Photos courtesy of Firouzan "Fred" Massoomi

CSTD Mounting Devices

Q&A

with Firouzan "Fred" Massoomi, PharmD, FASHP
Pharmacy Operations Coordinator
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Pharmacy Purchasing & Products: **Given the current emphasis on incorporating CSTDs into the compounding process, what do pharmacists need to know about CSTD mounting devices?**

Fred Massoomi: Mounting devices play a key role in the CSTD compounding process. Consider the fact that vials, even when they have the same neck diameter, often come with different stoppers of various densities. When a stopper is particularly dense, it can be difficult to properly seat the CSTD onto the vial. In fact, it is possible to push the stopper into the vial if the CSTD is not seated properly. Recognizing the importance of properly seating the CSTD and ensuring a true seal with the vial, some CSTD manufacturers have created a simple mounting device that attaches to the CSTD's vial adapter and ensures proper seating. Once the vial is seated on the mounting device, the vial is stable and there is no risk of it tipping over. This is particularly helpful when manipulating smaller vials, especially within an isolator. The mounting device makes the process less cumbersome overall and provides proper CSTD engagement on a consistent basis.

Mounting devices offer additional benefits for CSTDs that use a needle, as the device eliminates the risk of a needle stick resulting from a mismount. Perhaps most important, the mounting device enables a consistent and equal amount of pressure to be applied to the CSTD vial adapter (and the vial itself) to ensure proper seating and locking of the CSTD.

Vial mounting devices are available from BD, and CareFusion/BD. For Equashield's Equashield II, ICU Medical's ChemoLock, and the new Halo device from Corvida, the manufacturers have taken a different approach. The ability to mount and lock onto the vial is built into the CSTD vial device itself, precluding the need for an additional piece of equipment in the cabinet.

Vial Stability

The mounting device for BD/CareFusion's SmartSite VialShield ensures the CSTD is properly seated onto the vial.

PP&P: **How do the devices impact consistency?**

Massoomi: I highly encourage sites that utilize CSTDs with an available mounting device to consider implementing them, because in addition to averting improper seating of the vial, they perpetuate process consistency. We have used mounting devices at Nebraska Methodist since 2001. A total of 15 individuals are certified to compound hazardous drugs (HDs) at our facility, and as with any manual process, there is always the risk that procedures will not be consistently followed. Using these devices removes the variation in the CSTD and vial engagement process, thereby creating a standard function for pharmacy compounding technicians.

Perhaps equally as important as consistency, implementing the mounting device provides peace of mind to compounding technicians. Using the device gives them the assurance that each CSTD is properly mounted to the vial.

PP&P: **For facilities that have been using CSTDs without mounting devices, what are some suggestions for adopting them into workflow?**

Massoomi: The process is quite simple. I recommend starting outside of the compounding area using vials of saline or expired products to practice mounting CSTDs onto vials. You can request CSTD and mounting device samples from your vendor for training purposes. Conducting a side-by-side comparison using five different drugs with various vial stopper types helps demonstrate the variance from a tactile standpoint. Likewise, consult with compounding personnel who have the greatest working knowledge of those vials that require the greatest amount of force to pierce.

Of additional benefit to the employee, the use of CSTD mounting devices requires fewer manipulations, thus reducing the risk of repetitive strain injury. Consider compounding a product such as high-dose methotrexate, which may require anywhere from 10 to 20 vials for a given dose. A device that can reduce the strain from the process maximizes the value of the CSTD, while ensuring it will not fail.

PP&P: **How should the mounting device be used within the compounding area?**

Massoomi: The mounting device must be located within the primary engineering control (ie, biological safety cabinet [BSC] or compounding aseptic containment isolator [CACI]). It is best to have it located off to the side away from the direct compounding area. Once the vial is mounted, the technician brings the vial into the direct compounding area to complete the manipulations. As such, the device does not impede the compounding process or affect first air.

PP&P: **Do cleaning policies and procedures (P&Ps) need to be updated when a mounting device is added?**

Massoomi: Certainly. In our facility, the mounting device is used in a BSC with an open front and a moveable shield, as well as in a CACI. Of course, the mounting device in the BSC is much simpler to clean, as it can easily be moved allowing for access to the device and the surface it sits on. However, it is important to note that the device should not be removed from the cabinet

Placement within the PEC

Because the mounting device for BD's PhaSeal is set off to the side of the direct compounding area, it does not impede first air.

during the cleaning process, as there is a high likelihood of drug residue on the device. Just as we have learned that most HD vials enter the pharmacy with HD residue on the outside of the vial, we should assume that the mounting device is contaminated once it is placed in the cabinet. To minimize contamination of the mounting device and the compounding area in the PEC, all vials should be wiped down within the engineering control using the steps outlined in USP <800>: Deactivation; Decontamination; Detergent; Disinfection. HD vials and their corresponding packaging always should be considered contaminated and never should be handled with bare hands during any process from receipt to disposal.

It is important to incorporate the cleaning of the mounting device into overall cleaning P&Ps using the same agents that are used to prepare the cabinet. Thus, make sure the cleaning agents are compatible with the device; check with the manufacturer to ensure that the solvents and detergents used in your cabinets and isolators are equally effective for cleaning the mounting device.

Cleaning P&Ps need to address not just the point of contact for the vial, but also all of the seams, bars, and moving parts. Regular wipe tests should include the mounting device to determine cleaning effectiveness. Of note, some wipe sampling vendors state that a one square foot area should be sampled to be effective; given the small size of mounting devices, this is neither possible, nor necessary. Should the wipe test identify residue on the mounting device, share this feedback with your staff as part of the effort to improve cleaning processes within the cabinet.

As an additional precaution, Nebraska Methodist utilizes chemo prep mats within the BSC and CACI. The mounting device is placed on a chemo mat within the engineering control to contain contamination and prevent any surface scratches. At the conclusion of the compounding process, the chemo prep mat under the mounting device is changed out; this occurs at the same time that the main compounding chemo prep mat is removed and replaced.

PP&P: **Does the addition of a mounting device have an impact on competency assessments?**

Massoomi: Definitely. One of the reasons HD compounding is classified as a high-risk process (no relation to the USP <797> definition of a high-risk sterile compounded product) is due to the number of steps required in the process. Even simple doses, such as paclitaxel or methotrexate, require the completion of 20 to 30 steps for proper compounding.

An increase in the number of steps by two—putting the CSTD in the mounting device and then drawing it down to mount the vial—must be incorporated into the competency assessment to ensure staff members understand the process and follow it every time. Providing safety tools is an important priority, but follow up is required to ensure compounding staff can demonstrate that they use the tools correctly and consistently as part of annual competency testing.

For facilities with IV management software, the use of the mounting device can be incorporated into the standard workflow, thereby requiring staff to acknowledge and document the use of the device every time. Ultimately, if you can demonstrate the value of the device to your frontline staff, they will embrace it.

PP&P: **When it is time to replace the device, what is the proper disposal method?**

Massoomi: This is an important point—if you switch CSTD vendors and have a mounting device left over, the last thing you want to do is wipe it down and put it on your desk like a trophy, as I have done! Rather, it should be handled and disposed of as trace hazardous waste. Check with your state and regional EPA office for direction on how to dispose of trace hazardous waste. In Nebraska, it would be disposed of in a hazardous waste container (yellow) to ensure proper incineration. ■

Firouzan "Fred" Massoomi, PharmD, FASHP, received his doctorate from the University of Kansas School of Pharmacy and is the pharmacy operations coordinator at the Nebraska Methodist Hospital in Omaha. He currently serves on the Nebraska Pharmacists Association Board of Directors.

WHERE TO FIND

COMPOUNDING

Closed System Drug-Transfer Devices (CSTDs)

2findItnow.com

Suppliers
Allison Medical, Inc
B. Braun Medical Inc
BD
CareFusion (has joined BD)
Corvida Medical
Equashield LLC
ICU Medical, Inc