DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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To: Manufacturers of Enteral Feeding Tubes

Healthcare Professionals

Hospital Purchasing Departments

Dear Respected Colleague,

FDA is aware that standard luer lock connectors are found on a variety of tubing sets, solution bags and other medical products. The ease of connection between these luer lock connectors have led to misconnections that have inadvertently linked unrelated systems, and at times, have resulted in serious adverse events. Luer lock misconnections are often under-recognized; therefore, adverse events resulting from such misconnections are likely to be under-reported.

These misconnections can be dangerous and result in injuries. Luer connectors easily interconnect many medical components, accessories, and delivery systems across multiple medical applications. Because of the nature of the connector design, human factors, and the clinical environment, healthcare professionals may mistakenly connect the wrong devices and deliver substances through the wrong route.

Examples of misconnections include:

- Intravenous infusions connected to epidural lines, and epidural solutions (intended for epidural administration) connected to peripheral or central IV catheters.
- Bladder irrigation solutions using primary intravenous tubing connected as secondary infusions to peripheral or central IV catheters.
- Infusions intended for IV administration connected to an indwelling bladder (foley) catheter.
- Infusions intended for IV administration connected to nasogastric (NG) tubes.
- Intravenous solutions administered with blood administration sets, and blood products transfused with primary intravenous tubing.
- Primary intravenous solutions administered through various other functionally dissimilar catheters, such as external dialysis catheters, a ventriculostomy drain, an amnio-infusion catheter, and the distal port of a pulmonary artery catheter.[1]

[1] The Joint Commission, *Sentinel Event Alert*, Issue 36 - April 3, 2006, "Tubing misconnections—a persistent and potentially deadly occurrence"

In particular, misconnections with enteral feeding tubes and solutions have been associated with death and serious injury. Although these adverse events appear to occur at a low frequency, it is suspected that many misconnections are recorded as medication errors. When an enteral feeding tube misconnection occurs, the results can be very serious and, at times, fatal.

The Joint Commission has urged product manufacturers to implement appropriate "designed incompatibility" to prevent dangerous misconnections of tubes and catheters.[1] As stated in The Joint Commission and USP Medication Safety Forum, the solutions are multifactorial and can be grouped into three broad and not mutually exclusive areas: education, awareness and human factors; purchasing strategies; and design changes.[2]

1. What can manufacturers do?

   To reduce the likelihood of errors, some manufacturers have implemented design changes. For example, some have chosen to color code and label their enteral feeding tubes to flag which tubes must be connected with one another. Others have opted to create proprietary connections, following the principle of designed incompatibility, to ensure that devices that should not be connected cannot, in fact, be connected.

   FDA believes manufacturers should provide the necessary safeguards to ensure safe use of these devices and products. We encourage all manufacturers to assess the risks of misconnections for these devices, carefully consider both temporary and long-term options to mitigate the risk and validate the solution(s) they deem most appropriate. FDA will assess the validation of the proposed solution during the course of the premarket review, as appropriate.

2. What can healthcare professionals do?

   Healthcare professionals can institute practices such as, but not limited to:

   - Not modifying or adapting devices since that may defeat the safety system;
   - Tracing lines back to its origins when reconnecting devices;
   - Routing tubes and catheters that have different purposes in unique and standardized directions.

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[2] The Joint Commission and USP Medication Safety Forum
The Joint Commission Journal on Quality and Patient Safety, Volume 34, Number 5. May 2008 "Enteral Feeding Misconnections: A Consortium Position Statement," Guenter et al.

3. What can hospital purchasing departments do?

   Hospital purchasing departments should consider the safety of various systems and connections when purchasing new inventory.

The current Association for the Advancement of Medical Instrumentation/American National Standards Institute, Inc. (AAMI/ANSI) standard, ID54:1996/(R)2005 entitled "*Enteral feeding set adapters and connectors*" recommends that adapters provided with, or are for use with enteral feeding sets be designed so that they are incompatible with rigid luer connectors. However this standard does not set out any specifications for these adapters.

FDA wants to inform you that a new broad ranging standard is currently under development: ISO/IEC/FDIS 80369-1, "*Small-bore connectors for liquids and gases in healthcare applications.*" This standard, and the series of standards that will accompany it, are intended to address connector cross compatibility issues between products used for a variety of medical applications (e.g., enteral, parenteral, IV, epidural, etc.), and will likely identify specific designs for each application to eliminate the possibility of misconnections. FDA is actively participating in the development of the standard and believes this standard will help prevent device misconnections through, for example, the use of force function design and usability testing. FDA is considering recognizing this standard when it is published. If FDA recognizes the standard, due to the significant impact this standard may likely have on the safety of these devices, FDA will provide guidance to manufacturers regarding issues such as whether there will be a set period of time for currently marketed devices to come into compliance and the effect of the standard on new devices.

FDA appreciates your attention to this matter. If you have any questions, please contact Carolyn Neuland, Ph.D. at Carolyn.neuland@fda.hhs.gov or at (301) 796-6523.

Sincerely,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation