
**Cardiovascular implants and artificial
organs — Cardiopulmonary bypass
systems — Arterial blood line filters**

AMENDMENT 1: Connectors

*Implants cardiovasculaires et organes artificiels — Systèmes de
pontage cardio-pulmonaire — Filtres en ligne pour sang artériel*
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 — Cardiopulmonary bypass systems — Arterial blood line filters

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 A.1](#) through [A.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 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.

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Normative references

Add:

[ISO 15675:2016/Amd 1:2020](#)

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

Annex A

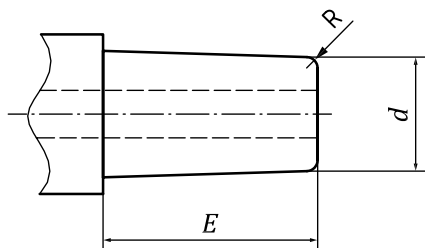
Add the following annex, before the Bibliography:

Annex A (informative)

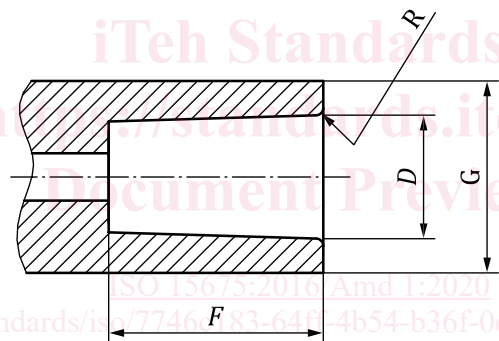
Examples of connectors and reference fittings

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](#).



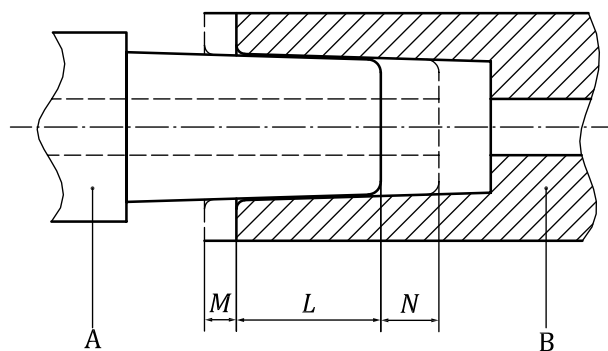
a) Male 6 % (Luer) conical fitting (“male fitting”)



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