Bibliography

Table of Contents

Key Research Findings ................................................. 1

Efficacy Studies

Antimicrobial ................................................................. 3

Sterile Surface ............................................................. 5

Barrier Properties ......................................................... 8

Adhesion ................................................................. 9

Wound Contamination .................................................. 13

Breathability, Conformability and Strength ......................... 16

Safety Studies

Preclinical Studies ....................................................... 17

Human Safety Studies .................................................. 18
Cardiovascular Surgical Procedures

  “The group in which the sterile film was employed, contamination of gloves and catheters was virtually eliminated.”

  “The adhesive drape proved to be a protection factor against contamination of the surgical wound, even in patients with long length of stay before surgery and/or long duration of surgery.”

  “…significantly improved drape adhesion during surgery.”

Orthopedic Surgical Procedures

  “The results of this study are self-evident. The Ioban 2 drape, when used in conjunction with an alcohol cleanse is not only easy, but supplies sufficient antimicrobial action….thus providing time and cost advantages without sacrificing sterility.”
General Surgical Procedures


  Infection rates were significantly higher in patients when the incise drape lifted from the skin during surgery. It was determined that the 3M™ Ioban™ 2 Antimicrobial Incise Drape was “thinner, more adherent, had a higher moisture vapor transmission rate, was more pliable, and had increased conformability that was associated with better adhesion.”


  When studying a subgroup of thoracic patients, it was found there were significantly fewer patients with high postoperative skin counts (>25 cfu/plate) in the two study groups receiving alcohol and Ioban 2 antimicrobial incise drapes.


  “The iodophor-impregnated plastic incise drape reduced the contamination of the wound. In particular, isolates of normal skin organisms were less frequent when the drape was used in clean and clean-contaminated procedures.”


  This study demonstrated the antimicrobial effectiveness of a one-minute alcohol wash followed by the application of an Ioban 2 antimicrobial incise drape. “This method of skin preparation offers advantages for many patients undergoing abdominal delivery.”
Efficacy – Antimicrobial

3M™ Ioban™ 2 Antimicrobial Incise Drapes have an iodophor complex incorporated into the adhesive that provides continuous antimicrobial activity.

Iodophors: Safe, Effective
The articles below support the safety and efficacy of iodophors and highlight their widespread use in antisepsis. Note: Iodophors are not recommended for use on patients with a known sensitivity to iodine.

  “…a sensitization to povidone-iodine is rare.”

  “Iodophors are broad-spectrum antimicrobial agents…They are relatively nontoxic and virtually non-irritating to skin.”

  “Povidone-iodine has a rapid lethal effect and is non-selective in its action on bacterial pathogens.”

Compatibility of Povidone-Iodine and Chlorhexidine Gluconate
3M Study No. LIMS 9198 (2000)

Povidone-iodine and chlorhexidine gluconate (CHG) are two of the most commonly used antimicrobials in healthcare. The efficacy of using a CHG prep prior to an iodophor prep, or vice versa, has been questioned by the medical profession in hopes of increasing the antimicrobial efficacy of each formulation used alone. The Berenbaum checkerboard method was used to analyze antiseptic combinations of iodophors and CHG against Staphylococcus aureus and Escherichia coli. All antiseptic combinations in this in vitro assay demonstrated an additive effect. These results support using combinations of products containing povidone-iodine and chlorhexidine gluconate.
In Vitro Time-Kill Study

3M Study No. LIMS 7213 (1997)

Purpose:
A common in vitro* method for characterizing the efficacy of an antimicrobial agent is a time-kill study. This particular study measured the rate of bactericidal activity of available iodine in the 3M™ Ioban™ 2 Antimicrobial Incise Drapes compared to a negative control [i.e., non-antimicrobial (clear) incise drape] over time.

Methods:
Replicate samples of Ioban 2 and clear incise drapes were directly inoculated with a bacterial suspension, and incubated for 30, 45 and 90 minutes. The samples were neutralized at each time point to stop the antimicrobial reaction and then blended into a solution. Solutions were plated onto a growth medium and incubated for 24-48 hours. Colonies were counted and data was converted to log10 CFU. Log reductions were calculated by subtracting the log10 CFU bacterial recovery of the Ioban 2 drape samples at each time point from the log10 bacterial recovery of the clear incise drape at the corresponding time point.

Results:
Ioban 2 drapes were tested against 11 different organisms (See Table 1). Results shown in Figure 1 indicate the bacterial log reduction of Ioban 2 drapes for each organism. Within 45 minutes of exposure to the Ioban 2 drape, six organisms exhibited greater than a 4-log reduction: S. epidermidis, S. aureus, S. marcescens, E. coli, E. faecalis, and P. vulgaris. After 90 minutes of exposure to Ioban 2 drapes, two more organisms exhibited a greater than 4-log reduction: K. pneumoniae and B. cepacia.

*Note: One cannot extrapolate from in vitro results to in vivo performance.

Table 1

<table>
<thead>
<tr>
<th>Organisms Tested</th>
<th>Type(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus epidermidis</td>
<td>ATCC 12228</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>ATCC 27217</td>
</tr>
<tr>
<td>Serratia marcescens</td>
<td>ATCC 8100</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>ATCC 19615-1</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>ATCC 15442</td>
</tr>
<tr>
<td>Proteus vulgaris</td>
<td>ATCC 27972</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>ATCC 15221</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>ATCC 10741</td>
</tr>
<tr>
<td>(also referred to as Streptococcus faecalis)</td>
<td></td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>ATCC 23357</td>
</tr>
<tr>
<td>Burkholderia cepacia</td>
<td>ATCC 25608</td>
</tr>
<tr>
<td>(also referred to as Pseudomonas cepacia)</td>
<td></td>
</tr>
<tr>
<td>Candida albicans</td>
<td>ATCC 10231</td>
</tr>
</tbody>
</table>

Figure 1
By definition, a skin surface covered by a sterile incise drape is bacteria-free at the beginning of surgery. Whereas a skin surface that has been prepped has only been disinfected, not sterilized.

The plastic surgical adhesive drape: An evaluation of its efficacy as a microbial barrier


Purpose:
This study compared plastic incise drapes to cloth drapes under surgical conditions. In addition, laboratory experiments were done to assess the potential for bacterial build-up and/or migration under the drape. The primary measures for the surgical study were surface contamination of the drape, glove and wound contamination.

Methods:
Fifty total hip arthroplasties (THAs) and 22 total knee arthroplasties (TKAs) were performed with 3M™ Steri-Drape™ plastic incise drapes and 15 THAs were done with cloth drapes. Baseline skin counts were taken prior to prepping the skin. Patients were then prepped using an iodophor scrub and paint. Subsequently, post-prep skin counts were taken. The proposed incision site was then wiped with alcohol and skin flora samples were taken again. The incise or cloth drape was then applied. Immediately after the incision was made, and every 15 minutes throughout the procedure, wound edge samples were taken. Additionally, the surface of the drape was sampled every 15 minutes throughout the procedure. At the conclusion of the procedure, but before the drape was removed, the surgeon’s gloved-hands were tested and new gloves were donned. Once the drapes were removed, the underside of the drape, the patient’s skin and the surgeon’s gloves were sampled. Deep wound tissue samples were obtained at the beginning and end of the case.

Results:
• Samples taken during the procedure on the surface of the plastic incise drape revealed low microbial contamination (0.1-4.7 cfu). [Fig. 1]
• Cloth drapes showed increased contamination on the surface of the drape over time (0.1-31.8 cfu). [Fig. 1]
• Wound cultures from patients receiving cloth drapes showed the greatest contamination.
• A significantly higher level of deep wound contamination occurred with cloth drapes vs. plastic adhesive drapes (60% cloth vs. 6.1% plastic). [Fig. 2]

Figure 1

Contamination Levels on Drape Surfaces During Total Hip Replacement Surgery

Figure 2

Deep Wound Contamination in Total Hip Replacement Surgery
The relative importance of routes and sources of wound contamination during general surgery


**Purpose:**

The purpose of this study was to investigate the relative importance of routes and sources of wound contamination during general surgery. The key measures were bacterial sampling of the skin, wound, bile and glove tips. Observation of fluid strikethrough on surgical gowns was also recorded.

**Methods:**

A total of 188 patients undergoing biliary tract surgery were studied over a 100-week period. The operative site was prepped with 0.5% chlorhexidine in 70% ethanol. The first 52 patients were draped with four disposable drapes. A 3M™ Steri-Drape™ Incise Drape was used for the remainder of the study. Skin was sampled at the incision site prior to skin preparation. The wound was sampled intraoperatively in six different areas of the visceral layer/wound wall. Bile was aspirated into a syringe by puncturing the gall bladder prior to removal. All available gloves used by surgeons and assistants were sent to the lab for processing. Throughout the study the surgical team wore cotton or disposable gowns on alternating weeks. The distance blood and fluid had penetrated up the inside of the cuff was measured. An estimate of the dampness of the surgeon’s shirt and trousers was considered evidence of fluid passing through the gown.

**Results:**

- “When the bile was infected, bacteria from the bile accounted for most of the bacteria in the wound (>99%). However, when the bile was sterile, it was determined that the patient’s skin contributed a significant number of bacteria to the wound.”
- A significant correlation (p<0.001) was demonstrated between high skin counts and high wound counts.
- The use of an incise drape was shown to reduce wound contamination by approximately one-third on the visceral layer of the liver when no bile bacteria were present.
Contamination reduction during central venous catheterization


**Purpose:**
The purpose of this study was to evaluate the effect of an alcohol prep plus a 3M™ Ioban™ 2 Antimicrobial Incise Drape on the bacterial contamination of glove tips and indwelling vascular catheters. The key measures were glove tip and catheter contamination.

**Methods:**
A total of 60 patients scheduled for elective coronary artery surgery were randomly assigned to one of two groups. Group 1 received a one-minute skin prep consisting of three separate povidone-iodine swabs, followed by draping with a sterile non-absorbent aperture sheet. Group 2 received a one-minute skin cleansing with 70% isopropyl alcohol, followed by draping with a sterile non-absorbent aperture sheet. The sterile Ioban 2 incise drape was then placed over the aperture. After catheter placement, glove tips were tested for bacteria. After removal, 15cm of the distal end of the catheter was cultured for bacteria.

**Results:**
- In Group 1, 83% (25/30) of the patients had positive glove tip cultures, compared to 0% (0/30) in Group 2 (p <0.005). [Fig. 1]
- Four (13%) out of 30 patients in Group 1 had positive catheter cultures, while none of the patients in Group 2 had contaminated catheter tips. [Fig. 1]
- *Staphylococcus epidermidis* was the organism most commonly isolated from glove tip cultures. [Fig. 2]
The efficacy of adhesive plastic incise drapes in preventing wound contamination


Purpose:
This study was conducted to determine the value of incise drapes in preventing bacteria from migrating into the surgical wound. The primary measure in this study was the collection of wound irrigates.

Methods:
3M™ Steri-Drape™ Incise Drapes were used on 30 patients undergoing screw-plate fixations or unipolar arthroplasties for femur fractures. All patients were prepped with a three-minute skin scrub with Betadine. The prep was allowed to air dry and residual iodophor was wiped with alcohol. After drying, the skin was sprayed with a suspension containing Human Albumin Microspheres (HAM) one inch away from the incision line. This simulated bacterial indicator suspension was allowed to dry, the surgical site was squared off and a plastic incise drape was applied. At the end of the surgical procedure, wound irrigates were collected to retrieve HAM particles that may have migrated into the wound. The irrigates were centrifuged, washed and stained for identification under the microscope.

Results:
In all 30 cases the investigators were unable to identify HAM particles (simulated bacterial indicators) in any wound irrigates.

The plastic surgical adhesive drape: An evaluation of its efficacy as a microbial barrier


Purpose:
In addition to a surgical study (see page 5), French et al. also conducted laboratory experiments to assess the potential for bacterial build-up and/or migration under the drape. The primary measures were bacterial penetration through the drape and bacterial growth and migration under the drape.

Methods:
Backs of volunteers were scrubbed with 70% isopropyl alcohol for five minutes and skin flora samples were taken. Templates measuring 2 in. x 2 in. with a 14mm hole in the center were applied to the test sites. A Staphylococcus epidermidis culture was applied into each 14mm hole, spread evenly and allowed to dry. The template was then removed. Samples of dry and wet cloth drapes and plastic incise drapes were applied to the center of the inoculated area. Rodac impressions were made of each test site after four hours. When the drape samples were removed, the subject’s skin and the underside of the drapes were also sampled.

Results:
• Bacterial penetration did not occur with the plastic adhesive drape. Penetration did occur with linen drapes, especially when wet.
• Migration studies indicated no lateral movement of bacteria with the adhesive drape. It was not possible to determine migration with the linen drapes since so many bacteria penetrated to the top surface of these drapes.
• Bacterial growth under the adhesive drape was not detected. It was not possible to determine this for cloth drapes.
Development of a safe and effective one-minute preoperative skin preparation


Purpose:
The purpose of this study was to demonstrate the efficacy of incise drapes in preventing wound infections. Initially the study was designed to test the clinical efficacy of an incise drape containing iodophor in the adhesive. However, poor adhesion of this product resulted in the design of a new product, the 3M™ Ioban™ 2 Antimicrobial Incise Drape. This change resulted in additional studies, for a total of three. Preliminary Study 1 tested the original incise drape containing iodophor. Preliminary Study 2 tested the newly designed Ioban 2 incise drape in addition to evaluating five methods for skin preparation. The Definitive Study contained three study groups to evaluate various combinations of skin preps and draping methods. The primary measure for each of the three studies was wound infection rates.

Methods:
Patients scheduled for an elective surgery in which an incise drape could be applied were used for all three studies.

Preliminary Study 1
Three methods for protecting the wound from skin bacteria were compared: 1) cloth towels; 2) 3M™ Steri-Drape™ 2 clear incise drapes; and 3) an incise drape containing iodophor in the adhesive (product discontinued). All patients were first prepped with a 5-10 minute iodophor scrub followed by painting twice with iodophor.

Preliminary Study 2
This study evaluated the newly designed Ioban 2 antimicrobial incise drape with five different methods of skin preparation to determine which was associated with the best drape adhesion and least quantitative bacterial count on the skin after surgery.
1. One-minute scrub with 70% isopropyl alcohol
2. One-minute scrub with chlorhexidine in alcohol
3. One-minute scrub with 2% iodine in 50% alcohol
4. One-minute scrub with 2% iodine in 70% alcohol
5. One-minute scrub with 2% iodine in 90% alcohol

Definitive Study
Patients were randomized into one of three groups:
1. One-minute scrub with 70% alcohol plus Ioban 2 incise drape
2. One-minute scrub with 2% iodine in 90% alcohol plus Ioban 2 incise drape
3. Ten-minute iodophor scrub with two applications of iodophor paint. Cloth towels were then clipped or sutured to the wound edge.

Reliable skin adhesion is an essential performance characteristic of incise drapes.
Results:

Preliminary Study 1
A total of 729 patients participated in this study. The overall infection rate for patients receiving the antimicrobial incise drape (discontinued product) was significantly higher ($p < 0.01$). It became apparent during the study that this drape was lifting from the skin during the operation, so investigators began collecting data regarding the severity of lift. Of the drape lift recorded for 3M™ Steri-Drape™ 2 clear incise drapes, only 15% was considered severe. For the antimicrobial drape, 23% of the drape lift was considered severe. This difference was highly significant ($p < 0.001$). More importantly, the infection rates were significantly higher in patients when the incise drape lifted ($p < 0.0003$). [Fig. 1]

Preliminary Study 2
A total of 115 patients were enrolled in this study. The one-minute scrub with chlorhexidine in alcohol did not appear to have an advantage over 70% alcohol, so it was dropped after 28 patients. A solution of 2% iodine in alcohol was associated with the least number of infections and highest incidence of negative skin cultures post surgery. “Increasing the alcohol content from 50-90% was associated with faster drying, lower bacterial counts and better adhesion.” Overall, the newly designed 3M™ Ioban™ 2 Antimicrobial Incise Drape was more adherent than the previous antimicrobial drape.

Definitive Study
There were a total of 480 patients enrolled in this study. There were no significant differences in infection rates between the three study groups. Drape lift was never severe in this study, and minor lift was not associated with an increased incidence of infection. Skin cultures showed no significant differences between the three groups.
Comparative Skin Adhesion Study

3M Study No. LIMS 6904 (1997)

A common method for evaluating adhesion characteristics of a product is an adhesion-to-steel test. However, through years of experience and testing, it is known that adhesion-to-steel does not directly correlate to skin adhesion. 3M developed test methods for evaluating the adhesive performance of products on the skin. These methods along with adhesion-to-steel testing are used to ensure product performance.

Due to the inherent variability of skin from one person to another, skin adhesion data cannot be compared from one study to another (i.e., each study must be evaluated independently). However, adhesion data for numerous products within a particular study can be compared since all subjects within that study received each of the products in random order.

Results:

Comparative testing on human skin indicates that 3M™ Ioban™ 2 Antimicrobial Incise Drapes adhere better to skin than other incise drapes. [Fig. 1] When Ioban 2 incise drapes are properly applied they adhere securely, and the barrier properties and antimicrobial activity are utilized all the way to the wound edge.

Figure 1

Superior Adhesion to Skin

Adhesion Force (grams/0.5 inches)

- 3M™ Ioban™ 2
- Microban
- KC 82040
- KC 81040
- MCD D2050
- MCD D1050
- Baxter

N=8 Subjects
Skin preparations in CABG surgery: A prospective randomized trial


Purpose:
The purpose of this clinical trial was to compare the efficacy of two commercially available preps [3M™ DuraPrep™ Surgical Solution and E-Z scrub detergent and paint (Parke Davis, Sandy, Utah)] along with the use of 3M™ Ioban™ 2 Antimicrobial Incise Drapes. The key measures in this study were skin prep time, visibility of the prep, incise drape adhesion and incidence of wound infections.

Methods:
A total of 200 patients undergoing coronary artery bypass graft surgery (CABG) were randomly assigned to one of two study groups. The experimental group was treated with DuraPrep solution on the chest and legs plus an Ioban 2 incise drape on the chest. The control group received a traditional 5-10 minute scrub of the chest and legs, followed by an iodophor paint. Again, Ioban 2 drapes were applied to the chest. The prepping time was recorded from the beginning of the prepping procedure until the chest and legs were ready for incision. Visibility of the prep and drape adhesion were recorded at the end of surgery. Wounds were considered infected if purulent material drained from the incision site.

Results:
- There were no differences in postoperative wound infections between the two study groups, but there was a trend of lower infection rates in the experimental group at the chest incision site, especially with diabetic patients.
- Incise drape adhesion was significantly better (p<0.0001) in the experimental group, where drape lift occurred in only 3.9% of the cases compared to 94.8% in the control group. [Fig. 1]
- The percentage of patients with visible skin prep at the end of surgery was significantly higher (p<0.0001) in the experimental group prepped with DuraPrep solution (99%) compared to the control group (6.3%).

Figure 1

![Graph showing drape lift comparison between Iodophor Scrub & Paint and DuraPrep Solution](image-url)

*Significant difference p < 0.0001
The use of an iodophor-impregnated plastic incise drape in abdominal surgery: A controlled clinical trial


**Purpose:**
The purpose of this study was to conduct a prospective randomized trial comparing the efficacy of 3M™ Ioban™ 2 Antimicrobial Incise Drapes to a standard skin preparation technique in abdominal surgeries. The primary endpoints of the study were bacterial wound contamination and wound infection rates.

**Methods:**
Abdominal surgery patients were randomly assigned to either receive the Ioban 2 antimicrobial incise drape or enter the control group. All patients were given a routine skin prep consisting of an iodophor antiseptic followed by alcohol. The Ioban 2 incise drape was then applied to those patients designated to the test group. At completion of the operative procedure, and following closure of the deep fascia, a bacterial swab sample was taken and cultured for aerobic and anaerobic organisms.

**Results:**
- A total of 1,016 abdominal patients completed the trial.
- Wound infection rates were not found to be significantly different between the two study groups. However, wound contamination was reduced by the use of the Ioban 2 antimicrobial drape.
- Wound contamination occurred in 6.2% of all draped wounds compared to 10.3% of all wounds without the drape (p <0.03).
- In clean wounds (219 patients total) there was a significant difference in wound contamination. Contamination occurred in 9.1% of the patients draped with Ioban 2 incise drapes compared to 16.2% of the patients without a drape (p <0.05). [Fig. 1]

**Figure 1**

Efficacy – Wound Contamination

Reducing surgical wound contamination helps reduce the risk of surgical site infection.
Woven drape versus antimicrobial adhesive drape: Comparison of surgical infection incidence


Purpose:
The purpose of this study was to compare the rate of surgical site infections and surgical field contamination between patients using a woven cloth drape to those using an antimicrobial adhesive drape. The primary endpoints of the study were incidence of wound contamination and infection rates.

Methods:
This was a prospective randomized controlled trial of 120 patients undergoing heart surgery. The control group received woven surgical drapes while the test group received a 3M™ Ioban™ 2 Antimicrobial Incise Drape. The wound edge of each patient was sampled just prior to suturing the skin.

Results:
• The surgical site infection rate was similar in both groups [3.3% in the test group vs. 5% in the control group (p=0.5)], but the sample size was not sufficient to draw conclusions regarding infection rate. However, the incidence of wound colonization was lower in the test group receiving Ioban 2 drapes (21.7%) compared to the control group (36.7%) (p=0.07). [Fig. 1]
• In the multivariate analysis, the length of stay before surgery (p=0.001) and the duration of the surgery (p=0.008) proved to be significant risk factors for surgical colonization, while the Ioban 2 drape acted as a protection factor (O.R.=0.28; p=0.014). [Table 1]

Table 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient of Logistic Model</th>
<th>O.R.</th>
<th>(C.I. 95%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimicrobial Incise Drape</td>
<td>-1.29</td>
<td>0.28</td>
<td>0.098; 0.774</td>
<td>0.0144</td>
</tr>
<tr>
<td>Diabetes</td>
<td>-1.12</td>
<td>0.33</td>
<td>0.056; 1.908</td>
<td>0.2138</td>
</tr>
<tr>
<td>ASA &gt; 2</td>
<td>+0.65</td>
<td>1.92</td>
<td>0.419; 8.793</td>
<td>0.4008</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>+0.01</td>
<td>1.01</td>
<td>0.966; 1.047</td>
<td>0.7796</td>
</tr>
<tr>
<td>Duration of Surgery (hrs)</td>
<td>+0.84</td>
<td>2.31</td>
<td>1.246; 4.293</td>
<td>0.0079</td>
</tr>
<tr>
<td>Length of Stay Before Surgery (days)</td>
<td>+0.13</td>
<td>1.14</td>
<td>1.066; 1.212</td>
<td>0.0001</td>
</tr>
<tr>
<td>Baseline</td>
<td>-5.71</td>
<td>—</td>
<td>—</td>
<td>0.0008</td>
</tr>
</tbody>
</table>

Figure 1

Colonization Incidence at the Wound Edge

Table 1: Multivariate Analysis of Risk Factors for Colonization of the Surgical Wound (Swab = Positive)
Efficacy – Wound Contamination (continued)

Retrospective evaluation of an iodophor-incorporated antimicrobial plastic adhesive wound drape


Purpose:
The purpose of this retrospective study was to evaluate the clinical capability of an iodophor impregnated film to achieve the primary objective of a surgical drape (i.e., reduce the possibility of post-op wound infections). The primary endpoint was incidence wound infection.

Methods:
During a two-year period, 3M™ Ioban™ 2 Antimicrobial Incise Drapes were routinely applied in conjunction with a one-minute alcohol cleanse, to 649 total arthroplasties (381 hip and 268 knee). Previously infected joints were excluded. Patients were followed for a minimum of one year after surgery.

Results:
Of the 649 procedures using Ioban 2 incise drapes, only three infections were encountered (0.46%). This infection rate is comparable to the incidence previously observed, but offers time and cost advantages without sacrificing sterility.
3M™ Ioban™ 2 Antimicrobial Incise Drapes are made of a durable, breathable film that conforms to body contours. The following are summaries of laboratory studies that tested the breathability, conformability and strength of Ioban 2 incise drapes.

**Breathability—**

**Moisture Vapor Transmission Rate**

3M Study No. LIMS 8679

**Purpose:**
The purpose of this method is to determine the moisture vapor transmission rate (MVTR) (i.e. breathability) of film-based medical products applied to skin. The test method used to evaluate the MVTR of Ioban 2 incise film was the Bottle Method described in ASTM E96.¹

**Methods:**
Samples (measuring 1.5 inches in diameter) of the Ioban 2 incise drape were prepared for testing. Several 4-oz. bottles were filled with 50ml of tap water. A rubber washer was placed on the opening of each of the bottles, followed by a foil ring, a drape sample, and another foil ring. The bottles were then capped loosely with a screw-top lid. The bottles were placed inside a controlled temperature and humidity chamber, and the lids were tightened. Four hours later the bottles were weighed and then returned to the controlled chamber for another 18 hours. A final weight was obtained at the end of the study.

**Results:**
A total of 15 samples of Ioban 2 incise drapes were tested. The MVTR was calculated as grams of moisture vapor transmission per square meter of sample in 24 hours for each sample. The average MVTR for Ioban 2 incise drapes was calculated to be 505.5 g/m²/24hr. Comparative testing indicates that Ioban 2 incise film has a similar MVTR to other drape films on the market. Additionally, the normal moisture generation for a person at rest is 400 g/24hr.²

**Conformability and Strength—**

**Tensile Strength, Elongation and Fn Modulus Test**

3M Study No. LIMS 8679

**Purpose:**
The purpose of this method is to determine the tensile strength, elongation and Fn modulus of Ioban 2 incise film. This method is based on ASTM D882³, D3759⁴ and PSTC-31.⁵ The tensile strength and elongation at break point is an indication of the durability and tear-resistance of the plastic incise film. The Fn modulus is the force (F) required to stretch a sample a specified percent (n%), which is an indication of the conformability of the incise film. When an incise film is conformable, it allows for limb manipulation without tension.

**Methods:**
One-inch samples of the drape film were prepared for testing. The device used for testing was a Constant Rate Extension/Tensile Tester equipped with smooth clamp-type jaws. Samples were placed into the jaws of the device and properly aligned to eliminate slack. The device was turned on and allowed to stretch the sample. Measurements of force were recorded on a chart recorder.

**Results:**
Tensile strength is the maximum force applied to the drape sample at the break point, and is reported in pounds per sample width. Elongation is the maximum percent of stretch reached by the drape sample to the break point. The Fn modulus was tested at both 25% and 100%. Comparative testing indicates that Ioban 2 incise film has similar strength to other drape films on the market. However, Ioban 2 incise film demonstrated higher than average elongation.

---

¹ 1999 Annual Book of ASTM Standards, Vol 04.06, Thermal Insulation; Environmental Acoustics.
⁴ 1999 Annual Book of ASTM Standards, Vol. 15.09, Paper; Packaging; Flexible Barrier Materials; Business Imaging Products.
Cytotoxicity

Ioban 2 antimicrobial incise drapes were cut into eight 1cm² samples. Cultures containing a monolayer of mouse fibroblast cells were prepared for the study. Four pieces of the test article were placed in the quadrants of an agar dish with the adhesive side down, and another four were placed in a second agar dish with the adhesive side up. Cultures were then incubated for 24 hours. The extent of cell lysis under and around the test article was used to determine cytotoxicity.

Results:

Ioban 2 drapes were considered non-cytotoxic.

Primary Skin Irritation

Each of six rabbits received two doses (1-inch x 1-inch squares) of the test article for 24 hours. One test site was intact skin and the other was abraded skin. After sample removal, the test sites were examined and scored for dermal irritation at 1, 24, 48 and 72 hours.

Results:

Ioban 2 drapes were considered to be a slight irritant to the intact and abraded skin of rabbits.
21-Day Cumulative Irritation Potential (HCIPT)

The adhesive side of 3M™ Ioban™ 2 Antimicrobial Incise Drape samples were applied to backs of 12 volunteers. Twenty-four hours later, the samples were removed, sites were evaluated and graded for erythema, and new samples were reapplied to the same sites. This was repeated daily for a period of 21 days, except on Saturdays and Sundays. Samples applied on Friday were not removed until Monday. An irritation score was calculated by summing each individual’s scores on each of 15 evaluation days, adding six scores for Saturdays and Sundays equal to the scores obtained for the following Mondays, and normalizing the data to ten subjects.

Results:
Ioban 2 drapes received an irritation classification of “possibly mild under normal use.” This classification is typical for a product with a more aggressive adhesive. The increase in irritation may also be due to skin stripping with the daily removal of the drape samples.

Repeat Insult Patch Test (HRIPT)

Each of 213 volunteers received nine induction applications (three per week for three weeks) of Ioban 2 drape samples on the skin of the upper arm. All induction applications were graded for erythema at 24 or 48 hours after sample removal. A rest period of approximately 2 weeks followed the last induction application. Following the rest period, a challenge application was conducted for 24 hours. The challenge consisted of applying a drape sample to a naive site located away from the original induction site (i.e. opposite arm) and a simultaneous application to the original site. The challenge sites were graded at 24 and 72 hours after sample removal. Observations of the naive site provide the basis for interpretation of contact sensitization. Positive reactions at the original site during the challenge phase are not considered significant evidence of sensitization unless confirmed by observations at the naive site.

Results:
Mild to moderate irritation was observed in 19 subjects during the induction phase of the study. Two subjects exhibited responses of mild to moderate erythema with edema during the challenge phase and were subsequently rechallenged. One subject had no visible reaction to the rechallenge drape samples. The second subject did react to the rechallenge drape samples. There were no other indications of contact sensitization during the study.

Although sensitization to povidone-iodine is rare, it is known to occur. The 0.5% (1/213) rate of contact sensitization seen in this study is not unexpected for a product containing iodine.