

American National Standard



ANSI/AAMI CN27:2021

General requirements for
Luer activated valves (LAVs)
incorporated into medical
devices for intravascular
applications

General requirements for *Luer activated valves (LAVs)* incorporated into medical devices for intravascular applications

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AAMI

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Abstract: This standard covers *Luer activated valves (LAVs)* for intravascular applications, which open and permit access to the fluid conduit when a male Luer connector is inserted

Keywords: *Luer activated valves (LAVs)*, connectors, misconnection

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Luer Activated Valves Working Group

This AAMI American National Standard (ANS) was developed and approved by the Small Bore Connectors Committee.

At the time this document was published, the **AAMI Luer Activated Valves Working Group** had the following members:

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Steve Bello, Atrion Corp (Halkey Roberts)
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Keith Wheeler, Fresenius Medical Care
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NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the *Luer Activated Valves Working Group* (AAMI/CN/WG01) of the AAMI Small Bore Connectors Committee and establishes minimum general, performance, biological, chemical, and labeling requirements for *Luer activated valves (LAVs)*. It is intended to assist manufacturers in design and development of *Luer activated valves* used in intravascular applications.

During a meeting on development of the ISO 80369 series of small-bore connector standards, the idea of developing a standard for needle-free connectors was born. Although a small component of the complex systems used in intravenous (IV) therapy and associated areas, needleless systems have a huge impact on patient and health professional safety. An AAMI working group subsequently was established to address this need. The working group consisted of representatives from industry, including manufacturers and thought leaders, and those with regulatory, clinical, and product management backgrounds. Although the standard is focused on the U.S regulatory environment and U.S. end use, to be inclusive, representation from around the globe has been added to the AAMI *Luer Activated Valves Working Group*.

AAMI and ANSI procedures require that standards be reviewed at least every five years and, if necessary, revised to reflect technological advances that might have occurred since publication.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments and knowledge gained from field experience with the devices. To remain relevant, it must be modified as technological advances are made and as new data come to light.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the ANSI/AAMI CN27, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications* (ANSI/AAMI CN27:2021), but it does provide important information about the development and intended use of the document.

Introduction

NOTE See Annex A.2.

During the development of ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors for intravascular or hypodermic applications*, it was determined that *Luer activated valves (LAVs)* should be interpreted as their own category, so limited guidance was provided to address the risk of misconnections to LAVs.

ISO 80369-7 covers the following:

- General requirements;
- Performance requirements;
- Type tests;
- Material used for *Luer connectors*;
- Dimensional requirements for *Luer connectors*;
- *Non-interconnectability* analysis (including a three-dimensional computer-aided design (CAD) engineering analysis);
- Mechanical tests for verifying *Non-interconnectability* characteristics (testing per ANSI/AAMI/ISO 80369-1, Annex B).

This standard addresses the following additional areas for LAVs:

- Risk of misconnections;
- Usability requirements;
- Performance requirements and test methods.

This standard does not cover the connection features of the *non-valve end*. Manufacturers are to assess the requirements of applicable standards and consider the risk of misconnections on the *non-valve end* *.

As the committee reviewed the terminology, it was determined that “*Luer activated valves (LAVs)*” is a more appropriate term than the term “*Luer connector activated medical devices*” because the technology is used both for a stand-alone device and for a component of a medical device. Although terms such as *needleless connector* and *needle-free connector* are used interchangeably, the term *LAV* will be used for purposes of this standard.

As part of the development of this standard, the committee reviewed the data from the FDA MAUDE database for needle-free connector technologies and considered the common issues encountered in the use-case scenarios for needle-free connectors/LAVs (e.g., leak, disassembly etc.).

For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard.
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard.
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

NOTE 1 Performance tests, including tests demonstrating *non-interconnectability*, are provided in Annex B.

NOTE 2 A summary of usability requirements for LAVs for intravascular applications is provided in Annex C.

NOTE 3 A summary of design considerations for LAVs is provided in Annex D.

NOTE 4 Guidance on microbial ingress testing is provided in Annex E.

General requirements for *Luer activated valves (LAVs)* incorporated into medical devices for intravascular applications

1 Scope

NOTE See Annex A.3.

The scope of this standard is limited to *Luer activated valves (LAVs)* for intravascular applications, which open and permit access to the fluid conduit when a male *Luer connector* is inserted.

This standard applies only to the *valve end* of LAVs.

This standard applies to LAVs as stand-alone devices or as components of a medical device.

This standard does not address *valves* that are opened by a female *Luer connector*.

This standard does not address the connection features of the *non-valve end* of LAVs and/or other integrated features (e.g., stopcock handles) (Figure 1).

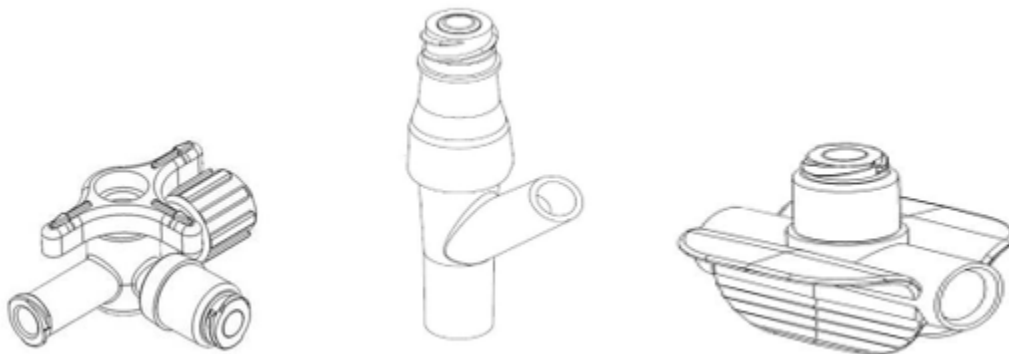


Figure 1—Examples of LAVs and their non-valve ends

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8536-4:2019, *Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed*

ISO 8536-8:2015, *Infusion equipment for medical use—Part 8: Infusion sets for single use with pressure infusion apparatus*

ANSI/AAMI/ISO 10993-1:2018, *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*

ANSI/AAMI/ISO 10993-4:2017, *Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood*

ANSI/AAMI/ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors for intravascular or hypodermic applications*

ANSI/AAMI/ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE For convenience, the sources of all defined terms used in this document are given in Annex F.

3.1

activation

act of opening an *internal pathway* on the normally closed end of a *LAV* by establishing a *connection*

3.2

activation force

peak axial force required to activate the *LAV*

3.3

application

specific healthcare field in which a *LAV* is intended to be used

3.4

assembly

combination of parts, components and units that form a functional entity

3.5

backflow

drawback

reflux

flow from the fluid pathway towards the *valve end*

3.6

back pressure

unactivated pressure

internal pressure that the *LAV* can withstand when in its normally closed state

3.7

cap

cover that is capable of being secured over the *connector*

3.8

caregiver

individual who provides care to the *patient*

3.9

check valve

accessory to an IV administration set that allows for unidirectional fluid flow

3.10

connection

union or joining of mating halves of a *connector*

3.11

connector

mechanical device consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

3.12

disconnection

separation of mating halves of a *connector*

3.13

displacement

volume of the fluid moved when a male *Luer* is disconnected from the valve end of the *LAV*

Note to entry 1: positive *displacement*

fluid expelled from the *LAV non-valve* end when a male *Luer* is disconnected from the valve end of the *LAV*

Note to entry 2: negative *displacement*

fluid drawn into the *LAV non-valve* end when a male *Luer* is disconnected from the valve end of the *LAV*

3.14

elastomeric

pertaining to an elastomer or having properties like those of an elastomer

3.15

flushing

the act of moving fluids, medications, blood, and blood products out of the vascular access device into the bloodstream; used to assess and maintain patency and prevent precipitation due to solution/medication incompatibility

3.16

haemolysis

liberation of hemoglobin from erythrocytes, either by destruction or through a partially damaged but intact cell membrane

3.17

intended life

period of usage of the *LAV*

3.18

intended use

use for which a product, process or service is intended according to the claims, specifications, instructions, and information provided by the manufacturer

3.19

internal pathway

fluid pathway in the *LAV* through which fluid flows