CLINICAL EVIDENCE

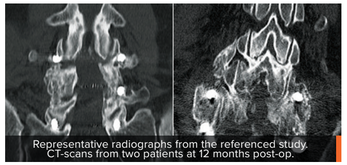
OsteoStrux® Osteoconductive Scaffold has been shown to be equally effective to autograft.[1]

OsteoStrux Osteoconductive Scaffold demonstrated equivalent fusion rate to autograft in a retrospective study on posterolateral lumbar fusion, 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]

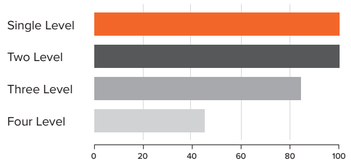
- OsteoStrux Scaffold demonstrated equivalent fusion rates to autograft
- Success in a patient population containing common comorbidities including smoking, diabetes and osteoporosis
- In cases of successful fusion, definitive, uninterrupted bridging of well-mineralized trabecular bone was observed 12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



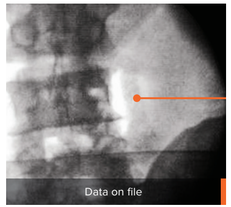
Representative radiographs from the referenced study. CT-scans from two patients at 12 months post-op.



RADIOGRAPHIC VISUALIZATION

The ß-TCP component of the OsteoStrux Scaffold 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



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ORDERING INFORMATION & INSTRUCTIONS FOR USE

OsteoStrux® Strip

Part #	Description	Size
56010100	Strip	10cc (100 x 25 x 4mm)
56010150	Strip	15cc (100 x 25 x 6mm)

OsteoStrux Putty

Part #	Description	Size
56070025	Putty	2.5cc
56070050	Putty	5cc
56070100	Putty	10cc
56070150	Putty	15cc

Indications for Use

OsteoStrux 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 extremeties, spine and pelvis not intrinsic to the stability of the bony structure. OsteoStrux 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), OsteoStrux Strip or Putty is resorbed and replaced with bone during the healing process.

Warnings

- Do not re-sterilize!
- 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 OsteoStrux Strip or Putty.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete postoperative wound closure is necessary.

Precautions

- Rinse surgical gloves to remove any glove powder prior to handling OsteoStrux Strip or Putty.
- The radiopacity of OsteoStrux Strip and Putty is comparable to that of bone and diminishes as it is resorbed. When evaluatingX-rays, the radiopacity of the material may mask underlying pathological conditions.
- Avoid over-filling of the defect site.

References

1. Mataragas, Nicholas. Radiographic analysis of fusion success with Integra Collagen Ceramic Matrix, as compared to autograft use, in posterolateral lumbar spine arthrodesis. 2010. Data on File. Dr. Mataragas was a consultant for Integra LifeSciences at the time of this investigation.
2. Geiger M, Li RH, Friess W. Collagen sponges for bone regeneration with rhBMP-2. Adv Drug Deliv Rev. 2003;55:1613-1629.
3. Test Data on File.
4. Data on File.
5. Ogose, Akira, Hotta, Tetsuo, et al. Comparison of Hydroxyapatite and Beta Tricalcium Phosphate as Bone Substitutes After Excision of Bone Tumors. Published online 16 September 2004 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/jbm.b.30136.

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OSTEOSTRUX® STRIP & PUTTY

OSTEOCONDUCTIVE SCAFFOLD
SALES BROCHURE

ADVANCED ENGINEERING

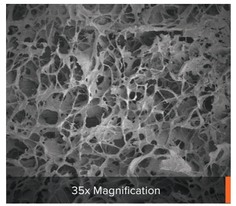
The blend of 20% Type-I collagen and 80% highly purified Beta-Tricalcium Phosphate (ß-TCP) in the OsteoStrux® Scaffold provides an osteoconductive material for bone regeneration. It was developed to resemble the composition and pore structure of natural human bone.[1]

OsteoStrux Strip

OsteoStrux Putty

Engineered Collagen Matrix

Capitalizing on over 20 years of development expertise, with collagen technologies that have been used in over 10 million patients, the SeaSpine® source of collagen is specifically engineered to optimize safety, handling and performance. The scaffold in OsteoStrux, processed from purified Type-I collagen derived from bovine tendon, is a critical design element that allows for rapid fluid imbibition, cellular ingrowth, and controlled resorption.

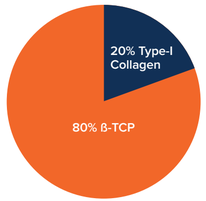


Highly Purified ß-TCP

The highly purified ß-TCP component of the OsteoStrux Scaffold 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 SeaSpine collagen is composed of highly purified Type-I collagen, the most abundant type of collagen found in bone
- Purification and biocompatibility minimizes the potential for immune response



SCAFFOLD FOR CELLS AND PROTEINS

Fluid Retention

With an interconnected pore structure engineered for absorbing fluids, the OsteoStrux® Scaffold effectively retains bone marrow aspirate within the material.

Cell Binding

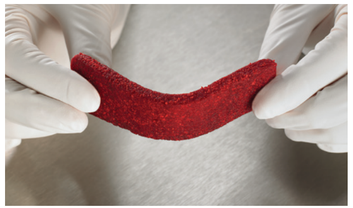
Higher densities of collagen provide greater protein binding sites and have been associated with more effective incorporation of bioactive proteins.[2] The OsteoStrux Scaffold has an interconnected pore structure that absorbs bone marrow aspirate, which contains cells and proteins that play an important role in bone formation. The SeaSpine® collagen facilitates the binding of bone-forming cells and proteins.

DIVERSE CONFIGURATIONS

The OsteoStrux Scaffold 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.

Osteostrux 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

Osteostrux Putty

Moldable putty with 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 of the spine or extremities

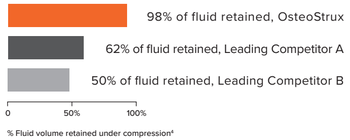
COMPRESSION RESISTANCE

The framework of ß-TCP and cross-linked Type-I collagen in the OsteoStrux® Scaffold resists compression and maintains its structure.[3] This configuration has fixed dimensions but is also flexible for various applications in the skeletal system, conforming to uneven surfaces.

- Retains bone marrow aspirate within the matrix, facilitating in 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 scaffold 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 the OsteoStrux Scaffold is engineered to support the replacement of the graft material by new bone.[5]

ß-TCP vs. Competing Graft Components[5]