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## BONE WAX

### DESCRIPTION

Bone Wax is a sterile mixture of beeswax, paraffin, and isopropyl palmitate, a wax-softening agent. It is opaque and has a waxy odor.

### INDICATIONS

Bone Wax is indicated for use in the control of bleeding from bone surfaces.

### ACTIONS/PERFORMANCE

Bone Wax achieves local hemostasis of bone by acting as a mechanical (tamponade) barrier. It does not act biochemically and is nonabsorbable.

### CONTRAINDICATIONS

Do not use Bone Wax where rapid osseous regeneration and fusion are desired.

The use of bone wax may be inappropriate in patients with known allergies to bees or bee byproduct including pollen.

### WARNINGS

Do not subject Bone Wax to excessive heat. Bone Wax may inhibit osteogenesis and may act as a physical barrier to the reparative process.

Do not resterilize; resterilization may alter the physical characteristics of this material. Do not manipulate with latex gloves as latex proteins deposited in the Bone Wax may precipitate an allergic reaction.

Do not use if package is opened or damaged. Discard open, unused Bone Wax.

### PRECAUTIONS

Use Bone Wax sparingly. Remove excess Bone Wax from the operative site. Open the package just prior to use to minimize the possibility of contamination and excessive drying.

### ADVERSE REACTION

Mild inflammatory reactions have been reported in tissues immediately adjacent to the site of implantation. Like all foreign

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bodies, Bone Wax may enhance an existing infection. Pollen granules imbedded in beeswax may elicit an allergic reaction.

### DOSAGE ADMINISTRATION

Use Bone Wax immediately after removal from the package. Using aseptic procedure, warm Bone Wax to desired consistency by manipulation with the fingers or by immersion of the unopened foil packet in a warm sterile solution. Apply the softened Bone Wax to the bone edges as indicated by surgical circumstances and the preference of the surgeon.

### HOW SUPPLIED

Bone Wax is available sterile in individual foil envelopes, each containing 2.5 g, and packaged in an individually sealed overwrap packet.

### STERILITY

Bone Wax is sterilized by Gamma radiation. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused Bone Wax.

### STORAGE

Recommended storage conditions: below 25°C, 77°F, away from moisture and direct heat. Do not use after expiration date.

\*CAUTION; Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

### DISPOSAL

Treat unused bone wax as biohazard material


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### SYMBOL DEFINITIONS

 Lot Number


 Expiration Date


 Do Not Reuse


 Do Not Resterilize

 See Instructions For Use

 Sterilized By Gamma Radiation

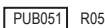
 Keep away from sunlight and heat

 Do not use if package is damaged

 Keep dry

 Manufacturer

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