solventum

3M™ Ioban™ 2 Antimicrobial Incise Drapes

Not all incise drapes are equal.

Clinical evidence summary

Contents

Trusted protection. Supported by evidence.

Ioban™ 2 Antimicrobial Incise Drapes are classified as Class III medical devices. This is because the iodine incorporated into the incise drape is a drug which works in the deeper layers of a patient's skin to reduce the risk of surgical site infections (SSI).[1,2]

In accordance with the Medical Device Regulation (Rule 14, MDR 745/2017) and the European Medical Device Directive (Rule 13, Annex IX, MDD 93/42/EEC), all devices containing a drug component (as defined in 2001/83/EC) which is liable to act on the human body with action ancillary to that of the device, are in Class III.[6,7]

To market a Class III medical device under the Medical Device Regulation (MDR) or Medical Device Directive (MDD) the manufacturer must present evidence to prove both the medical device and drug component are safe and effective. Solventum meets these criteria, and continuously updates technical and clinical evidence.

Ioban is the only Class III antimicrobial incise drape that has published clinical evidence across multiple specialites to support its use,[1–5] trusted by surgeons around the world to protect patients in millions of procedures.

Class IIa and IIb incise drapes have another intended use in comparison with Class III medical devices. These products are not classified as incorporating an active drug component that can penetrate the patient's skin.

You can check the classification of an iodophor impregnated incise drape by requesting copies of the EC design examination certificate and declaration of conformity from the manufacturer.

40 years of strong clinical evidence.

Extensively researched and peer-reviewed

3M™ Ioban™ 2 Antimicrobial Incise Drape has been extensively researched and has more published peer-reviewed studies than any other antimicrobial incise drape competitor (as of February 2023).

40+

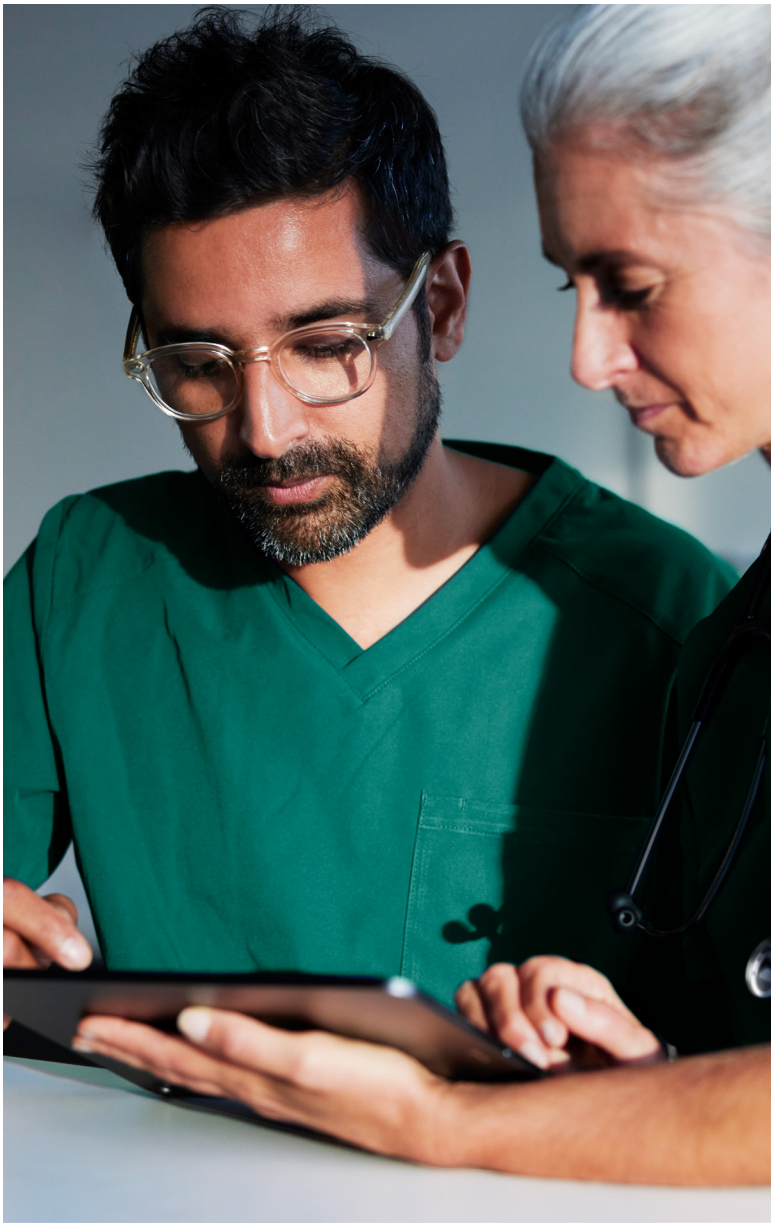
supporting pieces of published evidence
(as of February 2023)

Breadth of evidence

Ioban 2 Antimicrobial Incise Drape study publications have shown both clinical and economic results across a broad range of evidence ranging from poster presentations to randomised controlled clinical trials and global meta-analysis.

Strength of outcomes

Ioban 2 Antimicrobial Incise Drape is supported by evidence that met or exceeded the hypotheses across multiple endpoints including microbiological impacts that were associated with infection risk reduction outcomes as well as economic success when used as part of a comprehensive perioperative solution.[1,4,5]



Comparison of efficacy and cost of iodine impregnated drape vs. standard drape in cardiac surgery: study in 5,100 patients.[1]

Jonida Bejko, Vencenzo Tarzia, Massimiliano Carrozzini, Michele Gallo, *et al.* Comparison of Efficacy and Cost of Iodine Impregnated Drape vs. Standard Drape in Cardiac Surgery: Study in 5100 Patients. *J Cardiovasc Transl Res* 2015, 8:431–7.

Study design

Retrospective study considered prospectively collected data from 5,100 cardiac surgery patients between January 2008 and March 2015.

Study purpose

- To evaluate the impact of the use of two incise drapes (iodine-impregnated and non-iodine-impregnated) on incidence of surgical site infection in cardiac surgery.
- A detailed cost analysis was also completed.

Methods

Using a propensity-matched analysis, 808 patients from each group were matched for available risk factors.

Results

Surgical Site Infection (SSI) rate reduction

71%

SSI reduction

1.9% SSI rate (15/808) for patients receiving 3M™ Ioban™ 2 Antimicrobial Incise Drape vs. 6.5% (53/808) for the non-iodine-impregnated incise drape (p=0.001).*

Cost reduction

€773,495

The reason for this difference is the cost related to the treatment of the complications, such as negative pressure wound therapy, hospitalisation days, sternal wound revision, antibiotic therapy and antiseptics.

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study.

Key points summary

Ioban 2 Antimicrobial Incise Drape is a cost-effective intervention associated with a significantly lower incidence of SSI.

Plastic iodophor drape during liver surgery operative use of the iodophor-impregnated adhesive drape to prevent wound infection during high risk surgery.[2]

Yasuko Yoshimura, Shoji Kubo, Kazuhiro Hiroshashi, Masao Ogawa, *et al*. Plastic iodophor drape during liver surgery operative use of the iodophor-impregnated adhesive drape to prevent wound infection during high-risk surgery. *World J Surg*. 2003, 27:685–8.

Study design

Retrospective study of 296 patients undergoing liver resection for hepatocellular carcinoma (HCC).

Study purpose

To assess risk factors for wound infection after liver resection for HCC, with special attention to plastic adhesive drapes impregnated with iodophor.

Methods

- Retrospective regression analysis to assess risk factors for wound infection after liver resection surgery.
- The presence or absence of wound infection was recorded up to 30 days after operation.
- Variables examined included age, gender, BMI, alcohol abuse, smoking, systemic steroid use, DM, liver cirrhosis, laboratory test results, duration of preoperative hospital stay, preoperative transcatheter arterial embolisation, preoperative portal vein embolisation, type of skin incision, type of liver resection, operating time, intraoperative blood loss, autologous blood transfusion, and use of the plastic iodophor drape.

Results

Wound infection rate reduction

74%

wound infection reduction

Wound infections developed in 21 of 174 patients (12.1%) without the drapes and in 4 of 122 patients with the drapes (3.1%) (p=0.0096).

- Multivariate regression analysis showed that a low body mass index (BMI), smoking, and non-use of the iodophor drapes were independent risk factors for wound infections.
- Separation of the iodophor drape from the skin did not occur in any of the patients during the operation.
- None of the patients showed evidence of an allergic reaction to iodophor.
- Most wound infections were caused by skin organisms, including *Staphylococcus aureus* and *Staphylococcus epidermidis*.

Key points summary

Plastic adhesive drapes impregnated with iodophor appear to be useful for decreasing intraoperative contamination with skin bacteria, which may decrease the rate of wound infection, although a prospective study is necessary to obtain any definitive conclusions.

Incise draping reduces the rate of contamination of the surgical site during hip surgery: a prospective, randomised trial.[4]

Maryam Rezapoor, Timothy Tan, Mitchell Maltenfort, Javad Parvizi. Incise Draping Reduces the Rate of Contamination of the Surgical Site During Hip Surgery: A Prospective, Randomised Trial. *J Arthroplasty* 2018, 33:1891-5.

Study design

Prospective, randomised clinical trial, studying 101 patients undergoing open joint preservation procedure of the hip.

Study purpose

To evaluate the efficacy of iodophor-impregnated adhesive drapes for reducing bacterial count at the incision site.

Methods

- Patients without adhesive drapes were significantly more likely to have bacteria present at the time of skin closure, and at all time points when swab cultures were taken.
- Half the patients had the adhesive drape applied to the skin prior to incision, while the remainder underwent the same surgery without a drape.
- Culture swabs were taken from the surgical site at 5 points (pre-skin preparation, after skin preparation, post-incision, before subcutaneous closure, prior to dressing application) and sent for culture and colony counts.
- Mixed-effects logistic regressions were used to estimate effects of time and drape application on contamination rate.

Results

Bacterial contamination risk reduction

55%

reduction of risk of bacterial colonisation of incision site

12% of incisions with iodophor-impregnated adhesive drape and 27% without adhesive drapes were positive for bacterial colonization at closure of surgery (OR=2.38; 95% CI, 1.05–5.26; p=0.031).*

- Patients without an iodophor-impregnated drape were more likely to demonstrate a positive culture (adjusted OR 2.38; 95% CI, 1.053–5.263; p=0.031).*
- Patients without adhesive drapes were significantly more likely to have bacteria present at the time of skin closure, and at all time points when swab cultures were taken.
- Patients with no drape have increased odds (adjusted OR 5.89; 95% CI, 1.19–33.33; p=0.030) of bacterial contamination compared to those with drapes that demonstrated no lift off, whereas odds (adjusted OR 2.94; 95% CI, 0.24–33.33; p=0.397) seem to be reduced for patients with drape lift.*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study.

Key points summary

Iodophor-impregnated adhesive draping significantly reduces bacterial colonisation of the incision, specifically hip surgery.

Bacterial count at the skin was extremely high in some patients in whom adhesive drapes were not used, raising the possibility that a subsequent surgical site infection or peri-prosthetic joint infection could arise had an implant been utilised.

This study found that baseline bacterial colonisation predisposes the patient to an increased likelihood of colonisation at later time periods. However, the use of iodophor-impregnated drapes appears to mitigate this risk of colonisation. Furthermore, this study found that operative time was independently associated with culture positivity.

Antimicrobial activity and skin permeation of iodine present in an iodine-impregnated surgical incise drape.[8]

Casey AL, Karpanen TJ, Nightingale P, *et al.* Antimicrobial activity and skin permeation of iodine present in an iodine-impregnated surgical incise drape. *J Antimicrob Chemother.* 2015, 70:2255–60.

Study design

Ex vivo study on full-thickness human skin from 20 patients.

Study purpose

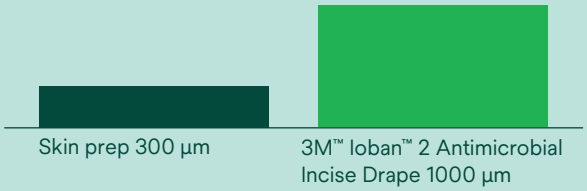
- To evaluate the antimicrobial efficacy of 3M™ Ioban™ 2 Antimicrobial Incise Drape against MRSA in a human skin model.
- To assess the presence of iodine from Ioban 2 Antimicrobial Incise Drape in the deeper skin.

Methods

- Donor skin was inoculated with either 1×10^3 or 1×10^6 cfu MRSA/cm^2 skin and mounted on Franz diffusion cells.
- Skin was incubated at room temperature for 5 minutes or 18 hours.
- The antimicrobial activity was assessed at 5 minutes, 2 hours and 6 hours after drape application, no additional skin antiseptic protocol done.
- Permeation of iodine into the skin was determined by assessing iodine concentration in different skin layers by mass spectroscopy (ICP-MS) following application of the incise drape for 6 hours.

Results

Antimicrobial activity



Iodine concentration in skin layers

- 1×10^3 EMRSA-15 and incubation for 18h: Application of the iodine-impregnated drape resulted in the recovery of significantly fewer cfu compared with the non-use of a drape (p=0.014).
- 1×10^6 EMRSA-15 and incubation for 18h: No significant difference in the number of cfu recovered when an iodine-impregnated or non-antimicrobial-impregnated drape was used or when no drape was used (p=0.935).
- 1×10^6 EMRSA-15 and incubation for 5m: Cfu counts were significantly lower for the iodine-impregnated drape than for the non-antimicrobial drape (p=0.001) and nonuse of a drape (p=0.002) skin permeation.
- Iodine concentration in skin layers up to 1000 µm are above MIC and MBC values.

Key points summary

Iodine-impregnated adhesive incise drapes show antimicrobial activity on the skin surface as well as in deeper skin layers and may help to suppress microbial re-colonisation around the surgical site. The use of iodine-impregnated incise drapes is preferable over the use of a standard incise drape or non-use of a drape.

Does an antimicrobial incision drape prevent intraoperative contamination? A randomised controlled trial of 1,187 patients.[9]

Anne Brun Hesselvig, Magnus Arpi, Frank Madsen, Thomas Bjarnsholt, et al. ICON Study Group. Does an Antimicrobial Incision Drape Prevent Intraoperative Contamination? A Randomised Controlled Trial of 1187 Patients. *Clin Orthop Relat Res*. 2020;478(5):1007–1015.

Study design

Prospective, multicenter, randomised clinical trial, of 1,187 patients undergoing primary knee arthroplasty between March 1, 2016 and April 13, 2018.

Study purpose

- To evaluate the effectiveness of antimicrobial surgical drapes reducing the risk of intraoperative microbial contamination in patients undergoing primary knee arthroplasty.
- To determine if other factors, such as sex, season, age and type of arthroplasty are associated with an increased risk of contamination.
- To determine if antimicrobial drape lift increases risk of contamination.
- A detailed cost analysis was also completed.

Methods

- Participants were patients older than 18 years undergoing primary knee arthroplasty.
- Patients were randomly assigned to operation with an antimicrobial drape (intervention group) or operation without (control group).

Results

Bacterial contamination risk reduction

33%

reduction of risk of bacterial colonisation of incision site*

10% contamination detected when iodinated drapes were used vs. 15% when they were not used (OR 0.61; 95% CI, 0.43–0.87, *p*=0.005).*

Drape lift

Antimicrobial drape lift of more than 10 mm separation from the skin had higher odds of contamination (OR 3.54; 95% CI, 1.64–11.05; p=0.0013).*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study.

Key points summary

The use of antimicrobial drape resulted in lower contamination risk than operating without an antimicrobial drape.

Procedures in females (OR=0.55; 95% CI, 0.39–0.80; p=0.002) and those performed in the central region were less likely to show contamination (OR=0.45; 95% CI, 0.25–0.78; p=0.006). No other factors were associated with the risk of contamination.*

Reducing the rate of surgical site infection using iodophor-impregnated adhesive incision draping in spine surgery compared with standard adhesive incision draping: a study in 2279 patients.[9]

Aylin Gencer, Christian Schichor, Joerg-Christian Tonn, Sebastian Siller. *Neurosurg Spine*. Nov 10 2023:1–7. doi:10.3171/2023.9.SPINE23764

Study design

Retrospective analysis of 2,279 patients in German high volume, tertiary care university spine centre.

Study purpose

Investigation of effect of iodophor-impregnated adhesive incision drape on Surgical Site Infection (SSI) rates and pathogen pattern compared to non-impregnated incision drape in patients undergoing spinal surgery.

Methods

- Retrospective analysis of all patients that underwent instrumental and non-instrumental spine surgery for non-septic spine disease between January 2018 and December 2021.
- With introduction of iodophor-impregnated incise drapes in Sep 2019 the total population was divided into a control cohort using non-impregnated incise drapes and a study cohort using iodophor-impregnated incise drapes.
- Epidemiological aspects, baseline characteristics, operative records and rates and characteristics of postoperative SSIs have been analysed.
- Patient surveillance was done for six months after surgery. SSI have been classified according to CDC criteria.

Results

Surgical Site Infection Rates

75%

SSI Risk Reduction

- Surgical Site Infection occurred in 2/1154 (0.2%) in the study group vs 9/1125 (0.8%) in the control group (p=0.036).
- Use of iodophor-impregnated incise drape was the only significant risk factor in uni- and multivariate analysis (Univariate: OR 0.22; 95% CI 0.05-0.99, p=0.049; multivariate: 0.19; 95% CI 0.04-0.9; p=0.04).
- Most SSIs were classified as “deep incisional” (45.5%) or “organ space” (45.5%).

Microbiological Findings

Staph aureus and *Staph epidemidis* were predominantly prevalent in both cohorts. Fecal germs such as *Enterococcus* or *Enterobacter* species were only found in the control group.

Key points summary

The study suggests that the use of iodophor-impregnated drapes significantly reduced SSI incidence in non-septic disease spine surgery compared with the use of non-impregnated incise drapes.

The effectiveness of sterile wound drapes in the prevention of surgical site infection in thoracic surgery.[3]

Kemal Karapinar, Celalettin Ibrahim Kocaturk. The Effectiveness of Sterile Wound Drapes in the Prevention of Surgical Site Infection in Thoracic Surgery. *Biomed Res Int*. 2019;2019:1438793. doi:10.1155/2019/1438793.

Study design

Retrospective analysis of 654 patients undergoing resection via thoracotomy with and without iodophor-impregnated incise drape.

Study purpose

Evaluate the effectiveness of iodophor-impregnated incise drape to prevent surgical site infection (SSI) and the effect on hospitalisation costs.

Methods

- Retrospective analysis of a control group without iodophor-impregnated incise drape between Jan 2013 and Dec 2014 and a study group with iodophor-impregnated drape after introduction of incise drapes between Jan 2015 and Dec 2016.
- Patients were stratified according to presence of risk factors and univariate analysis was performed.
- Hospital costs have been defined as data reported to social security institution and are including medication, materials and personnel cost throughout hospitalisation period.

Results

Surgical site infection rates

68%

SSI risk reduction

Surgical Site Infection occurred in 11/380 (2.90%) in the study group vs 25/274 (9.12%) in the control group (OR 0.3 95% CI 0.14-0.61, p=0.001).

Hospital cost

Hospital cost have been significantly lower in the study group (5942±2740) than in the control group (4813±1996) (OR 0.83;95% CI 0.78-0.98; p=0.0001).

Key points summary

The use of iodophor-impregnated drapes can be recommended to reduce SSI in lengthy thoracic surgical procedures.

A growing number of international guidelines recommend the use of antimicrobial drapes over non-antimicrobial drapes.

Guidelines are shifting to distinguish between the benefits of antimicrobial and non-antimicrobial incise drapes.

	Recommended by global organisations
KRINKO (2018)[10]	Increase of SSIs due to the non-antiseptically impregnated incision drape is reversed with using an antimicrobial incise drape.
APSIC (2019)[11]	When using adhesive drapes, do not use non-iodophor-impregnated drapes for surgery as they may increase the risk of surgical site infection. In orthopedic and cardiac surgical procedures where adhesive drapes are used, consider using an iodophor-impregnated incise drape, unless the patient has an iodine allergy or other contraindication.
NICE (2019)[12]	Do not use non-iodophor-impregnated incise drapes routinely for surgery, as they may increase the risk of SSIs. If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy.
AORN (2023)[13]	Do not use adhesive incise drapes without antimicrobial properties. Iodophor-impregnated adhesive incise drapes may be used in accordance with the manufacturer's IFU, unless contraindicated by a patient's allergy to iodine.
ICM (2018)[14]	Evidence indicates antimicrobial-impregnated incise drapes result in reduction in bacterial colonisation of the surgical site. "While bacterial colonisation of the incision may predispose to subsequent SSIs/PJIs, there is no literature to demonstrate that the use of incise drapes results in clinical differences in the rates of subsequent PJIs. Many surgeons prefer to utilise draping for physical isolation of sterile from nonsterile regions and to prevent migration of drapes during the procedure."

References

1 Bejko J, Tarsia V, Carrozzini M, *et al.* Comparison of efficacy and cost of iodine impregnated drape vs. standard drape in cardiac surgery: study in 5100 patients. *J Cardiovasc Transl Res*.2015;8:431–7.

2 Yoshimura Y, Kubo S, Hirohashi K *et al.* Plastic Iodophor Drape during Liver Surgery Operative Use of the Iodophor-impregnated Adhesive Drape to Prevent Wound Infection during High Risk Surgery. *World J. Surg*.2003;27:6.

3 Karapinar K, Kocatürk CI. The Effectiveness of Sterile Wound Drapes in the Prevention of Surgical Site Infection in Thoracic Surgery. *BioMed Research International*. 2019, doi.org/10.1155/2019/143879.

4 Rezapoor M, T, Maltenfort M *et al.* Incise Draping Reduces the Rate of Contamination of the Surgical Site During Hip Surgery: A Prospective, Randomized Trial. *The Journal of Arthroplasty* (2018), doi: 10.1016/j.arth.2018.01.013.

5 Hesselvig AB, Arpi M, Madsen F *et al.* Does an Antimicrobial Incision Drape Prevent Intraoperative Contamination? A Randomized Controlled Trial of 1187 Patients. *Clin Orthop Relat Res* (2020) 478:1007–1015. doi:10.1097/CORR.0000000000001142.

6 Medical Device Directive 93/42/EEC.

7 Medical Device Regulation 745/2017.

8 Casey AL, Karpanen TJ, Nightingale P, et al. Antimicrobial activity and skin permeation of iodine present in an iodine-impregnated surgical incise drape. *J Antimicrob Chemother.* 2015, 70:2255–60.

9 Aylin Gencer, Christian Schichor, Joerg-Christian Tonn, Sebastian Siller. *Neurosurg Spine*. Nov 10 2023:1–7. doi:10.3171/2023.9.SPINE23764.

10 KRINKO Surgical Site Infection Prevention Guidelines, 2018.

11 Asia Pacific Society of Infection Control Guidelines for the Prevention of Surgical Site Infections, 2019.

12 National Institute of Health and Care Excellence (NICE). Surgical site infections: prevention and treatment. (NG125) Published April 11, 2019. Accessed May 3, 2022.

13 Liz Cowperthwaite. AORN Guidelines for Perioperative Practice 2022. Denver, CO: Association for Perioperative Registered Nurses, 2022.

14 Gerald Atkins, Maria Alberdi, Andrew Beswick, *et al.* *J Arthroplasty*. 2019;34(2S):S85–S92.

KCI Medical Limited
Charnwood Campus
10 Bakewell Road
Loughborough
LE11 5RB

3M Healthcare EMEA Export Limited
2 Cumberland Place
Fenian Street, Dublin 2
D02 H0V5
Ireland