MedParkAllo
Moldable Allograft

INSTRUCTIONS FOR USE

※ This product is a sterile, single-use medical device.
Do not reuse (sterilized by irradiation).

1. Product Name:
MedParkAllo, S1-Allo Medical, MedPark S1 Allo

2. Model Name :

S1-ALLO-MS015	S1-ALLO-MS030	S1-ALLO-MS050	S1-ALLO-MS100
S1-ALLO-MS150	S1-ALLO-MS200	S1-ALLO-MS250	S1-ALLO-MS300

3. Packaging Unit : 1 vial / EA

4. Intended Use

This product is a bone graft biomaterial intended for use in surgical bone defects to fill and replace deficient bone tissue.

5. Product Description

The product is a bone graft material composed of processed human-derived bone (FDBA) blended with biocompatible cellulose. When implanted into a bone defect, the product provides an osteoconductive environment that supports new bone formation. Upon hydration, it exhibits a putty-like consistency, allowing for easy handling and placement. After implantation, the cellulose is gradually absorbed, and the bone particles are replaced by the patient's newly formed bone.

6. Directions for Use

A. Preparation Before Use

1) Verify the product's expiration date and the integrity of the package. Do not use the product if the packaging is damaged or if the expiration date has passed.
2) This product must be used only by qualified healthcare professionals in accordance with applicable laws and regulations. Use for any purpose other than the intended use is prohibited.
3) Review the patient's medical history and diagnostic imaging (e.g., X-rays) to confirm that the patient meets the indications for use and does not have any contraindications.

B. Preparation (Hydration and Mixing)

1) Using aseptic technique, open the package and transfer the contents into a sterile container.
2) Add the recommended amount of sterile normal saline or the patient's own blood (including bone marrow aspirate concentrate, if applicable).
3) Note: Follow the hydration volume specified in the product user guide.
4) Using sterile instruments, thoroughly mix the powder and liquid together for at least 30 seconds or until a homogeneous, putty-like consistency is achieved.
5) Do not leave the shaped graft material immersed in the solution. (to prevent dissolution of the carrier material).

C. Storage and Handling After Use

This is a single-use product. Any unused material remaining after the procedure must be discarded in accordance with applicable medical waste regulations. Do not reuse.

7. Precautions for Use

A. Warnings

1) Although this product has undergone rigorous donor screening and sterilization processes, the possibility of transmitting infectious diseases (including viruses or prions, e.g., CJD) cannot be completely eliminated due to the nature of human-derived tissues.
2) The carrier material (cellulose) in this product may absorb body fluids and expand in volume. When used in the spinal canal or in areas adjacent to nerve roots, excessive filling may cause nerve paralysis or pain due to expansion pressure. Exercise caution to avoid overfilling.
3) This product does not provide load-bearing support. When used at fracture sites, for interbody spinal fusion, or in other locations requiring structural stability, use this product in conjunction with rigid internal fixation devices (e.g., screws, plates, or cages).
4) Do not re-sterilize this product. Resterilization may alter the physical properties of the carrier material, resulting in a loss of viscosity and the formation of toxic degradation products.
5) This product is intended for implantation only into bone defects. Administering the product by any route other than implantation into a bone defect (e.g., oral, intramuscular, subcutaneous, or intravenous administration) may cause inflammatory reactions and, in severe cases, thrombosis, which can lead to death.

B. Contraindications

Do not use this product in patients with the following conditions:

1) An active infection at the surgical site
2) Insufficient soft tissue coverage at the surgical site, resulting in a risk of graft exposure or infection
3) A history of hypersensitivity to any component of this product (including allogeneic bone or cellulose)
4) Severe metabolic bone diseases, such as uncontrolled osteomalacia.
5) Necrotic bone defects in which the blood supply has been compromised.

C. Precautions

1) Exercise caution when mixing this product with antibiotics or other unverified agents, as they may cause a loss of viscosity of the carrier material or the formation of precipitates.
2) If graft particles enter the joint space, they may cause abrasive wear. Therefore, when operating near a joint, ensure adequate sealing to prevent particle migration.
3) If graft material leaks into adjacent muscles or between ligaments, it may cause heterotopic ossification. Thoroughly irrigate the surgical site after implantation to remove any residual graft material.

D. Adverse Reactions

The following adverse reactions may occur after the use of this product:

1) Inflammation, swelling, hematoma, pain, or fever at the surgical site.
2) Wound dehiscence and washout (loss) of the graft material.
3) Nerve compression or myelopathy resulting from graft migration.
4) Non-union, delayed union, or pseudoarthrosis.
5) Immune rejection or hypersensitivity reactions.

E. General Precautions

1) This product must be used only by qualified healthcare professionals in accordance with applicable laws and regulations.
2) Inform the patient that this product is derived from human tissue, and advise them of the potential risks associated with its use, including the risk of infection.
3) Smoking after surgery can significantly impair bone healing. Advise the patient to refrain from smoking during the postoperative period.

F. Interactions

1) The safety and effectiveness of concomitant use with other bone graft materials or medicinal products have not been established.
2) This product may be mixed with sterile normal saline or the patient's own blood. However, do not use this product in combination with bone cement from other manufacturers, as heat generated during the mixing process may cause tissue damage at the implantation site.

G. Use in Special Populations

The safety of this product has not been established in pregnant or breastfeeding women or in pediatric patients whose skeletal growth is not yet complete. Therefore, as a general rule, do not use this product in these populations.

H. Precautions During Application

1) Use the product immediately after opening. Do not leave it exposed to air for an extended period, as it may dry out.
2) Fill the bone defect adequately, but do not overfill the graft site.
3) Avoid applying excessive direct pressure to the graft material, as this may cause the graft to displace or dislocate.

8. Storage

Store at room temperature (1–30°C). Protect from direct sunlight, and avoid storage in areas of high temperature or humidity.

9. Shelf Life

3 years from the date of manufacture
(see package label for the expiration date).

10. Manufacturer Information

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For reporting adverse events related to this product, please contact the National Institute of Medical Device Safety Information (NIDS) at 82-1588-4183

Revised on 2026-07 / IFU.012.MP(0.20)EN