

A Blueprint for Reducing Healthcare Associated Infections

Healthcare Associated Infections are multifactorial in cause. As modern microorganisms have developed an exceptional ability to evolve and evade kill by most disinfectant chemistries, resistance continues to grow. This has created a great need for new disinfectant chemistries to supplement and advance existing protocols.

While most disinfectants cannot achieve complete kill against all microbial classifications, it is the toxic, fuming, flammable and corrosive nature of these chemicals that further inhibits both where and when these disinfectants can be applied; thus restricting application to high touch points and preventing comprehensive sterilization within healthcare. For example, most disinfectants cannot be applied to both hard and soft surfaces, or be sprayed with ease towards ceilings, walls, privacy curtains and across the complex surfaces of an operatory; or be applied within natal intensive care units, within food service, or be used within a patient care room while occupied by a patient, or be applied to delicate and expensive touch screen patient monitors, MRI's and so on. To avoid corrosion and damage, floors of the entire hospital are generally cleaned and disinfected with low level cleaners and disinfectants.

In general, if a disinfectant has a high level of efficacy it is also highly toxic and corrosive. If a disinfectant has a low level of efficacy, it is generally less toxic. Disinfectants of varying efficacy combined with varying protocols all the way through the healthcare environment can leave entire areas and equipment essentially untreated, facilitating cross contamination within the hospital setting and furthering the potential for HCAI's.

Another limiting factor; disinfectant chemistries such as bleach and alcohol evaporate quickly, before required dwell times can effect total microbial kill. As such, limited efficacy combined with the associated chemical dangers of most disinfectants that restricts use and provides an inadequate solution for reducing microbial contamination and associated HCAI's comprehensively throughout the complex healthcare environment.

In summary, the combinations of existing protocols and current products have not eradicated HCAI's as much as desired. Products that are too toxic or corrosive get limited use, and less toxic products lack the required efficacy. STERIPLEX SD sporicidal disinfectant represents a completely new paradigm of superior efficacy combined with superior safety, with the ability to sterilize all surfaces.

The First and Only

STERIPLEX SD is the first and only U.S. Environmental Protection Agency (EPA) registered broad-spectrum: Cleaner/Disinfectant/Deodorizer/Sanitizer that is Sporicidal, Tuberculocidal, Bactericidal, Virucidal, Fungicidal that can be safely used around humans, animals and plants, that is also fast, non-corrosive, non-fuming, non-flammable and environmentally friendly.

STERIPLEX SD Superior Properties

- ✓ **Broad spectrum: kills all types of micro-organisms**
- ✓ **Fast acting: produces a rapid kill**
- ✓ **One-Step cleaner and disinfectant: EPA-registered to clean and disinfect in one step**
- ✓ **360 degree sterilization: can be applied by advanced touchless spray systems**
- ✓ **Biofilms: penetrates biofilms and destroys microbial colonies**
- ✓ **Unaffected by environmental factors: remains active in the presence of organic matter, soaps, detergents, and other chemicals encountered in use**
- ✓ **Non-corrosive: does not damage surfaces or sensitive equipment**
- ✓ **Not toxic: is not harmful to the users**
- ✓ **Non-fuming: does not emit harmful fumes; no special ventilation requirements**
- ✓ **Wintergreen scent: has a pleasant wintergreen and vinegar scent that dissipates quickly**
- ✓ **Environmentally friendly: sustainable; does not damage the environment upon disposal**

References: STERIPLEX SD EPA Claims Sheet #84545-11 1.9s, STERIPLEX SD_MSDS_RTU FORMULA,

The Highest Level of Efficacy

STERIPLEX Sporicides: STERIPLEX formulas were the very first disinfectant Sporicides to be registered by the U.S. Environmental Protection Agency. STERIPLEX Ultra is the only EPA Registered Sporicide available for anthrax kill. **References:** EPA Registration numbers: STERIPLEX Ultra: 84545-8, STERIPLEX HC: 84545-4, STERIPLEX SD: 84545-11

STERIPLEX SD Proven to Kill Endospores: Some of the most deadly and resistant hospital 'superbugs' are endospores, such as *Clostridium Difficile* spores and consistently prove to be the most difficult to kill of all microorganisms. There are very few disinfectants that can kill *C. diff* and other endospores that are not also extremely toxic, fuming and corrosive. STERIPLEX SD is a hospital grade *C. diff* sporicide that does not contain bleach, is not toxic and is proven to achieve complete kill against endospores even on the most difficult surfaces. **Reference:** STERIPLEX SD EPA Claims Sheet #84545-11 1.9s

STERIPLEX SD achieves a >6-log reduction of endospores, including *Bacillus Subtilis*, *Clostridium Difficile*; and broad-spectrum kill against mycobacterium/acid-fast bacilli, naked virus, gram-negative bacteria, gram-positive bacteria, fungi/molds/yeast, and enveloped viruses *in vitro* in under 5 minutes. **Reference:** STERIPLEX SD EPA Claims Sheet #84545-11 1.9s

STERIPLEX SD Proven to Kill Mycobacterium: The second highest level potency of disinfectants is measured against Mycobacterium tuberculosis and is also recognized as a substantial benchmark. The U.S. CDC/MMWR states: "Because Mycobacteria have among the highest intrinsic levels of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label is considered capable of inactivating a broad spectrum of pathogens, including such less-resistant organisms as bloodborne pathogens (e.g., HBV, HCV, and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection." **References:** Disinfectant Sporicide-Tuberculocide_whitepaper, STERIPLEX SD EPA Claims Sheet

STERIPLEX SD Denatures DNA: Beyond achieving complete kill of all types of microorganisms, STERIPLEX SD has also been proven to denature DNA. An independent study proving that STERIPLEX SD is far more effective in denaturing DNA than Bleach was performed by the U.S. National Forensic Science and Technology Center. Where bleach achieves a 2-fold reduction of DNA, STERIPLEX SD achieves a 30-fold reduction of DNA. Given that resistant microbes have been proven capable of sharing their DNA and thus the ability to resist disinfectants and

antibiotics with other microbes, the ability of STERIPLEX SD to denature DNA from environmental surfaces is another critical element in preventing the spread, evolution and increasing resistance of microorganisms within the healthcare environment. This data is evidenced in the Huntsman Cancer Hospital End of Study Report Conclusion 7 30 2012, where after using STERIPLEX SD for 5 months, Bio-Contamination levels per ATP analysis were at an all time low as measured in Relative Light Units. Reference: [Huntsman Cancer Hospital End of Study Report Conclusion 7 30 2012](#), [STERIPLEX SD Forensics Study](#), [Evidence Technology Magazine - STERIPLEX vs BLEACH article_Dec 2011 issue](#)

STERIPLEX SD Efficacy Testing: All in vitro testing methods employed in the validation process of STERIPLEX SD are independent Scientific Association Dedicated to Excellence in Analytical Methods (AOAC) Good Lab Practices (GLP) as required by the U.S. EPA for submission of all classifications of microorganisms tested.

Sanitizer: STERIPLEX SD is an EPA-registered sporicidal sanitizer. STERIPLEX SD is the first and only sporicidal sanitizer. Reference: [STERIPLEX SD EPA Claims Sheet #84545-11 1.9s](#)

Environmentally Friendly: All of the food-grade ingredients of STERIPLEX SD break down into naturally occurring chemistries upon disposal. Reference: [STERIPLEX SD_MSDS_RTU FORMULA](#)

Excellent Materials Compatibility: STERIPLEX SD is effective and for use on stainless steel, titanium-coated and medical grade stainless steel, chrome, plastic (vinyl, LD and HD polyethylene, and polypropylene), silicone rubber, metal, Formica, medical tubing, vinyl rubber, laminated surfaces, glass, acrylic plastic, Plexiglas®, sealed fiberglass, glazed ceramic, glazed enamel, glazed porcelain, Corian®, sealed granite, sealed limestone, sealed marble, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, and sealed finished woodwork. STERIPLEX SD is also effective for use on water sensitive equipment surfaces such as instruments, touch screen monitors, monitors, sealed electronics, computer keyboards, cell phones, telephones, appliances, remote controls and so on. Reference: [STERIPLEX SD_MSDS_RTU FORMULA](#)

The Highest Level of Safety

Utilizing natural chemistries STERIPLEX SD has the best Health, Flammability and Physical Hazard ratings available with a Hazardous Materials Identification Systems Health Rating of '0', same as water. STERIPLEX SD is even approved for use on children's toys. This combination of safety and efficacy cannot be found in any other disinfectant chemistry. [References: STERIPLEX SD EPA Claims Sheet #84545-11 1.9s, STERIPLEX SD_MSDS_RTU FORMULA](#)

Enhanced Healthcare Worker and Patient Safety: As STERIPLEX SD achieves significant broad-spectrum reduction of microbial contamination, the natural ingredients profile of STERIPLEX SD can be applied without exposing patients and healthcare workers to damaging chemicals or fumes. This reduces worker and patient liability. STERIPLEX SD Leaves rooms smelling fresh, is not a skin irritant or sensitizer and can be applied without wearing a mask or gloves. [References: Huntsman Cancer Hospital End of Study Report Conclusion 7 30 2012, STERIPLEX SD EPA Claims Sheet #84545-11 1.9s; HMIS Rating Card - Hazardous Materials Identification System, STERIPLEX SD_MSDS_RTU FORMULA, STERIPLEX HC Toxicity Studies, Huntsman Cancer Hospital April BMT Project Report 2012 STERIPLEX SD Highlights](#)

Composition: Compositional information regarding STERIPLEX SD is provided on the STERIPLEX SD Material Safety Data Sheet. [Reference: STERIPLEX SD_MSDS_RTU FORMULA](#)

Acute Oral Toxicity Study: STERIPLEX is the first sporicidal chemical to achieve a perfect score on the Lethal Dose/50 toxicity test. The STERIPLEX SD acute-oral toxicity study was performed using 5,000 mg per kilogram, 2.5 times the required amount for testing. At the end of the 2 week trial, there was zero morbidity and zero toxicity in any of the animals tested. In fact, the test subjects ingesting STERIPLEX over the two week testing period gained the same amount of healthy weight as the control group, being fed normal food and water. STERIPLEX SD has no LD/50. [Reference: STERIPLEX SD_MSDS_RTU FORMULA](#)

In Compliance with CDC Guidelines

STERIPLEX SD is an EPA-rated One-Step Cleaner and Hospital Disinfectant:

In healthcare environments many substances can exist on surfaces in conjunction with microorganisms such as chemicals, proteins, bioburden, blood, soil, and debris, which poses a difficult challenge as the disinfectant must remain antimicrobially active while penetrating and mixing with other substances. Conversely, standard AOAC kill-time protocols require that the disinfectant is tested against a single microorganism only, with no other substances present.

The U.S. EPA and the U.S. Centers for Disease Control and Prevention (CDC) require that cleaning and disinfecting must be accomplished in two steps. First the surface must be cleaned. Second, the surface must be disinfected. Disinfectants that require cleaning and disinfection in two steps have not been proven capable of withstanding proteins, detergents or other chemicals while retaining the ability to kill microorganisms. It is for this reason that two-step disinfectants often fail in real world environments.

As such the EPA has established the One-Step cleaner and disinfectant rating and associated AOAC protocols for achieving this rating. The EPA One-Step cleaner and disinfectant rating is achieved when each and every required microorganism claimed on a disinfectant label is tested using a 5% serum or soil load. This is a far more difficult microbial test proving that the disinfecting chemistry is not inactivated in the presence of bioburden.

The CDC recommends implementation of a One-Step Process in Healthcare Facilities, stating: “The ultimate goal of the Recommendations for Disinfection and Sterilization in Healthcare Facilities, 2008, is to reduce rates of healthcare associated infections through appropriate use of both disinfection and sterilization. Under these guidelines per Section 5’s recommendations: “Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities”, the CDC recommends in Paragraph G: “Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where 1) uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or 2) uncertainty exists about the presence of multidrug resistant organisms on such surfaces.”

As a One-Step Cleaner and Hospital Disinfectant, STERIPLEX SD has been proven to remain highly active in the presence of other chemicals and debris, while achieving complete kill against all types of microorganisms. Reference: CDC Recommends One-Step Cleaner Disinfectant, http://www.cdc.gov/hicpac/Disinfection_Sterilization/17_00Recommendations.html, STERIPLEX SD EPA Claims Sheet #84545-11 1.9s

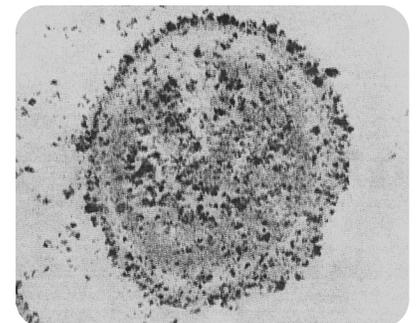
360° Sterilization, the New Protocol

Considering the toxic, fuming and corrosive nature of most disinfectant chemicals such as bleach, to aerosolize these chemicals by high volume spray methods would have very negative effects on users, patients and the healthcare environment. There are very few disinfectants that can be aerosolized or sprayed without negative effect.

STERIPLEX SD elevates efficacy and makes new protocols possible. With the very highest sporicidal kill and no toxic fumes or corrosion, STERIPLEX SD can be applied using the most advanced mechanical spray devices to disinfect both hard and soft surfaces from floors to ceilings, privacy curtains, complex surfaces, water sensitive equipment and everything in between, achieving 360 degree sterilization of all surfaces within minutes. STERIPLEX SD does not require wipe up, post rinse or to have the molecules removed from the air. Once applied, STERIPLEX SD dissipates from the air quickly and leaves zero toxic residues. STERIPLEX SD can also be used as a clean and disinfect gross matter in both mop and wipe application protocols, with both liquid and single use disinfecting wipes available.

Comprehensive, 360 degree sterilization achieves the greatest reduction of microbe counts and associated HCAI's. Thus, sterilize and 'treat' the total patient care environment, and more effectively treat the patient. An aseptic environment improves patient care outcomes, the healthcare working environment, significantly reduces costs and enhances reputation of the healthcare organization as a whole. [References: Huntsman Cancer Hospital April BMT Project Report 2012 STERIPLEX SD Highlights, Huntsman Cancer Hospital Touchless Infection Control Protocol_110112](#)

How Does STERIPLEX Work? STERIPLEX SD literally oxidizes the cell wall and intracellular makeup of single celled, pathogenic microorganisms. The following image is a kill profile of a single Salmonella cell utilizing scanning electron microscope SEM at 90,000 times.



Summary: STERIPLEX SD provides the highest antimicrobial kill kinetics against all microbial classifications while ensuring the highest user safety, materials compatibility, and environmentally safe chemical profile of any disinfectant technology available.

[Reference: STERIPLEX SD EPA Claims Sheet #84545-11 1.9s, STERIPLEX SD_MSDS_RTU](#)

STERIPLEX SD Clinical Trials

On February 1st, 2012 Huntsman Cancer Hospital began a clinical trial using STERIPLEX SD to disinfect the most sensitive areas of the hospital, the bone marrow transplant units, where patients have virtually no immunity and are thus highly susceptible to infection. In just 30 days of STERIPLEX SD use, documented monthly infection rates of *Clostridium Difficile*, *Methicillin-resistant Staphylococcus aureus* (MRSA), Extended Spectrum Beta Lactimase (ESBL) and Vancomycin resistance (VRE) were reduced to zero and remained zero throughout the twelve month trial. Reference: [Huntsman Cancer Hospital April BMT Project Report 2012 STERIPLEX SD Highlights](#), [Huntsman Cancer Hospital End of Study Report Conclusion 7 30 2012](#), [STERIPLEX SD Touchless Infection Control Protocol_110112](#)