American National Standard

ANSI/AAMI ID54:1996

Enteral feeding set adapters and connectors

AAMI Association for the Advancement of Medical Instrumentation

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American National Standard

ANSI/AAMI ID54—1996

Enteral feeding set connectors and adapters

Developed by:
Association for the Advancement of Medical Instrumentation
Approved 15 July 1996 by:
American National Standards Institute, Inc.

Abstract:

This standard provides safety requirements for enteral feeding set connectors and adapters.

Committee representation

Association for the Advancement of Medical Instrumentation

Infusion Device Committee

This standard was developed by the Enteral Feeding Set Working Group of the AAMI Infusion Device Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

The **AAMI Infusion Device Committee** has the following members:

Cochairs: David Meyers
Saul Miodownik, CCE

Members: Joseph P. Bagnell, Air Shields Vickers
Susan Beauregard, CRCST, McFaul & Lyons, Inc.
George Blackburn, MD, New England Deaconess Hospital
George C. Brdlik, Psicor, Inc.
Travis Carr, Abbott Laboratories
James E. Dillard, FDA, Center for Devices and Radiological Health
Joannes H. Karis, Duke University Medical Center
Kenneth Lynn, Baxter Healthcare Corporation
David Meyers, IMED Corporation
Chuck D. Mick, MS, 3M
Saul Miodownik, CCE, Memorial Sloan Kettering Cancer Center
Terry Pipp, University of California at San Francisco
Guiliano Premus, CCE, Mount Sinai Medical Center
Pierre Rebours, Becton Dickinson and Co.
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Al J. Somerville, IVAC Corporation
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Alternates: Dale Coleman, IMED Corporation
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Robert Gatling, FDA, Center for Devices and Radiological Health
Robert E. Grant, 3M
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Roy V. Merrick, IVAC Corporation
Greg Wease, IVAC Corporation
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The Committee's **Enteral Feeding Set Working Group** has the following members:

Cochairs: Susan Curtas, MSN, RN
Frank Pokrop
Members: John Bushnell, Zimmer
Susan Curtas, MSN, RN, American Society for Parenteral and Enteral Nutrition
Morris Hanan, Clintec Nutrition Co., Baxter Healthcare Corporation
Bruce Hansel, PhD, ECRI
Rodney A. Hasler, ME, IVAC Corporation
Robert J. Lang, Sandoz Nutrition
Gerald Moss, MD, PhD, Rensselaer Polytechnic Institute
Mardi K. Mountford, Enteral Nutrition Council
Frank Pokrop, Abbott Laboratories
Ahmad Sajadi, IMED Corporation
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Les Michels, Sandoz Nutrition
Tim Ritter, CBET, ECRI
Eugene F. Schrader, Sherwood Davis & Geck
Walter Scott, PhD, FDA, Center for Devices and Radiological Health
Larry G. Tucker, Ross Laboratories - A Division of Abbott Labs

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 is the first edition of the standard, *Enteral feeding set connectors and adapters*. Work on the standard, which was developed by the AAMI Enteral Feeding Set Working Group of the AAMI Infusion Device Committee, began in 1993.

The objective of this standard is to minimize the possibility of potentially harmful connections occurring between enteral feeding sets and rigid female luer connectors or other intravenous (IV) sets or by specifying safety requirements for connectors and adapters used with such devices. Such misconnections can have serious and even fatal consequences, and while compliance with this standard is voluntary, it is hoped that all products covered by the scope of the document will meet the standard within 6 months of publication. In the interim, hospitals and other health care facilities are encouraged to discard or discontinue the use of adapters with enteral feeding sets.

This standard reflects the conscientious efforts of concerned health care professionals, device manufacturers,

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and government representatives to develop a standard for those performance levels that could be reasonably achieved at this time.

The concepts incorporated in this document should not be considered inflexible or static. This standard, like any other, must be modified as advances are made in technology and as new data become available. AAMI standards development procedures require that all standards are reviewed and, if necessary, updated at least once every 5 years.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Recommendations for improving this standard are invited. Comments and suggested revisions should be sent to: AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE–This foreword is not a part of the American National Standard, *Enteral feeding set connectors and adapters* (ANSI/AAMI ID54—1996), but it does provide important information about the development and intended use of the document.

Enteral feeding set connectors and adapters

1 Scope

This standard specifies safety requirements for enteral feeding set connectors and adapters.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to use the most recent editions of the documents indicated below.

2.1 AMERICAN NATIONAL STANDARDS INSTITUTE. *Luer taper fittings and performance*, ANSI/HIMA MD 70.1—1983. New York (NY): ANSI, 1983. (Withdrawn.)

2.2 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Conical fittings with a 6 percent (luer) taper for syringes, needles and certain other medical equipment—Part One: General requirements*, ISO 594/1, Geneva, Switzerland: ISO, 1986.

2.3 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Conical fittings with a 6 percent (luer) taper for syringes, needles and certain other medical equipment—Part Two: Lock fittings*, ISO 594/2, Geneva, Switzerland: ISO, 1991.

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 adapter: Separate device, components, integrated fixtures, or other means or mechanisms, which permit a functional connection between two incompatible devices.

NOTE–Presently, adapters that allow a functional connection between enteral feeding sets and rigid female luer

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connectors are sold, given away, or provided to users by original manufacturers or other (third) parties.

3.2 compatible: Allowing a functional connection.

3.3 connector: An integral component of the enteral feeding set that joins the set to the enteral access device.

3.4 enteral feeding: Nutrition support for patients using liquids as a substitute for solid food that involves delivery of nutrient liquids into the alimentary tract (stomach, duodenum, or jejunum) using specialized tubes—including but not limited to nasoenteral, gastrostomy, jejunostomy, or oesophagostomy tubes. Feeding is administered by an enteral pump or gravity.

NOTE–The word "enteral" specifically excludes delivery of liquids into an artery or vein.

3.5 parenteral administration: Delivery of a specialized fluid or medicine specifically and only into a vein or artery; sometimes referred to as “IV” or “intravenous” delivery.

3.6 set: A system that consists of tubing and other components through which fluids are delivered to either an enteral or parenteral access device.

4 Requirements

4.1 Elimination of adapters

Adapters that are provided with, or for use with, enteral feeding sets shall not allow the direct or functional connection of an enteral feeding set to a rigid female luer connector. Examples of connections that shall not be possible by use of an adapter include but are not limited to the following:

a) enteral feeding set to a parenteral administration set;

b) enteral feeding set to an indwelling intravenous catheter or port;

c) enteral feeding set to an epidural catheter;

d) enteral feeding set to balloon inflation ports.

4.2 Enteral feeding set connectors

Enteral feeding set connectors shall not be compatible with rigid female luer connectors that meet ANSI/HIMA MD 70.1—1983, ISO 594/1, and/or ISO 594/2.

5 Tests

Compliance with 4.1 and 4.2 can be verified by inspection.

Annex A
(Informative)

Rationale for the development and provisions of this standard

The purpose of enteral adapters is to provide a means to connect enteral feeding sets to enteral access devices (e.g., jejunostomy tubes), which are constructed with rigid luer taper connectors that meet the American National Standard (now withdrawn), *Luer taper fittings and performance* (ANSI/HIMA MD 70.1-1983); International Standard *Conical fittings with a 6 percent (luer) taper for syringes, needles and certain other medical equipment—Part One: General requirements* (ISO 594/1) and/or International Standard *Conical fittings with a 6 percent (luer) taper for syringes, needles and certain other medical equipment—Part Two: Lock fittings* (ISO 594/2).

Some enteral access devices are constructed with rigid luer taper connectors, and one unintended consequence of these adapters is that they provide a link between two unrelated systems, i.e., enteral to intravenous (IV).

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These systems are intended to have unique methods of delivery, with distinctly different purposes, which these adapters can circumvent—possibly resulting in harm or serious injury to the patient.

In 1993, the AAMI Enteral Feeding Set Working Group began developing this standard in an effort to minimize the possibility of potentially harmful connections occurring between enteral feeding sets and indwelling IV ports, catheters, peritoneal catheters, and tracheostomy tubes.

It is intended that this standard will result in changes to the design of enteral feeding sets so that, within 6 months, all new enteral feeding sets will be incompatible with rigid IV female luers.

In addition to encouraging manufacturers to eliminate the use of rigid female luer connectors on enteral feeding access devices, the working group hopes that this standard will help educate users about the potential risk to patients of using enteral adapters already in their facility.

The ultimate goal is the prevention of any reasonable likelihood of connections between enteral feeding sets and devices other than enteral access devices.

In light of the serious risk involved, it was decided not to delay this functional standard for want of exact physical and dimensional specifications. However, the committee may eventually add dimensional requirements and requests that manufacturers provide the working group, via the AAMI Standards Department, with information about physical dimensional requirements that they have developed and permission to use same in a future edition of this standard.

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