Improving Patient Safety: Preventing Tubing Misconnections - ENFit®

This guide presents findings from the recent ENFit® Feedback Survey and includes insights on the importance of preventing tubing misconnections, historical legislative efforts, benefits to supply chain standardization, Vizient contracts and additional resources.

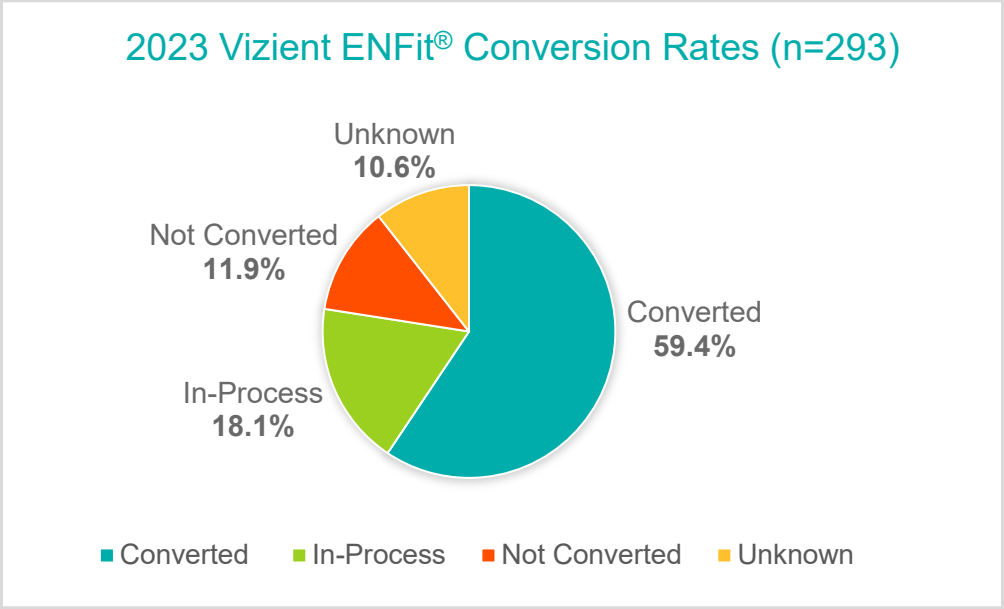
Survey synopsis

A recent survey, conducted by Clinical Solutions, Spend Management Contracting Center of Excellence between May 9 and July 31, 2023, assessed the adoption and conversion of ENFit® enteral feeding products and accessories, which were developed to prevent tubing misconnections that can lead to severe patient injury and in some cases, death. The survey was sent to Vizient providers and spans multiple classes of trade within the healthcare industry.

The survey results indicated that among Vizient members who responded (n=293), 59.4% have successfully completed the conversion from legacy enteral feeding products to ENFit® enteral feeding products, with 18.1% currently in the process of converting, 11.9% having not converted, and 10.6% reporting they were unsure if their institution had converted.

Among respondents who have not converted (n=35), 3.1% intend to convert within the next 1-5 months, 25% within 6-12 months, and 21.9% expect to convert after 12 months. Notably, of the respondents who have not converted (n=35), 50% of them have no current plans to convert.

Refer to the graph below for a summary of ENFit® conversion rates among Vizient members who responded to the 2023 survey. For ENFit® U.S. conversion rates among top hospitals, visit StayConnected.org.



According to the survey comments, 45.7% of respondents expressed challenges associated with internal practices and procedures, while 27.2% indicated issues pertaining to supply and supply availability. An additional 13% reported encountering challenges associated with a lack of regulatory mandates and reimbursement. 8.3% of those who have converted indicated no challenges or issues during the ENFit® conversion process.

Barriers And Challenges Associated With ENFit® Conversion			
45.7% Internal practices and procedures	**27.2%** Supply and supply availability	**13%** Regulatory and reimbursement	**8.3%** None

When asked to provide additional feedback on barriers and challenges to conversion, survey respondents identified key contributing factors, which included:

- Leadership and provider buy-in
- Human and capital resources
- System-wide integration
- Product availability, quality, and incompatibility
- Availability of/access to legacy enteral feeding products
- Outpatient reimbursement
- Lack of regulatory mandate

In summary, this survey shed light on the progress of Vizient membership conversion to ENFit® products and accessories. We encourage all stakeholders to explore solutions and resources available through StayConnected.org to facilitate and assist in their transition process.

Background information on ENFit® connectors for enteral feeding applications

In May 2021, ISMP published a Safety Alert! informing health care providers of a tubing misconnection caused while using legacy enteral feeding/management devices. The incident involved an 8-year-old patient who was inadvertently given three liquid medications through a cecostomy instead of a gastrostomy tube. According to The Joint Commissions Sentinel Event Alert 53, this preventable error continues to cause severe patient injury and death since tubes with different functions can easily be connected using luer connectors and can be ‘rigged” (constructed) using adapters, tubing or catheters (The Joint Commission, 2021).

Misconnections, defined as an inappropriate connection between two different device entities (U.S. Department of Health and Human Services, 2012), continue to occur in the health care setting despite publicity, safety warnings addressing potential and actual risks, and published recommendations for prevention.

According to research, more than 100 reports of Luer misconnections have been reported since 1972. However, this is believed to be a seriously underestimated number. Examples of adverse events that highlight the seriousness of the misconnection issue include:

- Connection of a feeding tube to a tracheostomy tube, delivering milk into an infant’s lung, resulting in death
- An epidural infusion set connected to a peripheral I.V., delivering epidural medication to bloodstream, resulting in patient death

- I.V. tubing misconnected to a nasal cannula used to deliver oxygen — the patient survived after being treated for congestive heart failure
- A feeding tube connected to an in-line ventilator suction catheter, delivering feeding contents into the patient's lungs, resulting in death
- A patient's heparin lock (peripheral I.V. route) connected to an automatic blood pressure cuff by a family member, delivering air to the bloodstream, causing death
- A feeding tube was coupled with a peripheral line of a pregnant woman, resulting in enteral nutrition delivered directly into the bloodstream; neither the 35-week-old fetus nor the woman survived

Legislative efforts

In January 2011, AAMI adopted the standard ANSI/AAMI/ISO 80369-1:2010, which provides general requirements for small bore connectors for liquids and gases, with additional standards being developed for application-specific designs as follows:

- **80369-2** — Small bore connectors for liquids and gases in health care — connectors for breathing systems and driving gases
- **80369-3** — Small bore connectors for liquids and gases in health care — connectors for enteral applications
- **80369-4** — Small bore connectors for liquids and gases in health care — connectors for urethral applications
- **80369-5** — Small bore connectors for liquids and gases in health care — connectors for limb cuff inflation applications
- **80369-6** — Small bore connectors for liquids and gases in health care — connectors for neuraxial applications
- **80369-7**— Small bore connectors for liquids and gases in health care — connectors with 6% (Luer) taper for intravascular or hypodermic applications

Since the development and adoption of the general requirements of the prevention standard, several healthcare facilities have converted and are currently using the new enteral feeding connectors, known as ENFit®.

Supply chain benefits of ISO standardization

GEDSA's Supply Chain Benefits of ISO Standardization to the ENFit® Enteral Feeding Connector news release highlights key information to the development of this standardization. Prior to the introduction of ENFit®, the absence of globally standardized connectors led to a proliferation of proprietary systems, resulting in compatibility issues and risks to patient safety. It underscores the internal logistical advantages of standardization, including cost reduction, increased efficiency and improved clinical practice. Additionally, the article discusses how standardization extends its benefits to the supply chain, particularly in addressing ongoing challenges exacerbated by factors like the COVID-19 pandemic and the increased demand for travel nursing.

Vizient ENFit® connector compatible contracted resources

Vizient provides access to these products from the following supplier(s):

Product Category	Supplier	Contract #	Expiration Date
Enteral syringes	Cardinal Health (formerly Covidien)	MS6212	12/31/2024
	Kentec Medical	MS6213	12/31/2024
	Medela	MS6214	12/31/2024
	Avanos (formerly NeoMed)	MS6215	12/31/2024
	Vesco Medical	MS6216	12/31/2024
	Vygon USA	MS6217	12/31/2024
Nasogastric feeding tubes and accessories (neonatal/pediatric)	Cardinal Health	MS6231	12/31/2024
	Avanos (formerly Halyard and NeoMed respectively)	MS6232, MS6235	12/31/2024
	Kentec Medical	MS6233	12/31/2024
	Medela	MS6234	12/31/2024
	Vygon USA	MS6236	12/31/2024
	NeoChild	MS6237	12/31/2024
Nasogastric feeding tubes and accessories (adult)	Cardinal Health	MS6221	12/31/2024
	Avanos Medical Sales (formerly Halyard)	MS6222	12/31/2024
Gastrointestinal (GI) tubes	Bard Medical (Awarded by MedAssets)	MS0632	12/31/2024
	Cardinal Health (formerly Covidien)	MS0630	12/31/2024
Percutaneous endoscopic gastrostomy tubes (PEG)	Avanos	MS9040	12/31/2024

Additional resources

- GEDSA Stay Connected
- ENFit® Legacy Feeding Tubes and Transition connector conversion schedule
- Vizient Webinar Recording for Implementation Best Practices
- AAMI: Ambitious Standards Initiative on Small-bore Connectors Moves Forward
- American Society for Parenteral and Enteral Nutrition: Enteral Nutrition Connectors and Misconnections
- Centers for Medicare & Medicaid Service: Luer Misconnection Adverse Events
- FDA: Safety Considerations to Mitigate the Risks of Misconnection with Small-Bore Connectors Intended for
- Enteral Applications- Guidance for Industry and Food and Drug Administration Staff

- Institute for Safe Medication Practices: “Will Color Tinted I.V. Tubing Help?”
- ISMP Medication Safety Alert, June 17, 2004: “Problems Persist with Life-Threatening Tubing Misconnections”
- International Organization for Standardization (ISO): Small-bore connectors for liquids and gases in healthcare organizations- General Requirements
- The Joint Commission

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See all resources.

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