



# The top 10 things you need to know about antimicrobial incise drapes, for procurement experts.

**Protect your patients beyond what the eye can see. To find out how best to protect patients during surgery, read our top 10 things you need to know.**

1

**You can not sterilise skin.**

Most surgical site infections are caused by microorganisms residing on the patients' skin. To prevent these microorganisms from ending up in the surgical wound, the skin of the patient is decontaminated with a skin antiseptic, and the patient is draped with surgical drapes. Studies show that microorganisms residing in the deeper skin layers are not affected by the decontamination of the skin surface.<sup>1,2</sup> This means that when the surgical site (the place where the incision is made) is decontaminated with skin antiseptic, it is not sterile. Without an (antimicrobial) incise drape, the surgical site is not sterile.

2

**How antimicrobial incise drapes work.**

Antimicrobial incise drapes stick to the surgical site, across the exposed skin area, covering the prepped skin area and over the edge to the surrounding fabric drapes. This is how a sterile surface is created. The surgeon then cuts through both the incise drape and the skin, so that the surface goes right up to the wound edge. At the same time the antimicrobial in the drape is killing bacteria on the skin and in the deeper layers of the skin to protect the wound from microorganisms, both mechanically with separation and chemically with antimicrobial.<sup>1,2</sup>

3

**Not all incise drapes are equal. Incise drapes can be divided in two groups.**

- 1 Transparent (plain) incise drapes are adhesive polymer films, they act as a mechanical barrier for microorganisms on the skin surface and they help to create a sterile field.
- 2 Antimicrobial incise drapes are completely different. Antimicrobial incise drapes contain an antimicrobial agent. First, they form a mechanical barrier for skin microorganisms, secondly they release an antimicrobial which kills microorganisms on the skin surface as well as in the deeper skin layers.<sup>1,2,4</sup> This antimicrobial effect makes them, according to the European Medical Device Directive, completely different products from the (plain) transparent incise drapes.<sup>5</sup>

4

**Antimicrobial incise drapes containing a drug component must be classified as Class III Medical Devices.**

According to the European Medical Device Directive, a 'medical device' is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for (amongst others) prevention of disease. With that definition, every incise drape is a medical device. All medical devices must be classified. Products which are generally regarded as 'low risk' are in a 'low(er)' class than products which are generally regarded as 'high risk'. In rule 13 of the Medical Device Directive it is defined that a medical device which contains a drug must be classified in the highest class (Class III). An antimicrobial as a skin antiseptic is a drug, therefore antimicrobial incise drapes must be classified as a Class III product.<sup>5</sup>

5

**Beware of imposters.**

Some products on the market look like antimicrobial incise drapes, but do not have Class III Certification, which is misleading. These are often only Class II certified, which means that only the device component has been approved and the antimicrobial has not been reviewed by the competent authorities. The drug component (antimicrobial) has not been proven effective.

6

**Imposters can be misleading.**

Since they can use the evidence from another manufacturer's product in their registration,<sup>5</sup> Antimicrobial efficacy of a medical device class III antimicrobial incise drape, must be proven by clinical investigations.

7

**Adhesion is important, and provides practical and clinical benefits.**

The surgeon will be focused on the ability of the drape to stay in place once adhered to the skin. Studies have shown that drape lift at the wound edge can cause contamination of the wound, therefore adhesion is critical.<sup>6</sup> Adhesion also assists in keeping surgical drapes in place during the procedure and maintaining the sterile field. Drapes that have poor adhesion can create issues.

8

**Guidelines recommend the use of antimicrobial incise drapes to reduce the risk of surgical site infection.**

Guidelines have increasingly become part of clinical practice, they translate best evidence into best practice. The NICE guidelines from the UK, as well as the recently revised guidelines from the German Robert Koch Institute, state that whenever an incise drape is used, it should be an iodophor impregnated one. Both guidelines are based on sound clinical evidence.<sup>7,8</sup>

9

**Surgeons prefer antimicrobial incise drapes.**

Surgeons like to use antimicrobial incise drapes for several reasons. Importantly, they provide peace of mind by creating and maintaining a sterile surface. Antimicrobial incise drapes are easy to use, conform to the skin of the patient and stay in place for the complete operation. Surgeons like the proven efficacy with regards to reduction of wound contamination and infection rates. Using antimicrobial incise drapes is guideline compliant and cost effective.<sup>7,8</sup>

10

**Using a proven Class III incise drape reduces cost.**

When a proven antimicrobial incise drape is used, it reduces the risk of infection. Treatment of infection adds significant cost to the institution in terms of length of stay, additional surgeries and other costs.

A recent study by Bejko et al showed that the use of iodophor impregnated incise drapes can significantly reduce infection risk and the associated cost.<sup>9</sup>

**References**

- 1 Casey AL, Karpanen TJ, Nightingale P, Conway BR, Elliott TS (2015) Antimicrobial activity and skin permeation of iodine present in an iodine impregnated surgical incise drape. *J Antimicrob Chemother* 70(8):2255–2260.
- 2 Kramer A, Assadian O, Lademann J (2010) Prevention of postoperative wound infections by covering the surgical field with iodine impregnated incision drape (loban 2). *GMS Krankenhhyg Interdisziplin* 5(2):Doc8.
- 3 Parks PJ, Nohra GK Reduction of Surgical-site Infections in Neurosurgery – The Advantage of Antiseptics Combined with a Sterile Surface. *European Neurological Review* 2009;4(2):116–119 DOI: <http://doi.org/10.17925/ENR.2009.04.02.116>.
- 4 Eyberg C, Morse D, Olson L, et al., An in vitro time kill study to compare the antimicrobial activity of three antimicrobial surgical incise drapes, 2009, 19th Annual Scientific Meeting of the Society for Healthcare Epidemiology of America (SHEA), 19–22 March 2009, San Diego, California.
- 5 Regulation (EU) 2017/745 of the European Parliament.
- 6 Grove, Gary & I Eyberg, Chou. (2012). Comparison of Two Preoperative Skin Antiseptic Preparations and Resultant Surgical Incise Drape Adhesion to Skin in Healthy Volunteers. *The Journal of bone and joint surgery, American volume*. 94. 1187–92. 10.2106/JBJS.K.00261.
- 7 Surgical Site Infections: prevention and treatment Clinical guideline Published: 22 October 2008 NICE National Institute for Health and Care Excellence.
- 8 Prävention postoperativer Wundinfektionen Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch Institut Bundesgesundheitsbl 2018-61:448–473.
- 9 Bejko J, Tarzia V, Carrozini M et al (2015) Comparison of efficacy and cost of iodine impregnated drape vs. standard drape in cardiac surgery: study in 5100 patients. *J Cardiovasc Transl Res* 8(7):431–437.