



Introducing a first-in-class microbial barrier designed to seal and immobilize bacteria.

Surgical Site Infections result in up to \$7 Billion in costs every year¹

Despite refined surgical techniques, environmental changes in the OR, and the use of preventive antibiotics, infection at the surgical site remains the second most adverse event occurring to hospitalized patients and a major source of morbidity following operating procedures.

Compared to uninfected patients, patients with an SSI²:

- Stay hospitalized seven days longer
- Are sixty percent more likely to spend time in the intensive care unit
- Are five times more likely to be readmitted within 30 days of discharge
- Have twice the mortality rate³

Endogenous skin flora remain the #1 cause of SSI.

Skin flora wound contamination is a key factor in the development of surgical site infections. Because skin can never be completely sterilized, when skin is incised, the exposed tissues are at risk for contamination with endogenous skin flora. That is why Kimberly-Clark has developed INTEGUSeAL* Microbial Sealant.

KIMBERLY-CLARK* INTEGUSeAL* helps protect against skin flora migration into surgical incisions.

INTEGUSeAL* Microbial Sealant 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. epidermis* and *E. coli*
- Breathable properties permit normal skin transpiration
- Unique mechanism of action does not promote bacterial resistance

KIMBERLY-CLARK* INTEGUSeAL* Microbial Sealant is just one of the clinical solutions you can trust to meet the demands of your fast-paced world.

Whether your needs involve preventing healthcare-associated infections, surgical and digestive solutions or pain management, with Kimberly-Clark you'll always have one less worry.

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 INTEGUSeAL* 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 INTEGUSeAL* 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

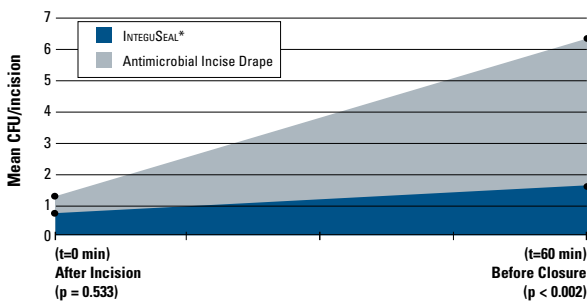


Figure 1. Mean colony forming units (CFUs) per incision of wound samples collected from *in vivo* porcine surgical incisions after surgical incision and before wound closure. Before wound closure, INTEGUSeAL* demonstrates superior performance compared to antimicrobial incise drapes in reducing the risk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

INTEGUSeAL* 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 INTEGUSeAL* 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 INTEGUSeAL*

Topical application of INTEGUSeAL* 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 INTEGUSeAL* were statistically significant ($p \leq 0.05$) for all three bacteria.

Figure 2
Mean Microbial Recoveries of Inoculated Skin Models

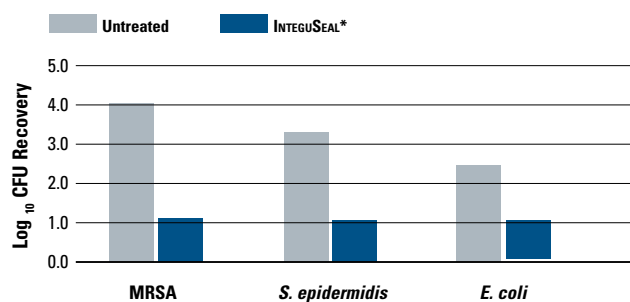


Figure 2. INTEGUSeAL* Microbial Sealant significantly reduces the amount of MRSA recovered in an *in vitro* surgical incision model by 99.9%, *S. epidermidis* by 99.5% and *E. coli* by 96.6% ($p \leq 0.05$).

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

Bacterial Immobilization: INTEGUSEAL* 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 INTEGUSEAL* and evaluated the ability of INTEGUSEAL* 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), INTEGUSEAL*, or 10% povidone iodine (aq) with INTEGUSEAL*. 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

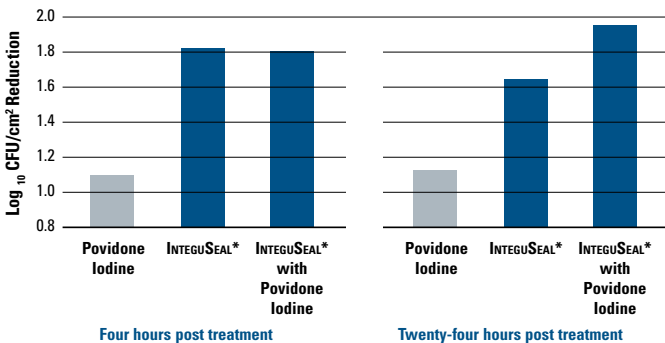


Figure 3. Mean reductions in the recovery of indigenous microorganisms (Log₁₀ CFU/cm²) from inguinal skin at four hours and 24 hours evaluated relative to baseline values. All treatments significantly reduced microbial recovery ($p \leq 0.0001$). Greater reductions in microbial recovery from sites treated with INTEGUSEAL* were observed relative to sites treated with povidone iodine (aq) alone at all time points evaluated ($p \leq 0.05$).

INTEGUSEAL* has long lasting microbial immobilization attributes as evidenced by significant reductions in the numbers of indigenous microorganisms collected from human skin. INTEGUSEAL* delivers these benefits when applied over a surgical preparation solution and when applied directly to untreated skin. INTEGUSEAL* 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 INTEGUSEAL* 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, INTEGUSEAL* Microbial Sealant, and INTEGUSEAL* 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

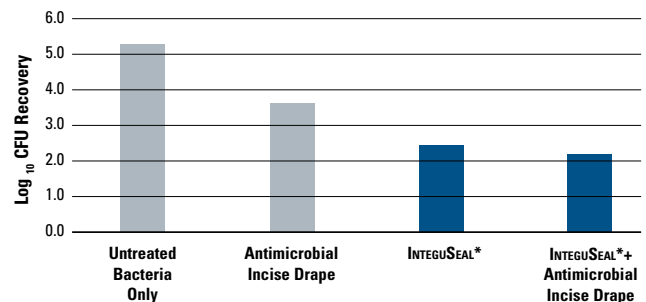


Figure 4. Mean microbial recovery from incisions in inoculated skin models treated with INTEGUSEAL* Microbial Sealant, antimicrobial incise drapes, and the combination of products. Both INTEGUSEAL* alone and INTEGUSEAL* followed by the antimicrobial incise drape resulted in reduced microbial recovery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

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

Quick, Easy, and Safe to Use

Intended for use after typical skin preparations and prior to a surgical incision, INTEGUSEAL* Microbial Sealant is a film-forming liquid that is quickly and easily applied to the patient's skin regardless of its contour, hair-content, and amount or type of flora present.

- Ergonomic single-use applicator delivers effective amounts of sealant, evenly covering incision area in a single stroke.
- Widely-used cyanoacrylate forms a safe, fast-drying, breathable barrier.
- Compatible with most common surgical techniques and materials.
- Need not be removed for skin closure; wears off naturally over five to seven days.
- Can be used with a variety of preps and incise drapes.
- Nonflammable, latex-free, non-irritating and non-cytotoxic.

Coverage for a Range of Surgical Applications

INTEGUSEAL* Microbial Sealant is available in two sizes:

- Model IS100 provides about 10 in. x 10 in. coverage.
- Model IS200 provides about 20 in. x 10 in. coverage.



Product Code	Description	Coverage Area (approx.)	Example of Procedures	Applicators Per Carton	Cartons Per Case
33731 33734	IS 100	25cm x 25cm 10 in x10 in	Cranial and spinal procedures, Laparotomies, Hernia Repair, Thyroid Surgery, Cardiac catheterization	10	4
33732 33735	IS 200	50cm x 25cm 20 in x 10 in	Cholecystectomy, Open Hearts, Lung Surgery, Total Joint Replacements	10	4

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

References:

1. 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.
2. 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.
3. Data on File, Kimberly-Clark Health Care.



Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call your sales representative, or visit our web site at www.kchealthcare.com/integuseal.

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