3M Science. Applied to Life.™

3M™ Ioban™ 2 Antimicrobial Incise Drapes

Not all incise drapes are equal.

Clinical evidence summary

3M™ Ioban™ 2 Antimicrobial Incise Drapes

Trusted protection. Supported by evidence.

Ioban 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[1] 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. 3M 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.

Comparison of efficacy and cost of iodine impregnated drape vs. standard drape in cardiac surgery: study in 5100 patients.

Bejko J, Tarzia 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(7):431–437. doi:10.1007/s12265-015-9653-1.

Objectives

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

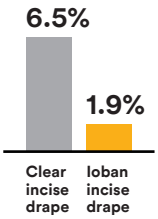
- To evaluate the impact of the use of 2 incise drapes (iodine-impregnated and not iodine-impregnated) on incidence of SSI in cardiac surgery
- A cost analysis was also completed

Methods

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

Results

Reduction in SSI incidence



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, as negative pressure wound therapy, hospitalisation days, sternal wound revision, antibiotic therapy and antiseptics.

Conclusion

- Ioban 2 Antimicrobial Incise Drape is associated with a significantly lower incidence of SSI and proved to be a cost-effective intervention in cardiac surgery

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

Rezapoor M, Tan TL, Maltenfort MG, Parvizi J. Incise Draping Reduces the Rate of Contamination of the Surgical Site During Hip Surgery: A Prospective, Randomized Trial. *J Arthroplasty.* 2018;33(6):1891–1895. doi:10.1016/j.arth.2018.01.013.

Objectives

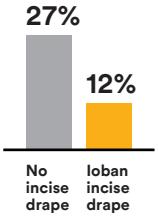
Prospective, randomised clinical trial, studying 101 patients undergoing open joint preservation procedure of the hip to evaluate the efficacy of iodophor-impregnated adhesive drapes for reducing bacterial count at the incision site.

Methods

- 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

Reduction of bacterial contamination of surgical site



12% of incisions with iodophor-impregnated adhesive drape and 27% without adhesive drapes were positive for bacterial colonisation at closure of surgery (OR = 2.38; 95% CI, 1.05–5.26; p =.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 = .031)
- Patients without adhesive drapes were significantly more likely to have bacterial 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 = .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

Conclusion

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.

- Iodophor-impregnated adhesive draping significantly reduces bacterial colonisation of the incision, specifically during 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 SSI 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

Does an antimicrobial incision drape prevent intraoperative contamination? A randomised controlled trial of 1187 patients.

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

Objectives

Prospective, multicentre, randomised clinical trial, of 1187 patients undergoing primary knee arthroplasty between 1 March 2016 and 13 April 2018.

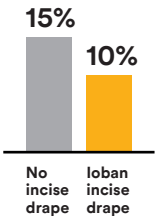
- To evaluate the effectiveness of antimicrobial surgical drapes in reducing the risk of intraoperative microbial contamination in patients undergoing primary knee arthroplasty
- To determine if other factors, such as sex, age, season and type of arthroplasty are associated with an increased risk of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

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

Reduction in bacterial contamination 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 increases risk of contamination

Antimicrobial drape lift of more than 10mm separation from the skin had higher odds of contamination (OR 0.6 [95% CI 0.43 to 0.86]; p = 0.005).

Conclusion

- 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
- The use of an antimicrobial drape resulted in lower contamination risk than operating on a patient without an antimicrobial drape. The findings suggest that antimicrobial drapes are useful in infection prevention

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

Clinical guidelines

Recommended guidance for incise drapes.

Organisation	Key guidance and recommendations
KRINKO (2018)[9]	▸ Increase of SSI due to the non-antiseptically impregnated incision drape is reversed with using an antimicrobial incise drape
NICE (2019)[8]	▸ Do not use non-iodophor-impregnated incise drapes routinely for surgery, as they may increase the risk of surgical site infection ▸ If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy
APSIC (2019)[10]	▸ When using adhesive drapes, do not use non-iodophor-impregnated incise drapes routinely for surgery, as they may increase the risk of surgical site infection ▸ In orthopaedic and cardiac surgical procedures where adhesive drapes are used, consider using an iodophor-impregnated drape, unless the patient has an iodine allergy or other contraindication
AORN (2022)[11]	▸ Do not use adhesive incise drapes without antimicrobial properties. Iodophor-impregnated adhesive incise drapes may be used in accordance with the manufacturer's instructions for use, unless contraindicated by a patient's allergy to iodine

Organisation	Consensus statement for incise drapes
ICM (2018)[12]	▸ 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."**

3M™ Ioban™ 2 Antimicrobial Incise Drapes

Make the right choice for your patient.

Antimicrobial effectiveness

Evidence demonstrates that iodine released over 6 hours from Ioban Antimicrobial Incise Drapes is able to penetrate the deeper skin layers at a concentration required for microbial death.[13]

Reduced risk of SSI

Reduction in the incidence of Surgical Site Infection (SSI) compared with standard drapes[1] or skin preps alone.[2]

Cost reduction

Ioban 2 Antimicrobial Incise Drape is a cost-effective intervention associated with significantly lower incidence of SSI.[1]

Recommended by clinical guidelines

Iodophor impregnated incise drapes are recommended in SSI guidelines around the world.[8–12]

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.

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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.

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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 NICE (2019) Surgical site infections: prevention and treatment, Clinical guideline [NG125]. Published April 2019.

9 RKI (2018) Prevention of postoperative wound infections: Commission recommendation for hospital hygiene and infection prevention (KRINKO).

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

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