

TECHNOTES

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Cleaning with Contamination Control Consumables

- Fume Hoods
- Chemical Workstations
- Biological Safety Cabinets
- Laminar Flow Hoods
- Other Front Access Fixtures





Contamination Control Consumables to be Used in Cleaning Fume Hoods, Chemical Workstations, Biological Safety Cabinets, Laminar Flow Hoods, or Other Front Access Fixtures

This document discusses the cleaning consumables used in the cleaning process of fume hoods, chemical workstations, biological safety cabinets (BSCs), and laminar flow hoods. The term “front access fixture” is used to describe fixtures that do not require users to place their hands into fixed gloves to access their interior. The cleaning process can be boiled down to two rules: clean from clean areas to contaminated areas and use unidirectional, parallel, overlapping strokes as you wipe. Be sure to follow your standard operating procedure (SOP) for which consumable, e.g., wipe, mop/cleaning tool (designed specifically for smaller work areas and limited access), swab, solution, e.g., cleaning agent or disinfectant, to use, and how to clean, what stroke length, where to start each stroke, etc., to bring the fixture back to its validated cleanliness level, which were determined by internal standards. Other considerations that are part of cleaning will be discussed later.

Maintaining the classification level of a fume hood, chemical workstations, BSCs, and laminar flow hood, or other front access fixture, like a cleanroom, requires periodic cleaning to return it to its original clean state. (See IEST-RP-CC018, “Cleanroom Housekeeping: Operating and Monitoring Procedures,” www.iest.org) for housekeeping recommendations.) The consumables that can be used in the cleaning process include sterile and non-sterile products such as wipers, mops and covers, dry, and pre-wetted wipers, swabs and disinfectants, isopropyl alcohol and denatured ethanol solutions at varying concentrations to remove residues after cleaning or disinfection. The determination of which sterile or non-sterile product is decided by the SOP for the process. Because these fixtures may have limitations for accessing all parts of the fixture due to their design, using only wipers may not ensure all surfaces can be reached for cleaning. Mops with their handles extend the reach of the person performing the necessary cleaning, disinfection or residue removal tasks, being able to reach all surfaces of the fixture. Swabs

can be used to clean small, hard-to-reach openings where a wiper or a small mop cannot be used. Swabs and wipers should be made of non-linting / low linting materials (often times this may be referred to lint free) to ensure all surfaces are clean. Two references are available for defining low-lint wipers. In USP <797>, the definition is found in its Glossary: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition. A second is from the IEST Recommended Practice, IEST-RP-CC004.4, “Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments, (www.iest.org), which defines non-shedding, low-lint, or lint free wipers: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the wiper material in a dry condition.

NOTE: Although there is not a contaminant-free or lint-free wiper, materials containing natural fibers (e.g., any cotton, or materials with a cellulose content of 65% or more) are generally not considered to meet this definition.

When manufacturing sterile products, including pharmaceutical compounding of sterile preparations, maintaining a sterile environment is an added requirement; otherwise, some product, even whole lots, can be lost due to microbial or other types of contamination. Maintaining microbial control requires the use of three activities: not bringing non-sterile materials into the sterile area, maintaining the sterility using sterile consumables, e.g., dry and pre-wetted sterile wipers, disinfectants, 70% isopropyl alcohol and denatured ethanol solutions, etc., and using good cleaning and disinfecting techniques and practices. Texwipe provides different consumables in its product lines for the different activities that are part of the contamination control process.

Helping Prevent Lost Product:

In pharmaceutical manufacturing and compounding, maintaining the prescribed condition of the equipment and environment is vital. Texwipe has a comprehensive suite of products designed specifically for effectively cleaning environments that demand a low level of contaminants, including microbial contamination, ensuring product sterility compliance and personnel safety.



Polypropylene Horizontal Laminar Flow Clean Bench

Constructed from all white seamless polypropylene for chemical resistance, AirClean® Systems horizontal laminar flow clean benches are the ideal solution for ISO Class 5 (Class 100) applications. Standard on all horizontal laminar flow workbenches, the UVTect™ controller constantly monitors filter conditions, alerting the operator of insufficient airflow.



PowderSafe™ Type B Enclosure

Seamless polypropylene construction provides the mass and vibration resistance crucial for accurate powder weighing to seven decimal places, while the AirSafe™ automatic safety filter controller monitors airflow and filter conditions. The full rear-wall HEPA filtration zone moves powders and particulate away from the operator in a smooth horizontal laminar pattern. HEPASafe™ technology allows filters to be safely and easily bagged-out under negative pressure.

Vertical Laminar Flow Workstation

AirClean® Systems vertical laminar flow workstation, having a clear polycarbonate shell for 360° visibility, are ideal for non-hazardous applications that require a clean work area. These compact, lightweight workstations provide positive-pressure, ISO Class 5 air, keeping airborne particulate away from sensitive applications. Given the small footprint and ease of installation (simply plug in the power cord), this vertical laminar flow workstation is an excellent choice for mobile 'clean zones' within a facility.



Sterile BSCs and laminar flow hoods are crucial in the aseptic manufacturing, sterility testing, cell culturing, and product purification processes, anything that requires separating the product or process from the external environment, within the manufacturing process. We recognize the importance of ensuring your working environment remains free from contaminants, and the need to maintain the highest level of sterility. Texwipe sterile products are x-ray or gamma irradiated, depending on product manufacturing country, to a Sterility Assurance Level of 10^{-6} , according to AAMI Guidelines (ANSI/AAMI/ISO 11137-1 (Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices) and -2 (Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose)). Certificates of Compliance, Analysis, and Processing/Irradiation are available on our website for each lot of our sterile product. Sterile Validation Documentation is available upon request.

If You Clean and Disinfect Front Access Fixtures:

Process details or suggestions for cleaning, disinfecting and removing residues are found in Texwipe's TechNotes ICT-1 & ICT-2. These TechNotes cover items to be considered as starting points for equipment cleaning and disinfecting SOPs. Best practices and a typical sequence for cleaning and correctly using cleaning tools like the Mini AlphaMop™ mop and its cover, sterile, dry, and pre-wetted wipers, swabs, and disinfectants, and 70% isopropyl alcohol and denatured ethanol solutions, used for residue removal, for optimal contamination control are covered. Our products are ideal for cleaning processes requiring low particles, fibers, and extractables for effective contamination control.

Items to remember before and as you clean:

Cleaning is thankless, but important work. Usually, the surfaces do not appear to be contaminated, that is, we clean what we do not see. Over time, the contamination level will overcome the protection of the environment, and the uncontrolled contamination will damage the product or process. Cleaning maintains the equipment and protects the product and operator in the environment. Because of this, when you clean:

- *Focus on the cleaning process. Pay attention to the cleaning steps, the materials needed, etc., most importantly, the cleaning task itself.*
- *Remember to use low linting (lint-free) cloths. Depending on the air particle cleanliness level (ISO Class) of the environment, these wipes can range from a nonwoven material to knitted polyester. Note: The ISO Class of the environment does not determine the type of wiper used. This is determined by risk level, application, etc., or other properties of the wiper.*
- *Next, use cleaning and disinfecting agents that are compatible with the fixture components and consumables.*
- *When using trigger or aerosol sprayer-equipped cleaning agents or disinfectants, never spray the surface directly. The force of the spray onto the surface will spread contamination into the air and onto other surfaces. If the unit has HEPA filters on the back panel, the spray may also reach the filter and cause damage. Do spray into a wipe, outside of the hood, if possible, certainly not toward the working surfaces inside. Generate as little overspray as possible to prevent contaminating already cleaned surfaces. Pre-wetted wipers are an alternative to spraying solutions onto a wipe and provide a consistent wetness level for use.*

Texwipe thanks AirClean Systems for supplying product photographs and information.

- Clean in the order specified in your SOP, generally top to bottom, back to front (depending on air flow design), cleanest to dirtiest. Remember to never touch a HEPA filter as wetness and physical touch can permanently damage the filter.
- Cleaning and disinfecting are two different steps when both are performed. Cleaning is first to remove contaminants, which can inactivate or decrease the efficacy of a disinfectant. Remove the cleaning residues using the water used in the environment or with a 70% alcohol solution (sterile, as needed), which allows organic and inorganic species to dissolve into the solution for removal. If you need to disinfect the environment, apply the disinfectant or sporicide at a level such that the surface remains wet for the specified contact time. The specified time ensures the product is working as intended. Afterwards, remove these residues, using water or an alcohol solution.
- Nothing is done until it is documented. Be sure to document that you have cleaned (and disinfected, if applicable) the environment. This shows it is ready for the next batch of material to be processed. Documentation may be electronic or written. If written, cleanroom compatible paper and notebooks should be used. The documentation and corresponding documentation materials should also be done outside of the hood.

Remember to follow the cleaning process and conform to the instructions documented in the cleaning SOP.



In front access fixtures, cleaning hard-to-reach areas like the back side of the viewing window, the ceiling, or the fixture's back wall may be a challenge. In these areas, a hand and wiper may not work. To reach these areas, a tool to extend your reach is needed. Texwipe developed the Mini AlphaMop™, the Isolator Cleaning Tool, TX7101, to meet this need. This tool has two handle sizes that aid in reaching all areas within front access type fixture. The TX7101 is an easy-to-manuever, light weight tool that allows one-handed operation. It has a low profile and swivel head to reach behind items or difficult to reach areas. The mop head is padded, and the mop covers are easy to remove and replace. The padding allows the mop head to consistently contact the surface beneath it. It also has rounded edges to clean isolator corners and prevent scratches or damage to surfaces. The various compatible mop covers are listed on the following page.

Applications:

The applications for the TX7101 are mopping and cleaning hard-to-reach surfaces, inside and outside the fixture. It can be used for spill control and to apply and remove cleaning and disinfecting agents.

For sterile fume hoods, BSCs, and other front access fixtures: Cleaning and disinfecting these fixtures are performed routinely. USP <797> and USP <800> (Compounding sterile preparations) prescribe daily cleaning and disinfection and when the surface is known or suspected to be contaminated. Texwipe's TX650 TexQ® Disinfectant is a ready-to-use, one step disinfectant, in a sterile, 22 oz. size. (Note: Texwipe liquid solutions may not be available in your region, please contact your local Texwipe or distributor representative for product availability). This disinfectant can be used in the cleaning step and again in the disinfection step of this daily routine as part of a disinfectant rotation. As with any quaternary ammonium chloride (quat) disinfectant, these disinfectants are to be used only with polyester products as cellulose- and nylon-containing products may deactivate quats. This product can be used on any surface in a front access fixture, on the outside of the fixture, including equipment, ceiling, walls, and floors. This product is also available as a one-gallon product (TX652) for mopping large surfaces. Please check with Texwipe or your distributor since disinfectants may not be available globally.

After the cleaning and disinfection steps, the residues must be removed. Texwipe's Sterile 70% USP-grade Isopropyl Alcohol TX3270 (16 oz.) and TX3273 (32 oz.) or Sterile 70% Denatured Ethanol TX3265 (32 oz.) and TX3267 (16 oz.) all sterilized to a Sterility Assurance Level (SAL 10⁻⁶) can be used to remove residues after cleaning, disinfecting, and using a sporicidal agent.

Front Access Fixture Environments:

- ISO Class 3 – 8
- Class 1 – 100,000
- EU Grade A – D

Industries: Pharmaceutical and Biotechnology manufacturing facilities, Pharmacies (USP <797, USP <800> non-hazardous and hazardous Pharmaceutical Compounding of Sterile Preparations). It is suitable for use in Veterinary Clinics and Laboratories, Medical Device manufacturing facilities, and Hospitals.

Shelf Life: For TX650 TexQ® Disinfectant in TX650 (22 oz.) and TX652 (1-gallon) sizes: two years from date of manufacture.

For Sterile 70% IPA solution products in TX3270 (16 oz.), TX3273 (32 oz.) and TX3290 (1-gallon) sizes: two years from date of manufacture.

For Sterile 70% Denatured Ethanol TX3265 (32 oz.) and TX3267 (16 oz.) sizes: two years from date of manufacture.

For Non-Sterile 70% IPA solution products in TX167 (16 oz.) and TX117 (1-gallon) sizes: three years from date of manufacture.

Texwipe featured products for use in front access fixtures and their applications

TX7101 Mini AlphaMop™ Isolator Cleaning Tool and Compatible Handles:

Designed for easy maneuverability and thorough cleaning, quickly reaching interior surfaces, including hard-to-reach spaces.

- A rapid-change system saves time, allowing users to replace covers/pads easily and quickly.
- It conforms to surfaces with its polyester pad, ensuring optimal surface contact while cleaning.
- Low profile, swivel head reaches difficult areas, ensuring all surfaces are effectively cleaned.
- 100% polyester covers prevent introducing particles, fibers, and contaminants while cleaning.
- Lightweight handles and mophead construction make cleaning less ergonomically demanding.



TX7102 and TX7103 ClipperMop™ and Compatible Handles:

- Low profile, swivel head with lightweight handle enables easier cleaning, getting to hard-to-reach areas.
- The tethered clips allow for replacement of wipers easily and frequently, adhering to strict cleaning protocols.
- Compatible with any 9" x 9" or 12" x 12" cleanroom wipers.
- Loading multiple wipers streamlines the mopping process.



Sterile 70% Isopropanol TX3270 and TX3273 and Non-Sterile 70% Isopropanol TX167:

A convenient sterile or non-sterile solution for dispensing 70% IPA onto dry wipers or mop covers, perfect for cleaning gloves and removing cleaning and disinfection residues.



Sterile 70% Denatured Ethanol TX3265 and TX3267:

A convenient solution for dispensing sterile 70% denatured ethanol onto dry wipers or mop covers, perfect for cleaning gloves and removing cleaning and disinfection residues.



Mini AlphaMop™ Compatible Covers for the Mini AlphaMop™



- TX7114 Isolator Cleaning Tool Polyester Covers and Polyester Pads, 150 covers/case (double-bagged)
- STX7114 Isolator Cleaning Tool Polyester Cover and Polyester Pads, Sterile, 125 covers and 25 pads/case (triple-bagged)
- TX7114M Isolator Cleaning Tool Microdenier Covers and Polyester Pads, Sterile, 150 covers/case (double-bagged)
- STX7114M Isolator Cleaning Tool Microdenier Covers and Polyester Pads, Sterile, 125 covers, and 25 pads/case (triple-bagged)

Dry or pre-wetted, sterile and non-sterile wipers:

Texwipe has several product lines of wipers. These wipes have varying fabric bases, edge types, pre-wetted or dry, sterile or non-sterile selections. Our brochure describing these selections can be accessed through our brochure web page <https://www.texwipe.com/brochures>.



TX3340, TX3342, TX3343 TOC Cleaning Validation Kit:



Texwipe's TOC Cleaning Validation Kits were designed to simplify sampling as part of a cleaning validation protocol. These kits are an organized, convenient, and secure method for transporting swabs and vials from the storage area to sampling sites to laboratory with minimal chance of contamination.

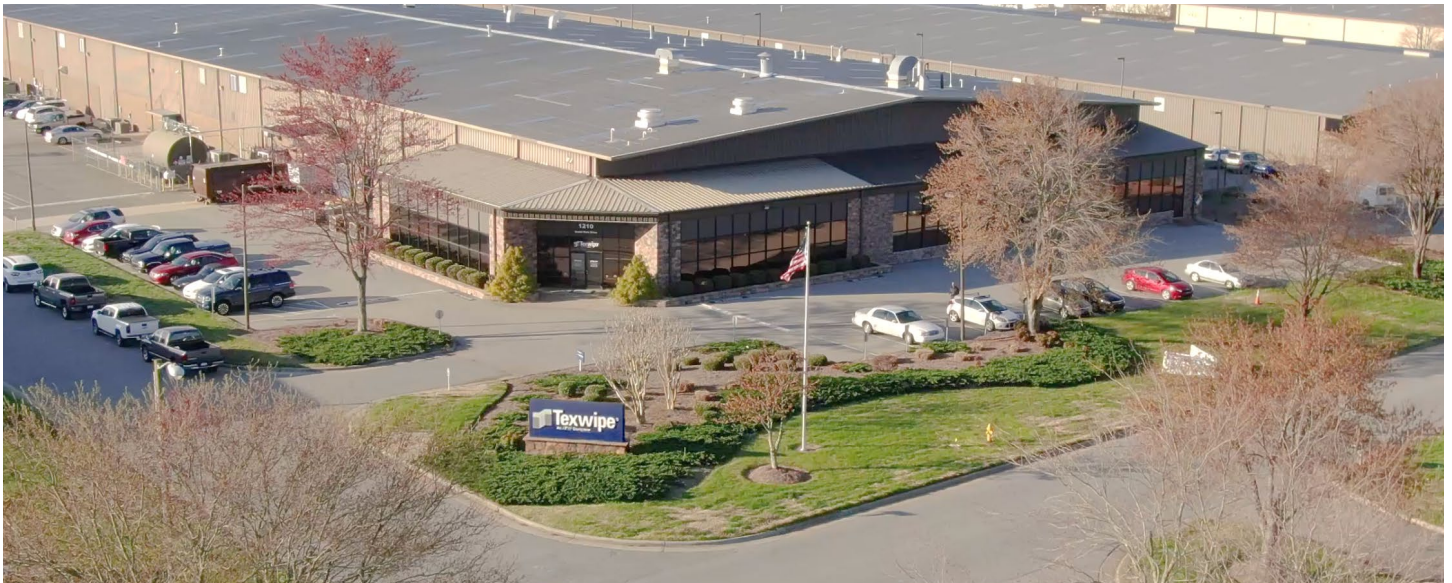
Revolve™ 2-in-1 sustainable mop covers



- TX1720 Revolve™ Mini AlphaMop™ Cover/Pad Integrated Covers, non-sterile, 100 covers/case (double-bagged)
- STX1720 Revolve™ Mini AlphaMop™ Cover/Pad Integrated Covers, sterile, 100 covers/case (triple-bagged)

Dry wipers are ideal for absorbing spills, applying solutions such as disinfectants, and cleaning surfaces. For sterile applications, sterile wipers can be wetted with sterile 70% IPA for removing residues of cleaning and disinfecting agents. This is also applicable to non-sterile applications. Pre-wetted wipers are ready for removing surface contamination or cleaning and disinfection residues, on equipment, surfaces, in critical environments and can also be used to wipe down gloves and other items, ensuring a sterile environment.

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Why Choose Texwipe:

Texwipe's commitment and reputation for consistent quality and technology leadership in contamination control make us an ideal partner. Our website offers educational videos, safety and technical datasheets, technotes, published papers, test methods, and other helpful resources, such as our product section guide. You can also contact our sales team or customer service for support in selecting and developing products tailored to your critical environment applications.

Contact Information:

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Scan the QR code to visit our product catalog and learn more about our isolator cleaning solutions.

