



Procedural Solutions for Complex Spine

Reproducibly achieve
precise osteotomies
and robust fusions with
minimal blood loss.¹⁻⁴



Deliver the care your patients deserve with the **Bioventus Surgical portfolio.**

High-quality bone graft substitutes SIGNAFUSE and OSTEOAMP—matched with the efficient, effective bone-cutting technology of BoneScalpel—allow you to customize your approach and achieve strong outcomes for each patient.^{1,2,5,6}

SIGNAFUSE



OSTEOAMP in five formats:



Versatile

Bone Graft Substitutes: The Bioventus Surgical portfolio provides surgeons a full complement of biologic solutions to support fusion. SIGNAFUSE, a synthetic, is offered in putty and strips. OSTEOAMP is a premium 100% allograft designed to maintain an array of growth factors and available in five formats to meet various delivery needs.^{*7}

*In vitro performance may not be predictive of performance in humans.

BoneScalpel: The 20 and 25 mm blades allow surgeons to complete en bloc spinal osteotomies no matter the pathology. The unilaterally cutting Hook Shavers and 360° Diamond Shavers resect large quantities of cancellous bone in complex spinal procedures.

BoneScalpel options:



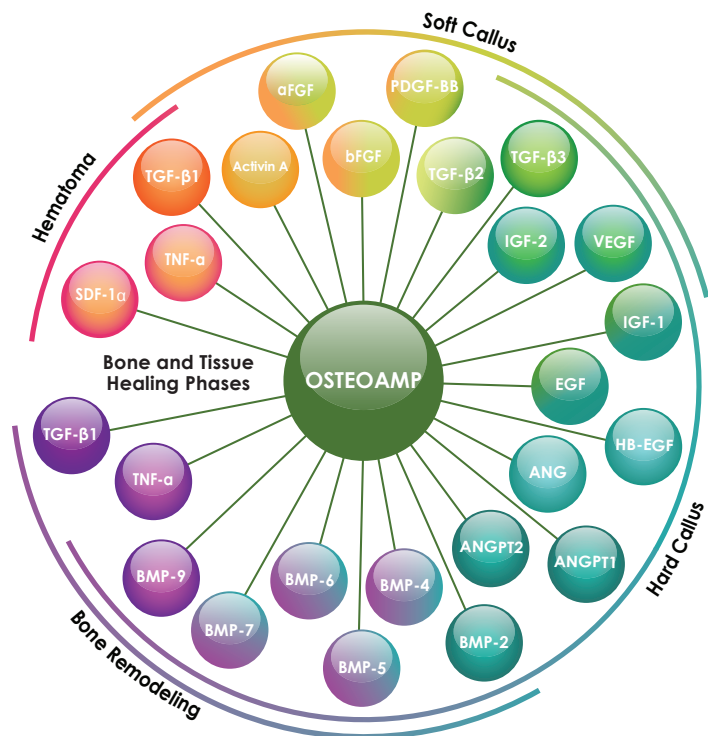
Clinically Supported

Bone Graft Substitutes: SIGNAFUSE is a synthetic bone graft made of bioglass and a biphasic mineral of beta-tricalcium phosphate (β TCP) and hydroxyapatite (HA) to support new bone formation. The 40:60 (β TCP:HA) composition of the biphasic mineral is clinically supported by multiple prospective and randomized controlled trials.⁸⁻¹¹

OSTEOAMP is supported by multiple peer-reviewed, clinical publications with positive fusion assessments in over 350 patients who received OSTEOAMP in a variety of surgical settings.^{1,2,5,6,12-14} OSTEOAMP demonstrated high fusion rates in posterior lumbar fusion (PLF) procedures, including two-level procedures, as well as high rates of improved patient outcomes, with no product-related serious adverse events.^{2,14}

The biphasic mineral in SIGNAFUSE is supported by clinical data in cervical, lumbar, and deformity surgeries. See the SIGNAFUSE table at right.

| Biphasic Mineral Clinical Outcomes | |
|------------------------------------|---|
| Cervical | no statistical difference between the biphasic mineral and ICBG, 86% and 87% respectively. ⁸ |
| Lumbar | 94% fusion rate ⁹ |
| Deformity | no statistical difference in radiographic results between biphasic mineral and autograft. ¹¹ |



In vitro performance may not be predictive of performance in humans.

Newton/Bartley Study

| Legend | BoneScalpel | Most Recent control | p value | Cobb-matched control | p value2 |
|---------------------------|--------------|---------------------|--------------|----------------------|--------------|
| Levels fused, n | 11.5 +/- 1.1 | 11.0 +/- 2.0 | 0.547 | 11.3 +/- 1.3 | 0.589 |
| Levels released, n | 5.5 +/- 1.1 | 5.2 +/- 1.6 | 0.499 | 5.5 +/- 1.2 | 0.9 |
| Surgical time, minutes | 247 +/- 62 | 233 +/- 42 | 0.41 | 229 +/- 30 | 0.25 |
| EBL, mL | 550 +/- 359 | 799 +/- 376 | 0.39 | 886 +/- 383 | 0.007 |
| Cell Saver transfused, mL | 94 +/- 146 | 184 +/- 122 | 0.42 | 198 +/- 115 | 0.017 |
| EBL/levels fused, mL | 48 +/- 30 | 72 +/-28 | 0.01 | 78 +/- 30 | 0.003 |
| EBL/levels released, mL | 100 +/- 50 | 163 +/- 71 | 0.003 | 178 +/- 116 | 0.009 |

EBL = Estimated blood loss

BoneScalpel: Ultrasonic bone cutting can reduce blood loss during procedures involving Ponte osteotomies by 30-40% when compared to procedures utilizing non-ultrasonic tools.¹⁴ Further research has shown blood loss reduction can reach up to 46% when using BoneScalpel to treat neuro-muscular scoliosis patients.¹⁵

See the Newton/Bartley study table at left.

Precise and Controlled

BoneScalpel: The non-rotational, longitudinal action of the BoneScalpel blades and shavers lets surgeons precisely remove bone without the traditional concerns of skipping and skiving. Furthermore, the thin design of the BoneScalpel blade allows for healthy bone preservation.

Bone Graft Substitutes: SIGNAFUSE Strips are available in various lengths, including a 200 mm strip, for ease of use and precise placement in long construct deformity procedures in the postero-lateral gutters.

OSTEOAMP Fibers are structurally entangled, providing versatile handling while maintaining integrity and position for accurate placement. The nanotextured surface provides a conduit for cell migration.^{15,17}

SIGNAFUSE



Powerful

BoneScalpel: The “Limit-Less” power of the BoneScalpel allows for large en bloc osteotomies and bone shaving in complex spine surgeries.

Bone Graft Substitutes: SIGNAFUSE was designed to mimic the natural architecture of human bone via macro and micro porosity, allowing for diffusion of biological fluids. It offers a large surface area for exchange of calcium and phosphate ions.^{16,17} The SIGNAFUSE Strip induced higher levels of osteoblast differentiation compared with other synthetic bone graft strips.¹⁸ The ability to start fast with bioglass, sustain bone growth with β TCP, and finish strong with HA offers benefits throughout the bone growth cascade.

OSTEOAMP is a differentiated allograft with unique processing designed to retain an array of growth factors that support each stage of the bone-healing cascade.^{*7} In one study, OSTEOAMP exhibited higher rates of fusion than local autologous bone at 12 months, and in another study, independent of bone marrow aspirate (BMA) presence, successful fusion was seen.^{1,2}

Alkaline phosphatase expression from media of MG63 cells conditioned with SIGNAFUSE Strip, growth media only (control), and other synthetic strips at day 5 and 7. Data are mean \pm S.D.

^{*}In vitro performance may not be predictive of performance in humans.

"I use the Bioventus BoneScalpel for every complex spine case I perform. BoneScalpel provides accurate cuts with excellent tactile feedback while minimizing the amount of excessive bleeding from the bone. I also feel this device is safer for my learners when there are delicate soft tissue structures at risk.

In addition, I like to use the SIGNAFUSE synthetic strips offered by Bioventus when I have posterior osteotomies spanning several segments. The thickness and pliability of the material allows me to adequately cover the spinal canal, minimizing the risk of getting small chips of bone into the canal. This combination of Bioventus products is irreplaceable in my complex spinal cases."

Robert Lark, MD

Orthopaedic Spine Surgeon

Dr. Lark is a paid consultant for Bioventus.



Efficient

Bone Graft Substitutes: SIGNAFUSE strips hydrate quickly and are available in multiple formats, including a 200 mm strip, for efficient placement along the gutters. Compared to ACTIFUSE® ABX, SIGNAFUSE has shown higher rates of spine fusion and new bone formation in a validated posterolateral spine fusion rabbit model.¹⁹

OSTEOAMP Fibers mix efficiently with local autologous bone and handle efficiently for placement in the posterolateral gutters and interbody cages. Also, OSTEOAMP Flowable is available for difficult-to-reach graft placements, such as backfilling cages and the disc space.

*In vitro performance may not be predictive of performance in humans.

BoneScalpel: Ultrasonic bone cutting allows surgeons to complete bony resections in complex cases with just one handpiece. The clinically supported reduction of blood loss and self-irrigating probes can create additional efficiencies during osteotomies.^{14,15}

BoneScalpel



OSTEOAMP SELECT Fibers





For more information, visit
bioventus.com/products/surgicalsolutions/
or scan the QR code.

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The potential limitations of the retrospective spine fusion studies for OSTEOAMP include the following. Retrospective analysis limited by availability of radiographs and medical record data. Endpoint of interest limited to radiographic assessment of fusion and radiographic evidence of complications, with no corresponding clinical outcomes or general adverse events. Data from a subset of the patients may have been included in other retrospective analyses. Use of adequate sample sizes to detect differences in variables explored, including comparisons between OSTEOAMP and rhBMP-2, is unknown. Treating surgeons were unpaid consultants and held shares for Advanced Biologics. However, none of the authors have financial ties to Bioventus, and radiographic fusion was assessed by an independent, blinded radiologist. In the Lumbar Spine Study reported by Roh et al., radiographic assessments for a majority of patients (>70%) in the OSTEOAMP group were based on standard x-ray images while assessment for majority of patients (60%) in the rhBMP-2 group were based on CT images.

The potential limitations of the biphasic mineral studies include the following. Older studies may not comply with current good clinical practice and limited details on methods and results are provided in the paper. The Delecrin paper appears to be a subset of the French patients in Ransford et al.

Use of SIGNAFUSE is limited to posterolateral use in the spine as a bone graft extender with autograft. Use in the interbody space is off label in the US.

Indications for Use for BoneScalpel and BoneScalpel Access:

BoneScalpel is indicated for the fragmentation and emulsification of hard and soft tissue. For a complete list of indications and contraindications, please visit misonix.com/ifu.

BoneScalpel Access is indicated for the fragmentation and emulsification of hard and soft tissue. For a complete list of indications and contraindications, please visit misonix.com/ifu.

Indications for Use for OSTEOAMP:

OSTEOAMP & OSTEOAMP SELECT may be used in situations where an autograft is appropriate. It should be restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects.

Full prescribing information can be found in product labeling, at bioventussurgical.com or Customer Service at 1-800-637-4391.

Indications for Use SIGNAFUSE:

SIGNAFUSE is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SIGNAFUSE is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine fusion procedures).

SIGNAFUSE can also be used with autograft as a bone graft extender in posterolateral spine. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

Full prescribing information can be found in product labeling, at bioventussurgical.com or Customer Service at 1-800-637-4391.

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Innovations For Active Healing