AltaPore
Bioactive Bone Graft
Enhanced Porosity with Silicate Substitution

INSTRUCTIONS FOR USE - IMPORTANT PRODUCT INFORMATION

Please read before use

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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 is 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 is supplied in a sterile applicator 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 is available in 1.5ml, 2.5ml, 5ml, 10ml, and 20ml configurations.

ALTAPORE 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 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 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 undergoes cell-mediated remodeling and is replaced by natural bone.

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

Contraindications
ALTAPORE is not designed or sold for any use except as indicated. Do not use ALTAPORE in the presence of any contraindication. ALTAPORE is contraindicated where the device is intended as structural support in the skeletal system. ALTAPORE 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 is not intended for load-bearing uses without internal or external fixation devices. It is important to ensure that the area where ALTAPORE 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 on patients with the following conditions: documented renal disease, pregnancy and nursing, and radiation bone therapy
- The effect of mixing ALTAPORE with substances other than Bone Marrow Aspirate (BMA) or autologous bone
- The effect of ALTAPORE 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 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 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
Step 1. Open both outer (non-sterile) and inner (sterile) packaging in the sterile field.
Step 2. If desired, ALTAPORE may be mixed with Bone Marrow Aspirate (BMA) or autologous bone. Mixing equipment must be sterilized prior to use.
ALTAPORE can be mixed with autologous Bone Marrow Aspirate (BMA) up to a ratio of 2:1 by volume of ALTAPORE:BMA. ALTAPORE can be mixed with autologous bone up to a ratio of 1:3 by volume of ALTAPORE:autologous bone. For use in posterolateral spinal fusion procedures, ALTAPORE must be mixed with autologous Bone Marrow Aspirate (BMA) up to a ratio of 2:1 by volume of ALTAPORE:BMA or must be mixed with autologous bone up to a ratio of 1:3 by volume of ALTAPORE:autologous bone.
Step 3. Implant by packing gently into the osseous defect. Secure the surgical site after implanting to prevent micro-motion and implant migration. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. 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.

Storage Conditions, Shelf Life and Disposal
ALTAPORE should be stored between 10–70% Relative Humidity and 5-32°C (41-90°F).

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

ALTAPORE is environmentally friendly. No special disposal is necessary.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of ALTAPORE, 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 has not been established.

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