BONGENER

DESCRIPTION
Bongener is made using Demineralized bone matrix (DBM) which contains Bone Morphogenic Proteins(BMPs).
Bongener is formulated into a gel-like form and is provided in a sterile, single use package. It is packaged in various sizes by volume for single patient use.

INDICATIONS FOR USE
Bongener is intended for use as a bone graft substitute in bony voids or gaps that are not intrinsic to the stability of the bony sturcture. Bongener is intended for filling bony voids or gaps of the skeletal system(i.e., the extremities, spine and pelvis), and filling and /or augmenting intraoral/maxillofacial osseous defect. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

INSTRUCTIONS FOR USE
These instructions are intended as guidelines for the use of Bongener as a part of established surgical techniques. They are no intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation. Procedures involvoing bone grafting can experience highly variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:
- Age of patient
- Quality of the patient's bone
- Location of the defect
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Ability to achieve direct apposition of the graft to viable host bone
- Presence/addition of autogenous bone or bone marrow at the graft site
- Elimination of gaps in the graft site
- Complete coverage of the graft material to prevent migration

For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

INSTRUCTIONS
1. Peel open package
2. Using aseptic technique, transfer contents to sterile field
3. Remove protective cap from syringe tip
4. Apply pressure to the plunger to extrude product
5. Discard any unused portion

PREOPERATIVE PREPARATION :
Aseptic techniques must be maintained to minimize the risk of postoperative complications. The amount needed is based on the type of procedure and size of the defect being treated. Bongener does not require rehydration prior to use. Radiological evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of Bongener and fixation devices.
Surgical Procedure Note: Bongener does not possess sufficient mechanical strength to support reduction of a graft site prior to tissue ingrowth. Therefore, anatomical reduction and rigid fixation in all planes, should be obtained independent of Bongener.
For best results, Bongener must fill the defect and contact as much viable bone as possible. Bongener must not be used to repair bone defects where complete soft tissue coverage cannot be achieved. Only experienced physicians, who have had appropriate training and experience in the field of implant materials and implant surgery, should use Bongener.

POSTOPERATIVE CARE :
Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices. The patient should be cautioned against early weight bearing and premature ambulation which could lead to loosening and/or failure of the fixators or loss of reduction.
The length of time a defect should remain in a reduced state of loading is determined by the complexity of the defect site and the overall physical condition of the patient. Hardware should not be removed until the defect is healed.

CONTRAINDICATIONS
Bongener is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:
- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and /or alcohol
- Renal impairment
- Active or latent infection in or around the surgical site

Bongener is contraindicated when there is significant vascular impairment proximal to the implantation site and when there are metabolic or systemic bone disorders that affect bone or wound healing, or when stabilization of the defect is not possible. The use of Bongener is contraindicated in cases where interaoperative soft tissue coverage is not planned or possible and in infected or contaminated sites.

WARNINGS AND PRECAUTIONS
Bongener is sterile during the stated shelf life in an unopened and undamaged package. The product must be used prior to the expiration date.
Do not use if the packaging has been damaged and/or the product has been contaminated . In the event of contamination, discard the product. Damaged packaging should be returned to CGBio Co., Ltd.
Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
As with all biological products, the tissue in Bongener has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral seroconversion using demineralized bone powder.
When filling a closed defect, care must be taken while extruding Bongener from the syringe as possible pressurization of the device could result in fat embolization and/or embolization of the material into the blood stream.
As with any surgical procedure, the possibility of infection exists.
Although the production technique is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.
Adverse outcomes potentially attributable to the product must be reported promptly to the manufacturer. If any dissatisfaction with the product performance of packaging occurs, notify CG Bio Co., Ltd. immediately and promptly return product and/or packaging.
When introducing Bongener, care must be taken to avoid excessive compaction.
Overfilling the implantation site must be avoided to achieve a tension-free closure of the wound

STERILIZATION
Bongener has been sterilized by gamma irradiation. The inner package and its contents are sterile. The package should be inspected prior to use to ensure the sterility barrier has not been compromised. This product is for single use only and may not be re-sterilized. The product must not be used beyond the stated expiration date.

DO NOT RE-STERILIZE

STORAGE
Do not refrigerate or freeze. Do not expose to extreme heat. Store at room temperature(15℃ to 30℃)in a clean, dry place.

CAUTION : This device is restricted to sale, distributon, and use by or on the order of a physician.
For additional information, contact CGBio Co., Ltd. sales representatives or customer service.

SYMBOLS

LOT Batch code	Manufacturer	Date of manufacture	Keep away from sunlight
Keep dry	REF Catalog number	Do not reuse	Do not resterilize
Temperature limitation	Use by date	STERILE R Sterilized using irradiation	Consult instructions for use
Do not use if package is damaged		EC REP European authorized representative	SN Serial number
Caution, consult accompanying documents		Rx only Federal law(U.S.) restricts this device to sale by or on the order of a physician	

Manufacturer CGBIO CELL & GROWTH FACTOR BIOTECHNOLOGY
CGBio Co., Ltd B1, 1F, 2F, C-dong, 29, Jeyakdanji-ro, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea Tel : +82-2-550-8300 FAX : +82-31-352-0135
CSBG-109-4 / Jul 01 2020

품목명	본제너 설명서 – 해외통합
디자인담당자	조정우 010–9980–1012
규격	140 x 290 mm 단면
종이	모조 80g
인쇄	먹 1도
코팅	없음
접지	O
접착 (양면테이프)	없음
제본	없음
오시 (줄수)	없음
절취선 (미싱/줄수)	없음
돌출코팅 (에폭시)	없음
형압 (사이즈)	없음
박 (사이즈)	없음
기타	없음