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BAXTER ANNOUNCES U.S. FDA CLEARANCE OF ALTAPORE SHAPE BIOACTIVE BONE GRAFT FOR USE IN SURGERY

- *Designed to enhance bone growth and help achieve fusion in surgeries involving the skeletal system*
- *Recent study shows posterolateral fusion success associated with improved patient outcomes, including reduced pain from baseline*
- *New configurations give surgeons versatile options that are easy to mold*

DEERFIELD, Ill., JULY 9, 2020 – Baxter International Inc. (NYSE:BAX), a global leader in advancing surgical innovation, today announced U.S. Food and Drug Administration (FDA) clearance of **Altapore Shape** Bioactive Bone Graft, the latest addition to the company's next-generation bone graft substitute product line. **Altapore Shape** is designed to enhance bone growth and help achieve fusion, which can lead to reduced pain and other improved clinical outcomes for patients.

"We are introducing this new format in our **Altapore** product line to give surgeons versatile tools as they work to advance the art of healing and improve clinical outcomes in the operating room," said Wil Boren, president of Baxter's Advanced Surgery business.

A 2019 prospective, open-label, non-randomized clinical study evaluated 102 patients with degenerative disc disease, spondylolisthesis and spinal stenosis undergoing instrumented posterolateral fusion (PLF) procedures per protocol using **Altapore** Bioactive Bone Graft. The study found that successful fusion was achieved in 86.3% of those patients at month 12. **Altapore** Bioactive Bone Graft and **Altapore Shape** share similar properties and handling characteristics, and the study indirectly supported the FDA submission for **Altapore Shape**. At month 12, patients reported a 60% improvement in total pain from baseline using the Visual Analog Scale and a 48% improvement in disability from baseline using the Oswestry Disability Index. Patients also reported an

improved quality of life post-surgery, and more than 50% of patients achieved neurological success, defined as maintaining or improving functionality in five parameters including motor, sensory, reflex, straight leg raise and femoral stretch. The study design did not include a comparator treatment, so no direct comparison to other treatments can be made.[1]

Altapore Shape is used as a standalone bone graft substitute or as an autograft extender to fill bony voids or gaps in the skeletal system, including in the pelvis, extremities and posterolateral spine, that are surgically created or result from trauma. **Altapore Shape** resorbs and is replaced with bone during the healing process and comes in four configurations – three cylinders of differing sizes (1.6 ml, 2.6 ml and 8 ml) and one strip (15.8 ml) – to aid surgeons in molding the product to fit various surgical needs.[2]

The entire **Altapore** product line is designed to enhance bone growth with optimized porosity that promotes earlier vascularization. Vascularization plays a central role in the bone formation process by providing oxygen, nutrients and growth factors critical for bone development.[3] **Altapore Shape**'s porosity also increases cellular activity by providing more surface area for cells to travel along the surface of the graft, which promotes new bone formation. Additionally, the product features Baxter's proprietary silicate-substituted technology, which contains 0.8% silicon by weight and was shown to be optimal for bone formation in preclinical studies.[4] Both **Altapore Shape** and **Altapore** consist of identical silicate-substituted calcium phosphate granules, and the differences in absorbable carrier phase do not alter the intended therapeutic use of the devices.

Rx Only. For safe and proper use please refer to full device Instructions for Use for Contraindications, Warnings, and Precautions.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

Indications for Use for Altapore Shape Bioactive Bone Graft

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, 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 Shape** resorbs and is replaced with bone during the healing process.

Important Risk Information

Altapore Shape is contraindicated where the device is intended as structural support in the skeletal system. **Altapore Shape** has not been cleared for use in vertebroplasty. Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of mixing **Altapore Shape** with substances other than autologous blood or autologous bone is unknown.

*This release includes forward-looking statements concerning **Altapore Shape**, including potential benefits associated with its use. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

Baxter, **Altapore** and **Altapore Shape** are registered trademarks of Baxter International Inc.

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[1] Bolger Ciaran and Jones, D. (2019, 7). Evaluation of an increased strut porosity silicate-substituted calcium phosphate, SiCaP EP, as a synthetic bone graft substitute in spinal fusion surgery: a prospective, open-label study. European Spine Journal, 28(7), 1733-1742.

[2] Altapore Shape Bioactive Bone Graft Instructions for Use – Important Product Information

[3] Campion CR, Chandler C, Buckland T, Hing K. Increasing strut porosity in silicate-substituted calcium-phosphate bone graft substitutes enhances osteogenesis. J Biomat Mater Res Part B: Appl Biomater. 2011;97B:245-254.

[4] Hing K et al. Effect of silicon level on rate, quality and progression of bone healing within silicate substituted porous hydroxyapatite scaffolds. Biomaterials. 2006;27(29):5014-5026.