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ISMP
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Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Action needed to address risk with custom and multi-chamber bag parenteral nutrition—Part II

Problem: The complexity of parenteral nutrition (PN) coupled with the heightened risk of causing significant patient harm when used in error, calls for targeted safeguards throughout the medication-use process. In **Part I**, published in our March 13, 2025 newsletter, we shared results from a recent survey completed by 280 practitioners who prescribe, dispense, compound, and/or administer multi-chamber bag parenteral nutrition (MCB-PN) or patient-specific compounded (i.e., custom) PN. The survey revealed that whether an organization purchases MCB-PN, compounds custom PN, or provides a combination of formulations, errors are common and organizations should take action to enhance systems and processes to prevent harm. Responses also highlighted an urgent need for focused PN-related pharmacy education.

Safe Practice Recommendations: Organizations should evaluate PN-related systems and processes and consider the following risk-reduction strategies.

Conduct an FMEA. The results revealed a common opportunity for organizations to evaluate their current PN practices by conducting a proactive risk evaluation, such as a failure mode and effects analysis (FMEA). During the analysis, be sure to review the labeling and packaging of products and identify how mix-ups will be prevented; how MCB-PN bags and/or custom PN will be ordered in your electronic health record (EHR) and displayed on your medication administration records (MARs); and the method that will be used to remind practitioners to activate MCB-PN bags. Consider if there should be any restrictions for MCB-PN use, such as in fluid-restricted patients. Incorporate clinical guidelines and refer to recommendations such as those provided by the American Society for Parenteral and Enteral Nutrition (ASPEN).

Implement standard times. Establish cutoff times when PN orders need to be entered or transmitted to the pharmacy. Designate specific times (e.g., 10 am until 2 pm) when staff should prepare and dispense PN. These times should be when adequate pharmacy staff are available to manage PN orders without being interrupted. If outsourcing to a compounding pharmacy to prepare PN solutions, the order should be transmitted to the pharmacy during the day shift so it can be checked by a hospital pharmacist with PN expertise before it is sent to be compounded. Pharmacy staff should be aware of all patients who are receiving PN and check if orders have not been received by the established time.

Prevent transcription errors. The ISMP ***Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology*** calls for organizations to implement automated compounding devices that are interfaced with the EHR to eliminate transcription errors. If an interface is not available, a process must be in place for transcribed orders/prescriptions to be verified by a second individual using an independent double-check and the technology should prompt for the second check. Build order templates with standardized units for defined patient populations (i.e., dose per day for adults, dose/kg/day for pediatric and neonatal patients).[1]

Evaluate system functionality. Test EHR functionality (e.g., compatibility, drug-drug interaction checking, duplicate therapy alerts, cyclic PN titration rates, central versus peripheral line administration, MAR warning to confirm the MCB-PN is activated) to determine how key information is displayed to end users. Work with vendors to enhance these functions, if needed. Whether your systems are interfaced or not, evaluate what clinical decision support is available (in the

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SAFETY briefs

Manufacturer's levETIRAcetam 1,000 mg/100 mL premixed IV bags mislabeled as 500 mg/100 mL. On March 13, 2025, Dr. Reddy's Laboratories issued a recall of just one lot number (A1540076) of lev**ETIRA**cetam 1,000 mg/100 mL bags because the label was incorrect. The infusion bags themselves were incorrectly labeled as 500 mg/100 mL but the aluminum overwrap label correctly identifies the product as 1,000 mg/100 mL lev**ETIRA**cetam. If a practitioner removes the overwrap from the infusion bag, they may believe that the bag only contains lev**ETIRA**cetam 500 mg/100 mL when it actually contains 1,000 mg/100 mL. If a practitioner infuses double the prescribed amount of lev**ETIRA**cetam to a patient, this could lead to immediate and serious side effects including hypersensitivity reactions, liver injury, hematological toxicity, somnolence, fatigue, dizziness, coordination difficulties, agitation, aggression, depressed level of consciousness, respiratory depression, and coma.

If your organization purchased this product, check your inventory. If an infusion bag overwrap labeled as 1,000 mg/100 mL lev**ETIRA**cetam with lot number A1540076 is found, sequester the product for return/replacement, and notify Dr. Reddy's Laboratories. Educate staff to read the infusion bag labels prior to barcode scanning and administration, and to be vigilant when checking the actual infusion bag for Dr. Reddy's Laboratories lev**ETIRA**cetam injection, regardless of the lot. Report issues to ISMP, the US Food and Drug Administration (FDA), and the manufacturer.

HIGH-ALERT

Prevent intravenous lipid bag mix-ups with ViperSlide. When preparing parenteral nutrition for a neonate, a pharmacy technician removed a 100 mL bag of what he thought was **SMOFLIPID** (20% lipid injectable emulsion) from a bin. It was **VIPERSLIDE**, a non-drug product that acts as a lubricant to reduce friction with

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EHR and/or automated compounding device) and ensure there are soft warnings and hard stops to warn practitioners when approaching or exceeding limits (e.g., single dose, daily dose, infusion rate, maximum solubility of calcium and phosphate, osmolarity). Regularly review alert overrides to determine appropriateness and to improve the safety of PN practices.

Conduct effective verification processes in the pharmacy. A pharmacist should be required to verify the initial PN order entry. If a compounder is used for preparation, and transcription of the order into the compounder is required, an independent double-check by a second pharmacist must occur and should include a check of all components, as well as dose calculations and compatibility checks. When setting up the compounder, scan the barcodes of all products for verification and ensure proper line tracing. Conduct quality control checks and verification of replacement solutions on the compounder, if used. All source containers used should be presented to the pharmacist for verification, not just a representative vial when multiple vials are used. An intravenous workflow management system (IVWMS) with barcode scanning should be used to verify the vials and syringes that contain all manually prepared additives before they are injected into the PN admixture. Additionally, using gravimetric analysis of the PN admixture ingredients for verification can help detect errors before reaching the patient. A pharmacist should review the final compounded PN prior to dispensing.

Gather stability data. Contact manufacturers and document stability data for any pharmacy additives, and make this information readily available to prescribers, pharmacists, and nurses. Based on the literature on PN compatibility and stability,[2] ASPEN recommends PN generally have an expiration date of 30 hours at room temperature and 9 days refrigerated,[3,4] unless there is specific extended stability data for the components used in the PN formulation. Additionally, the hang time for PN should not exceed 24 hours, and the hang time for a separate injectable lipid emulsion (ILE) infusion should not exceed 12 hours.[5] The ASPEN PN Committee authored an article about this important topic.[6] Ensure your organization's policy and procedures related to PN follow these updated standards and include an appropriate beyond-use date (sterility), expiration date (stability), and hang time for PN to avoid patient harm. For additional MCB-PN-specific information, refer to ASPEN's resources.

Store MCB-PN safely. Store MCB-PN products separately in the pharmacy, away from similar-looking bags. Avoid storing MCB-PN in an ADC, as nurses may not be familiar with the need to activate all chambers. Storing MCB-PN in the ADC also poses safety risks if additives (e.g., multivitamins, trace elements) are required (e.g., additives are omitted, additives not added in a sterile environment).

Require pharmacy activation and compounding. Require the pharmacy to activate all MCB-PN bags, and add any prescribed additives, such as multivitamins and trace elements, in a sterile environment. Then dispense the activated PN (with additives, if required) to patient care units.

Apply auxiliary labels. Consider applying auxiliary labels to the overwrap of MCB-PN bags upon procurement in the pharmacy to differentiate similar-looking products with and without electrolytes. After pharmacy activation, consider applying auxiliary labels directly on MCB-PN bags for nurses to confirm that pharmacy has activated the product prior to administration.

Employ barcode technology. Use barcode scanning technology prior to compounding, dispensing, and administration to ensure the correct PN product is being used.

Trace infusion lines and confirm the programming. When PN and ILE infusions are started, reconnected, or changed (i.e., new bag), trace the tubing by hand from the solution container to the pump (and channel), to the connection port, and then to the patient to verify the proper infusion, pump/channel, and route of administration. Confirm that the infusion dose and rate are programmed accurately in the smart pump; verify that the order in the MAR and the medication label match what is programmed in the pump when performing line tracing before starting the infusion. During

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devices used during atherectomy procedures. The technician scanned the barcode using the intravenous workflow management system (IVWMS) and received an alert that it was the incorrect product. Assuming it was a commonly occurring nuisance alert, the technician bypassed the warning. The pharmacist did not catch the error during the first visual check, but the final pharmacist check detected the error before reaching the patient.

The products come in similar packaging and both are milky white liquids (**Figure 1**). The ViperSlide bag is labeled as "lubricant" in tiny font size, which is easy to overlook since the container looks like an infusion bag. The technician who selected the ViperSlide said it did not occur to them to read the label on the bag because there were no other milky white infusion bags in the pharmacy. Pharmacy staff were not even aware that ViperSlide was available in the organization, so they did not know about this risk. The cardiac catheterization laboratory had ordered the ViperSlide and a pharmacy technician retrieved it when doing rounds and placed it in the SMOFlipid bin in the pharmacy in error.

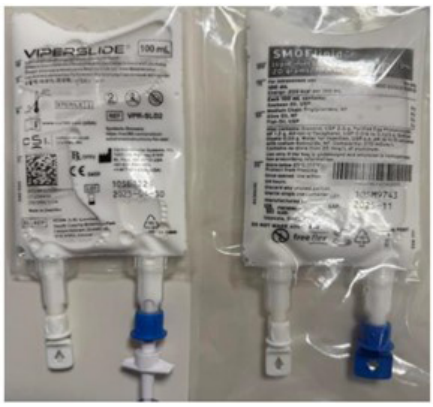

Figure 1. The bag of ViperSlide (left) looks similar to a bag of SMOFlipid (right).

Our June 28, 2012, and January 27, 2022, newsletters advised about a similar risk of mix-ups between 100 mL bags of **INTRALIPID** (20% lipid injectable emulsion) and ViperSlide. In our prior ***Safety* briefs**, we mentioned that many procedural areas stock bags of 20% lipids as an antidote for local anesthetic and other lipophilic drug toxicities. However, due to the visual similarity of these products, one can imagine a scenario where

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handoffs, nurses should round on the patient together to check medications that are infusing on the pump. During shift changes, oncoming nurses should trace the lines and verify the pump settings and infusion labels paying particular attention to the risk of inadvertent PN versus ILE rate swaps.

Administer PN using a 1.2-micron filter. ASPEN recommends using a 1.2-micron in-line filter for the administration of total nutrient admixtures (TNAs), dextrose-amino acid admixtures, and ILEs. For TNAs, place the filter as close to the catheter hub as possible. For dextrose-amino acid admixtures, place the filter below the Y-site where the dextrose-amino acid admixture and ILE co-infuse.[7]

Reconcile medications including home PN. Add scripting to your medication reconciliation procedures that specifically ask patients about prescription medications, over-the-counter medications (including herbals and dietary supplements), and non-enteral medications (e.g., infusions, including PN). Obtain a copy of their home PN order and share this with the applicable practitioners (e.g., prescriber, pharmacist, dietitian). During transitions of care, work with home infusion pharmacies to determine if orders need to be converted from MCB-PN to patient-specific compounded PN. Require an independent double-check of all calculations to verify accuracy. Confirm the patient's weight is accurate or clarify any discrepancies. For additional information, refer to *Safe care transitions for patients receiving parenteral nutrition*.

Document and communicate. Changes to the PN order (e.g., rate change, ingredient amounts, held order) must be documented in the EHR and communicated to applicable practitioners. During interdisciplinary team rounding, discuss the plan of care for the patient's PN therapy including any laboratory monitoring.

Educate practitioners. Provide initial and annual competency assessments for any practitioners who prescribe, activate, compound, dispense, or administer PN. Educate practitioners about how to calculate the amount of macronutrients, electrolytes, and additives patients will be provided from the PN bag, based on the ordered rate of infusion. Educate prescribers about how to enter orders for PN in the EHR. Teach practitioners how to review stability data for pharmacy additives. Establish a formal training process and validate competency for pharmacy technicians who compound PN, and for pharmacists who check the compounded PN solution. If compounding services are provided for neonatal and pediatric patients, include age-specific training emphasizing weight-based dosing, and validate the competency of all who may prepare or check pediatric PN. Ensure pharmacy staff know how to activate MCB-PN bags and add necessary additives (e.g., multivitamins, trace elements) prior to dispensing, and educate nurses to confirm the bag has been activated prior to administration. Since MCB-PN products are commercially standardized, alert nurses to the likely waste of excess PN volume since each bag may contain more than required for a particular patient (e.g., the patient may receive only 1,500 mL from a 2,000 mL bag in 24 hours) and communicate this during handoffs.

Report errors and share lessons learned. It is only when practitioners, like those who participated in our survey, share stories of PN-related errors that learnings can be distributed widely. Please report PN-related medication errors and close calls internally and to ISMP so that we can continue to share lessons learned.

References

1) Ayers P, Adams S, Boullata J, et al. A.S.P.E.N. parenteral nutrition safety consensus recommendations. *JPEN J Parenter Enteral Nutr.* 2014;38(3):296-333.

2) Boullata JI, Mirtallo JM, Sacks GS, et al. Parenteral nutrition compatibility and stability: a comprehensive review. *JPEN J Parenter Enteral Nutr.* 2022;46(2):273-99.

3) Boullata JI, Gilbert K, Sacks G, et al. A.S.P.E.N. clinical guidelines: parenteral nutrition ordering, order review, compounding, labeling, and dispensing. *JPEN J Parenter Enteral Nutr.* 2014;38(3):334-77.

4) Mays A, Ayers P, Monczka J, Cober MP. Safety in parenteral nutrition compounding. *Nutr Clin Pract.* 2023;38(6):1253-62.

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a patient in cardiac arrest due to an overdose of local anesthesia could receive ViperSlide in error.

We reached out to the US Food and Drug Administration (FDA) and Abbott, the manufacturer of ViperSlide, and recommended making changes to the ViperSlide packaging to ensure practitioners know this is a non-drug lubricant for device use only. If your organization uses ViperSlide, develop a policy and procedure to safeguard purchasing, delivery location, and storage. Ensure staff are educated on this product's use so they can be aware of the potential for mix-ups. Avoid storing ViperSlide in the pharmacy (even in an operating room pharmacy), in a perioperative medication room, or in an automated dispensing cabinet (ADC) where lipid rescue kits are stored. Place "Caution: Surgical Lubricant" auxiliary labels on ViperSlide bags to help differentiate them from lipid bags. Use barcode scanning when receiving, dispensing, filling the ADC, and prior to administration. Develop an escalation process for what to do if you receive an alert (e.g., wrong product) after scanning a barcode. Monitor overridden alerts and actions taken in response to the alerts, and make system changes when needed.

PCC—Prothrombin complex concentrate or protein C concentrate? A prescriber called a pharmacist and asked for "PCC 100 units/kg followed by 60 units/kg every 6 hours for 3 doses," for a patient when they were unable to order this in the electronic health record (EHR). The pharmacist asked the prescriber if they intended to order **BALFAXAR** but did not specify the generic name (prothrombin complex concentrate) or the indication. The prescriber confirmed they wanted Balfaxar and stated that the patient needed it right away; so, the pharmacist entered the verbal order in the EHR. The pharmacist noted the dose was higher-than-normal but knew it was time-sensitive. Assuming it was being used for the appropriate indication, reversal of vitamin K antagonist in patients with acute major bleeding, she dispensed the first dose. The nurse initiated the infusion.

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5) Nickel B, Gorski L, Kleidon T, et al. Infusion therapy standards of practice, 9th edition. *J Infus Nurs.* 2024;47(1S Suppl 1):S1-S285.

6) Cogle SV, Mulherin DW, Sacks GS, Mirtallo JM. Beyond-use dates for parenteral nutrition must take compatibility and stability into consideration. *Pharmacy Practice News.* Published June 23, 2023. Accessed January 23, 2025.

7) Worthington P, Gura KM, Kraft MD, et al. Update on the use of filters for parenteral nutrition: an ASPEN position paper. *Nutr Clin Pract.* 2021;36(1):29-39.

Syringe design hinders emergency medication delivery

A prescriber ordered atropine for a patient during a code event. The nurse obtained the 1 mg/10 mL atropine injection (by Amneal) from the code tray, which came in a package of 5 single-dose glass syringes (**Figure 1**). When attempting to remove the luer cover/cap (**Figure 2**), the nurse inadvertently twisted off the luer lock connection, which was overlaid onto a slip-tip connection. The nurse was unable to replace the luer lock connection and could not administer the medication to the patient through the intravenous (IV) line via a needleless luer connector. The nurse tried using a second syringe and the same thing occurred. The nurse called the pharmacist who delivered a different manufacturer's atropine syringe, and the nurse administered it to the patient. This resulted in a treatment delay for a patient requiring emergent drug treatment. Due to concerns with the syringe design, the hospital removed this product from the organization and now only purchases it from a different manufacturer.

Figure 1. Carton of 5 atropine sulfate injection (1 mg/10 mL) syringes by Amneal.

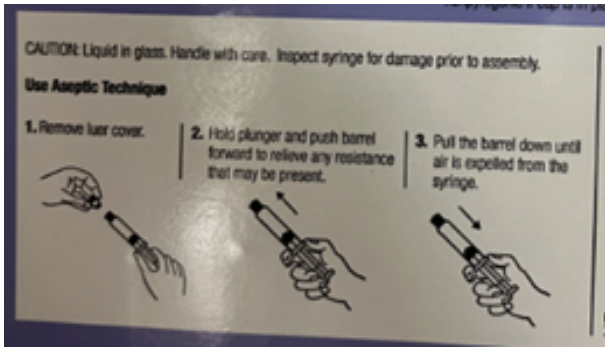

Figure 2. Directions included in the cartons containing 5 syringes do not warn against twisting the cap off.

Amneal also provides 1 mg/10 mL atropine injection that comes in cartons containing 24 single-dose syringes. The carton label for this product has specific instructions on how to remove the luer cover/cap by carefully tilting it back and forth (DO NOT TWIST CAP) until the cap disconnects, and then pull the cap in a straight upward direction to remove it (**Figure 3**). However, this information does not appear on the label for the carton containing 5 single-dose syringes.

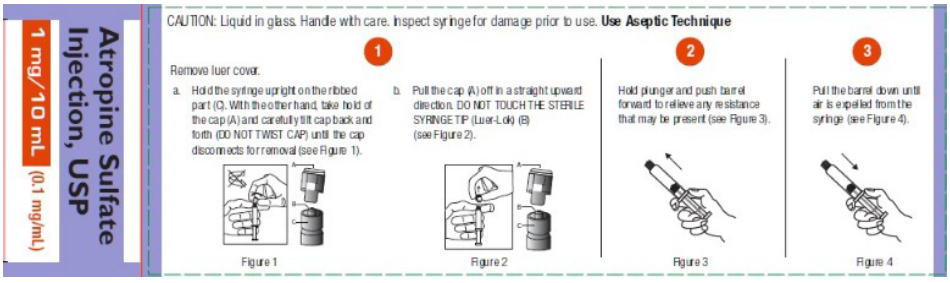

Figure 3. Instructions on Amneal's 1 mg/10 mL atropine injection that comes in a carton containing 24 single-dose syringes state to pull the cover/cap off in a straight upward direction and DO NOT TWIST CAP.

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Shortly after, the pharmacist reviewed a clinical note in which the prescriber noted the patient's diagnosis of purpura fulminans and referred to "PCC" as *protein C concentrate*. The pharmacist realized that the prescriber intended to order **CEPROTIN** (protein C concentrate) rather than prothrombin complex concentrate. Ceprotin is indicated for the prevention and treatment of venous thrombosis and purpura fulminans in patients with severe congenital protein C deficiency. Ceprotin was not on the organization's formulary, and not available in the pharmacy, which was why the prescriber could not find the drug in the EHR. The pharmacist notified the prescriber of the error and informed the nurse to stop the Balfaxar infusion. The pharmacist contacted local hospitals to inquire about borrowing Ceprotin, but this was not something they kept in stock either. The prescriber ended up ordering fresh frozen plasma as an alternative treatment. No patient harm was reported.

To ensure patient safety, organizations should make it a policy and expectation to not use acronyms (e.g., PCC) or drug name abbreviations when referring to medications. Educate practitioners about how the use of acronyms could lead to an error. Coach staff to always clarify the full medication name if another practitioner uses an acronym. When a pharmacist receives a verbal order from a prescriber, they must repeat the medication name and always confirm the dose and indication make sense given the patient's clinical condition. Build order sets that include the drug's indication and maximize clinical decision support (e.g., dose range checking). The pharmacy and therapeutics committee should regularly review non-formulary medication requests to assess the need for a formulary addition or ensure an alternative agent is readily available.

Special Announcements

Apply for New Fellowship

Applications are now being accepted for the first ***Ochsner Children's & ISMP Safe Medication Management Fellowship***!

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In another case, a patient in labor who was being administered oxytocin and an epidural infusion began experiencing hypotension and fetal deceleration. The prescriber ordered **EMERPHED** (e**PHED**rine) 10 mg IV as needed (PRN) for hypotension. The nurse removed an Emerphed 25 mg/5 mL prefilled syringe (by Nexus, packaged in a BD Hypak glass syringe) from the automated dispensing cabinet (ADC). She removed the cap (**Figure 4**) and connected it to the patient's needleless connector IV access site but could not push any medication out of the syringe. She removed another syringe from the ADC and tried again. The same thing occurred. When she removed the syringe from the patient's port, it looked like the end was clogged with a piece of plastic. She obtained a third syringe, and when removing the cap, the entire luer lock connection pulled off the syringe, revealing a slip-tip (**Figure 5**). The nurse tried to connect the slip-tip to the patient's IV port, but the plunger could not be depressed. The IV port began leaking after this attempt. The nurse called the anesthesiologist to come to the bedside. The anesthesiologist brought e**PHED**rine made by a different manufacturer and was able to administer the medication. The anesthesiologist gave the dose 10 minutes after it was ordered. Fortunately, the patient was not harmed by the delay in administration. The organization sequestered the Nexus e**PHED**rine syringes and now purchases the medication from an alternative manufacturer.

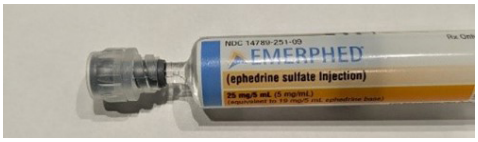

Figure 4. When the gray cap is removed from the Emerphed (e**PHED**rine) 25 mg/5 mL prefilled syringe, there is a luer lock connector that covers a slip-tip syringe connector.

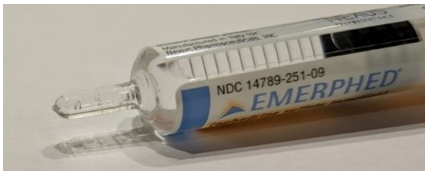

Figure 5. The nurse could not administer medication from the slip-tip connector on the Emerphed (e**PHED**rine) glass syringe after the luer connection had come off.

A second organization reported the same issue of not being able to administer Emerphed (by Nexus) from the prefilled syringe due to the BD Hypak glass syringe design.

We reported the issue to the manufacturers and the US Food and Drug Administration (FDA). We have warned about medications in glass syringes that are incompatible with needleless connectors several times over the last few years and have called for syringe manufacturers to make changes to the product design to enhance compatibility between syringes and IV connectors, particularly in emergent situations that could potentially result in serious harm.

We recommended that Amneal update the package labeling on the carton that contains 5 atropine syringes to instruct users how to remove the cap properly. Amneal notified us that they have revised the carton label to provide more detailed instructions and pictorials specifically addressing DO NOT TWIST CAP so that all Amneal atropine sulfate injection labels will have the same warning for practitioners.

Used by other companies for various drug products, BD's Hypak design requires a twist-off motion to remove the cap, unlike other syringes. To address user error, BD has redesigned their syringe. In November 2024, Nexus began distributing Emerphed 5 mL prefilled syringes using the new BD syringe that remediates the inadvertent luer lock disconnection issue and is compatible with needleless connectors. However, products in the BD Hypak syringe may still be on the market. Nexus is also transitioning their 10 mL prefilled syringe to the newly redesigned BD syringe. Additionally, they have updated the package insert instructions to clarify that the proper way to remove the cover from the Emerphed syringe is to **twist off the cap** (do not pull), and sent a notice to customers that depicts these instructions (**Figure 6**).

Figure 6. Practitioners must twist the gray cap off to remove it (do not pull) so that the luer connector is not improperly removed and the Emerphed can be administered without delay.

If your organization purchases any of these products, ensure staff are aware of how to remove the luer cover properly. Consider applying auxiliary labels with a warning or purchasing the product from an alternative manufacturer. Continue to report any issues to the manufacturer, FDA, and ISMP.

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This unique one-year program for pharmacists offers the opportunity to learn from and work with top experts in medication safety while supporting error prevention strategies in pediatrics at Ochsner Health. The fellowship begins in the summer of 2025 and requires working onsite at Ochsner Health in New Orleans, LA and remotely with ISMP. For more information and to apply, please visit: *Safe Medication Management Fellowships*.

Human Factors Engineering (HFE) training courses available

ECRI's human factors engineers will be providing an in-person training course on **April 2 and 3, 2025** in Philadelphia, PA: *Systems Thinking to Enhance Patient Safety*. This two-day course will provide the foundational knowledge to understand and conduct proactive assessments and reactive near-miss and adverse event analyses. After learning the model of healthcare as a complex sociotechnical system, participants will be taught techniques to analyze the system component parts and understand the component interactions. They will learn how to develop solutions from a human-centered systems perspective for solutions that support the work of healthcare professionals. Finally, participants will be taught stakeholder engagement techniques to make implementation of solutions manageable and successful. Additional courses and locations are being planned for the fall. For more information and to register, click here.

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