




BAXTER CONFIDENTIAL - INTERNAL USE ONLY

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AltaPore Shape

Bioactive Bone Graft

Enhanced Porosity with Silicate Substitution

INSTRUCTIONS FOR USE - IMPORTANT PRODUCT INFORMATION

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Please read before use

- REF** 1508043 ALTAPORE SHAPE 1.6ml
- REF** 1508044 ALTAPORE SHAPE 2.6ml
- REF** 1508045 ALTAPORE SHAPE 8ml
- REF** 1508046 ALTAPORE SHAPE 15.8ml

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 SHAPE 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 SHAPE is supplied in sterile pouches and contains ALTAPORE microgranules, sized 1–2 mm, 80-85% total porosity, suspended in an Alkylene Oxide Copolymer carrier. ALTAPORE SHAPE does not set in-situ following implantation. ALTAPORE SHAPE is available in 1.6ml, 2.6ml, 8ml, and 15.8ml configurations.

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

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

Indications For Use

ALTAPORE SHAPE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). ALTAPORE SHAPE can be used by itself, or with autograft as a bone graft extender in posterolateral spinal fusion procedures. 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 SHAPE resorbs and is replaced with bone during the healing process.

Contraindications

ALTAPORE SHAPE is not designed or sold for any use except as indicated. Do not use ALTAPORE SHAPE in the presence of any contraindication. ALTAPORE SHAPE 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 SHAPE is not intended for load-bearing uses without internal or external fixation devices. It is important to ensure that the area where ALTAPORE SHAPE has 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 SHAPE on patients with the following conditions: documented renal disease, pregnancy and nursing, and radiation bone therapy
- The effect of mixing ALTAPORE SHAPE with substances other than autologous blood or autologous bone
- The effect of ALTAPORE SHAPE 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 Electron Beam radiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.

ALTAPORE SHAPE 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 SHAPE 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 outer (non-sterile) pouch and deliver the inner (sterile) pouch to the sterile field. Open inner pouch to access ALTAPORE SHAPE.

Step 2. ALTAPORE SHAPE can be mixed with autologous blood or autologous bone at the discretion of the surgeon but this may affect handling. Mixing equipment must be sterilized prior to use. For use in posterolateral spinal fusion procedures, ALTAPORE SHAPE can be mixed with autologous bone up to a ratio of 1:3 by volume of ALTAPORE SHAPE:autologous bone.

Step 3. Implant. Secure the surgical site after implanting to prevent micro-motion and implant migration. When excess fluid is present at the surgical field, the surgeon may use cauterization, suction, and application of bone hemostat (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of ALTAPORE SHAPE.




Storage Conditions, Shelf Life and Disposal

ALTAPORE SHAPE 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 SHAPE AFTER THE EXPIRATION DATE.








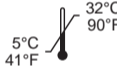
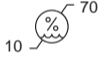



ALTAPORE SHAPE is environmentally friendly. No special disposal is necessary.

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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
	Consult Instructions for use; Indicates the need for the user to consult the instructions for use.	5.4.3
	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

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

ALTAPORE SHAPE is not made with natural rubber latex

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