

Devices with Inflation Ports – Risk for Medication Error-induced Injuries

ISMP Canada has received correspondence from a Canadian hospital recommending safety improvements to medical devices with a “balloon inflation valve/port” also known as a “BLA”. The balloon inflation valve is used to inflate the cuff portion of a catheter (or tube) and the inflated cuff helps to ensure correct catheter placement during medical treatment of the patient. Such devices include tracheostomy tubes, endotracheal tubes, gastrostomy tubes and Foley catheters.

The recommendation stems from a critical adverse medical event where medications were inadvertently delivered into the balloon inflation valve portion of a catheter instead of directly into the catheter itself. A case report describing a similar error has been previously published.¹ In the published case, intravenous medications were infused into a balloon inflation valve of a tracheostomy tube. The balloon valve was mistaken for a central line IV port. As a result of hyperinflation of the cuff, the patient’s airway was obstructed causing respiratory arrest. An alert was provided to US hospitals in 2001, by ISMP US.²

As we consulted healthcare professionals in our research on this issue, we received descriptions of two additional incidents where ports connected to the cuff (or balloon) had been accessed in error to administer medications. In each of the cases the balloon expanded and caused harm to patients. This bulletin intends to raise awareness regarding the risk for error-induced injuries with balloon inflation valves. This bulletin will also be shared internationally in the hope of compelling manufacturers to make changes and that government authorities will

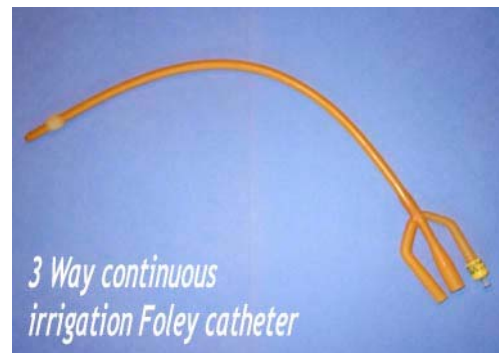
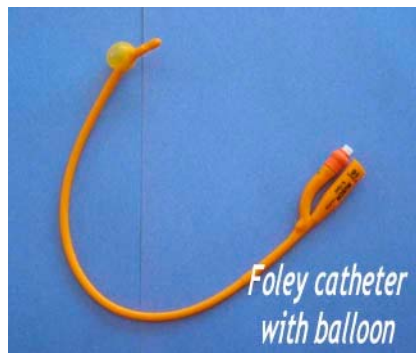
mandate improvements to products with balloon inflation valves.

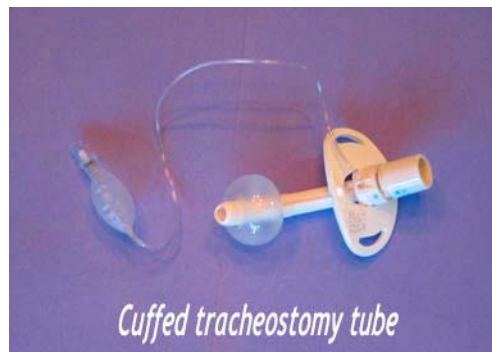
Balloon inflation valves are designed to meet ISO standards for accommodating connection with parenteral syringes used to inflate the cuff with saline or air. These same ISO standards are used by manufacturers of IV tubing and IV ports to accommodate connection with parenteral syringes. Human factors engineering specialists warn us that the use of identical designs carries inherent risks for error-induced injuries. Because of the ‘technology interconnectivity’ the design invites human error and therefore warrants consideration of safeguards.

Photographs of several tube/catheter device products are included here to illustrate that use of the inflation port is not intuitive, that manufacturers do not label the port, and in the minority of cases where they are labelled, the information is not prominent.

By marking pertinent information directly on a product, either with bold print on the port extension, or by utilizing a non-removable label, the manufacturer could provide the user with a prompt, rather than requiring the user to rely entirely on memory or experience. Point of care information can be especially valuable for the novice healthcare professional, and for emergency situations where quick action is needed.

Improved labelling is not the complete remedy. The risk for error still exists if one can easily connect a syringe or IV tubing to an inflation port. Ideally, inflation and





infusion should be absolutely incompatible. The interconnectivity should be removed through product redesign. In addition there may also be technological strategies which could prevent hyperinflation of the balloon (cuff). Redesigns would need to be researched by human factors engineering experts.

ISMP Canada makes the following recommendations for immediate action:

- **To manufacturers:** Print 'balloon valve' clearly and prominently directly on the valve extension or adhere a clear and visible (e.g., fluorescent) non-removable label to the port. Identifying information is critical and can be displayed

prominently with minimal cost and potentially substantial benefit to patient safety.

- **To hospitals:** Distribute this bulletin to healthcare practitioners. Communicate the risks of balloon inflation valves and recommended improvements to manufacturers of such products.
- **To Health Canada:** Consider requiring Canadian manufacturers and distributors to label inflation ports clearly and prominently directly on the port extension.

References:

1. Pope M. A mix-up of tubes. Am J Nursing. 2002;102(4):23.
2. ISMP Medication Safety Alert! IV connection to tracheostomy cuff inflation port reflects larger problem. November 28, 2001. Available at <http://www.ismp.org/msaarticles/connection.html>; accessed 01 June 2004.

FMEA Workshops

ISMP Canada has recently developed a unique failure mode and effects analysis (FMEA) model which is being introduced in a one-day workshop in Winnipeg. This is the first of a series of patient safety workshops requested and supported by Manitoba Health for healthcare practitioners in the province. Over 60 practitioners are to participate. Plans are underway for FMEA workshops in Ontario and on Vancouver Island in the next few months.

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org or (ii) email us at info@ismp-canada.org or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.

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