

BONEWAX™

FEATURES

- Ivory white
- Intended to aid mechanically in the control of bleeding of bone injuries, whether attributable to trauma or surgical intervention.
- It is composed of refined beeswax with a softening agent added and is supplied sterile in thin sheets.
- It is opaque and has a waxy odor.

APPLICATIONS

- Achieves local hemostasis of bone by acting as a mechanical (tamponade) barrier.
- It does not act biochemically and is non-absorbable



Product Overview

- | | | |
|------------------------|---|------------------|
| • Structure | : | Slab of 2.5 gm |
| • Colour | : | Colourless |
| • Chemical Composition | : | Natural bees wax |
| • Sterilization | : | Gamma radiation |
| • Product Code | : | BW810XL |

Meril's Global Presence

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For more information about Bonewax Please contact your local representative.

Please see the package insert for complete device description, product selection information, indications, contraindications, precautions, adverse effects, warning, materials, sterilization and patient guidance associated with the Bonewax.

Bonewax is the registered trade mark of Meril Endosurgery Pvt. Ltd.



TECHNICAL SPECIFICATION

BONE WAX

Manufacturing Site:

M/s Meril Endo Surgery Pvt Ltd , Third floor, E-1-E-3, Meril Park , Survey No 135 / B & 174 / 2, Muktanand Marg, Chai, Vapi - 396191 manufacture Bone Wax products under required Manufacturing License Mfg.Lie.No.: MFG/MD/2018/000027.

The Bone Wax material is procured in the form of Raw material which undergoes a series of process to get converted to final Finished products. The entire manufacturing is under Clean room Class - ISO-8 or Class -D ie Class 100,000. The Clean room Class has Controlled Environment with appropriate system for temperature, humidity & pressure differential.

Quality Management System:

The manufacturing process comply to EN ISO 13485:2016, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 11135:2019 & EN ISO 11137: 2006.

The Quality system followed is ISO 13485:2016/NS.

Device Description

Bone wax is an ivory white wax strip/ slab with rounded ends placed in a silicon coated paper, intended to aid mechanically in the control of bleeding of bone injuries, whether attributable to trauma or surgical intervention. It is composed of refined bees wax with a softening agent added, and is supplied sterile in thin sheets. It is opaque and has waxy odors.

Bone wax contains Bees wax 80% and Liquid Paraffin 20%.

Indication: Meril Bone wax™ is intended to aid in the control of bleeding in bone injuries.

Packaging:

Bone wax product is packed in three layer of packaging material so that its protected adequately till usage. The packaging description of Meril Bone wax is mentioned below:

1. Primary packaging:

Meril Bone Wax is a Wax strips with rounded ends placed in silicon coated paper & sealed in Nurcel foil. Nurcel foil consist of Primary top component which is yellow colour foil with printed text matter, while primary bottom component is plain silver colour.

2. Secondary packaging:

Each primary pack of Nurcel foil is packed over wrapped and sealed in Grid lacquer coated paper 2FS Tyvek pouch.

3. Tertiary Packaging

Twelve primary packs are packed in Dispenser Box.

Sizes and SKU descriptions in detail

Product Code	Device Description	Brand Name
BW810	BONEWAX X 2 GM	MERIL BONEWAX
BW810XL	BONEWAX X 2.5 GM	MERIL BONEWAX

These are available in a Box of 12 packs.

Sterilization:

Meril Bone wax TM is sterilized by Gamma radiation. The minimum absorbed dose should not be less than 25 kGy, so as to achieve a Sterility Assurance Level ie SAL 10^{-6} .

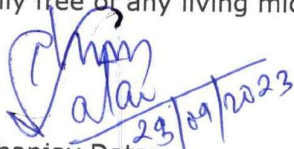
Recommended Storage Condition:

Meril Bone Wax™ should be kept in original packaging under dry, controlled conditions between 15°C to 25°C, and protected from direct sunlight.

Shelf Life:

The Shelf Life of Meril Bone Wax™ is 5 years.

Note: We further declare that all our Meril Bone Wax products range are sterile with an SAL 10^{-6} , totally free of any living microorganisms & safe for usage on the patient till its Shelf life of 5 years.


Dhnanjay Datar
AGM- Quality Control

