WAXOCARE®
NON-ABSORBABLE SURGICAL BONE WAX

C688-014/QOS

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

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

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 is contraindicated in patients with known sensitivities or allergies to bees wax, paraffin wax and iso propyl palmitate.

WARNINGS
a. Do not subject Bone Wax to excessive heat. Bone Wax may inhibit osteogenesis and may act as a physical barrier to the reparative process.
b. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.
c. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
d. Contamination of the device may lead to injury, illness or death of the patient.
e. 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. Bone Wax melts at 62°C – 64°C.

ADVERSE REACTIONS
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
Bone Wax is available sterile in individual foil envelopes, each containing 2.5 g. and packaged in an individually sealed overwrap packet.
Use bone wax immediately after removal from the package. Using aseptic technique, take 1 to 1.5 grams of bone wax, manipulate with the fingers to soften, and apply to bone surface.

STERILITY
Bone Wax are sterilized by gamma radiation. Do not re – sterilize. Do not use if package is opened or damaged! Discard opened unused bone wax.

STORAGE
Recommended storage condition 10°C - 35°C, away from moisture and direct heat. Do not use after expiry date.

SYMBOLS USED ON THE LABELS

	Do not re-use	LOT	Batch number
	Date of manufacture	CE 2460	CE Mark with Notified Body Number
	Date of expiry	®	Registered
STERILE R	Sterilized by Gamma Radiation	EC REP	EU REPRESENTATIVE
	Temperature limitation	2 STERILIZE	Do not re-sterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

DISPOSAL
Discard used bone wax contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

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