Silicon Containing Coralline Hydroxyapatite Bone Graft Substitute (Patent No: US 7,008,450)

INSTRUCTION FOR USE

BoneMedik-S BLOCK & CHIP

Indications for use

For Single Use Only

- **BoneMedik-S** is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be gently packed into bony voids or gaps of the skeletal system(i.e. extremities, pelvis). These defects may be surgically created from osseous defects or osseous defects created from traumatic injury to the bone. This product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

Description

- **BoneMedik-S** silicon containing coralline hydroxyapatite bone graft substitute is indicated for use as a cancellous bone substitute or augmentation material for the repair of bone defects and is to be used in conjunction with rigid internal fixation as dictated by the clinical requirements in skeletally mature individuals.
- **BoneMedik-S** is a non-osteogenic bone graft substitute similar in structure and composition to human cancellous bone. It is supplied in different shapes of blocks and also supplied in vials containing various sizes & volumes of chips.
- **BoneMedik-S** is derived from the exoskeleton of marine coral which has a natural trabecular structure of **BoneMedik-S** that consists of large pores which run parallel to the major growth axis and smaller interconnecting pores which run perpendicular to the major growth axis. This structure resembles the multidirectional, interconnected porosity of cancellous bone. The marine coral is machined to block or chip configurations.
  A chemical process converts the coralline calcium carbonate structure in the blocks to a mixture which contains a minimum of 95% crystalline hydroxyapatite and a maximum of 1% silicon.
  The interconnected pores of the **BoneMedik-S** trabecular network have a median pore diameter 400 microns. Some difference in pore size occurs due to the natural biological variability in the exoskeleton.

Instructions for use

- These instructions are intended as guidelines for the use of **BoneMedik-S** blocks and chips as a part of established surgical techniques by well-trained and experienced surgeons. They are not intended to replace or change standard procedures of treatment of defects involving bone grafting and internal fixation.
- **BoneMedik-S** is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be gently packed into bony voids or gaps of the skeletal system(i.e. extremities, pelvis). These defects may be surgically created from osseous defects or osseous defects created from traumatic injury to the bone. This product provides a bone graft substitute that resorbs and is replaced with bone during the healing process.
- **Preoperative Preparation**: Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of the BoneMedik – S and internal fixation devices.
- **Surgical Procedure Notes: BoneMedik-S** does not possess sufficient mechanical strength to support the reduction of a defect site prior to soft and hard tissue ingrowth. Therefore, anatomical reduction and rigid internal fixation, in all planes, must be obtained independent of the **BoneMedik-S** using accepted internal fixation techniques until ingrowth has occurred and the defect is healed.
  The site, size and geometry of the defect will determine the surgeon's operative placement of the **BoneMedik-S**.
- For best results, the **BoneMedik-S** blocks should fill the defect and contact viable bone as much as possible. If intraoperative shaping is required to maximize bony contact, the implant can be carved to optimum shapes by wetting the implant with sterile normal saline and carving with a #10 or #15 scalpel blade. The implant can also be shaped with bone cutting forceps or rongeurs. After final shaping, the implant should be thoroughly rinsed in sterile normal saline or sterile distilled water to remove any particulate matter from the surface pores.
- **CAUTION**: NO ATTEMPT SHOULD BE MADE TO ALTER THE SIZE OF THE **BoneMedik-S** CHIPS.
- Fixation must ensure reduced loading of the **BoneMedik-S** site and must be sufficient to prevent collapse and deformity secondary to axial or functional loading. Fixation with plates and/or screws is recommended. Wires can be used as adjuncts to rigid fixators.
- **Spine surgery**
  For example postero–lateral fusion, interbody fusion (as cage filling material), vertebrectomies (as filling material of the vertebral implants), refilling of bone graft harvesting sites.
- **BoneMedik-S** must not be used to repair defects where complete soft tissue coverage cannot be achieved.
- After implantation of the **BoneMedik-S** block, residual local bone or **BoneMedik-S** chips of not less than 1mm in diameter may be used to re-establish continuity around the implant.
- **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 repair involving the use of internal fixation devices.

  The patient should be cautioned against early weight bearing and premature ambulation which could lead to loosening and/or failure of the internal fixators or loss of reduction.
  The length of time the defect must remain in a reduced state of loading is determined by the complexity of the patient's defect(s) and the overall physical condition of the patient. Hardware should not be removed until the defect is completely healed and the articular area is no longer subjected to abnormal loading.

Contraindications

- **BoneMedik-S** is contraindicated for fractures of the epiphyseal plate, when there is significant vascular impairment proximal to the graft site; 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 **BoneMedik-S** is also contraindicated in cases where intraoperative soft tissue coverage is not planned or possible and in infected or contaminated wounds.

Warnings

- **BoneMedik-S** does not possess sufficient mechanical strength to support the reduction of a defect site prior to soft and hard tissue ingrowth. Standard internal fixation techniques for fracture fixation must be followed to obtain rigid stabilization in all planes. External stabilization alone is not sufficient to achieve the rigidity necessary for bony ingrowth of the **BoneMedik-S**.

Precautions

- **BoneMedik-S** is intended for use by surgeons familiar with bone grafting and internal fixation techniques. Complete postoperative wound closure is essential. The **BoneMedik-S** must not be used to fix screw or to stabilize screw placement. Screws used in conjunction with the **BoneMedik-S** and fixation devices must fix into the host bone.
- **BoneMedik-S** is radiopaque.
- **BoneMedik-S** should be stored at room temperature.

Sterility

- **BoneMedik-S** is supplied sterile in dated, individual, double aseptic packages. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.
- **BoneMedik-S** is non-pyrogenic

Shelf life

- Shelf life is 5 years from manufacturing date.
- The device should not be used after the expiration date on the package label.
- This product should not be resterilized.

Symbols

- Use By
- LOT Batch Code
- STERILE R Sterilization using irradiation
- Consult operating instructions
- Do not reuse
- Do not resterilize
- Manufacturer
- Date of manufacture
- REF Catalogue number
- Do not use if package is damaged
- Keep away from sunlight

Made in Korea

Manufactured by
META BIOMED CO.,LTD.

270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea
Tel:+82-43-216-0433
Fax:+82-43-217-1988
E-mail: info@meta-biomed.com
Web site: http://www.meta-biomed.com

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