MedParkAlloD S1

INSTRUCTIONS FOR USE

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

1. Model Name :

MPAllo-DS015	MPAllo-DS030
MPAllo-DS050	MPAllo-DS100
MPAllo-DS150	MPAllo-DS200
MPAllo-DS250	MPAllo-DS300

2. Packaging Unit : 1 vial / EA

3. Intended Use

This product is an allograft intended for use in filling bone defects or bony voids in the oral and maxillofacial region

4. Product Description

MedParkAlloD is a mineralized freeze-dried bone allograft (FDBA) derived from processed human corticocancellous bone and combined with cellulose based hydrogel. Upon hydration hydrogel provides cohesiveness and viscosity, resulting in a putty-like consistency that facilitates handling and placement of the graft material. MedParkAlloD primarily acts through osteoconduction by providing a scaffold that supports new bone formation at the graft site.

5. Directions for Use

A. Preparation Before Use

1) This product is sterile and must be kept under aseptic conditions. Open and prepare it for use only in a clean, hygienically controlled clinical environment.
2) Do not use the product if the inner packaging is torn, opened, or otherwise visibly damaged.
3) Do not use the product after the expiration date.
4) In accordance with applicable regulations, qualified healthcare professionals must read and fully understand these instructions for use and the product's characteristics before surgery.
5) Before the procedure, qualified healthcare professionals must review the patient's medical history and confirm that the patient is not allergic or hypersensitive to any component of this product.
6) To prevent infection at the surgical site, ensure proper aseptic handling of this product and use only sterile surgical instruments.

B. Directions for Use and Operating Procedure

1) Expose the alveolar bone defect and completely remove all granulation tissue, inflamed tissue, and other soft tissue from the defect site.
2) Before using the product, inspect the surgical site and thoroughly irrigate it with sterile water or sterile normal saline.
3) Open and use an appropriate amount of the product according to the size of the surgical site. Once opened, the product cannot be stored for reuse because sterility cannot be guaranteed. Use the entire contents immediately and discard any unused portions.
4) Since the product is sterile, open the package immediately before use and transfer the contents to a sterile container.
5) Before application, verify the appropriate hydration volume according to the amount of product used. Hydrate the graft thoroughly for at least 30 seconds using sterile normal saline or the patient's own blood.
6) Apply the product to the defect site, shaping it as necessary to ensure intimate adaptation to the surrounding bone.
7) If necessary, cover the graft with a barrier membrane or suture the soft tissue securely to stabilize the graft and prevent migration of the material from the surgical site.

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.

6. Precautions for Use

A. Warnings

1) This product is a sterile, single-use medical device. Do not reuse.
2) Do not use the product after the expiration date.
3) Only qualified healthcare professionals must use this product in accordance with applicable regulations.

B. Contraindications

1) Necrosis or degenerative bone disease at the intended surgical site
2) Osteomyelitis
3) Severe hepatic impairment
4) Severe cardiac dysfunction
5) A known history of hypersensitivity or allergic reactions to any component of the product (including human-derived bone or cellulose) or to substances used during the manufacturing process.

C. Precautions

1) Do not mix this product with antibiotics or other unverified chemical agents, as this may cause adverse effects or significantly alter the product's physical properties (e.g., viscosity).
2) Since the graft material may dislodge due to external physical forces, ensure stable fixation of the graft during the procedure.
3) During implantation, gently compress the graft material as needed to adapt it intimately to the bone defect.
4) When treating defects adjacent to neural structures, confirm the anatomical structure using appropriate imaging, and avoid overfilling or excessive compression.
5) Use caution in patients with active infections, such as uncontrolled periodontitis or gingivitis, at or adjacent to the surgical site.

D. Adverse Reactions

The following adverse reactions may occur with the use of this product

: The clinician should fully inform the patient of these potential risks before treatment.

- Potential adverse reactions include swelling, bleeding, localized inflammation, bone loss, infection, and pain at the surgical site.

E. General Precautions

1) The product should be used immediately after opening. Care should be taken to prevent contamination by bacteria or other microorganisms.
2) If use is delayed after opening the package, the product should be discarded, as contamination is likely and resterilization is not possible.
3) Mixing this product with products from other manufacturers may result in compatibility or performance issues.

F. Interactions

1) The safety and effectiveness of concomitant use with any agents other than sterile normal saline or blood 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

1) Because there is no clinical data regarding the use of this product in pregnant or lactating women, it should not be used in these populations for safety reasons.
2) This product should not be used in children with immature skeletal development.

H. Precautions During Application

1) Do not overfill the bone defect or surgical site.
2) To maintain adequate adhesiveness of the graft material, use an appropriate amount of sterile normal saline or blood during hydration. When necessary, the use of a suitable barrier membrane or secure soft tissue closure is recommended.
3) Do not re-immerse the product in solution or leave it soaking after hydration.
4) Insufficient mixing during graft preparation may leave internal voids within the graft material, resulting in structural instability at the graft site, reduced primary implant stability, and failure of new bone formation.
5) When irrigating with pressurized saline, use caution, as excessive irrigation pressure may disperse or wash out the graft material from the defect site.

7. Storage

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

8. Shelf Life

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

9. Manufacturer Information

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