Instructions for Use
CuraWax®
non-absorbable haemostatic bone wax

EN

1. PRODUCT DESCRIPTION

CuraWax® is a non-absorbable haemostatic bone wax which is fabricated from a mixture of beeswax and isopropyl palmitate. It is obtained by fusion with hot water from the walls of the honeycomb *Apis mellifera Linné*, and isopropyl palmitate, which is a solvent with good emulsifiability. CuraWax® is opaque and has a distinctive odor and color.
CuraWax® is used to control bleeding from osseous surfaces, acting by physical tamponade of the bone canals, to achieve local haemostasis of osseous structures.
The non-absorbable CuraWax® product is supplied in two box sizes: a box with 12 pieces and a box with 24 pieces (containing 2.5 gram bone wax per pouch). CuraWax® is packaged individually in a double pouch packaging, sterilized by gamma irradiation, and is for single use only.

2. INDICATIONS

CuraWax® is used to control bleeding of osseous surfaces, acting by physical tamponade of the bone canals, to achieve local haemostasis of osseous structures. Once open, and before CuraWax® is applied to the bone surface, it should be softened by the use of an aseptic technique until the desirable consistency is achieved. After achieving the desirable consistency, CuraWax® can be applied to the bone surface according to the preferences of the surgeon during the surgical procedure.
CuraWax® is used for the mechanical haemostasis in osseous structures in: Thoracic surgery, Neurosurgery, Orthopaedics and Traumatology, Dental, Oral and Maxillofacial surgery.

3. CONTRA-INDICATIONS

CuraWax® should not be used when bone fusion is required as it can act as an artificial barrier and counteract bone regeneration (osteogenesis).

4. SIDE EFFECTS

The adverse effects associated with the use of CuraWax® include: transient local irritation in the wound area and in tissues immediately adjacent to the site of implantation. CuraWax® can worsen existing bacterial infection.

5. MODE OF ACTION

CuraWax® achieves local bone haemostasis by acting as a mechanical barrier since it is a non-absorbable and inert material that does not have a biochemical action with the organism. CuraWax® is only recommended as local bone haemostatic.

6. DIRECTIONS FOR USE

Once CuraWax® is opened it should be softened by the use of an aseptic technique until the desirable consistency is achieved. After achieving the desirable consistency, CuraWax® can be applied to the bone surface according to the preferences of the surgeon during the surgical procedure.
Before using CuraWax®, the user must have good knowledge of surgical procedures and techniques, as well as the techniques applicable to this type of device. In order to handle infected or contaminated wounds, appropriate surgical techniques should be followed.

7. IMPORTANT NOTICE!

Do not reuse, since it is a sterile implantable medical device for single-use only. Any part not used by the end of surgery should be discarded. CuraWax® **should not be reused** for reasons of asepsis, because it could contravene the surgical technique and put the patient at risk for possible infection.
CuraWax® ***should not be re-sterilized*** by any method since it can cause an important alteration in the chemical or physical composition and put the patient at risk. Do not use CuraWax® if the packaging is opened or damaged as the sterility of the product will have been lost.

8. WARNINGS

Before using CuraWax®, the user must have good knowledge of surgical procedures and techniques, as well as the techniques applicable to this type of device. In order to handle infected or contaminated wounds, appropriate surgical techniques should be followed. Do not use when the package has been opened or has been damaged.
CuraWax®, non-absorbable haemostatic bone wax is a single-use product which is not suitable for re-sterilization.

9. GENERAL STORAGE AND HANDLING

The product should be stored in its original sealed protective outer packaging and must be protected from direct sunlight and heat. It must be preserved in its original packaging in a clean and dry environment at a temperature between 15-30 °C (288-303K) and with relative humidity no greater than 65%. Do not use the product after the expiration date.
Prior to opening, the packaging ensuring the integrity of the sterile barrier has to be inspected. Open the package just prior to use in a patient.

9.1 Packaging and sterility
The products are packaged sterile.
The packaging consists of:
- Storage and transport packaging
- Sterile packaging (sterile primary and secondary packaging)

The packaging is subject to and conforms to European & International legislation and other applicable standards. The packaging protects the product from external influences and guarantees its sterility during storage.

9.2 Handling of the sterile packaging
Remove the product from the sterile package using acceptable aseptic technique.

9.3 Sterilization
The products are sterilized by Gamma radiation.

9.4 Storage
The product must be protected from direct sunlight and heat, preserved in original packaging in a clean and dry environment at a temperature between 15-30 °C (288-303K) and a relative humidity with a maximum of 65%. Do not use the product after the expiration date.

9.5 Expiration date:
5 years from date of manufacture indicated on the label.

9.6 Discarding unused or contaminated material
Discard all contaminated material and unused opened product following standard hospital procedures and the precautions for disposal of infectious biological waste, in accordance with the applicable laws of each country.

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Do not re-use		Do not resterilize	
Consult instructions for use		Store between 15 °C and 30 °C	
Date of Manufacture, Year/Month/Day	YYYY/MM/DD	Keep away from sunlight	
Use-by date, Year/Month/Day	YYYY/MM/DD	Keep dry	
Reference number, Catalogue number	REF	Do not use if package is damaged	
Batch Number	LOT	Sterilized using Gamma Irradiation	STERILE R