# Changing standards for medical device manufacturers

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# Changing standards for medical device manufacturers

- Standards under development
- New guidance published by the FDA around luers, Y-sites, and small-bore connectors *recommends*:
  - Devices conform to new standard
  - Enteral connectors be tested to ensure incompatibility with nonenteral devices
  - Proprietary connectors, or transition connectors, be designed and tested using new standards

# ISO 80369

- Small bore–inner-fluid pathway of a connection with a diameter less than 8.5 mm
- Connection–union or joining of mating halves of a connector
- Connector–mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

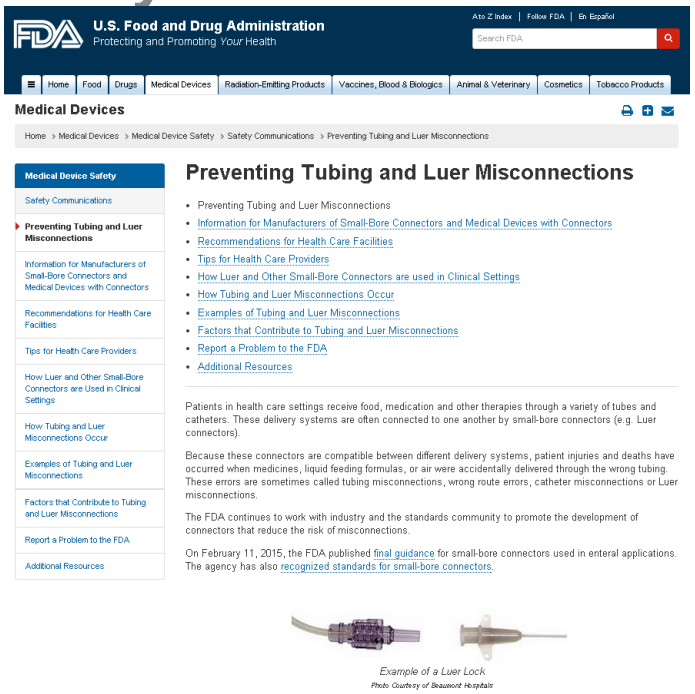
# Case studies from the FDA

- Feeding tube connected to trachea tube
- Epidural tubing connected to IV tubing
- Oxygen tubing connected to needleless IV port
- IV tubing connected to enteral feeding tube
- Foley catheter connected to NG tube
- Enteral feeding tube connected to ventilator in-line suction catheter

http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM134873.pdf

# Product safety concerns

## Flexible connector safety concerns




Lead to

### International problem solving

- International working group of product designers and clinicians
- Working on the problem since 2010

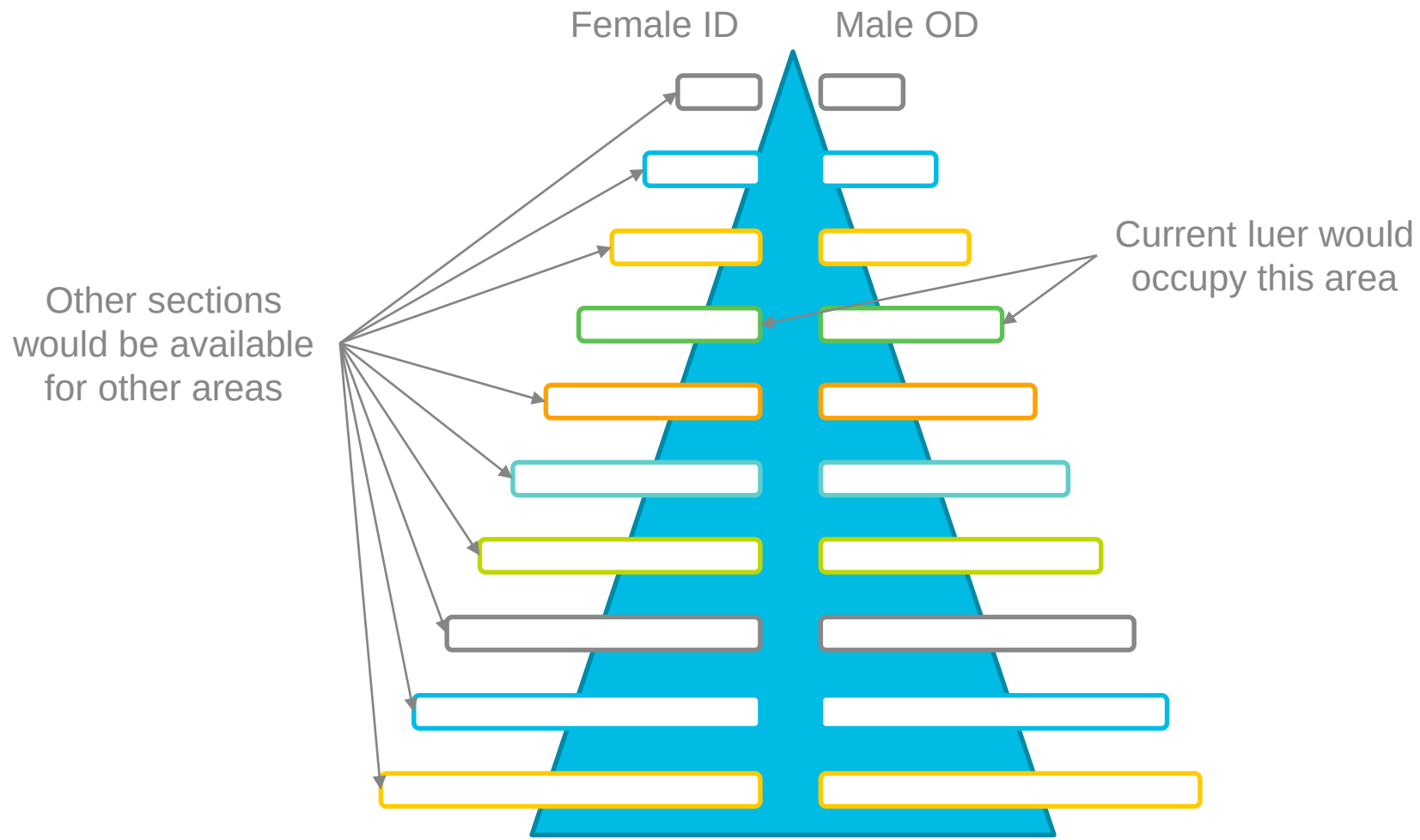
### Move to create and adopt new international standards

- ISO 80369
- First published in 2013
- Areas to be included
  - Enteral feeding and gastric
  - IV or hypodermic
  - Breathing systems, driving gases
  - Urethral and urinary
  - Limb cuff inflation
  - Neuraxial devices

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

**What if your current connectors do not meet new standards?**

# How ISO standards would prevent misconnections



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# Stay connected

- Top GPOs and The Joint Commission are on board for standardization.

The Joint Commission

Novation

PREMIER

GEDSA

# Device manufacturers face many challenges.

- Brand image
- Cost control
- Product and patient safety
- Regulation
- Speed to market
- Product quality
- Preserving market share

# Changes in product standards

*How does this impact your business?*

New product development projects require time and $$

If no new product

Changes in product quality perceptions

Results in

Hospital penalties for poor outcomes

- Health care systems hypersensitive

Lost market share

- End users use competitor’s new product.
- Brand equity damage
- Lost sales

# Your challenge… staying ahead of standard shifts

## Today…

- Lose share
- Lose margins
- Compete on price
- Several design rounds before successful part manufactured

## Wouldn't you rather commit company resources to…

- Developing
- Marketing
- Selling your higher quality products

# What if you could ...

- Comply with anticipated shifts in standards
- Make changes quickly to materials that meet new standards
- Eliminate rework in part and mold design
- Improve end users perceptions of your product quality and safety

# **Value to you**—*with one material change!*

**Eastman Tritan™ copolyester for small-bore connectors**

- Rigid material meeting ISO 80369 standards
- Excellent solvent bonding to PVC or TPU tubing
- Chemical resistance, toughness, clarity
- Color stability after E-beam or gamma sterilization
- Technical design and molding services


**Increased product quality**

One material choice helps you hit these targets!

# **Value to you**—*with one material change!*

## Resulting benefits to you...

- Improved patient safety
- Enhanced and protected brand image
- Improved part development and molding efficiency

# What's keeping you from adopting Eastman Tritan™ copolyester for your small-bore connector applications?

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## Check out the new ISO Standards today

http://www.iso.org/iso/catalogue_detail.htm?csnumber=45976

## See how a group purchasing organization is educating the industry on this new standard

https://www.premierinc.com/events/advisor-live-new-standards-medical-tubing-connectors-ready/

# Thank You