

## Patient Information Leaflet for Ethicon™ Bone Wax

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your device can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

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| Product Codes: W31C |
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### Device Description

ETHICON™ Bone Wax is made by mixing natural wax made by bees (beeswax) with materials to soften the wax.

ETHICON™ Bone Wax provides a physical barrier to stop bleeding from bones. It does not contain any medicine to stop bleeding.

ETHICON™ Bone Wax should be used only by doctors who have been trained to control bleeding from bones.

ETHICON™ Bone Wax is sterile (free of germs). It is opaque and has a waxy odour. It is made by mixing the three materials shown below.

| Material                           | Approximate Percent |
|------------------------------------|---------------------|
| Beeswax (natural wax made by bees) | 72.45%              |
| Paraffin (soft wax)                | 15.02%              |
| Isopropyl Palmitate (wax softener) | 12.5%               |

### Information for Safe Use

The selection of device for any given patient is a function of numerous factors including, but not limited to, the patient's past medical and surgical history, current medical condition (i.e., comorbidities), surgical technique, and size and location where temporary wound or organ support is required.

There is always a chance of adverse reactions with any type of surgery. Some reactions could be due to your overall health condition. Some reactions could be related to just having the surgery. Some reactions could be related to the materials being placed into the body. It is difficult to know the source of some adverse reactions. Contact your doctor about any signs of infection or adverse reactions. Be sure to keep up with your doctor visits after surgery.

This device will not cause any issues with a medical test called MRI. MRI means magnetic resonance imaging.

### **Possible Adverse Reactions**

Your doctor will provide information about the adverse reactions of your operation. All operations have adverse reactions. The risk of a serious adverse event is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns about your procedure.

Possible adverse reactions may include:

- Infection (or make an existing infection worse)
- Inflammation (redness, swelling, pain and feeling of heat)
- Interference with bone healing

These adverse reactions may require additional treatment. This list does not include all adverse reactions. Your doctor can further explain the possible adverse reactions of your operation.

### **Expected Implant Lifetime and Follow Up**

ETHICON™ Bone Wax is not absorbed by the body. It will remain for life unless it is removed

### **Reporting Adverse Reactions**

If you wish to report any adverse reactions you believe are a result of your procedure implant, please speak with your doctor/medical team or report the information to Johnson & Johnson Medical Product Safety Department at [productsafetyjjmanz@its.jnj.com](mailto:productsafetyjjmanz@its.jnj.com) or the Therapeutic Goods Administration at <https://www.tga.gov.au>

For access to this leaflet, please visit: <https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets>

### **Sponsor**

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