Science.
Applied to Life.™

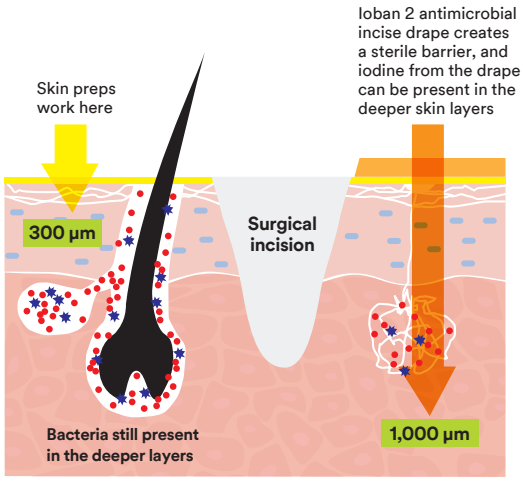
3M™ Ioban™ 2 Antimicrobial Incise Drape A Class III medical device

Introducing Ioban incise drapes.

Ioban 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 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, 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 licensed for sale within the European Union.

How can I find out whether a product is licenced as 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 directives 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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A Class III medical device

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. This is due to evidence suggesting that non-iodophor incise drapes can increase the risk of surgical site infection.

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 incise drapes mean to you?

As a customer of Ioban incise drapes, you can be assured that the device meets the highest regulatory requirements. In line with the Medical Device Directive, 3M resubmits technical data every five years to maintain its licence. 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.

Creates a sterile surface, reducing the risk of bacteria transferring into the surgical wound

Antimicrobial impregnated film ensures constant contact with a patient's skin – even during irrigation

Provides continuous broad-spectrum antimicrobial activity all the way to the incision edge

Adheres securely to the skin to help prevent drape lift and prep wash-off

Low memory stretch allows limb mobilisation or heavy retraction with reduced tension to the skin

Made from a breathable, latex-free film

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