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Observe for possible fluid leakage when preparing parenteral syringes

The Institute for Safe Medication Practices (ISMP) has heard from three hospitals about occasional instances of medication leaking from syringes. Leaks have extended past the first and second rib on the black stopper on the parenteral syringe plunger rod into the surface of the syringe barrel that is exposed to air (**Figure 1**). The situation appears to occur as liquid is drawn into the syringe rather than after the syringe has been filled. In some cases, personnel said that it has happened rarely, and they may not have realized the situation was out of the ordinary, so instances may have gone unreported.

The reported syringes have been manufactured by BD, and both the company and the US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) are aware of the situation. We are not certain if this

issue may also involve syringes from other manufacturers. While syringes in the reported cases have been of varying sizes, BD reports that the syringes involved in its review have predominantly been the 10 mL size. There is a corrective action project underway to address the issue with the 10 mL syringes.

In assessments BD has made, the company found that leakage into the area between the first and second ribs of the stopper retains the sterility of the fluid and in most instances has no impact on the volumetric accuracy of the delivery of the medication.

Proper user technique when preparing syringes can be helpful in preventing this situation, especially with

larger syringe sizes (e.g., 30 mL and 60 mL). As a syringe is being filled with the vial inverted and the syringe below the vial, there may be a tendency to pull the plunger rod at an angle toward the user and not always maintain a vertical alignment with the syringe barrel. With an increased amount of fluid in the syringe, the ribs of the stopper may be angled enough to cause leakage past the stopper ribs. BD says that it is always important to ensure vertical alignment of the plunger rod with the syringe barrel when withdrawing a solution using this inverted vial technique.



Figure 1. Medication or solutions drawn into this syringe have leaked below the black plunger (circled in red), which may pose a problem with sterility and safe handling of hazardous drugs.

ISMP recommends sharing this information with sterile syringe production personnel and clinical personnel who prepare medications in parenteral syringes. Ask them to always observe prepared syringes for this situation.

If leakage is observed beyond the first and second ribs of the stopper and into the area exposed to air, the syringe and medication may have been contaminated and should not be used. Additional precautions to avoid contaminating work surfaces and exposing personnel are required if leaking syringes contain hazardous drugs.

If a leaking syringe is identified, the syringe lot number should be identified and recorded, and such instances should be reported to the FDA MedWatch Program (www.ismp.org/sc?id=1660), the ISMP National Medication Errors Reporting Program (MERP) (www.ismp.org/MERP), and the syringe manufacturer.

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN Alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.