BONE WAX PRODUCT INSERT

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.

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 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.

SYMBOLE DEFINITIONS

LOT

Expiration Date

Do Not Reuse / Resterilize

See Instructions For Use.

STERILE [R]

Sterilized By Gamma Radiation

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