

ONGUARD™ CONTAINED MEDICATION SYSTEM WITH TEVADAPTOR® COMPONENTS

FAQs

Questions and Answers

Q: What is the definition of a closed system drug-transfer device (CSTD)?

A: NIOSH defines a CSTD as, "A device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system."

Q: Does the ONGUARD Contained Medication System comply with the NIOSH definition of a CSTD?

A: Yes. Through the combination of a hydrophobic 0.2micron sterilizing grade membrane and the TOXI-GUARD™ activated charcoal drug binding matrix, the ONGUARD system has been shown to maintain the sterility of the drug vial contents, while preventing the escape of hazardous drugs in any form – meeting the definition criteria of the NIOSH document for CSTD.

The NIOSH definition of a “closed system drug-transfer device” is focused on the ability of the system to contain hazardous drug in all forms – liquid, particulate, or gaseous. The NIOSH definition is an outcomes expectation standard, rather than a device design specification.

Q: Can your system be used in place of a biological safety cabinet (BSC) and personal protective equipment (PPE)?

A: Currently all regulatory bodies recommend the use of CSTDs inside of a BSC or CSI and with proper use of PPE. Please follow your facility protocol and all current regulatory requirements for handling admixture and drug delivery processes of hazardous medications.

Q: Is this device compliant with 2000 NIOSH recommendations for needle stick protection?

A: Yes. Additionally, the ONGUARD Tevadaptor Syringe Adaptor features a design which requires no user action to work properly and provides healthcare workers with passive protection from sharps injuries.

Q: Is the ONGUARD System approved by NIOSH?

A: B. Braun has confirmed that NIOSH does not render approvals, or opinions, of CSTD. As a result, no manufacturer or distributor can claim to have a “NIOSH approved” CSTD.

Q: Is your system easy to learn and use?

A: Yes. The ONGUARD system has four primary components designed for nearly intuitive use for admixture, IV infusion and IV Push applications. Because the system can be easily integrated into your current practice, training can be completed in a timely manner.

Q: How many times can the device septums be pierced?

A: Each device's septum can be pierced up to ten times.

Q: What is the gauge of the steel cannula that penetrates through the device component's septum?

A: The ONGUARD Syringe Adaptor has a 16-gauge stainless steel pencil point cannula.

Q: Are all the device components latex-free?

A: Yes.

Q: How are the ONGUARD products packaged?

A: Each Tevadaptor component within the ONGUARD System is individually packaged and completely sterile within the undamaged/unopened package.

Q: What are the approved solutions that can be used to disinfect the component's septum?

A: The Tevadaptor Vial Adaptor and Luer Lock Adaptor septum surfaces are not recessed and therefore are easily disinfected using your facility's approved disinfecting agents that are properly applied according to your institution's protocol. Please follow your institutional protocols for disinfection of septum surfaces prior to accessing any manufacturers' devices.

Q: How does the ONGUARD system differ from "balloon-type" systems?

A: ONGUARD is designed to passively maintain neutral vial pressure equally well with both liquid filled vials and lyophilized vials requiring reconstitution. Unlike "balloon-type" vial access devices the ONGUARD vial adaptor is designed to permit fluid to be injected into, or withdrawn from, the vial without additional steps to "reset" or evacuate a balloon which has a limited capacity/volume. Partially emptied vials with an ONGUARD Tevadaptor Vial Adaptor attached DO NOT have a partially filled balloon that can be compromised by sharps when discarded. The ONGUARD Tevadaptor Syringe Adaptor provides passive needle stick prevention in comparison to devices that need to be actively manipulated by the user to ensure proper needle stick protection.

Q: Is an assembly fixture needed to secure vial access device to the drug vial?

A: No, an assembly machine is not required to make the vial and adaptor assemblies. The ONGUARD Tevadaptor Vial Adaptor is designed to be easily connected by hand to the medication vial for a safe and secure assembly.

Q: Can the ONGUARD CMS be used with drugs in ampoules?

A: No, ONGUARD is designed for use with vials only.

Q: Does your system permit immediate fluid withdrawal from fluid filled medication vials without first injecting air from the syringe into the vial to avoid a vacuum?

A: Yes. Due to the unique design of ONGUARD's Tevadaptor Vial Adaptor the vial pressures are passively equalized by utilizing a 0.2 micron sterilizing grade hydrophobic membrane ensuring the air entering the vial is sterilized. Injected air that is first not sterilized by bacterial filtration could possibly be contaminated air and therefore would not be compliant with the NIOSH definition of a CSTD.

Q: Does your system permit injection of diluent into a vial that requires reconstitution of lyophilized powder?

A: Yes. The ONGUARD Tevadaptor Vial Adaptor is designed to passively equalize vial pressures during diluent injection into powdered drug vials. All exiting air is cleansed of toxic substances by passing through the TOXI-GUARD Activated Charcoal Drug Binding Matrix. There is no need to collect and discard contaminated air in a syringe.

Q: Can vials of chemo medication be stored once the Vial Adaptor is attached?

A: Yes. The vial assembly can be stored at room temperature or in the refrigerator for up to seven days or until the expiration of the prepared drug vial, whichever comes first. Additionally, a vial adaptor cap is provided to enhance cleanliness of the vial access septum during storage. Always use aseptic technique when accessing any vial or vial access device which includes swabbing the vial septum with an approved disinfectant using friction prior to re-accessing the vial.

Q: Must I purchase multiple vial adaptors to access both 13mm and 20mm vials of various volumes?

A: No. A single Tevadaptor Val Adaptor, packaged with 13mm vial converter ring, allows you to access both 13mm and 20mm vials of various volumes.

Q: How can ONGUARD CMS Tevadaptor Luer Lock Adaptor (LLA) be used on a split septum or standard injection site or Y-site of an IV tubing set?

A: The LLA must be assembled to an appropriate converter device (typically a shrouded steel or plastic cannula) prior to accessing a standard, or split septum, injection site or Y-site on an IV tubing set. Use manufacturer specific converters for accessing splits septum sites.

Q: Will the ONGUARD components work with various luer slip tips on syringes and IV tubing sets?

A: To maintain the most secure connections, the ONGUARD CMS Tevadaptor Syringe Adaptor and Luer Lock Adaptor Components are intended for use with Luer Lock devices only.

Q: What is the proper method of removing air from the syringe when drawing up fluid from a vial using the ONGUARD system?

A: With vial and syringe assemblies connected, withdraw ¼ - ½ of the required fluid volume into the syringe. Maintain the vial above the syringe and consolidate any existing air bubbles to the syringe tip by gently tapping the syringe. Inject ONLY the consolidated air bubble back into the vial. Do not inject fluid into vial with vial above the syringe. Complete aspiration of drug dose to required fluid volume. Prior to use of the ONGUARD System please refer to complete Instructions for use.

Q: Can ONGUARD be used with 28mm vials?

A: Yes, the ONGUARD System offers a Vial Adaptor for use with 28mm vials.