Texas Children's Hospital®

CareFusion Product Issues Meeting
Closed Medication Administration Set - #MZ8003
Pressure Disk Administration Set- #10011496

Monday, August 15, 2016; 3:30 PM

Attendees: Rick McFee, Hope Jackson, Dr. Eric Williams, Dr. Joan Shook Gail Parazynski, Miranda Rodrigues,; Karla Abela, Shannon Holland, Tarra Kerr, Robbie Norville,; Alex Luton, Heather Cherry, Sharon Jacobson,; Erin Davies, Angela Morgan Dr. Paul Checchia, Jennifer Sanders,; Brandi McGowan, Amanda Wollam, Anthony Bentley, Lindsy Broome, Lisa Davenport; Robert Kriener, CareFusion; and Gaylene Grossma, CareFusion's Quality Dept.

Meeting Purpose: Discuss product issues related to numerous reported leaks and other product failures of the Carefusion Closed IV Medication Administration Set and the Pressure Sensing Disk IV Administration Set and develop a corrective Action Plan.

Background: Over the past two months there have been an increasing number of product complaints related to these two IV Administration Sets.

Issues have included at least one of the following problem being reported:

• **Leaks at the filter**	• **Male Luer port broke off in the MaxZero injection site**
• **Leaks / cracks at the female luer connector**	• **Leaks at the MaxZero site**
• **Leaks at the white one-way valve**	• **Closed Tubing Set would not Flush**

ACTION PLAN / NEXT STEPS

Action Items	Notes	Next Steps	Responsible Party
Since 7/1/2016 there have been 22 documented issues with these two sets. Additional defective product needs to be delivered to CareFusion	Product Code - #1001146 – Pressure Disk Set Product Cost – MZ8003 – Closed Admin Set Additional product samples provided to CareFusion at end of meeting	Deliver additional defective product samples to CareFusion Quality Department for investigation and evaluation	Robert Kriener, CareFusion
Obtain Investigative Reports on All defective product collect prior to 8/6 has been forward to CareFusion QC for evaluation	TCH has not received a evaluative Report on the samples	Follow-up with CareFusion Quality Department on Status of their investigation on each of the product samples returned for evaluation – **Follow-up Call established for 12 Noon Tuesday 8/16**	Rick McFee / Supply Chain

Action Items	Notes	Next Steps	Responsible Party
Investigate available replacement products	Investigate available replacement products in the CareFusion supply chain with focus on new lot #, same item number; and possible substitute products of the same configuration but different product codes	Report on Available Stock and alternative products available	Robert Kriener, CareFusion
Identify Lot #s of the Products in Use at TCH	Need to assess the current quantity of product at TCH in all user and stock locations	Collect Lot numbers from the warehouse and Supply Areas housewide	Rick McFee / Supply Chain
Proposed Replacement of all existing Lot Numbers at TCH for both products with new Lot #'s	Need to collect QOH required for each stock location and warehouse	Establish required stock needed and assess available stock and estimated delivery time from CareFusion. Coordinate delivery and distribution	Hope Jackson / Supply Chain
Nursing Communication and Staff Education on issue and action being taken to resolve.	Need to update bedside staff on issues and need to continue to report new issues. Provide advice on the information needed for each report including details on saving the product for investigation.	Send Communications Out	Shannon Holland / Tarra Kerr
Establish a Daily Status Update on the Action Plan	**Call at 3:30 pm each day until issue resolved**	Set up call – starting 8/16	Rick McFee
Report back to DOB on Action Plan		Update DOB	Rick McFee

Respectfully submitted;

Rick McFee
Director of Supply Chain

Department/Unit	File ID	Event Date	Specific Event Type	Brief Factual Description:
Pedi ICU	292423	07-26-2016	tubing issues	CareFusion MaxZero closed med tubing broken, leaking medication, open to air, connected to CVL TYPE OF LINE IS CVL, NOT ARTERIAL LINE CVL NOT AN OPTION
Cardiovascular ICU	292594	07-29-2016	equipment/supply issue	Alaris pressure sensing tubing broke when priming for line change, line not connected to patient. Faulty material given to Virginia Little, Educator.
Pedi ICU	292571	07-29-2016	tubing issues	Closed med tubing would not flush, new tubing obtained. I have defective tubing
11 WT - Surgical/Ortho	292719	08-01-2016	tubing issues	The new closed system syringe pump tubing's connection into the lumen was cracked. It clicked around when connecting instead of connecting securely.
8WT - BMT Unit	292785	08-02-2016	tubing issues	Mother asked for nurse to come to the bedside, leak noted, puddle of fluid collected on the floor. I came to the bedside to assess patient and location of the leak. I traced the patient's line and saw the syringe med line tubing was broken in half and fluid counter flowed causing the puddle of fluid.
Pedi ICU	292823	08-03-2016	equipment/supply issue	Type of Line/Tube: Alaris pump not an option (incorrect line selected to submit SS) New Carefusion Alaris Pump malfunction Epinephrine drip infusing, <10% alarm beeping unable to silence pump Had to change pumps and line change
15 WT Cardiology	292999	08-06-2016	tubing issues	Closed medication system tubing with leakage noted at clear connection area below y-site.
Pedi ICU	293044	08-07-2016	tubing issues	Not an arterial line- however, there is no medline option. When I came on shift this morning I found the tip of my closed med tubing broken off into my blue cap. Meds were infusing on the bed. The tips are very cheaply made, and hard to get off at times. The med line has been given to Angela Morgan.
Cardiovascular ICU	293170	08-08-2016	tubing issues	Alaris small volume tubing w/ sensor disk was found leaking. (Line attached to RIJ introducer sheath running w/ hep 1:1. Manager notified.
5 West	293220	08-10-2016	tubing issues	When I disconnected the medication tubing from the white lumen CVC to heplock it after Nafcillin infusion and saline flush were complete, I noticed a crack in the plastic screw connector of the medication tubing. A blue cap was placed on the tubing. Hands gloved, 15/15 scrub practiced on CVC, heplocked, + blood return and flushed well, and blue cap placed on white lumen. I showed the tubing to charge nurse Taylor Henson, RN and also Ruth, PCM. As received in shift report from day shift nurse Melissa S., the tubing was changed during day shift. A new closed medication/flush setup was hung.

Department/Unit	File ID	Event Date	Specific Event Type	Brief Factual Description:
Pedi ICU	293183	08-10-2016	tubing issues	CareFusion MaxZero closed med tubing broken, leaking medication at hub, open to air, connected to CVL TYPE OF LINE IS CVL, NOT ARTERIAL LINE CVL NOT AN OPTION
15 WT Cardiology	293276	08-11-2016	tubing issues	RN to room to change heparin carrier syringe. When syringe disconnected, noted leaking on glove. Assessed that syringe was connected properly to tubing, syringe correctly in place. Tubing leaking from below connection site. RN notified charge RN and requested new milrinone and heparin syringes to change tubing.
Cardiovascular ICU	293235	08-11-2016	tubing issues	Closed med system used for administration of intermittent meds through central line leaking at valve portion during infusion of medication.
15 WT Cardiology	293289	08-12-2016	tubing issues	New closed medication line was found leaking around the filter while flushing before medication. Charge RN notified and medication line replaced. Tubing saved for further inspection in managers office.
8WT - BMT Unit	293342	08-12-2016	tubing issues	Y-site at the end of CVC tubing, with collection of blood at the hub, clotting of line, can not flush or draw back. Blood sitting at the site above the hub, appears to be a clot. Happened with several other patients as well. Patient's were identified and all Y's were changed out.
Cardiovascular ICU	293352	08-12-2016	tubing issues	Attempted to give Potassium Chloride bolus, but alaris pump kept alarming "occluded". Calcium bolus had just been given without any difficulties. Closed medline noted to have some white sedimentation buildup sporadically up to ~6 in from filter. New closed medline tubing connected. Potassium Chloride bolus given per order without anymore difficulties.
Cardiovascular ICU	293365	08-13-2016	tubing issues	30 minutes after changing my Precedex syringe, I noticed that the tubing was leaking at the connection site of the cap/tubing and there was air in line after the pressure sensing disc. Had to change the line out.
Cardiovascular ICU	293359	08-13-2016	tubing issues	Type of tubing was actually on a Peripheral IV. The medline tubing was leaking. The leaking occurred when I disconnected line from the pump and I flushed the line with saline.
Pedi ICU	293378	08-13-2016	tubing issues	Dopamine tubing broke apart at pump insertion site during transport.
Cardiovascular ICU	293369	08-14-2016	tubing issues	I checked all of my tubing connections to ensure that there was no leaking since I had experienced leaking at the connection site previously with the new tubing. I found that the tubing for Epinephrine was leaking. I reported it to my charge nurse and the tubing was set aside to be evaluated.
Pedi ICU	293372	08-14-2016	tubing issues	Patient noted to be agitated and tachycardic. Patient was given multiple doses of PRN Versed, Dilaudid, and Ketamine with little response. Patient remained tachycardic to 170s. Dr. Anderson noted something dripping from the pump. Upon examination, Versed was leaking from tubing but source was difficult to isolate. Large puddle noted on the floor underneath the pump. Tubing was immediately changed. Extra Versed syringe not available at this time so the same syringe was used. Defective tubing placed in sample bag and labeled for collection. Patient agitation and tachycardia improved after new tubing and subsequent bolus given.

Department/Unit	File ID	Event Date	Specific Event Type	Brief Factual Description:
Neonatal Intensive Care Unit	293476	08-15-2016	equipment/supply issue	Pressure sensing disc tubing found to be leaking at female to male connection between line and max zero. Noted a hairline crack at site. Line was infusing Normal Saline with Heparin 1 unit/mL via UAC. Infusion was stopped and new art line setup was primed and attached to umbilical catheter. Art line stopped working at this point, (line would not pull back or flush) MD was notified and line was pulled.