

Product Description

1. Bone-XB is a xenograft using bovine cancellous bone and its main ingredient is HA (Hydroxyapatite).
2. Pores in this material are interconnected, facilitating the formation of new bone tissue into the material when implanted in oral and maxillofacial bone.
3. During the manufacturing process, the organic components were completely removed through several chemical treatments and subsequent high temperature heat treatment.
4. Bone-XB should be used by trained / qualified licensed persons familiar with bone grafting.

Intended Use

MedPark Bone-XB is a xenograft material using bovine cancellous bone for the purpose of securing a space where a new bone tissue is formed by filling defects or bony voids of the oral and maxillofacial region due to a surgical injury or a non-surgical injury.

Preoperative Preparation

1. Deliver a double packed product to the operating room while keeping it sterilized.
2. Do not use Bone-XB if the sterile package is damaged or opened.
3. Do not use Bone-XB if any foreign materials are found inside the vial.
4. Do not use Bone-XB bone graft after the expiration date.
The shelf life of Bone-XB is 3 (three) years from the date of manufacture.
5. Read and fully understand 'Directions for Use' before surgery.
Be sure that clinicians exactly know how to use Bone-XB.
6. Surgical instruments must be sterilized prior to surgery.
7. Bone-XB is an implantable medical device and it should be used in a clean environment, operating room.

Directions for Use

The general principles of sterile handling and patient medication must be followed when using Bone-XB.

1. When using it, peel off blister Tyvek film. Holding the vial firmly, remove the cap. Dispense the granules of Bone-XB into a sterile container.
2. After exposing the bony defect with mucoperiosteal flap, completely remove the granulation tissue and inflammatory tissue.
3. When opening the sterile package, never keep or store the remaining product.
4. After wetting the Bone-XB granules, fill up the defect area with the bone graft.
5. Xenograft materials can be mixed with autogenous bone at the discretion of a clinician.
6. After complete wetting of the granules of Bone-XB in saline solution, remove any excessive fluid, and it is filled into the bone defect. The graft material should be treated carefully neither to damage nor to change the transplant material.
7. After filling the graft, cover the surgical site with mucoperiosteal flap and should be fixed by sutures. Be sure to completely seal the implantation site to prevent the exposure.

※ Fundamentally, the use of powder type is recommended for small defects (up to 2 dental alveoli) and for augmenting autogenous grafts. The chip type is recommended for large defects (> 2 dental alveoli, sinus lifts), however, dentist's preferences on granule size are vary. Powder and Chip type can be mixed together at the dentist's discretion.

Precautions

1. Warnings
 - 1) Discard any unused material after opening. Never reuse!
 - 2) Do not use if package is opened or damaged or if expiration date has been exceeded.
 - 3) This product should only be used by trained dentists or a oral surgeons.
2. Patients with the following diseases are prohibited.
 - 1) Patients with osteomyelitis
 - 2) Patients with severe liver dysfunction
 - 3) Patients with severe cardiac dysfunction
3. Side Effect
Incompatibility reactions by using MedPark Bone-XB cannot be totally excluded.
Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection, or pain.
4. General precautions
 - 1) In general, the conditions considered as standard contraindications for bone graft are metabolic diseases, osteoporosis, steroid therapy, autoimmune diseases, nicotineism.
 - 2) For bone regeneration, the product is only implantable to bone tissue that is directly connected to living bone tissue and host bone.
In the case of large injuries, the addition of autogenous cancellous bone or bone marrow can improve the regeneration process.
Experience has shown that movement due to increased physical loads (compression loads) or implantation of implants (2-step procedures) should be avoided until several weeks after insertion of the product. Experiments have shown that the physical loading (compression load) of this product augmented areas is possible after 6 months at the earliest.
Implant placement time is determined by the amount of remaining local bone.
5. Pregnant and lactating women, infants, children Do not use this product for pregnant or lactating women because of the lack of clinical data on pregnant women and lactating women.
Do not use skeletal development even for immature children.
6. Application notes
 - 1) Do not leave any parenchyma or other soft tissues on the defective area to be implanted.
 - 2) Since this product has a low mechanical strength, so be careful when filling the contents.

- 3) Do not overfill defective or surgical sites.
- 4) When closing the surgical site, the site of the implanted Bone-XB should be completely sutured.

Storage and Expiration date

This product is supplied in a sterile container. Store as it is at room temperature (1°C to 30°C) in the shade before use.

If the sterile packaging has been damaged or opened, the product must not be used. The contents of the blister package or vial are designed for single use only. Discard any unused material after opening.















Expiration date is 3(three) years from date of manufacture.

Do not use and re-sterilize the products that have expired.

Product List

Type	Model Name	Size (mm)	Contents
Powder	MBXB-P021-015	0.2	0.15g
	MBXB-P021-025		0.25g
	MBXB-P021-050		0.5g
	MBXB-P021-100	1.0	1.0g
	MBXB-P021-200		2.0g
Chip	MBXB-C120-025	1.0	0.25g
	MBXB-C120-050		0.5g
	MBXB-C120-100	2.0	1.0g
	MBXB-C120-200		2.0g

Symbol Description

	Batch code		Catalogue number
	Caution		Consult instructions for use
	Do not re-sterilize		Do not re-use
	Manufacturer		Date of manufacture
	Temperature limit		Use by
	Keep away from sunlight		Keep dry
	Sterilized using irradiation		Do not use if package is damaged

Manufacturer

MedPark

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