1.2.4.1 to A.1.2.4.4.

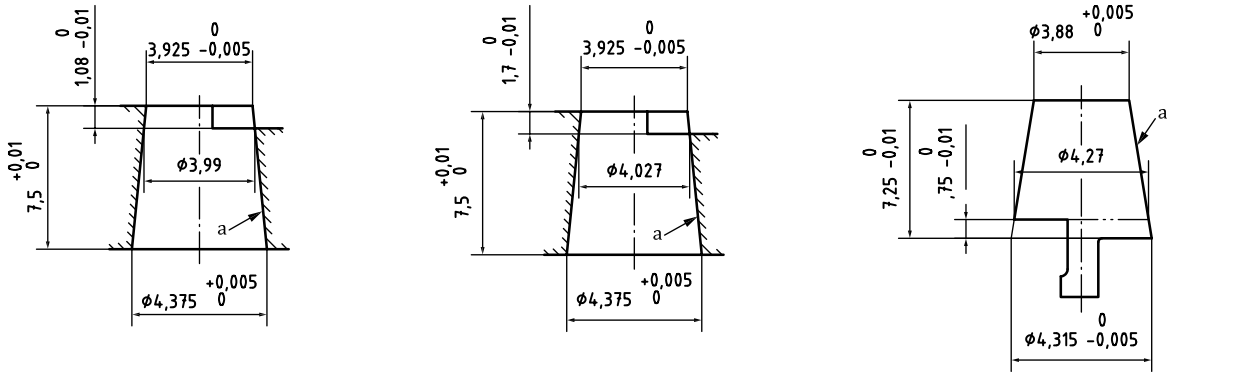
A.1.2.4.1 Carry out the test using steel gauges as illustrated in Figure A.3.

A.1.2.4.2 Carry out the test at a temperature of (20 ± 5) °C.

A.1.2.4.3 Prior to testing, condition products made from hygroscopic materials at (20 ± 5) °C and (50 ± 10) % relative humidity for not less than 24 h. Conditioning is not required for products made from non-hygroscopic materials.

A.1.2.4.4 Apply the gauge to the conical fitting with a total axial force of 5 N, without the use of torque. Remove the axial load.

Dimensions in millimetres



a) Gauge for testing rigid male conical fittings

b) Gauge for testing semi-rigid male conical fittings

c) Gauge for testing female conical fittings of all materials

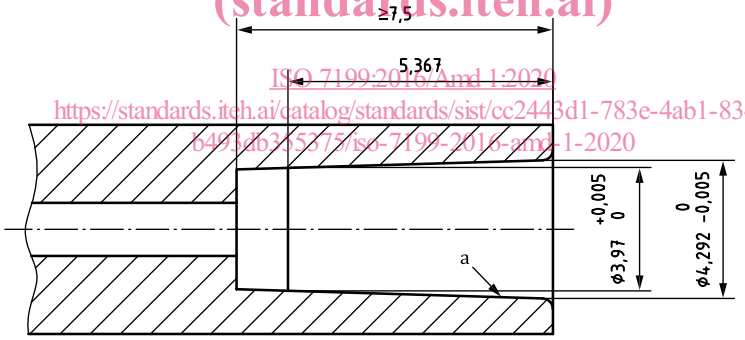
NOTE Cone taper (0,06:1).

Figure A.3 — Gauges for testing 6 % (Luer) conical fittings

A.1.3 Reference steel fittings

A.1.3.1 Figures A.4 and A.5 depict male and female reference steel fittings.

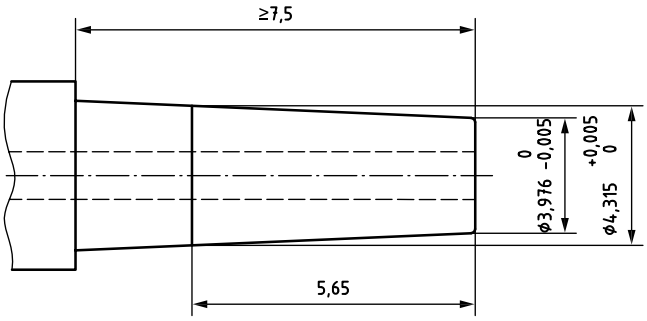
Dimensions in millimetres



NOTE Cone taper (0,06:1).

Figure A.4 — Reference steel female conical fitting

Dimensions in millimetres



NOTE Cone taper (0,06:1).

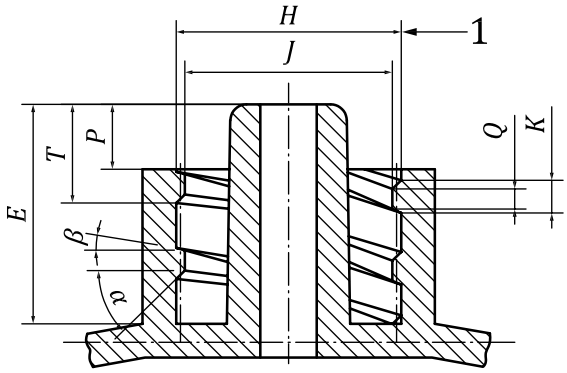
Figure A.5 — Reference steel male conical fitting

A.2 Luer Lock Fittings

A.2.1 Figures A.6 to A.9 depict Luer lock fittings while Figures A.10 and A.11 depict female reference steel fittings for testing male 6 % (Luer) conical lock fittings. For corresponding dimensions, see Table A.2.

NOTE 1 If a female 6 % (Luer) conical lock fitting as shown in Figure A.8 has lugs in a plane inclined to the axis of fitting, the lugs should form a part of the thread form shown in Figure A.9. In this case, 'V' does not apply.

NOTE 2 All outside edges of lug or thread form as shown in Figures A.10 and A.11 should have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

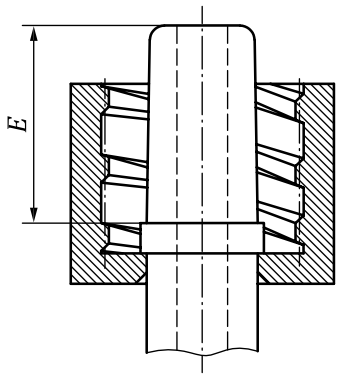


Key

1 double start, right-hand thread of 2,5 mm pitch

NOTE See Key and dimensions given in Table A.2.

Figure A.6 — Male 6 % (Luer) conical lock fitting with permanently connected internally threaded collar



NOTE 1 For other dimensions, see Figure A.6.

NOTE 2 See Key and dimensions given in Table A.2.

Figure A.7 — Male 6 % (Luer) conical lock fitting with rotatable internally threaded collar