INTERNATIONAL STANDARD

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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

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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

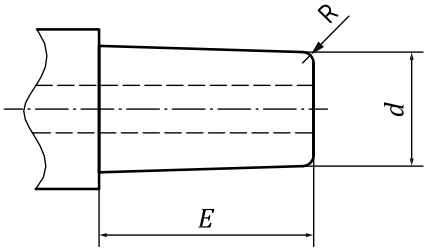
Add the following annex after Annex A, before the Bibliography:

Annex B
(informative)

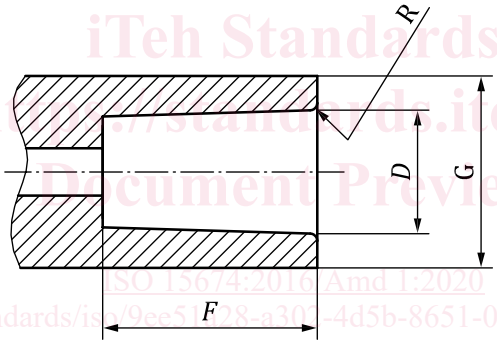
Examples of connectors and reference fittings

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.



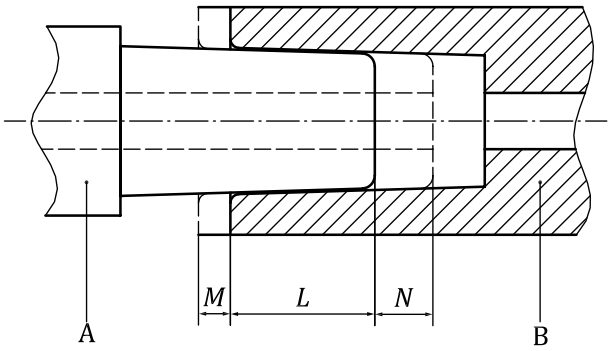
a) Male 6 % (Luer) conical fitting ("male fitting")



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