SLOVENSKI STANDARD
SIST EN ISO 7199:2017/oprA1:2018

01-julij-2018

Vsadki (implantati) za srce in ožilje ter umetni organi - Izmenjevalniki krvnih plinov (oksigenatorji) - Dopolnilo A1: Konektorji (ISO 7199:2016/DAM 1:2018)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) - Amendment 1: Connectors (ISO 7199:2016/DAM 1:2018)

Kardiovaskuläre Implantate und künstliche Organe - Blutgasaustauscher (Oxygenatoren) - Änderung 1 (ISO 7199:2016/DAM 1:2018)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang extracorporels (oxygénateurs) - Amendement 1 (ISO 7199:2016/DAM 1:2018)

Ta slovenski standard je istoveten z: **EN ISO 7199:2017/prA1**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 7199:2017/oprA1:2018 **en**

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DRAFT AMENDMENT
ISO 7199:2016/DAM 1

ISO/TC **150**/SC **2** Secretariat: **ANSI**

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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: .

ICS: 11.040.40

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Foreword

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Amendment 1 to ISO 7199:2017 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

Modify 4.2.4 Connectors to read:

4.2.4 Connectors

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, or 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 the informative Annex A (formerly defined by ISO 594-1/-2) 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, Clause 6, using the reference fittings given in Annex A.

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.

Add to **Clause 2 Normative references**:

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

Add to **Bibliography**:

ISO 8637-1:2017, *Extracorporeal systems for blood purification – Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

Add the following informative **Annex A, Examples of connectors**:

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Annex A
(informative)

Examples of connectors

A.1 Luer Slip Fittings

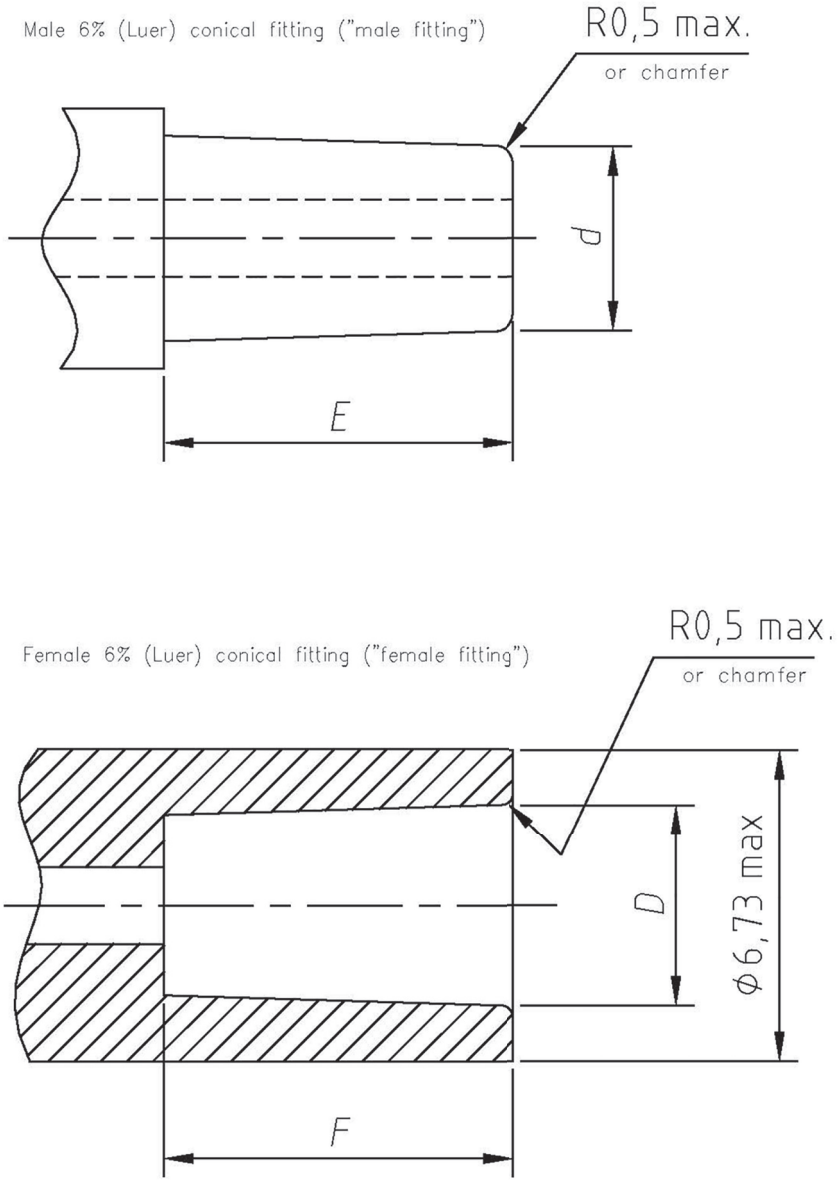

Figure A.1 — Typical 6 % (Luer) conical fittings (see the Key and dimensions in Table A.1)

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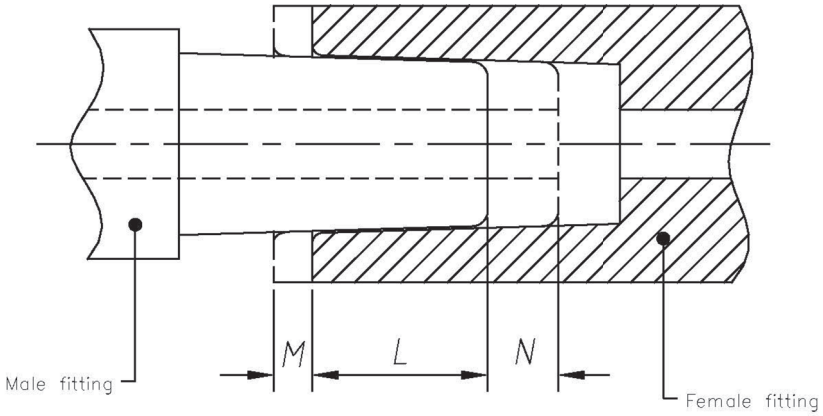

Figure A.2 — Typical assembly of 6 % (Luer) conical fittings (see the Key and dimensions in Table A.1)

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

Reference			Designation	Dimensions (mm)	
				rigid material	semi-rigid material
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
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] max.		Radius of curvature	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.1.1 Gauging test

When tested in accordance with A.1.1.3, the conical fitting shall satisfy the requirements specified in A.1.1.1 and A.1.1.2.

A.1.1.1 The small end of the male conical fitting shall lie between the two limit planes of the gauge and the larger end of the tapered portion shall extend beyond the datum plane of the gauge. Rocking shall 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.1.1.2 The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.

A.1.1.3 The procedure shall be carried out as specified in A.1.1.3.1 to A.1.1.3.4.

A.1.1.3.1 Carry out the test using steel gauges as illustrated in Figure A.3.

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