

MediClear™ PreOp

Antimicrobial Self-Adherent
Silicone Film Drape for
PreOperative Skin with
Chlorhexidine and Silver

Now with:

FDA

Over the Counter
Clearance

Paradigm Shift in PreOperative Skin Preparation

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Executive Summary

“Surgical site infections (SSIs) are the number one most costly hospital acquired infection (HAI)”

Surgical site infections (SSIs) are the number one most costly hospital acquired infection (HAI), and the second most common.^{1,2,3} They can lead to the prolonged patient suffering, extended hospitalizations, and cost the healthcare industry billions of dollars, much of which is no longer reimbursable through historical channels. Clinical evidence of well-known antimicrobial agents such as chlorhexidine in washes and wipes has shown that they are effective at reducing the levels of bacteria on a patient’s skin pre-operatively and subsequently decrease the incidence of SSIs when employed correctly; however, these techniques are only as good as the compliance of the patient. Complicated take-home instructions, combined with the potential for skin irritation, sticky residue and the stress of the upcoming surgery, are likely contributors to the well-documented issue of patient compliance; a critical limiting factor in effective implementation of preprocedural skin antiseptic practices.

The majority of SSIs are caused by the native flora of the patient’s skin, mucous membranes or hollow viscera.⁴ When the skin is incised, the underlying tissue is exposed to endogenous flora, increasing the risk of potential infection. It has been shown that preoperative skin preparation products that help to decrease endogenous and exogenous pathogens reduce the risk of SSIs and subsequent mortality.⁵

To address this issue, Covalon Technologies Ltd., a leader in innovative antimicrobial medical products, has developed an antimicrobial self-adherent silicone film drape for preoperative skin with chlorhexidine and silver — MediClear™ PreOp. MediClear™ PreOp is formulated to be a one-time application, which effectively removes patient compliance from the efficacy equation. MediClear™ PreOp harnesses the synergistic effect of silver and chlorhexidine, killing 99.99% of microorganisms associated with SSI and suppressing re-growth even if it’s worn seven days before the procedure. Furthermore, its soft silicone adhesive is gentle on the skin while the breathable polyurethane backing provides a physical barrier to external contamination.

Why Should We Care?

Up to
55% of
SSIs are
PREVENTABLE

The Economic Burden of HAIs

In the USA, SSIs account for 15-30% of all HAI.^{1,2} SSIs are the second most common HAI and the number one most costly overall, costing hospitals between \$3.5-\$10 billion a year.³ This additional economic burden on the hospital is the result of prolonged hospitalization, additional diagnostic tests, antibiotic treatment and surgery.⁶ If a patient acquires an SSI they are twice as likely to die, 60% more likely to spend time in an ICU and over 5 times more likely to be readmitted.⁷ It was estimated that on average, SSIs extend the length of stay by 9.7 days while increasing costs by \$20,000-25,000 per admission^{5,8} (and greater than \$90,000 for methicillin-resistant staphylococcus aureus (MRSA) infections).⁹ It has been estimated up to 55% of SSIs are preventable using evidence-based strategies, such as preoperative infection prevention products.¹⁰

The Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for certain HAIs, including SSIs, CLABSIs, catheter-associated urinary tract infections (CAUTIs), and mediastinitis.^{11,12} Hospitals are now held financially accountable for HAIs and must absorb the associated costs. The CMS's focus is on reducing cost and improving quality of care by eliminating or reducing adverse events through the adoption of evidence-based practices.¹³ Infection prevention strategies have become an essential part of this.

The 2015 National and State Healthcare-Associated Infections Progress Report provided details on the nation's progress towards the goal of eliminating HAIs from hospitals.¹⁴ Despite overall progress the nation did not reach the 2013 goals established by the Health and Human Services (HHS).¹⁵ For example, only an 8% decrease was observed between 2011 and 2013 for hospital-onset MRSA infections. This was 17% short of their 25% targeted decrease.

The Need For Something Different

A Cochrane Review¹⁶ analyzed the results of six randomized controlled trials using preoperative bathing with skin antiseptics to prevent SSIs. This review found that the use of chlorhexidine did not decrease the risk of SSIs compared to a placebo or bar soap, with the exception of one large study revealing a benefit to chlorhexidine washing.¹⁷ This review, as well as other reports showing no clinical benefit associated with preoperative antiseptic showering, have since been criticised, stating they were technically and scientifically flawed, lacking rigorous standardization and did not take into account patient compliance.¹⁸ Since this study, poor patient compliance has been highlighted as the main cause for the ineffectiveness of preoperative skin antiseptics. When patient compliance is taken into consideration, numerous studies have reported that preoperative skin cleansing is a successful approach to reduce the risk of HAIs (Table 1).

The US Centers for Disease Control and Prevention (CDC) and Association of perioperative Registered Nurses (AORN) both recommend that patients shower or bathe with either soap or a skin antiseptic at least the night before the surgery.^{19,20} AORN's recommendation, which was recently updated in 2015, is now less exclusive, referencing all surgeries and any antiseptic agent, whereas previous recommendations had specified the use of chlorhexidine gluconate for Class I surgical procedures below the chin.²¹ This modification and consistent messaging between both CDC and AORN, highlights their commitment towards the use of preoperative skin cleansing for current standard of care.

The medical device industry has also clearly recognized the potential, and importance of preventing infections from occurring, evidenced by the recent acquisition of Sage Products LLC by Stryker Corp. for \$2.78 billion.²² This approach from large multinationals is surely targeted at building a consistent disposable revenue stream that is complimentary to their capital equipment offerings.

When implemented appropriately, it is clear from the clinical evidence, CDC and AORN recommendations, and investment by large Medical Device companies that preoperative skin preparation products reduce the incidence of HAI. The following section highlights the key issues that prevent consistent and effective implementation in the healthcare system.

“PREOPERATIVE SKIN CLEANSING is a *successful* approach to **REDUCE THE RISK OF HAIs**”

Table 1: Clinical evidence supporting the use of skin preparatory antiseptics when patient compliance is taken into consideration.

Study	Key Findings
<i>The Journal of Clinical Nursing</i>	The risk of infection was found to be 4.76 times higher among patients undergoing abdominal surgery who did not receive a chlorhexidine cleansing prior to surgery. ²³
<i>Orthopedic Nursing</i>	When patients admitted for a total joint procedure used a skin antiseptics protocol incorporating 2% CHG no-rinse cloths, SSIs rate was reduced from 3.19% to 1.59%, representing a 50.16% reduction. ⁵
<i>The Journal of Bone and Joint Surgery</i>	During a single-center study on 5293 patients undergoing orthopaedic surgery, the incident of SSI was significantly lower 0.19% (13-cases) vs. 0.45% (24-cases), when institution-wide pre-screening of methicillin-resistant and methicillin-sensitive <i>Staphylococcus aureus</i> was combined with preventative treatment using chlorhexidine showers for identified carriers ($p = 0.0093$). ²⁴
<i>The Journal of Arthroplasty</i>	A lower incidence of SSI was found in patients who used chlorhexidine wipes one day preoperatively and the morning of their operation, for total hip arthroplasty, ²⁵ or total knee arthroplasty, ²⁶ compared to patients who did not comply with this protocol. Patients with partial compliance were excluded from both studies.
<i>AORN Journal</i>	When a quality improvement intervention was developed to identify surgical patients with nasal colonization of MRSA and treat them with mupirocin and a preoperative skin antiseptics protocol using 2% chlorhexidine gluconate cloths, the total number of SSIs was reduced by 63%, and MRSA SSIs decreased by 78%. This intervention saved two community hospitals an estimated \$240,000. ²⁷
<i>The Department of Health and Sage</i>	The use of chlorhexidine cloths prior to caesarean section delivery in seven hospitals over four months reduced associated SSIs from 10.4% to 7.6%, a reduction in incidence of 39%. Furthermore, the cost benefit analysis in the study found the incorporation of a preoperative skin preparation treatment into routine practice to be favourable. ²⁸
<i>The Journal of Knee Surgery</i>	A statistically lower incidence of SSI was found in patients using chlorhexidine cloths (0.6%) compared with patients undergoing in-hospital preoperative skin preparation only (2.2%). ²⁹

Downfalls of Current Preoperative Antiseptic Wipes and Washes

“Only **6%** of Infection Preventionists were very confident that their patients were properly following skin cleansing protocols at-home”

Protocol Variations and Inconsistencies

Depending on the facility and guidelines it follows, preoperative skin cleansing protocols can vary greatly with respect to differences in the number of perioperative cleanses (one, two, three etc.), the type of cleaning product (soap vs. antiseptic) and the product form (soap, wipes, vs other). In an Infection Control Today survey of infection preventionists' (IPs) and surgical services directors, 27% admit that they do not have a formal pre-surgical skin cleansing protocol, while 6% were uncertain of an existing protocol.³⁰ A lack of standard guidelines creates confusion on the part of healthcare workers and patients – leading to poor compliance and increase risk of harm.

Poor Patient Compliance

A survey conducted by Clorox Healthcare found that only 6% of IPs were very confident that their patients were properly following skin cleansing protocols at-home.³¹ Failure to understand and/or remember application instructions,³² use of unfamiliar medical terminology, dislike of the sticky residue left behind by many chlorhexidine-based washes and wipes, social isolation, low education level, and socioeconomic status,³³ were all factors associated with patient noncompliance.

Additional Resources Required to Ensure Patient Compliance

In a survey conducted by Covalon Technologies Ltd. in 2015, 22% of the perioperative nurses questioned said they spend more than 20 minutes explaining soap/wipe instructions, 44% spend 5-10 minutes and 33% spent less than 5 min.³⁴ To address patient compliance, the use of electronic patient alert systems, text messaging, email and/or voicemail have been implemented to remind patients to adhere to their preoperative skin cleansing regimens.¹² Although such methods have proven effective, they ultimately still rely on patient compliance, require additional resources, costing the healthcare system time and money.

External Contamination

Cross contamination by the patients surrounding environment (e.g. bed sheets, animals, clothes etc.) is another key issue preventing consistent efficacy of preoperative skin antiseptics. After a patient cleanses with the preoperative antiseptics (wash or wipe) there is no physical barrier preventing the patient from contaminating the surgical site. Furthermore, the added burden on patients to follow strict instructions around using cleanly laundered clothes, sheets and towels adds another risk to the patient's non-compliance.

What's New?

“It has been shown that **preoperative skin preparation** products that help to decrease endogenous and exogenous pathogens **reduce the risk of SSIs** and subsequent mortality”

Over the last decade, the techniques to prevent and reduce HAIs has remained largely unchanged. It has been demonstrated that the current leading antiseptic washes and wipes have a patient compliance problem and do not allow for consistent implementation in the healthcare system. The market is in dire need for innovative products.³⁵

Improving Patient Compliance

MediClear™ PreOp can either be (1) purchased by a patient to apply at home, (2) applied by a member of the surgeon's staff at the presurgical appointment and worn up until the time of surgery, and/or (3) applied to the patient on the morning of the surgery. Immediately prior to the surgery, the clinician simply removes MediClear™ PreOp and completes the skin preparation as per the facilities protocol. In a 2015 survey conducted with perioperative nurses, 78% rated the ease of application of MediClear™ PreOp to be extremely easy and 22% rated it easy. Furthermore, 90% said they would recommend this product, when it becomes commercially available.³⁴

Superior Antimicrobial Protection

The majority of SSIs are caused by the native flora of the patient's skin, mucous membranes or hollow viscera.⁴ When the skin is incised, the underlying tissue is exposed to endogenous flora, increasing the risk of potential infection. It has been shown that preoperative skin preparation products that help to decrease endogenous and exogenous pathogens reduce the risk of SSIs and subsequent mortality.²³

MediClear™ PreOp combines silver and chlorhexidine in a soft silicone adhesive. Together these antimicrobials act synergistically providing superior antimicrobial protection, compared to either alone, over an extended period of time.³⁶ The synergistic effect of combining multiple antimicrobials into a single product has been cited by numerous sources.^{37, 38, 39} Reichman et al. first noted this benefit when combining chlorhexidine or iodine formulations with alcohol, compared to either alone.⁴⁰ This combination therapy extends the range over which antimicrobials work and help to prevent the emergence of resistant strains.⁴¹

(Continued)

What's New?

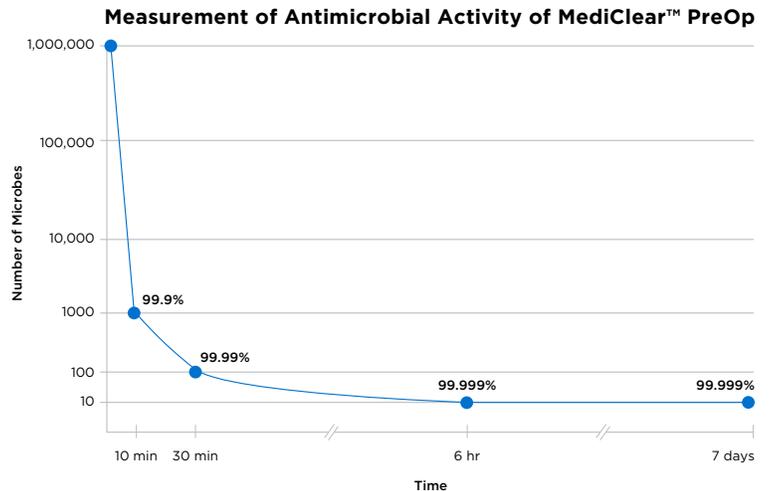
Superior Antimicrobial Protection (Continued)

The FDA requires that antimicrobial products are effective at preventing microbial rebound growth on treated skin sites for 6 hours after application. For this reason, chlorhexidine and silver-containing products are favored over traditional povidone-iodine preparations for their persistent and long lasting antimicrobial properties.³⁹ In addition, both chlorhexidine and silver act via non-specific mechanisms of action to kill bacteria, thereby preventing bacterial resistance over time.⁴³

On average, MediClear™ PreOp exhibited a 99.9% reduction of microbial levels after 10 minutes, and a 99.99% reduction after 30 minutes (Figure 1). A 4-log or greater reduction for all microorganisms is achieved by 6 hours and maintained for 7 days, setting MediClear™ PreOp apart as a versatile preoperative skin preparation that provides dual antimicrobial protection to reduce bacterial load and prevent regrowth leading up to surgery. MediClear™ PreOp provides an additional level of protection from external contamination by incorporating a polyurethane film in its design, which helps to physically protect the underlying area prior to surgery.

Figure 1: MediClear™ PreOp average log reduction when tested against *MRSA*, *VRE*, *S. epidermidis*, *E. cloacae*, *K. pneumoniae*, *P. aeruginosa*, *C. albicans* and *C. tropicalis*.

**In vitro effectiveness does not predict clinical performance.*



What's New?

“In an article published by Malangoni et al., the authors recommend that a preoperative skin antiseptic should ideally kill all skin organisms, is nontoxic and hypoallergenic, does not result in significant systemic resorption, has residual activity and is safe for repetitive use”

Preventing Skin Irritation

Several reports have cautioned against excessive washing with chlorhexidine preoperatively, as no studies have proven benefits of greater than three washings and such practices may lead to skin irritation.⁴¹ In a study performed by Edmiston on over 60 patients, showering or cleaning with chlorhexidine resulted in 10% of the patients having episodes of skin irritation.⁴⁴ Furthermore, the package inserts of products such as 2% CHG Prep Cloths, caution against use in or around mucous membranes, which in some cases may lead to serious adverse events up to and including blindness. It might be suggested that this risk avoidance by the patient may be a contributing factor in the low compliance of these products. Biocompatibility testing has demonstrated that MediClear™ PreOp is non-irritating to the skin, a result of the combination of the inert nature of silicone, combined with a low, but effective load of synergistic antimicrobials. In addition, the silicone adhesive in MediClear™ PreOp is flexible and able to conform well to the body's contours. A soft silicone adhesive like the one used in MediClear™ PreOp is so gentle on the skin that it is preferred by pediatric^{45, 46} and elderly patients, as well as patients with genetic skin conditions (e.g. epidermolysis bullosa), who have paper-thin, friable skin that is very vulnerable to injury and sensitive to numerous chemical products.⁴⁷ Furthermore, MediClear™ PreOp's one-time application provides further skin protection when compared to a wash or wipe that requires reapplication every 6 hours (e.g. 2% CHG Prep Cloths).

In an article published by Malangoni et al. the authors recommend that a preoperative skin antiseptic should ideally kill all skin organisms, is nontoxic and hypoallergenic, does not result in significant systemic resorption, has residual activity and is safe for repetitive use.⁴⁸

Conclusion

“MediClear™ PreOp is formulated to be a **one-time application**, which effectively removes patient compliance from the efficacy equation”

The high prevalence and associated cost of SSIs, continue to negatively impact our healthcare system. Although clinical evidence of chlorhexidine in washes and wipes has been correlated to reducing the levels of bacteria on a patient's skin and subsequently decreasing the incidence of SSIs, their efficacy is often limited by poor patient compliance.

Covalon Technologies Ltd., a leader in innovative antimicrobial medical products, has developed an Antimicrobial Self-Adherent Silicone Film Drape for PreOperative Skin with Chlorhexidine and Silver, MediClear™ PreOp.

MediClear™ PreOp's one-time application was designed to specifically address patient compliance issues. MediClear™ PreOp harnesses the synergistic effect of silver and chlorhexidine, killing 99.99% of the microorganisms commonly associated with SSI and suppresses re-growth even if it's worn seven days before the procedure. Furthermore, its soft silicone adhesive is gentle on the skin while providing a physical barrier preventing external contamination, and eliminating the need for reapplication every 6 hours.

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