



Determine if Critical Site® Sterile Wipes in peel and reseal packaging reduce contamination potential in PECs (Primary Engineering Controls) vs. the use of individually wrapped sterile alcohol preparation (prep) pads.

Use of Critical Site Wipes is effective in reducing the introduction of particulate contamination in the PEC.

Reduced particulates in PECs vs. the use of individually wrapped alcohol prep pads may result in less risk of contamination to Compounded Sterile Preparations (CSPs).

The Benefits of Contec® Critical Site® Wipes over Traditional Sterile Alcohol Prep Pads

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Sterile and nonsterile alcohol prep pads look very similar, which has created confusion for purchasers and users. In 2011, Triad was forced to recall its alcohol prep pads due to potential contamination with *Bacillus cereus*.¹ Prep pads were often made with materials that could migrate into intravenous fluids and, therefore, the patient.² Even though most sterile prep pads are now made of nonwoven materials that are low-linting, they are still inadequate for the needs of most sterile compounders.

At this time, it is considered best practice to use only sterile wipes and disinfectants in the ISO 5 space; however, USP <797> - Pharmaceutical Compounding – Sterile Preparations published November 1, 2022, becoming official November 1, 2023 states the following:

- “All cleaning and disinfecting supplies (e.g., wipes, sponges, pads, and mop heads) ... must be **low-lint**.... In addition, cleaning and disinfecting supplies used in the PEC must be **sterile**....”
- “Critical sites (e.g., vial stoppers, ampule necks and intravenous bag septums) must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants.”
- “Vial stoppers on packages...must be wiped with sterile 70% IPA to ensure critical sites are wet and allowed to dry before they are used....”

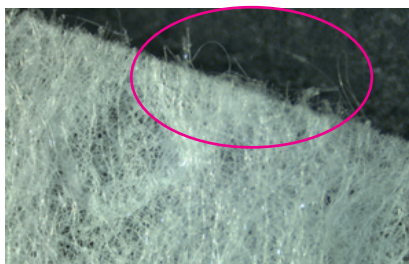
1. US Food and Drug Administration. Class 2 Device Recall Triad Alcohol Prep Pads. 2011. Retrieved 4/12/22.

2. Lee KA, Lankers M and Valet O. Particulate Identification for Improvement of Pharmaceutical Production. Drug Development & Delivery. September 2016. Retrieved 4/8/22.

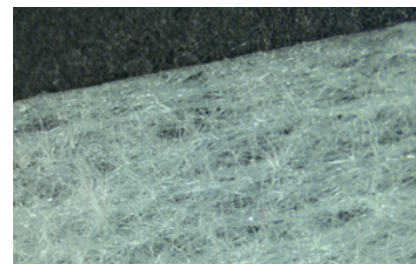
The table below compares traditional alcohol prep pads found in healthcare settings with Contec's Critical Site Wipes.

	Traditional Alcohol Prep Pad	Critical Site® Wipe
Specific Design Purpose	Preparation of skin prior to an injection	For use in the sterile compounding setting for the preparation of critical sites
Size	1.2" x 1.2" or slightly smaller, which dries quickly, limiting the number of critical sites that can be wiped effectively	4" x 4" size conducive to wiping larger surfaces and a higher number of critical sites ensuring sufficient wetting
Material	Variable materials depending on the manufacturer; woven and nonwoven materials are not always low-lint	• Nonwoven, synthetic polyester complies with low-lint requirement defined by USP • Releases 80 times fewer fibers and 122 times fewer particles when compared to a popular alcohol prep pad* • Generates 78 times fewer particles, and 44 times fewer fibers when used to wipe vial septum than popular alcohol prep pad*
Packaging	• Hard to identify sterile vs. nonsterile • Packaging not sterile • Packaging difficult to sanitize	• Packaging and contents validated sterile to a 10⁻⁶ Sterility Assurance Level (SAL) • Packaging easy to sanitize • Packaging produces 308 times fewer particles when opened compared to a popular alcohol prep pad*
Wetness	Size leads to fast drying	Maintains wetness longer
Ease of use	• Multiple wipes needed, with packaging that must be opened/discarded • Sterile gloved hands potentially contaminated by packaging as many times as prep pads are opened	• Easy to sanitize sterile packaging reduces contamination to sterile gloves and DCA • Easy to open and reseal packaging with easy-to-pick wipe edge

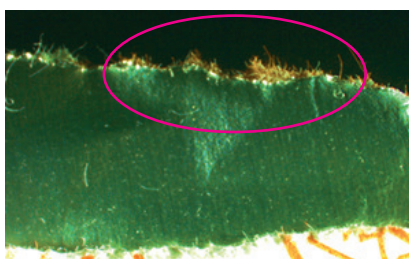
Popular Brand of Alcohol Prep Pad



Contec Critical Site Wipe



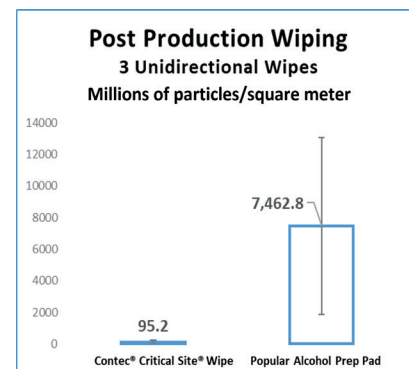
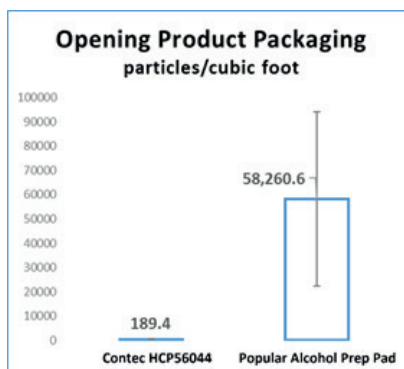
Packaging of Popular Brand of Alcohol Prep Pad



Packaging of Contec Critical Site Wipe



Contec performed testing in a laminar airflow workstation. Contec's Critical Site Wipes generated an average of 189 particles per cubic foot versus a popular competitor's product which generated an average of 58,261 particles per cubic foot. These results have clinical and practical significance when the goal is to decrease the generation of particles and fibers in the ISO 5 space. Displayed below are two product comparisons.



*Comprehensive testing method descriptions and outcome data is available by contacting your Contec Healthcare representative.

A (Right Product) + B (Right Practice) = C (BEST Repeatable Outcome)

No product can eliminate the risk of contamination, so it falls to sterile compounding operations to ensure effective, efficient and consistent practices. Please consider the following recommendations which may improve your operation's practices:

- Wipe each pouch (60 wipes/pouch) using a sterile, presaturated alcohol low-lint wipe before placing it inside the PEC
- Once the pouch is inside, do not remove the pouch from the PEC
- Pull the resealable tab to easily remove one wipe by grasping the pickable edge without touching other wipes in the packaging.
- Immediately reseal the package by expressing excess air and then smoothing the peel and reseal label over the pouch to prevent premature drying.
- If using the wipe to sanitize critical sites, it is not necessary to fold the wipe
- Critical sites must be fully wetted with alcohol (for chemical action), vigorously wiped in one direction (for mechanical action) and allowed to dry completely before puncture
- Shift the wipe to wetter surfaces during repeated use
- Discard the Critical Site Wipe when it no longer generously wets the surface being sanitized or based on facility practices.