Reducing the Risk of Medical Device Tubing Misconnections
Created by GEDSA for informational purposes only.

Contributors and reviewers include:
- The Joint Commission
- Association for the Advancement of Medical Instrumentation (AAMI)
- American Society of Parenteral and Enteral Nutrition (A.S.P.E.N.)
- Institute for Safe Medication Practices (ISMP)
- The Oley Foundation
- Premier Safety Institute
- Novation
The Problem with Universal Luer Design

- Medicine
- Oxygen
- Fluids
Circumstances Where Misconnections Can Occur

Physically Compatible Connectors
Circumstances Where Misconnections Can Occur

- Low Lighting
- Multiple Devices
- Multiple Lines
- Time Pressure
- Physically Compatible Connectors
- Disconnections
- Lack of Tactile Feedback
- Unintended Use of Tubes
- Moving Patient Setting

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Ineffective Attempts Demanded a Comprehensive Solution

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Ineffective Attempts Demanded a Comprehensive Solution

Reducing risk requires a complete design change
A Global Effort to Enhance Patient Safety

Technical Experts

ISO 80369
Small-bore connectors

Clinical Experts

Regulatory/Standards Experts
Design standards for system-specific applications start with enteral

ENFit 80369-3
The new design standard impacts the entire enteral system
NUTRITION END
changed in 2012
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changed in 2012
SYRINGES
From oral, catheter, or Luer tip to enteral-specific fitment:
• Administer Medicine
• Flush
• Hydrate
• Bolus Feed
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ADMINISTRATION SET
From Male Stepped Connector to Female ENFit:
- Pump Set
- Gravity Set
- Other Bolus Feed or Venting Devices

FEEDING TUBE
From Female Flexible Port to Male ENFit:
- NG Tubes
- G Tubes
- Low-Profile Extension Sets
- J-Tubes

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TRANSITION SET
ENFit Transition Connector
• Temporary fitment
• From new ENFit connector to current feeding port
A Gradual Transition Designed to Prevent Disruption

Key dates for US, Canada, Puerto Rico

2014 Q4
Administration sets with transition pieces

2015 Q1
Enteral-specific syringes

2015 Q2
Feeding tube

Pending FDA 510(k) clearance
A Gradual Transition Designed to Prevent Disruption

Key dates for Europe, Middle East, Africa, Australia and New Zealand

2015 Q3
Administration sets with transition pieces

2015 Q4
Enteral-specific syringes

2016 Q1
Feeding tube

Pending regulatory authority clearance
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References


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