Reducing the Risk of Medical Device Tubing Misconnections
Tubing Misconnections Adverse Events

• **IV tubing misconnected to a nasal cannula** used to deliver oxygen — the patient survived after being treated for congestive heart failure

• **Feeding tube to a tracheostomy tube**, delivering milk into an infant’s lung, resulting in death

• **Epidural infusion set connected to a peripheral IV**, delivering epidural medication to bloodstream, resulting in patient death

• **Feeding tube connected to an in-line ventilator suction catheter**, delivering feeding contents into the patient’s lungs, resulting in death

• **Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff**, delivering air to the bloodstream, causing death

• **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
ENFit: Transitioning Challenges

1. **No Mandate:** Except for California, healthcare facilities and home care providers either aren’t aware of ENFit or don’t feel compelled to change.
2. **Lack of Priority:** Enteral devices are low on the medical profession totem pole.
3. **Manufacturers:** Confusion with product numbers and availability. Many reps are not educated.
4. **Financial:** Unknown impact on/probable increase in consumable budgets.
   - No credit for unused inventory.
5. **Compatibility:** Will pumps operate with new syringes?
6. **Complexity:**
   - One health system has identified >180 products from 27 manufacturers used within its facilities.
   - Varying needs of multiple clinical environments.
   - Patients with products from other facilities.
   - Coordinating and providing clinician training.
   - Determining product availability (Where to start???)

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Meeting Objectives

• Review why we are here

• Discuss some of the challenges with the ENFit introduction

• Identify common solutions to drive adoption
ENFit Testing & Validation

Mike Maryan
Cook Medical
ISO Design standards developed for system-specific applications

**80369 Series**
-1 General requirements

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<th>Urological</th>
<th>Limb Cuff</th>
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**Requirements:**
- Not connectable with others in series
- Rigid or semi-rigid
- Passes Misconnection, Risk Analysis, Usability/Human Factors Testing
- Not connectable with Luer or needleless connector ports
ISO 80369-1 General Requirements

- Published in Dec 2010; Recognized in the Federal Register (List 26) in March 2011.
- Intended as a reference document:
  - Provides the methodology, measures and procedures to prevent/reduce misconnection for new designs of small bore connectors.
  - Does not provide new designs
  - Does not specify requirements of devices intended to use new connectors w/in the ISO 80369 series.

- Materials – rigid/semi-rigid for all connectors within a connection.

- Non-interconnectable with each other and with those already standardized.
  - Determined by mechanical force function testing (annex B)

- Clause 7 – design acceptability w/in application – Human Factors and Usability

- Color/labeling not considered acceptable to reduce misconnection
**Connector dimension allocation diagram**

Exclusions: PG3: Cross assembled 2011-04-27 (M), Cross bag port 2011-04-27(F), Engage Cap S12-r00 (F), Engage Spike S16-r01(M), JMS 2011-04-01 (F), JMS 2011-04-01 (M)

PG6: Intervene Surety SpinalLok needle tip-V1 (M), Neuraxial lok4-r04(M), Vygon Neuraxial 2010-05-24 (M)

PG7: Luer Lock-r2 (F), Luer Lock-r2 (M), Needless-r2 (F)

as of June 11, 2011
CONNECTION SCREENING WORKSHEET

Overlapping MAX/MIN ID and OD:

Possible Misconnection (RED)

Within RESIDUAL INTERFERANCE
or RESIDUAL GAP

Questionable (YELLOW)
Or
UNDEFINED

No overlap or intended to connect

Non-connectable (GREEN)
Or
Designed to Connect
Sample Misconnection Assessment Chart
New Small Bore Connector Dimensions Proposal

When organized other bands would be available for other therapeutic areas.

Female ID

Male OD

Current Luer would occupy this band.
Significant Testing Conducted to Verify & Validate Enteral Standard Design

Testing & Assessments

• Clinical Assessment - 20 Physicians, Nurses & Pharmacists

• Usability/Human Factors - 53 Clinicians (including 15 NICU)

• Misconnections Assessment

• Syringe Accuracy Report

• User Survey – 35 respondents in 3 European markets

• Acceptability and Suitability Study - 48 Clinicians in 6 European Markets
Plus 10 Years of Empirical In-Market Evidence

United Kingdom:

- Mandated by NHS for over 10 years for all enteral products to use “REVERSE LUER SYSTEM”
- Solved misconnections between IV & Enteral but not other potential misconnections
- During ISO process, UK Mirror Group urged “Reverse Orientation” for enteral solution based on real life experience & success
- Used with millions of patients without a reported misconnection or dose accuracy concern.
- Recent Dose Accuracy Concerns caused NHS to expedite transition to ENFit as soon as Low Dose Tip Syringes became available
ENFit Low Dose Tip RE - Verified & Validated

Testing & Assessments

• Performance Testing
  • Compared to common existing enteral/oral syringes
  • Compared to other reverse orientation syringes

• Usability Testing – 140 respondents in 8 countries
  • Physicians
  • Nurses
  • Pharmacists
  • Caregivers

• Misconnection Risk Assessments
  • Did the male inner lumen cause any high risk misconnections?
What About Color?

• Manufacturers have introduced color to try to trigger clinicians to prevent misconnections.
• However, color does not prevent the misconnection.
• Colors are not standardized across device types.
• May have a green connector for an EN device, an IV device, and a respiratory device so this defeats the purpose of color.
• Color is not required in the new connector standard.

MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity
## Supporting Organizations

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<th>ASHP</th>
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<td>HealthTrust</td>
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<td>Vizient</td>
<td>Medication Safety Collaborative</td>
<td>National Patient Safety Foundation</td>
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Global Introduction of ENFit – NOW!

North America
Global Introduction of ENFit – 2016/17
Europe, Middle East, Africa, Australia & New Zealand
Global Introduction of ENFit – 2017/18
South America, Asia
California Legislation

• California Senate Bill No.158: “Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for...”.

• Assembly Bill 444 delayed the effective date to for hospitals and suppliers to July 1, 2016

• GEDSA, AdvaMed, CHPSO, CHA have been in communication with the state to provide updates on manufacturers progress

• No indications from CA Department of Health as to how and when they will enforce

• Be prepared!

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