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AMENDMENT 1
2020-02

**Cardiovascular implants and artificial
organs — Hard-shell cardiotomy/
venous reservoir systems (with/
without filter) and soft venous
reservoir bags**

AMENDMENT 1: Connectors

*Implants cardiovasculaires et organes artificiels — Systèmes
réservoirs de cardiotomie/veineux à paroi dure (avec/sans filtre) et
sacs réservoirs veineux mous*

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 — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

AMENDMENT 1: Connectors

4.2.3 Connectors

Replace the text of 4.2.3 with the following text:

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.3, allow a secure connection (see [Figures B.1](#) through [B.11](#) for examples of connectors).

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 B](#) 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, using the reference fittings given in [Annex B](#).

Normative References

Add:

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

Annex B

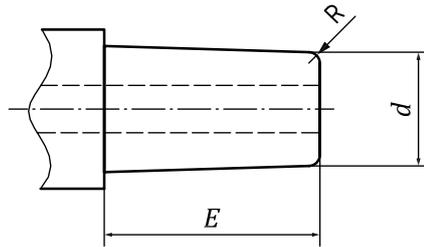
Add the following annex after Annex A, before the Bibliography:

Annex B (informative)

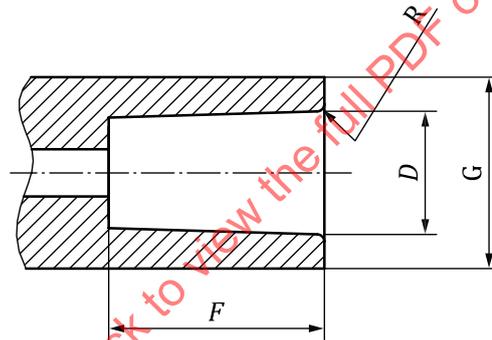
Examples of connectors and reference fittings

B.1 Luer Slip Fittings

B.1.1 [Figures B.1](#) and [B.2](#) depict Luer slip fittings. For corresponding dimensions, see [Table B.1](#).



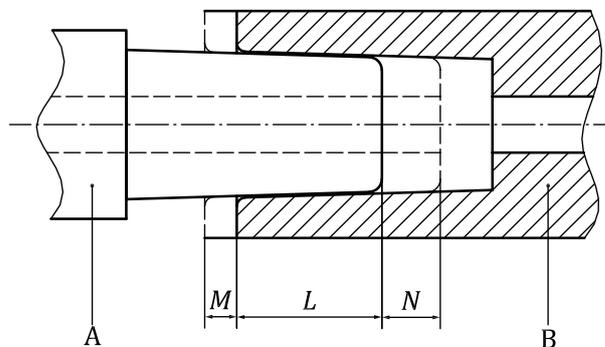
a) Male 6 % (Luer) conical fitting (“male fitting”)



b) Female 6 % (Luer) conical fitting (“female fitting”)

NOTE See Key and dimensions given in [Table B.1](#).

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



NOTE See Key and dimensions given in [Table B.1](#).

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

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

Reference		Designation		Dimension (length in mm)	
				Rigid material	Semi-rigid material
A		Male fitting		N/A	N/A
B		Female fitting		N/A	N/A
Basic dimensions	<i>d</i>	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
	<i>D</i>	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
	<i>E</i>	Minimum length of the male conical fitting		7,500	7,500
	<i>F</i>	Minimum depth of the female conical fitting		7,500	7,500
	<i>G</i>	Maximum outside diameter of female conical fitting		6,730	6,730
Other dimensions	<i>L</i> ^a	Minimum length of engagement		4,665	4,050
	<i>M</i> ^a	Tolerance for length of engagement of the female conical fitting		0,750	0,750
	<i>N</i> ^a	Tolerance for length of engagement of the male conical fitting		1,083	1,700
	<i>R</i> ^b	Radius of curvature (maximum)		0,5	0,5
^a Dimensions <i>L</i> , <i>M</i> and <i>N</i> are derived from the basic dimensions.					
^b Or equivalent entry chamfer without any sharp corners.					

B.1.2 Gauging test

B.1.2.1 When tested in accordance with [B.1.2.4](#), the conical fitting should satisfy the requirements specified in [B.1.2.2](#) and [B.1.2.3](#).

B.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.

B.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.

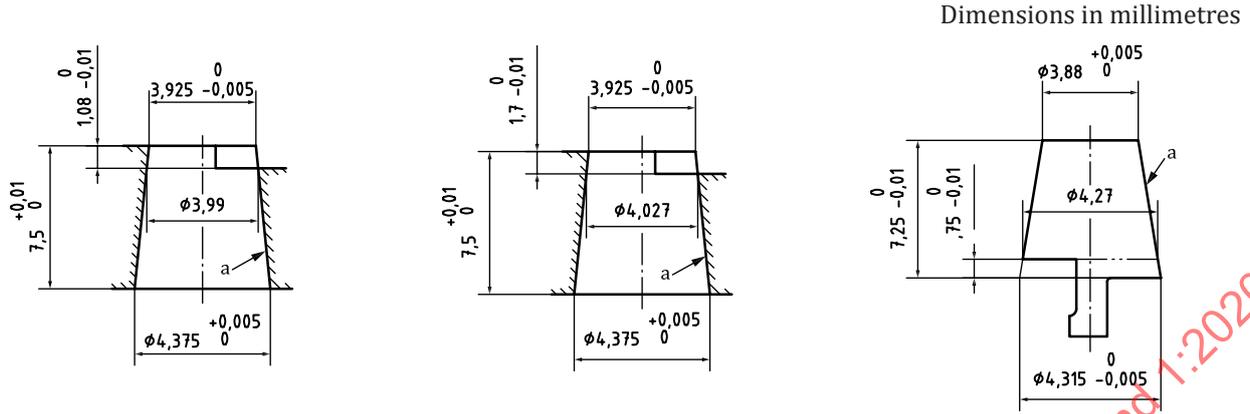
B.1.2.4 The procedure should be carried out as specified in [B.1.2.4.1](#) to [B.1.2.4.4](#).

B.1.2.4.1 Carry out the test using steel gauges as illustrated in [Figure B.3](#).

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

B.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.

B.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.



a) Gauge for testing rigid male conical fittings

b) Gauge for testing semi-rigid male conical fittings

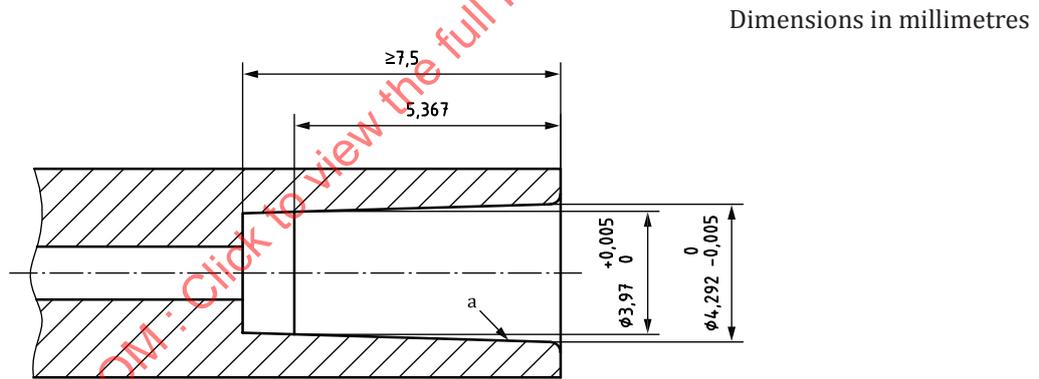
c) Gauge for testing female conical fittings of all materials

NOTE Cone taper (0,06:1).

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

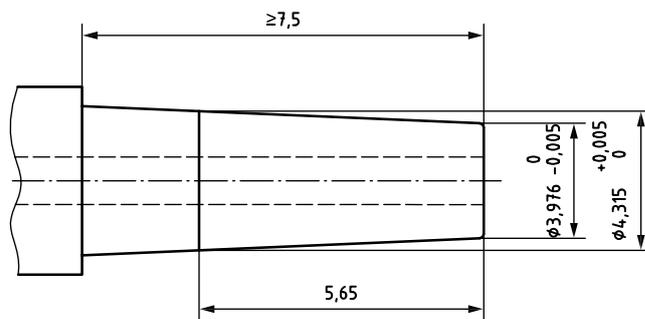
B.1.3 Reference steel fittings

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



NOTE Cone taper (0,06:1).

Figure B.4 — Reference steel female conical fitting



NOTE Cone taper (0,06:1).

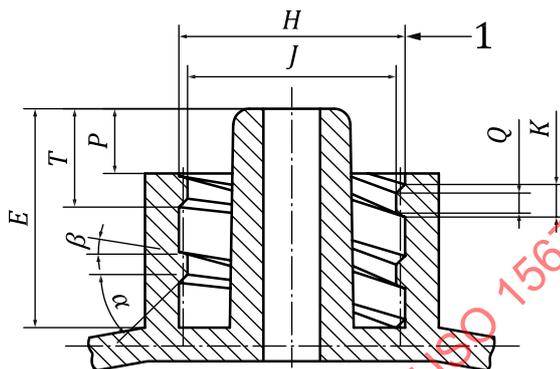
Figure B.5 — Reference steel male conical fitting

B.2 Luer Lock Fittings

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

If a female 6 % (Luer) conical lock fitting as shown in Figure B.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 B.9. In this case, 'V' does not apply.

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

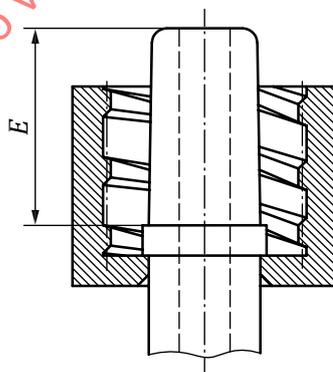


Key

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

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

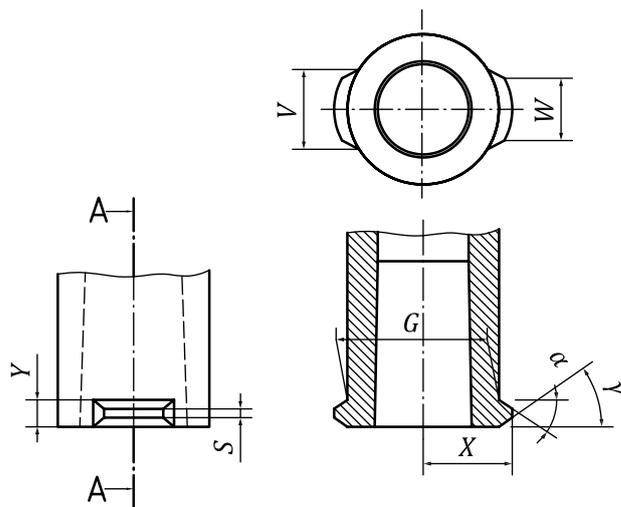
Figure B.6 — Male 6 % (Luer) conical lock fitting with permanently connected internally threaded collar



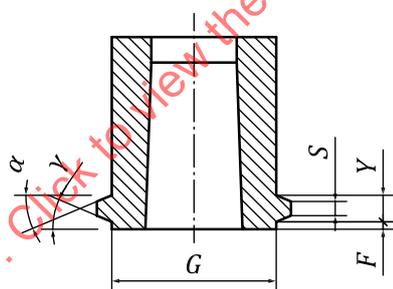
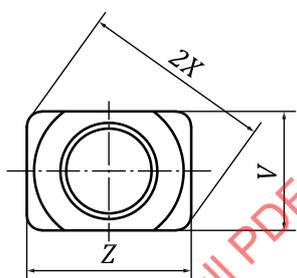
NOTE 1 For other dimensions, see Figure B.6.

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

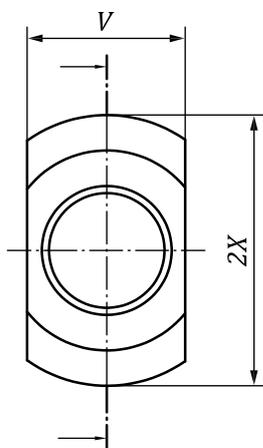
Figure B.7 — Male 6 % (Luer) conical lock fitting with rotatable internally threaded collar



a) Variant A



b) Variant B



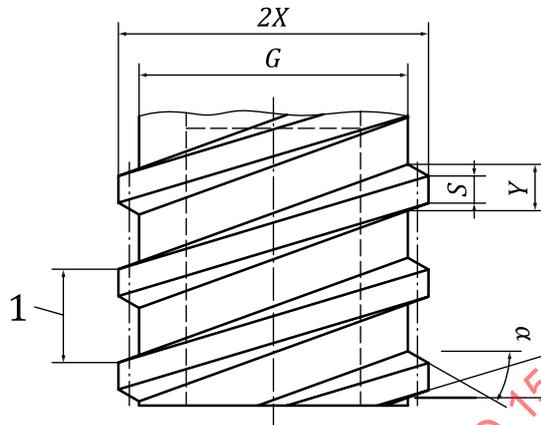
c) Variant C

NOTE 1 Variants B and C are intended to be used for the design of rigid fittings only.

NOTE 2 To ensure compatibility with existing rigid fittings, a maximum $K = 0,8$ mm is preferred.

NOTE 3 See Key and dimensions given in [Table B.2](#).

Figure B.8 — Female 6 % (Luer) conical lock fittings with lugs in a plane at right angles to axis of fitting



Key

1 pitch

NOTE 1 For other dimensions, see [Figure B.8](#).

NOTE 2 See Key and dimensions given in [Table B.2](#).

Figure B.9 — Female 6 % (Luer) lock conical fitting with external thread

Table B.2 — Dimensions of 6 % (Luer) rigid conical lock fittings

Dimensions in millimetres

Symbol	Designation	Dimensions	
		Figures B.6, B.7, B.8 a) and B.9	Figures B.8 b) and B.8 c)
α	Angle of thread or lug bearing surface against separation with the plane perpendicular to the axis of lock fitting	$25^{+5}_0^\circ$	$25^{+5}_0^\circ$
β	Minimum angle of internal thread non-bearing surface against separation with the plane perpendicular to the axis of lock fitting	25°	—
γ	Minimum angle of external thread or lug non-bearing surface against separation with the plane perpendicular to the axis of the lock fitting	0°	0°
E	Minimum length of male lock fitting	7,5	—
F	Nominal distance from the face of the fitting to the base of the lug	—	0,20
G	Maximum outside diameter of female lock fitting at base of lugs or maximum inside diameter of external thread; this diameter should not be increased for a distance from the hub face of 5,5 mm	6,73	5,7
H	Root diameter of the thread of male lock fitting	$8,0 \pm 0,1$	—
J	Crest diameter of the thread of male lock fitting	$7,0 \pm 0,2$	—
K	Maximum thread width of male lock fitting at root	1	—
P	Minimum projection of nozzle from collar	2,1	—

Table B.2 (continued)

Symbol	Designation	Dimensions	
		Figures B.6, B.7, B.8 a) and B.9	Figures B.8 b) and B.8 c)
<i>Q</i>	Minimum thread crest width of male lock fittings	0,3	—
<i>S</i>	Lug crest width or thread crest width of female lock fitting with lugs or external thread	0,3 min.	0,27 max.
<i>T</i>	Maximum distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread	3,2	—
<i>V</i>	Maximum chord length at base of lug in a plane at right angles to axis of fitting only, to be measured on a chord of a circle the diameter of which is <i>J</i> min. (7,0 mm)	3,5	5,0
<i>W</i>	Minimum chord length at extremity of lug in a plane at right angles to axis of fitting only (<i>W</i> should not be greater than <i>V</i>)	2,71	—
<i>X</i>	Distance from axis of female lock fitting to extremity of lug	—	—
<i>2X</i>	Outside diameter across the lugs or external thread	$7,83_{-0,1}^0$	$7,80_{-0,1}^0$
<i>Y</i>	Maximum width of base of lug (axial) or thread at base, of female lock fitting to be measured at a point corresponding to an outside diameter equal to <i>G</i> (6,73 max.)	1,2	1,30
<i>Z</i>	Width across the lugs at external thread	—	$6,50_{-0,1}^0$
Pitch	Nominal pitch of double-start, right-hand thread of female lock fitting — 5 mm lead	2,5	—