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3M™ Ioban™ 2 Antimicrobial Incise Drape

A Class III medical device

Introducing Ioban 2 Antimicrobial Incise Drape

Ioban 2 antimicrobial incise drapes are designed to help reduce the risk of surgical site infection. They are applied to a patient's skin at the site of a surgical incision to create a sterile surface and deliver broad-spectrum antimicrobial activity throughout the surgical procedure.

Ioban 2 antimicrobial incise drapes contain an adhesive impregnated with an iodophor, which has a microbiocidal effect on the patient's skin flora.

As the active ingredient in Ioban drapes is an iodophor, it is classed as a drug-containing medical device. Therefore, it is categorised a Class III medical device in accordance with the European Medical Device Directive.

Medical Device Directive 93/42/EEC – Rule 13, Annex IX

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive M5 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

Why does the classification of a medical device matter?

Medical device products are rated by their potential risk, from low (Class I) to high (Class III). To be approved for sale in the EU and the UK, class III medical devices containing a drug component must undergo a special evaluation process, called a consultation procedure.

During the consultation procedure the responsible Notified Body carries out a review of the technical product documentation, as provided by the manufacturer. The Notified Body is then responsible for consulting the relevant drug authority, to assess the quality, safety and efficacy of the drug component.

Only when the medical device and the drug component are fully approved can the product be placed on the market within the European Union and the UK.

How can I find out whether a product is a Class III medical device?

Once approved for sale within the EU, the manufacturer receives an EC Design Certificate for the product, as well as an EC Certificate. The manufacturer is then able to issue a Declaration of Conformity, which indicates that the product meets all necessary requirements of the regulation applied to the product.

It is this Declaration of Conformity that will indicate the Classification of the medical device. All certificates can be requested from the manufacturer, as an indication that the product has been evaluated for safety, efficacy and performance.

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Should all iodophor-impregnated incise drapes be Class III medical devices?

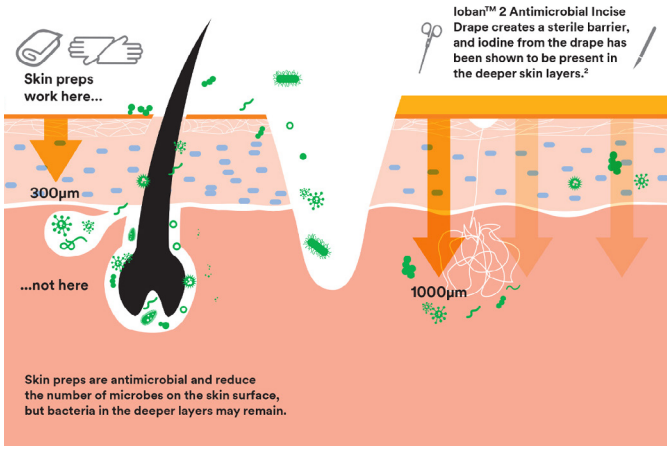
Numerous clinical guidelines across the world state that if an incise drape is to be used, it should be iodophor-impregnated. NICE guidance states trhat using a non-iodophor-impregnated drape routinely for surfery may increase the risk of SSIs.[1]

In accordance with the Medical Device Directive, any device containing a drug (i.e. an iodophor) must be Class III. If a medical device contains a drug product and is classified as class II, then the drug component has probably not been evaluated, and therefore has not been assessed to guarantee the safety, efficacy and performance of the device. Only Class III medical devices can provide this level of assurance.

What does the Class III certification of Ioban 2 antimicrobial Incise drapes mean to you?

As a customer of Ioban 2 antimicrobial Incise drapes, you can be assured that the device meets the highest regulatory requirements. In line with the Medical Device Directive, Solventum resubmits technical data every five years to maintain its certification. This proves that the product is safe and effective.

In addition, Ioban incise drapes are backed up with three decades of scientific and clinical evidence. It has been used in millions of procedures, across the world, all meaning you can trust and rely on Ioban drapes, time and time again.



Benefits

- Creates a sterile surface at the beginning of surgery, reducing the risk of bacteria transferring into the surgical wound[2]
- Clinically proven to help reduce the risk of contamination and immobilise bacteria on the skin[2,3]
- Provides continuous broad-spectrum antimicrobial activity all the way to the incision edge
- Adheres to the operative site, eliminating the need for towel clips/clamps, and hold the drapes in place[2]
- Low memory stretch allows limb mobilisation or heavy retraction with reduced tension to the skin
- Made from a breathable, latex-free film

1. National Institute of Health and Care Excellence (NICE). Surgical site infections: prevention and treatment. (NG125) Published April 11, 2019. Accessed May 3, 2022.
2. French MLV, Eitzen HE, Ritter MA. The plastic surgical adhesive drape: an evaluation of its efficacy as a microbial barrier. *Ann Surg.* 1976; 184: 46–50.
3. Dewan PA, Van Rij AM, Robinson RG, Skeggs GB, Fergus M. The use of an iodophor-impregnated plastic incise drape in abdominal surgery – a controlled clinical trial. *ANZ J Surg.* 1987; 57: 859–63.

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