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AMENDMENT 1
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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

Reference number
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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

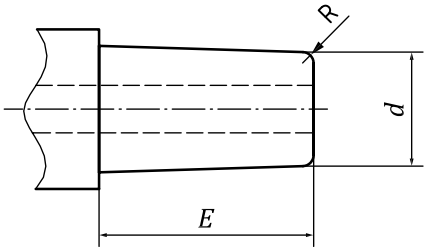
Add the following annex, before the Bibliography:

Annex A
(informative)

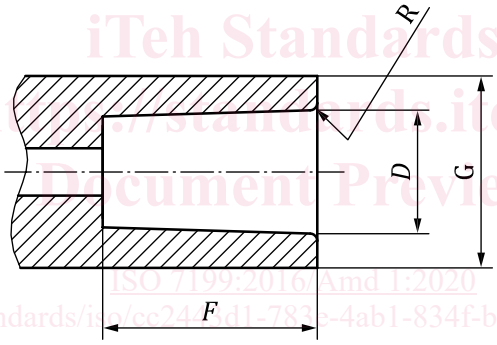
Examples of connectors

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.



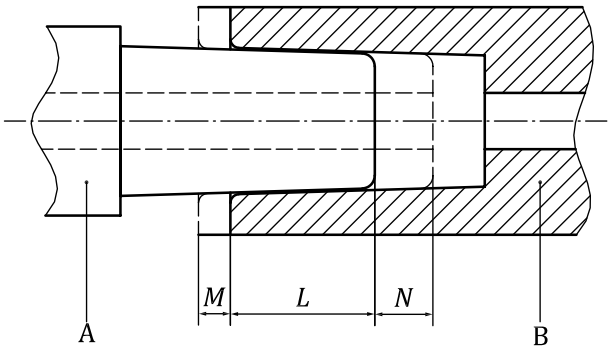
a) Male 6 % (Luer) conical fitting ("male fitting")



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