



New Help in the Fight Against the Leading Cause of Surgical Site Infections

According to the CDC, each year in the US almost 500,000 surgical site infections (SSIs) occur, making them the second most-common healthcare-associated infection.¹ And numerous studies have documented that patients who incur a postoperative infection have a significantly longer and more costly length of stay, either initial or readmission—and are twice as likely to die.²

KIMBERLY-CLARK* InteguSeal Microbial Sealant Helps Stop Contamination at the Source

In clean surgeries, direct inoculation of the patient's own skin flora is the primary source of incisional contamination. Because the skin cannot be completely sterilized and rebound growth of bacteria deep in the skin occurs during surgery, Kimberly-Clark developed INTEGUSeal* Microbial Sealant.

INTEGUSeal* Microbial Sealant is a film-forming liquid that locks down bacteria residing deep in the skin as well as those surviving typical pre-operative prepping.

- Seals and immobilizes dangerous pathogens in the site of application, including MRSA, *S. epidermidis*, and *E. coli*.
- Non-irritating and breathable to permit normal skin transpiration
- Does not promote bacterial resistance

Now Available in 3 Sizes for Use in a Full Range of Procedures

With the introduction of our new size IS 50, you can select INTEGUSeal* Microbial Sealant in the right size for every application. It's safe, easy to apply and fast drying—just prep, seal and drape to lock skin flora out of your surgical site throughout the procedure, from the smallest incisions to full open-chest procedures.



Demonstrated efficacy and compatibility with current practices

Effective throughout a Surgical Procedure

A controlled *in vivo* porcine study performed by a facility external to Kimberly-Clark under Good Lab Practice (GLP) standards evaluated the effectiveness of INTEGU SEAL* at reducing the risk of skin flora contamination throughout a surgical procedure.

In a simulated surgical environment, all surgical sites were treated with 10% povidone iodine (aq) surgical preparation and treated with either INTEGU SEAL* Microbial Sealant or an antimicrobial incise drape. After treatment application, a full thickness incision was created prior to a 60-minute surgical procedure involving wound retraction, simulated surgical manipulations, and wound lavage. Surgical incisions were sampled for bacterial contamination after incision and before wound closure. For each incision, contamination was evaluated according to the total colony forming units (CFUs).

Figure 1
Reduction of Contamination Before Wound Closure

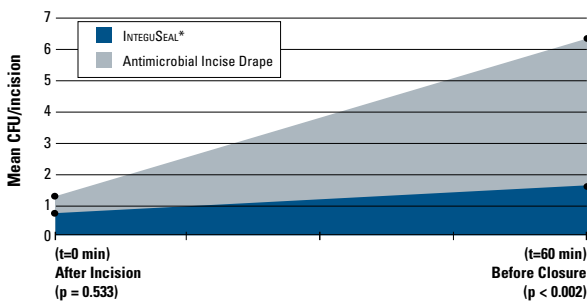


Figure 1. Mean colony forming units (CFUs) per incision of wound samples collected from *in vivo* porcine surgical incisions after surgical incision and before wound closure. Before wound closure, INTEGU SEAL* demonstrates superior performance compared to antimicrobial incise drapes in reducing the risk of skin flora contamination throughout a surgical procedure ($p < 0.002$).³

INTEGU SEAL* is effective in reducing the risk of skin flora contamination throughout a surgical procedure.

Effective against common and dangerous skin pathogens

In vitro studies demonstrated the ability of INTEGU SEAL* to immobilize methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis* and *Escherichia coli* on skin incision models.

In vitro experiments were performed using three bacteria species: a) methicillin-resistant *S. aureus* (MRSA), b) *S. epidermidis*, c) *E. coli*. In each experiment, porcine skin samples were randomly assigned to one of the following three test conditions:

- Non-inoculated skin (negative control)
- Inoculated skin (positive control)
- Inoculated skin with INTEGU SEAL*

Topical application of INTEGU SEAL* Microbial Sealant significantly reduces the amount of MRSA recovered from inoculated skin in an *in vitro* surgical incision model by 99.9%, *S. epidermidis* by 99.5% and *E. coli* by 96.6% ($p \leq 0.05$). The differences between mean microbial recovery from inoculated skin with and without INTEGU SEAL* were statistically significant ($p \leq 0.05$) for all three bacteria.

Figure 2
Mean Microbial Recoveries of Inoculated Skin Models

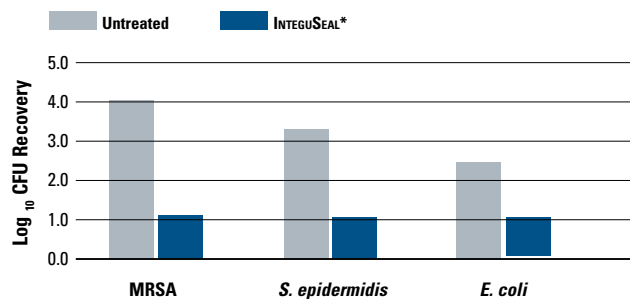


Figure 2. INTEGU SEAL* Microbial Sealant significantly reduces the amount of MRSA recovered in an *in vitro* surgical incision model by 99.9%, *S. epidermidis* by 99.5% and *E. coli* by 96.6% ($p \leq 0.05$).³

Immobilizes bacteria such as MRSA, *S. epidermidis* and *E. coli*.

Bacterial Immobilization: INTEGU SEAL* and 10% Povidone Iodine

An *in vivo* study performed by a facility external to Kimberly-Clark using Good Clinical Practice (GCP) regulations determined the bacterial immobilization attributes of INTEGU SEAL* and evaluated the ability of INTEGU SEAL* to reduce the risk of skin flora contamination. A standardized cup scrub method (ASTM E-1173-01, 1874-97) quantified the recoverable bacteria present on the skin.

Baseline samples were collected from inguinal sites and each site was then treated with one of the following randomly assigned treatments: 10% povidone iodine (aq), INTEGU SEAL*, or 10% povidone iodine (aq) with INTEGU SEAL*. Samples were collected from randomly assigned sub-sites at 15 minutes, 4 hours, and 24 hours after treatment.

Figure 3

Highly effective with a variety of prep solutions

Reduction of bacteria recovered *in vivo* using a cup scrub sampling technique four hours and twenty-four hours post treatment.³

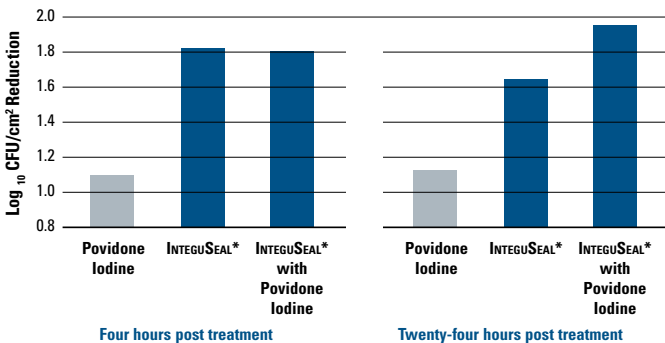


Figure 3. Mean reductions in the recovery of endogenous microorganisms (Log_{10} CFU/cm²) from inguinal skin at four hours and 24 hours evaluated relative to baseline values. All treatments significantly reduced microbial recovery ($p \leq 0.0001$). Greater reductions in microbial recovery from sites treated with INTEGU SEAL* were observed relative to sites treated with povidone iodine (aq) alone at all time points evaluated ($p \leq 0.05$).³

INTEGU SEAL* has long lasting microbial immobilization attributes as evidenced by significant reductions in the numbers of indigenous microorganisms collected from human skin. INTEGU SEAL* delivers these benefits when applied over a surgical preparation solution and when applied directly to untreated skin. INTEGU SEAL* is compatible with Iodophors, 2% CHG and Isopropyl Alcohol.

Can be used with or without Antimicrobial Incise Drapes

An *in vitro* study performed by a facility external to Kimberly-Clark evaluated the bacterial immobilization attributes of INTEGU SEAL* Microbial Sealant when used with and without an antimicrobial surgical incise drape.

The study was performed using a seeded *in vitro* skin incision model. Four test conditions were evaluated including bacteria only (microbial recovery control), antimicrobial incise drape, INTEGU SEAL* Microbial Sealant, and INTEGU SEAL* Microbial Sealant plus an antimicrobial incise drape. After treatment application, skin incisions were evaluated to determine the number of bacteria present in each incision.

Figure 4

Mean Recovery Using an *in vitro* Skin Incision Model

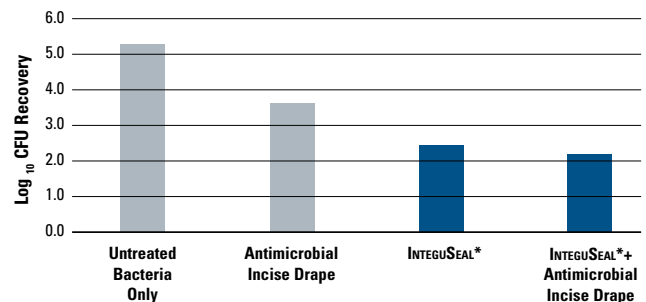


Figure 4. Mean microbial recovery from incisions in inoculated skin models treated with INTEGU SEAL* Microbial Sealant, antimicrobial incise drapes, and the combination of products. Both INTEGU SEAL* alone and INTEGU SEAL* followed by the antimicrobial incise drape resulted in reduced microbial recovery relative to the control and the incise drape alone ($p \leq 0.05$).³

INTEGU SEAL* has bacterial immobilization attributes as evidenced by a reduction in the recovery of bacteria from skin incisions.

Prep, Seal and Drape to Protect the Surgical Site

With today's heightened focus on preventing SSI's, many clinicians are incorporating INTEGUSEAL* Microbial Sealant in their perioperative process. INTEGUSEAL* is applied to the surgical site after prep and prior to incision, and forms a seal to immobilize skin flora pathogens residing deep in the skin.³

- **PREP:** INTEGUSEAL* is compatible with most commonly-used prep solutions, including iodophors, 2% CHG, and isopropyl alcohol. Always allow prep to dry before applying INTEGUSEAL*.
- **SEAL:** INTEGUSEAL* is easily applied to the patient's skin, regardless of contours or hair content. The ergonomic, single-use applicator evenly covers the incision area in a single stroke.
- **DRAPE:** Allow INTEGUSEAL* to dry—about 2 minutes—and then apply drapes as normal. Can be used with regular fenestrated or incise drapes.

When the procedure is complete, there is no need to remove INTEGUSEAL* before closing. It wears off naturally and gradually in a few days. INTEGUSEAL* is nonflammable, latex-free, non-irritating, and non-cytotoxic.³



Product Code	Description	Coverage Area (approx.)	Applicators Per Carton	Cartons Per Case
33730	IS 50	5 in x 10 in 12 cm x 25 cm	10	2
33733				4
33736	IS 100	10 in x 10 in 25 cm x 25 cm	10	2
33734				4
33737	IS 200	20 in x 10 in 50 cm x 25 cm	10	2
33735				4

All codes in **bold** indicate a sterile product. Non-sterile product available for custom trays.

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1. Perencevich EN, Sands KE, Cosgrove SE, Guadagnoli E, Meara E, Platt R. Health and economic impact of surgical site infections diagnosed after hospital discharge. *Emerg Infect Dis.* 2003;9(2):196-203.
2. Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol.* 1999 Nov;20(11):725-30.
3. Data on File, Kimberly-Clark Health Care.



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