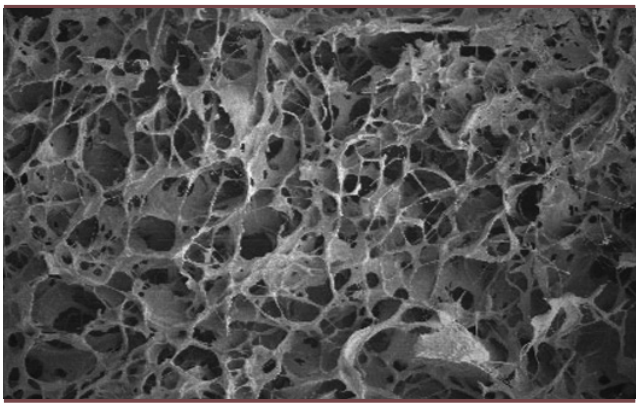
BoneSync™ Putty and Strips

Arthrex®

BONESYNC

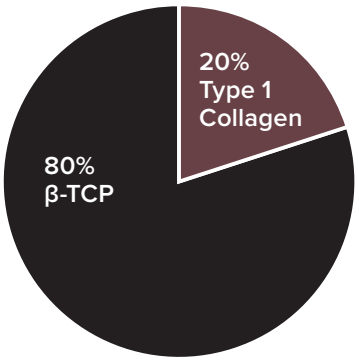
Advanced Engineering

The blend of 20% type I collagen and 80% highly purified beta-tricalcium phosphate (ß-TCP) in the BoneSync™ putty and strips provides an osteoconductive material for bone regeneration. It was developed to resemble the composition and pore structure of natural human bone.[1]



Engineered Collagen Matrix
Capitalizing on over 20 years of development expertise, with collagen technologies that have been used in over 10 million patients, the source of collagen found in BoneSync bone void filler is specifically engineered to optimize safety, handling and performance. The scaffold in BoneSync putty and strips, processed from purified type-I collagen, is a critical design element that allows for rapid fluid imbibition, cellular ingrowth, and controlled resorption.

Highly Purified ß-TCP
The highly purified ß-TCP component of the BoneSync putty and strips is designed for a resorption profile consistent with bone formation. The porous architecture is specifically engineered for osteoconductivity.[1]



Benefits of the Collagen-Engineered Matrix in Orthopedic Applications

- Specifically engineered to provide a scaffold with a porosity resembling natural bone
- Facilitates incorporation of cells in bone marrow aspirate and tissue cells during the healing process[2]
- The highly purified type I collagen in BoneSync bone void filler is the most abundant type of collagen found in bone
- Purification and biocompatibility minimize the potential for immune response

Putty and Strips for Cells and Proteins

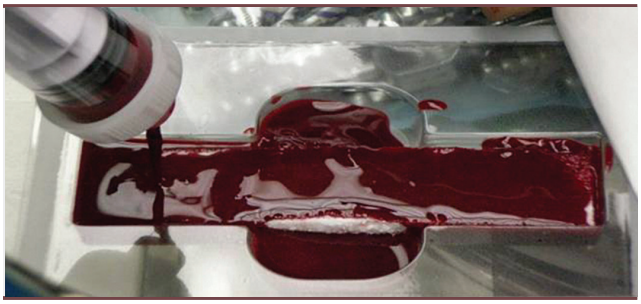
Fluid Retention

With an interconnected pore structure engineered for absorbing fluids, BoneSync™ putty and strips effectively retain bone marrow aspirate within the material.

Cell Binding

Higher densities of collagen provide greater protein binding sites and have been associated with more effective incorporation of bioactive proteins.[2]

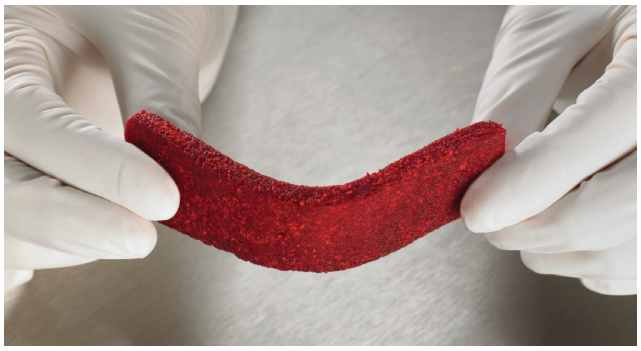
BoneSync putty and strips have an interconnected pore structure that absorbs bone marrow aspirate, which



contains cells and proteins that play an important role in bone formation. The collagen in BoneSync putty and strips facilitates the binding of bone forming cells and proteins.

Diverse Configurations

BoneSync filler is offered in both putty and strip configurations to meet varying application needs and preferences. Each configuration benefits from purified biomaterials and advanced engineering while offering unique advantages to the surgeon.



Strip

Compression-resistant matrix combines the cell-binding benefits of cross-linked type-I collagen with the volume and radiopacity of highly purified ß-TCP granules.[2]

Configuration Benefits:

- Excellent carrier for bone marrow aspirate
- Bends to conform to uneven surfaces
- Maintains postoperative graft volume

Putty

Moldable putty has the cell-binding benefits of type-I collagen and the volume and radiopacity of highly purified ß-TCP granules.

Configuration Benefits:

- Versatile with excellent handling
- Optimal for placement in irregularly shaped defects

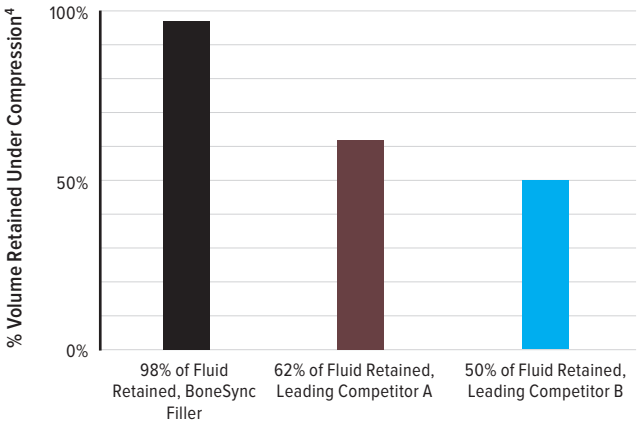
Compression Resistance

The framework of ß-TCP and cross-linked type-I collagen in BoneSync™ putty and strips resists compression and maintains the structure of the material.[3] This configuration has fixed dimensions but is also flexible, conforming to uneven surfaces, for various applications in the skeletal system.

- Retains bone marrow aspirate within the matrix, facilitating bone fusion
- Maintains graft volume under compression

Compression-Resistant Matrix

A matrix with compression resistance has an increased ability to retain bone marrow aspirate and its active cells.



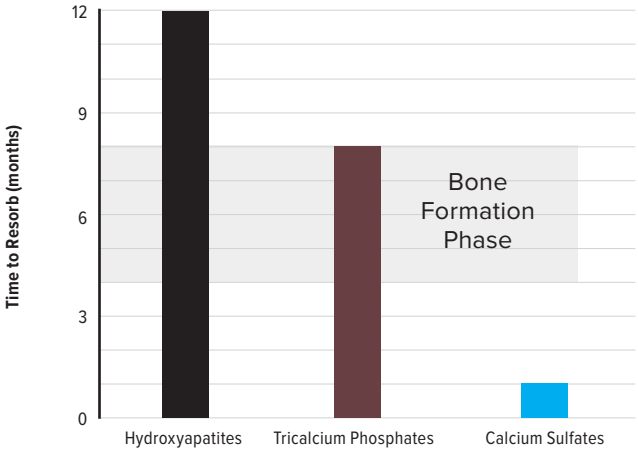
Resorption Profile

Resorption Profile Consistent With the Formation of New Bone

The residence time of an osteoconductive strip is a crucial factor for bone healing. A relatively short resorption profile often results in limited or weak bone growth, while longer residence time often results in ineffective tissue incorporation.

The composition and microarchitecture of the ß-TCP component of BoneSync putty and strips is engineered to support the replacement of the graft material by new bone.[5]

ß-TCP vs Competing Graft Components[5]



BoneSync Strip

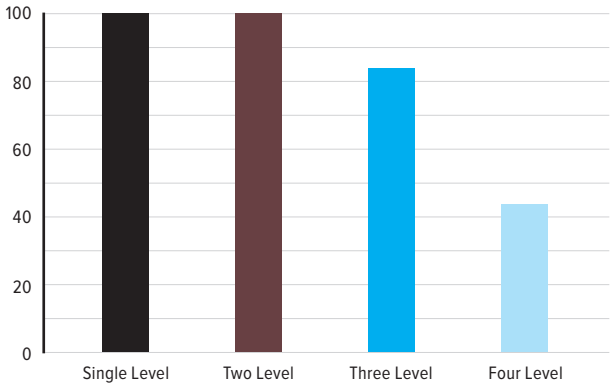
BoneSync Putty

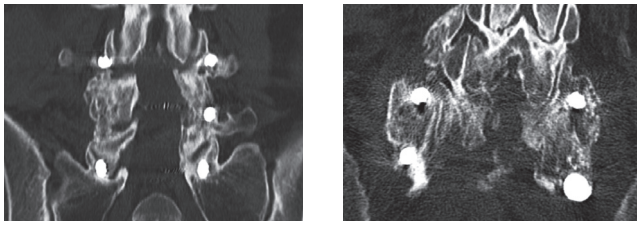
Clinical Evidence

A BoneSync equivalent osteoconductive scaffold demonstrated fusion rate that was equivalent to autograft in a retrospective study on posterolateral lumbar fusion. This clinical study, which included patients with common comorbidities such as smoking, diabetes, and osteoporosis. This clinical study found 100% fusion in all single- and two-level procedures, with an overall fusion rate of 90%. No significant differences were observed for the fusion scores in patients that received putty versus strip.[1]

- Fusion rates for BoneSync equivalent scaffold equivalent to autograft
- Success in a patient population containing common comorbidities including smoking, diabetes, and osteoporosis
- In cases of successful fusion, definitive, uninterrupted bridging of well-mineralized trabecular bone observed 12 months after surgery, as determined by an independent radiologist blinded to treatment
- BoneSync equivalent scaffold applied as indicated with bone marrow aspirate alone, no addition of autograft or allograft
- Spinal fusion comparisons performed in each patient individually; the BoneSync equivalent scaffold applied to the symptomatic side and autograft to the contralateral side

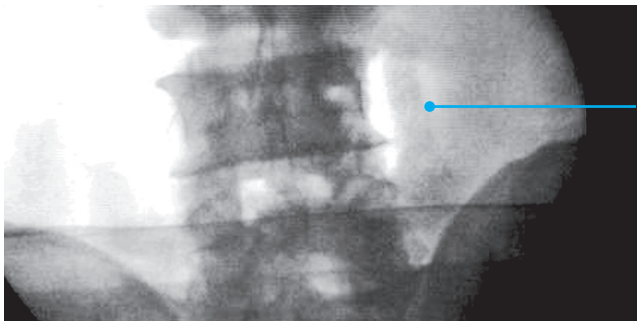
Clinical Performance – 90% Overall Fusion[1]
Fusion rates were equivalent to autograft, including the ability to achieve fusion in 100% of single- and two-level procedures.





Representative radiographs from the referenced study.[1]
CT scans from two patients at 12 months post-op.

Radiographic Visualization



Data on file

The ß-TCP component of BoneSync filler is engineered with a porosity level that balances radiopacity, residence time, and structure. An extremely porous graft material will likely limit radiopacity and structure, while an extremely dense material will likely limit graft incorporation into natural tissue.

- Provides radiographic visualization of graft placement
- Indicates active resorption during healing

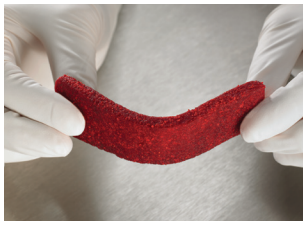
Ordering Information

BoneSync™ Strip

Product Description	Item Number
Strip, 10 cc (100 × 25 × 4 mm)	ABS-**3310**
Strip, 15 cc (100 × 25 × 6 mm)	ABS-**3315**

BoneSync Putty

Product Description	Item Number
Putty, 2.5 cc	ABS-**3202**
Putty, 5 cc	ABS-**3205**
Putty, 10 cc	ABS-**3210**
Putty, 15 cc	ABS-**3215**



Strip

Putty

To order, please call Arthrex at 1.800.934.4404 or call your local Arthrex representative for additional information.

Indications for Use

BoneSync strip and putty, combined with Bone Marrow Aspirate (BMA), are intended for use as bone void filler to fill voids or gaps of the skeletal system in the extremities, spine and pelvis not intrinsic to the stability of the bony structure. BoneSync strip and putty are also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), BoneSync strip and putty are resorbed and replaced with bone during the healing process.

Warnings

- ***Do not resterilize!***
- Do not use if the product package is damaged or opened.
- Do not use to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes.
- Screws must gain purchase in the host bone as opposed to the BoneSync strip and putty.
- Do not use to repair bone defects where soft-tissue coverage cannot be achieved as complete post-operative wound closure is necessary.

Precautions

- Rinse surgical gloves to remove any glove powder prior to handling BoneSync strip and putty
- The radiopacity of BoneSync strip and putty is comparable to that of bone and diminishes as it is resorbed. When evaluating X-rays, the radiopacity of the material may mask underlying pathological conditions
- Avoid overfilling of the defect site

BoneSync strip and putty are manufactured by:

IsoTis OrthoBiologics, Inc.
2 Goodyear, Suite A, Irvine CA 92618
Phone (800) 550-7155 | Fax (800) 471-3248
SeaSpine.com IsoTis OrthoBiologics, Inc. is a member of the SeaSpine Orthopedics Corporation family of companies.
Made in the USA.

Warning: Applicable laws restrict these products to sale by or on the order of a physician.

References

1. Mataragas, N. Radiographic analysis of fusion success with Integra Collagen Ceramic Matrix, as compared to autograft use, in posterolateral lumbar spine arthrodesis. Integra Life Sciences Corp. Data on file. 2010.

2. Geiger M, Li RH, Friess W. Collagen sponges for bone regeneration with rhBMP-2. *Adv Drug Deliv Rev*. 2003;55:1613-1629.

3. SeaSpine. Test data on file. Carlsbad, CA.

4. SeaSpine. Data on file. Carlsbad, CA.

5. Ogose A, Hotta T, Kawashima H, et al. Comparison of hydroxyapatite and beta tricalcium phosphate as bone substitutes after excision of bone tumors. *J Biomed Mater Res*. 2005;72B(1):108. doi: 10.1002/jbm.b.30136.

View U.S. Patent information at
www.arthrex.com/corporate/virtual-patent-marking