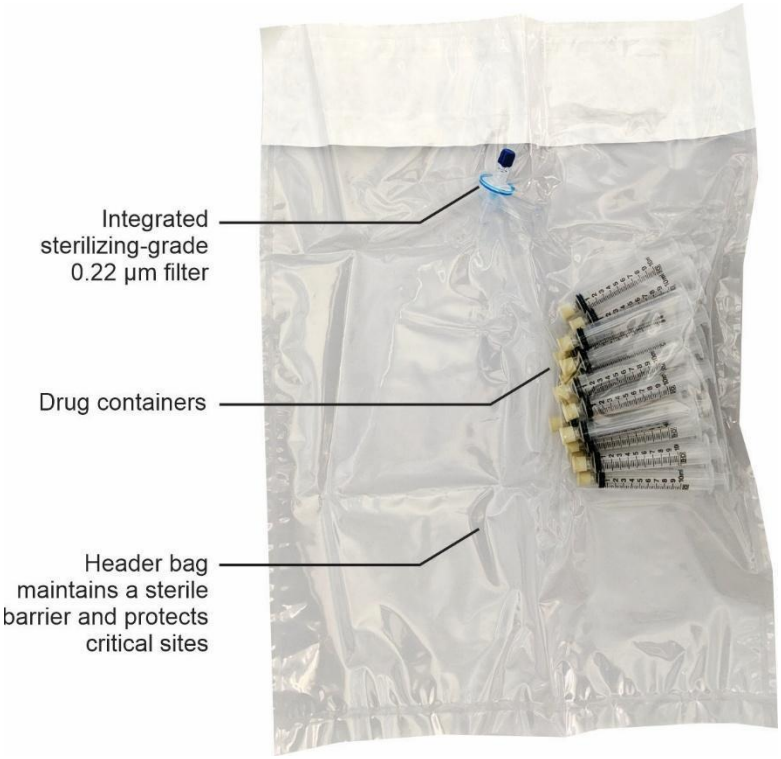
AseptiKits™

Revolutionizing Sterile Preparations

PALA Technology Frequently Asked Questions and Answers

Question Index

Q: What is PALA Technology?



A: PALA technology is the integration of a 0.22-micron sterilizing grade filter into a medical-grade sterile package like a header bag. The contents of the package include sterile syringes, vials or other drug containers. The package remains closed during the filling and capping process to maintain sterility. Clinicians fill each container by injecting drug through the sterilizing-grade filter and into each container, then capping each container. Once the containers are filled and capped, the package is opened, and the sterile-filled containers may be removed.

The PALA Technology kit is a self-contained primary engineering control, sterile clean room that sterilizes drug as it enters the kit.

Q: How does PALA Technology prevent contamination?

A: A PALA technology kit prevents contamination by keeping the syringes, vials, or other drug containers inside the sterile package, manufactured in a clean room under GMP conditions, during the filling process. The package prevents clinicians from inadvertently touching critical sites or interfering with critical air flow that could result in a contamination. The containers are capped before the kit is opened to protect critical sites during storage.

Q: How do PALA technology kits provide and maintain a sterile environment?

A: The package is made from a medical-grade header bag which maintains a sterile barrier until all syringes, vials or other drug containers are filled and capped. Drug entering the kit passes through a built-in 0.22 micron sterilizing grade filter.

Q: Can I use PALA technology kits outside of a clean room or laminar flow hood?

A: Yes. Each PALA technology kit is designed to be a complete, self-contained, primary engineering control (PEC) for the sterile preparation of drugs.

Q: If I use PALA technology kits for my sterile preparations, do I need a clean room or laminar flow hood?

A: A PALA technology kit is a complete, self-contained PEC which eliminates the need for a clean room or laminar flow hood. Note: PALA technology kits use 0.22-micron sterilizing-grade filters to sterilize drugs. Some large molecule drugs are not compatible with 0.22-micron filters. Aseptikits offers other patented non-filter sterile solutions for these specific drugs.

Q: Can you tell me how PALA technology kits are equal to, or better than an ISO Class 5 clean room or laminar flow hood?

A: PALA technology kits are assembled in a clean room and terminally sterilized (SAL 10^{-6}). By design, they maintain a sterile primary engineering control environment for sterile preparations throughout the filling process.

Conversely ISO Class 5 clean rooms are not sterile environments. Instead, they are designed to limit particulates to 3520 particles per m^3. Some of those particles are vectors for pathogens.

The following table compares the features of PALA Technology kits and ISO Class 5 clean rooms or laminar flow hoods.

Criteria	ISO Class 5	PALA Technology
Sterile environment	Not sterile	Terminally sterilized (SAL 10^{-6})
Closed environment	Open	Closed
Sterilizes drug and maintains sterility	No. Terminal sterilization needed for assured sterility - not compatible with most drugs. HEPA filters provide a .3-micron filter pore size	Yes, with a 0.22-micron sterilizing grade filter
Prevents touch contamination of critical sites	No	Yes
Pyrogens	May be present	Does not contain pyrogens
Pathogens	May be present	Terminally sterilized (SAL 10^{-6})
Particulate specification	Up to 3250 per m^3	
Validation requirements	Complex and repetitive	Simple, single use kits
Maintenance	Complex and expensive	
Training	Complex, multiple SOPs	Short in-services, intuitive use, based on conventional aseptic technique

Q: Are PALA technology kits primary engineering controls, or secondary engineering controls?

A: Conventional clean rooms or laminar flow hoods are open, incomplete PECs. For this reason, SECs (e.g. sterile gloves, garbing, IPA sprays or wipes, anterooms, buffers, etc.) are necessary to reduce or limit contamination of the PEC and the drug prepared inside. Said differently, PECs are constantly contaminated via biological ingress. Therefore, PECs must be supported by SECs and training to provide a drug preparation environment.

Conversely, PALA technology kits are complete, self-contained, closed system PECs - meaning they maintain a sterile environment throughout the filling process including sterilizing drug and other fluids when entering the PALA bag via the .22-micron filter and final fill containers. The containers are capped closed before the kit is opened.

Q: Can I use PALA technology kits inside a clean room or laminar flow hood to support my existing processes?

A: Yes. Note: the exterior of some PALA technology kits should be cleaned before entering a clean room according to institutional protocol. Please contact Aseptikits for more information.

Q: Are secondary engineering controls (SECs) like sterile gloves, garbing or isopropyl alcohol sprays necessary when using PALA technology kits?

A: Firms should assess the need for SECs. PALA technology kits are designed to be a complete, self-contained, closed system, primary engineering control (PEC) for the sterile preparation of drugs. Functionally, the 0.22-micron sterilizing-grade filter prevents the introduction of pathogens into the syringes, vials, eye drop bottles or other medical containers inside the PALA technology kit. The drug containers are capped before the sterile package is opened to maintain sterility.

Q: Do PALA technology kits comply with USP <797> standards?

A: Yes. PALA technology kits are primary engineering controls designed for sterile preparations. USP <797> permits the use of new technologies as stated in section 1 Introduction and Scope:

The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose (USP <797>)

Q: Do PALA technology kits impact Beyond Use Dating (BUD)?

A: BUD testing should be conducted according to your regulatory body's requirements.

Q: May PALA technology kits be used with all categories of compounded sterile preparations (CSPs)?

A: PALA technology kits may be used to prepare Category 1, 2 and 3 CSPs.

Q: What drugs can be used with PALA technology kits?

A: Any drug that is compatible with a 0.22-micron sterilizing-grade filter can be used with PALA technology kits. Note: some large molecule drugs are not suitable for use with PALA technology kits. Other PALA Technology Kits for drugs not compatible with .22-micron filters are in development.

Q: How can I be assured that the filter functioned properly?

A: As per the Instructions for Use and common practice, conduct a filter pressure verification ("bubble test") test after filling the containers inside the kit.

Q: Are PALA technology kits registered with the FDA?

A: Yes, PALA technology kits are registered with the FDA as medical convenience kits as follows:

Device	System/device, pharmacy compounding
Regulation Description	Intravascular administration set.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	NEP
Submission Type	510(K) Exempt
Regulation Number	880.5440
Device Class	2
GMP Exempt?	No

For more information on convenience kits, please refer to the FDA guidance here: https://www.fda.gov/media/71358/download

Q: Has PALA technology kits been independently reviewed?

A: Yes, Alvamed, Peak Consulting and ProPharma have independently evaluated PALA technology. Their findings are available for your review upon request.

Q: How do I order PALA technology kits?

A: PALA Technology Kits can be ordered via the AseptiKits website: www.aseptikits.com by email at sales@aseptikits.com , or by phone at 844-863-5170.