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Altapore MIS System

BIOACTIVE BONE GRAFT

INSTRUCTIONS FOR USE - IMPORTANT PRODUCT INFORMATION

Please read before use

REF 1508032 ALTAPORE MIS System Applicator + 7.5 ml Cartridge

REF 1508047 ALTAPORE MIS System 7.5 ml Refill Cartridge

Caution: U.S. Federal law restricts this device to sale by or on the order of a Physician (or properly licensed practitioner).

Product Description

ALTAPORE MIS System contains ALTAPORE, a bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler. The interconnected and open porous structure of the silicate-substituted calcium phosphate phase of ALTAPORE is similar to human cancellous bone and is intended to support bone growth with macro- and micro- porosity. ALTAPORE is composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si). ALTAPORE MIS System is supplied prepackaged in a sterile 7.5 ml cartridge and contains ALTAPORE microgranules, sized 1–2 mm, 80-85% total porosity, suspended in an absorbable aqueous gel carrier. ALTAPORE does not set in-situ following implantation. ALTAPORE MIS System is supplied as an applicator and 7.5 ml cartridge and separate 7.5 ml refill cartridges.

ALTAPORE MIS System is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, the product can be mixed with Bone Marrow Aspirate (BMA) or autologous bone at the discretion of the surgeon (see Instructions for Use section for mixing directions).

ALTAPORE MIS System is bioactive based on *in vitro* studies that show it forms a surface apatite-layer when submerged in simulated body fluid that contains the same ion concentrations as human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

ALTAPORE MIS System is osteoconductive based on *in vivo* animal studies that show it achieves bone healing in a critical defect model as confirmed with radiographic, histopathological, histomorphometric, and mechanical analyses. ALTAPORE MIS System undergoes cell-mediated remodeling and is replaced by natural bone.

Indications For Use

ALTAPORE MIS System is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). ALTAPORE MIS System can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE MIS System resorbs and is replaced with bone during the healing process.

Contraindications

ALTAPORE MIS System is not designed or sold for any use except as indicated. Do not use ALTAPORE MIS System in the presence of any contraindication. ALTAPORE MIS System is contraindicated where the device is intended as structural support in the skeletal system. ALTAPORE MIS System has not been cleared for use in vertebroplasty.

Other conditions representing contraindications include: severe vascular or neurological disease, uncontrolled diabetes, severe degenerative disease, uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol, hypercalcemia, abnormal calcium metabolism, existing acute or chronic infections (especially at the site of the operation), inflammatory bone disease such as osteomyelitis, malignant tumors, and severely impaired renal function.

Warnings

ALTAPORE MIS System is not intended for load-bearing uses without internal or external fixation devices. It is important to ensure that the area where ALTAPORE MIS System have been implanted be properly secured mechanically with rigid fixation to strengthen the surroundings. Attempts should not be made to modify their shape.

Further, the following is unknown:

- The effect of ALTAPORE MIS System on patients with the following conditions: documented renal disease, pregnancy and nursing, and radiation bone therapy
- The effect of mixing ALTAPORE MIS System with substances other than Bone Marrow Aspirate (BMA) or autologous bone
- The effect of ALTAPORE MIS System in pediatric patients

Possible Complications

Successful results may not be achieved for every surgical case due to variation in patient condition and surgical technique. Reoperation to remove or replace an implant may be required due to certain patient-specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- wound complications including hematoma, edema, swelling and fluid accumulation, tissue thinning, bone fracture, infection, and other complications that are possible with any surgery
- fracture of the implant with or without generation of particulate debris
- bone deformity at the site
- delayed or non-union
- transient hypercalcemia

Precautions

Content of package is STERILE by prior exposure to gamma radiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.

ALTAPORE MIS System is opaque to x-rays. This may mask areas under or above the implant on a radiograph.

The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.

Fully fill the bony defect ensuring maximal contact between ALTAPORE MIS System and the host bone.

Do not overfill or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fat embolization or embolization of the device into the bloodstream.

Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.

Instructions for use

Open both outer (non-sterile) and inner (sterile) packaging.

Step A. Remove plug from bayonet fitting of cartridge (1). Attach filled cartridge to applicator with bayonet fitting (2) by locating bayonet tangs and twisting clockwise (3) so that marks on cartridge and applicator are aligned. Remove cap (4) from cartridge end.

Step B. Depress handle (5) to express ALTAPORE MIS System from the cartridge.

Implant. ALTAPORE MIS System is designed to be used alone. ALTAPORE MIS System can be mixed with autologous blood or bone marrow aspirate at the discretion of the surgeon but this may affect handling. Secure the surgical site after implanting to prevent micromotion and implant migration. When excess fluid is present at the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of ALTAPORE MIS System.

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To load another cartridge:

Step C. Depress handle (6) and hold while withdrawing plunger (7).

Step D. Remove empty cartridge by twisting anticlockwise (8) and dispose of properly.

Storage Conditions, Shelf Life and Disposal

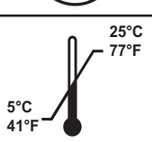
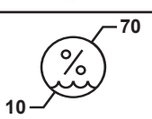
ALTAPORE MIS System should be stored between 10–70% Relative Humidity and 5-25°C (41-77°F).

The expiration date is printed on the label. DO NOT USE ALTAPORE MIS System AFTER THE EXPIRATION DATE.

ALTAPORE MIS System is environmentally friendly. No special disposal is necessary.

Symbols Used in Labeling

Symbols are referenced from ISO 15223-1:2016 Medical Devices: Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements

Symbol	Title and Definition of Symbol	Reference Number
	Manufacturer; Indicates the medical device manufacturer	5.1.1
	Use-by Date; Indicates the date after which the medical device is not to be used.	5.1.4
	Batch Code; Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalog number; Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6
	Sterilized using irradiation; Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not resterilize; Indicates a medical device that is not to be resterilized.	5.2.6
	Do not use if package is damaged; Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Temperature limit; Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Humidity limitation; Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8
	Do Not Reuse; Indicates a medical device that is intended for use on a single patient during a single procedure.	5.4.2
 https://edocs.baxter.com	Consult Instructions for use; Indicates the need for the user to consult the instructions for use. The Instructions for use are available at Baxter's website.	5.4.3, Annex A15
	Not made with natural rubber latex; Indicates natural rubber latex was not used in the construction of this product	5.4.5, Annex B.2

Not made with natural rubber latex.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of ALTAPORE MIS System, and for the choice of post-operative follow-up procedures rests entirely with the surgeon. Clinical data in humans on the bioactive nature of ALTAPORE MIS System has not been established.

These instructions are available electronically at https://edocs.baxter.com. To request a paper copy of this document at no additional cost, call 1-888-229-0001 or email cfs_customer_service@baxter.com.

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