



FOR IMMEDIATE RELEASE

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**BAXTER ANNOUNCES U.S. FDA CLEARANCE OF ALTAPORE BIOACTIVE BONE GRAFT
IN POSTEROLATERAL SPINE SURGERY**

- *Specially designed to enhance and accelerate bone growth with proprietary silicate-substituted technology and optimized micro and macro porosity*
- *Features precise handling characteristics*
- *Can now be used in posterolateral spinal fusion procedures when combined with autograft or autogenous bone marrow aspirate, as well as standalone bone graft substitute to fill bony voids or gaps in orthopedic applications*

DEERFIELD, III., SEPT. 26, 2018 – Baxter International Inc. (NYSE:BAX), a global leader in advancing surgical innovation, today announced U.S. Food and Drug Administration (FDA) clearance of **ALTAPORE Bioactive Bone Graft**, a next-generation bioactive and osteoconductive bone graft substitute, for use as an autograft extender in posterolateral spinal fusion. **ALTAPORE** had previously been cleared for use in orthopedic surgical procedures in the extremities and pelvis.

ALTAPORE is designed to enhance bone growth with optimized porosity that promotes earlier vascularization, which plays a central role in the bone formation process by providing oxygen, nutrients, and growth factors critical for bone development. **ALTAPORE**'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, **ALTAPORE**'s unique chemistry contains 0.8 percent silicon by weight, which was shown to be optimal for bone formation in preclinical studies.

“**ALTAPORE** utilizes Baxter’s proprietary silicate-substituted technology and has an enhanced porosity that provides for earlier vascularization, increased cellular activity and improved volume of new bone growth. I’ve had a good experience with **ACTIFUSE** bone graft substitute, and am looking forward to taking advantage of the novel characteristics of **ALTAPORE** for my patients,” said Roger



Härtl, M.D., professor of Neurological Surgery, director of Spinal Surgery, and director of the Weill Cornell Medicine Center for Comprehensive Spine Care in New York.

ALTAPORE has been formulated to meet surgeons' needs, as it is easy to store, handle and implant. Its precise handling characteristics allow the putty to be molded into multiple shapes to adapt to various surgical needs. Additionally, in a pre-clinical posterolateral spinal fusion model, **ALTAPORE** used as an autograft extender exhibited similar fusion rates to iliac crest autograft, which is considered the current standard of care in spine surgical techniques. The iliac crest is an area of the pelvis commonly used for acquiring autogenous bone graft.

“Providing surgeons with versatile tools like **ALTAPORE** is critical to our commitment to partner with clinicians to advance healing in the operating room,” said Wil Boren, president of Baxter’s Advanced Surgery business. “With this clearance, more surgeons will have access to this innovative bone graft substitute as we look to improve outcomes across our entire portfolio of surgical products.”

ALTAPORE Bioactive Bone Graft is the latest addition to Baxter’s growing osteobiologics portfolio of surgical products, which includes **Actifuse Shape**, **Actifuse MIS**, **Actifuse ABX** and **Actifuse Flow**. Baxter received 510(k) clearance for the use of **ALTAPORE** as an autograft extender in posterolateral spine in August 2018. The company has started the process of packaging inventories carrying the new FDA-approved labeling and expects to start selling product in the United States by year-end. Baxter intends to unveil **ALTAPORE** at the 2018 North American Spine Society annual congress Sept. 26-29 in Los Angeles.

About Baxter’s Surgery Portfolio

Baxter is committed to partnering with clinicians to make a meaningful impact on patient care in operating rooms (OR) in nearly 60 countries. Surgeons rely on our hemostats to stop bleeding during surgery, our sealants to close wounds, and our repair patches and biologics to promote healing. We are focused on pioneering innovative and dependable surgical tools and programs that help improve clinical outcomes while reducing the total cost of care.

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 Bioactive Bone Graft

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.

Important Risk Information

ALTAPORE is contraindicated where the device is intended as structural support in the skeletal system. **ALTAPORE** 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** with substances other than bone marrow aspirate or autologous bone is unknown.

Rx Only. For safe and proper use of this device, refer to the full Instructions for Use.

*This release includes forward-looking statements concerning **ALTAPORE**, including potential benefits associated with its use and its anticipated market launch date. 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**, **Actifuse Shape**, **Actifuse MIS**, **Actifuse ABX** and **Actifuse Flow** are registered trademarks of Baxter International Inc.

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