

# M Surgical Safety Solutions Not all incise drapes are created equal

### **Class Matters**

-	3M™ Ioban™ Incise Drapes are classified as Class III medical. This is because the
	iodine in the incise drape is a drug which works in the deeper layers of a patient's
	skin <sup>1</sup> to reduce the risk of surgical site infections. <sup>2-3</sup>

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In accordance with the European Medical Device Directive (Rule 13, Annex IX, MDD 03/42/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.<sup>5</sup>



To be awarded a Class III status, the manufacturer must present evidence to prove both the medical device and drug component are safe and effective. 3M meets these criteria, and resubmits technical and clinical evidence every five years to maintain this prized status.

/	Class II iodophor incise drapes do not offer the same level of assurance. Their drug
	component has not been assessed for safety or efficacy as the manufacturer has
	submitted evidence that the drug component does not act on the human body.
	That means any drug contained within these devices is not considered to act
	on the human body.



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.

When choosing an incise drape, there are many factors to consider in terms of effectiveness and patient safety.

Clinical guidelines across the world stipulate that if an incise drape is used, it should be an antiseptic impregnated one, as non-antiseptic impregnated incise drapes may increase the risk of surgical site infections (SSIs).<sup>67</sup>

## **Sterilisation Method**

Incise drapes are usually sterilised using either gamma irradiation or ethylene oxide. The method used can have an impact on the chemical composition of the iodine contained within the drape.

It is well-documented that when products containing iodine come into contact with ethylene oxide, ethylene iodohydrin can be produced. This can be a skin irritant and is why 3M sterilises 3M<sup>™</sup> Ioban<sup>™</sup> Incise Drapes using gamma irradiation.

## Products you can trust

Ioban drapes have been used in millions of procedures worldwide for over 30 years. Its effectiveness has been documented in numerous clinical studies dating from the 1980s right up to the present day. No other incise drape offers this level of assurance.

Clinical studies have shown that loban drapes are effective at reducing wound contamination<sup>3-4</sup>, surgical site infections<sup>2-3</sup>, and most recently, cost.<sup>2</sup>



## **Unrivalled support**

3M is dedicated to providing customer education and training to ensure the right product is used at the right time. Contact your local 3M representative to arrange:

#### **In-service training**

Our clinical specialists provide hands-on product application and removal training.

#### **Clinical education**

Our technical experts regularly run education sessions either at a hospital level or at local 3M study days, seminars and events throughout the year.

#### **Copies of clinical evidence**

3M can provide summaries of all the supporting clinical evidence if required.

#### Access to 3M<sup>™</sup> Health Care Academy

Learn at a time suitable for you, with our on-demand education.



We're on a mission to protect patients from preventable surgical site infections.

## Join us!

#### **References:**

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