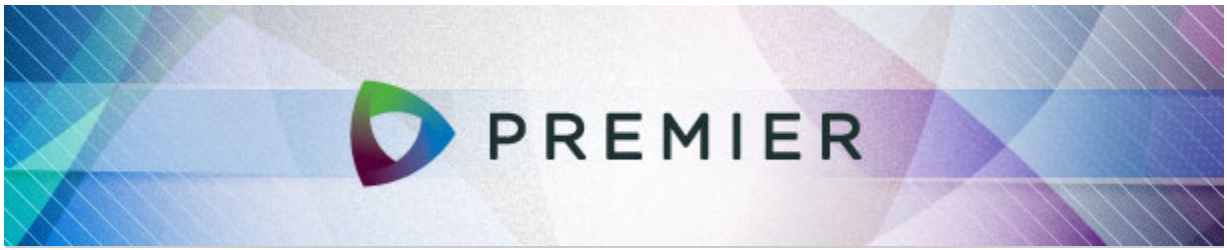

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SafetyShare®

New standards to prevent tubing misconnections will have unprecedented impact on supply chain and patient safety

What if you could no longer connect any of the equipment that you have in stock to give enteral feedings (e.g., feeding sets, tubes, oral syringes). That is the likely scenario - once new standards to prevent tubing misconnections are released - without a carefully crafted implementation plan across all settings where care is delivered.

The very simple and universal design of most *connectors* in all of health care creates a serious risk that tubes from totally unrelated systems can be inadvertently connected leading to patient death or serious injury. This means that an enteral feeding tube could be accidentally connected to an IV line, delivering formula into a vein with fatal consequences. An international group of stakeholders are working together to solve this problem by developing unique design standards for every delivery system so that unrelated systems can never be mistakenly connected together.

What do these new standards mean for healthcare

New and unique international standards are being developed for connectors for each gas and liquid delivery system in healthcare to make it virtually impossible to connect unrelated systems[1]. These new connector standards will include new designs for connectors of enteral, respiratory, limb cuff inflation, neuraxial, and intravascular systems. It is anticipated that the standards for enteral connectors will be the first to be released in 2014. There will be a phase-in period for product development, market release and implementation guided by the FDA, existing state legislation, suppliers, and national

organizations working together.

Preventing unintended consequences requires planning

Manufacturers and suppliers will be preparing to change the designs of the connectors of each delivery system to meet the new standards, timeline requirements, and to work with customers to synchronize the transition of the existing product to the new products.

Imagine... a patient is admitted to your facility with a long-standing feeding tube that is now incompatible with the new connectors/tubing in your inventory?

How to prevent this: Be aware of new standards; prepare for changes; adopt new products; and measure compliance

All healthcare providers that supply products in any capacity or are involved in planning or delivering care will be impacted by these changes with special efforts needed to manage inventory. To reduce the risk of unintended consequences, healthcare organizations and providers should identify a leader to stay informed, assist with development of a multidisciplinary plan for implementation, and keep staff fully aware of these impending changes on an ongoing basis. This includes all patient care providers and staff from supply chain, patient safety, quality, infusion therapy, risk management, pharmacy, dietary, administration, health technology management, and support staff across all settings where care is provided.

Panel discusses new standards and releases FAQs to help prepare

In October, the Premier Safety Institute® participated in a panel discussion with other healthcare leaders from AAMI, FDA, CMS, Joint Commission, ASPEN, Novation, GEDSA, BD[2] at the Healthcare Supply Chain EXPO to discuss the new standards and a coordinated approach for implementation and transition to products meeting the standard. A new resource - *Stay Connected - Frequently Asked Questions*, was released by the panel to help the healthcare community prepare for the upcoming changes to standards. Download the FAQs and listen to the panel discussion.

Stay Connected - FAQs
Frequently Asked Questions

- **What is the time line?**
- **Are these standards mandatory?**
- **What about existing inventory?**
- **What are the California state requirements?**
- **How will transition be handled?**

More

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1. An international group of clinicians, manufacturers and regulators, including the FDA, is collaborating with the International Standards Organization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop international ISO Standards for delivery-specific connectors.

2. AAMI (Association for the Advancement of Medical Instrumentation), FDA (Food and Drug Administration), CMS (Centers for Medicare and Medicaid Services), ASPEN (American Society for Parenteral and Enteral Nutrition), GEDSA (Global Enteral Device Supplier Association), BD (Becton Dickinson)

Additional resources on tubing misconnections

- **FDA website - Tubing Misconnections**
- **Premier Safety Institute website**
- **AAMI website**
- **GEDSA**
- **ASPEN**

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