

## INSTRUCTIONS FOR USE

# SYNTHECON BONE WAX

### NON–ABSORBABLE HAEMOSTATIC BONE WAX

#### DESCRIPTION:

SYNTHECON BONE WAX is a non-absorbable, sterile (free of germs) opaque surgical wax made by mixing natural wax made by bees (beeswax) with materials to soften the wax. It is has a waxy odor.

#### INDICATIONS:

SYNTHECON BONE WAX is indicated for use in surgical operations as a physical barrier to stop bleeding from bones. When pressed onto a bleeding cancellous bone surface, it physically blocks the bone channels and stops bleeding (tamponade effect). It does not contain any medicine to stop bleeding and does not chemically clot blood.

#### ACTIONS:

SYNTHECON BONE WAX is a blood flow mechanical barrier which will not be absorbed by the body. It will remain for life unless it is removed.

#### HANDLING BEFORE APPLICATION:

- Bone wax should be softened by warming, not by wetting;
- Remove from sterile packaging
- Warm and knead gently between sterile gloved fingers until pliable
- Press directly onto the bleeding bone surface
- Body heat is sufficient to achieve the correct consistency.

#### CONTRAINDICATIONS:

Contraindications for bone wax include situations where rapid bone fusion is needed, such as in spinal fusion or fracture repair, because bone wax inhibits osteogenesis and acts as a physical barrier to bone healing. It is also contraindicated in patients with a known allergy to its components (beeswax, paraffin wax, isopropyl palmitate) or in areas of active infection, as it can worsen the infection and potentially impede bacterial clearance.

#### WARNING:

Users should be familiar with surgical procedures and techniques involving the use of non-absorbable BONE WAX. Acceptable surgical practice must be followed with respect to the application of BONE WAX on infected or contaminated wounds. BONE WAX can act as a physical barrier to bone fusion, delay healing, increase the risk of infection, and cause a foreign body reaction. BONE WAX

should not be used in infected wounds, and cannot be used in areas where bone fusion is needed. Do not re-sterilize; re-sterilization may alter the physical characteristics of this medical device. Do not use if package is open or damaged or if the expiration date has been exceeded.

#### PRECAUTIONS:

In handling this or any other surgical medical device, care should be taken to avoid damage from handling by using aseptic technique. Soften BONE WAX properly to make it pliable. Apply only the necessary amount of BONE WAX. Ensure the removal of BONE WAX after it has served its purpose to prevent complications like infection and granulomas. Always check the BONE WAX packaging for sterility, damage, or expiration dates before opening. Avoid storing BONE WAX product at elevated temperatures.

#### ADVERSE REACTIONS:

All operations have adverse reactions. Although the risk of a serious adverse event is low, there is a risk that a patient may require additional operations or treatments for several reasons. Adverse effects associated with the use of this device include:

- Infection (or make an existing infection worse)
- Inflammation (redness, swelling, pain and feeling of heat)
- Interference with bone healing

These adverse reactions may require additional treatment. This list does not include all adverse reactions. A qualified medical doctor can provide further explanations on the possible adverse reactions.

#### STERILITY:

SYNTHECON BONE WAX is sterilized by Gamma Irradiation. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused pouches.

#### STORAGE:

Recommended storage condition is between 18°C-25°C, away from moisture and direct heat. The shelf life of SYNTHECON BONE WAX is five years. Do not use after the expiry date.

#### SUPPLY:

SYNTHECON BONE WAX is available sterile and individually packed in pouches of one dozen in a box. SYNTHECON BONE WAX is available at a weight of 2.5g for each pouch.

#### DEVICE READINESS:

Ready to use as found inside the container.

#### MANUFACTURING CONDITIONS:

Manufactured under an ISO 13485 Quality Management System to ensure these medical devices are safe, effective, and ready for clinical use with minimal risk and maximum patient benefit.

#### PRODUCT COMPOSITION:

Material	Approximate Percentage (%)
Beeswax (natural wax made by bees)	72.45%
Paraffin (soft wax)	15.02%
Isopropyl Palmitate (wax softener)	12.5%

#### DISPOSAL:

To be disposed as per user's country disposal regulations and hospital/clinic protocol.

#### EXPLANATION OF SYMBOLS:

Symbol	Explanation
	Manufacturer
	Manufactured date
	Use until
<b>STERILE EO</b>	Sterilization by Ethylene oxide
	Do not re- use
	Do not re-sterilize
<b>LOT</b>	Batch
	Keep from Sunlight
	Keep dry
	Warning
	Temperature limitation
	Don't use when packing damaged

#### MANUFACTURED BY:



 **Synthecon**

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