

Clinically Proven

Integra Mozaik™ Osteoconductive Scaffold has been shown to be equally effective to autograft¹

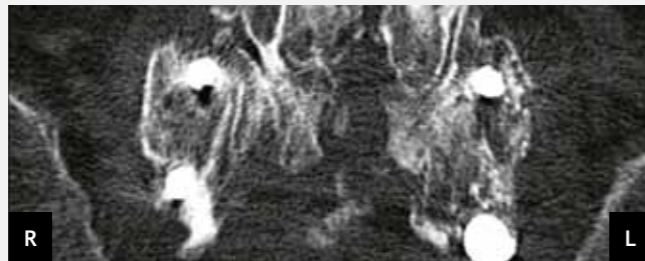
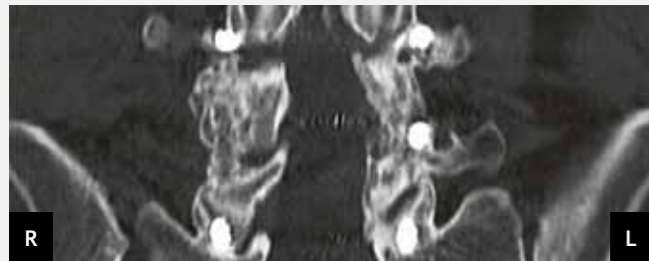
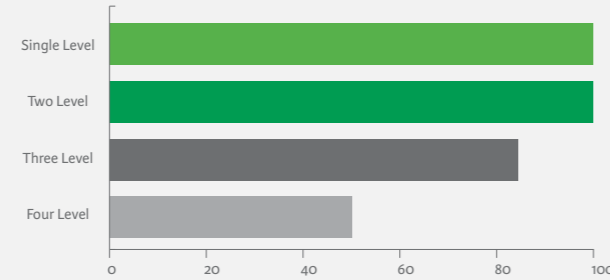
A key clinical study on the use of the Integra Mozaik™ Osteoconductive Scaffold (versus autograft) in posterolateral lumbar fusion supports the product's safety and effectiveness as an alternative to autograft.

90% OVERALL FUSION¹

- Equivalent performance between the Integra Mozaik™ Osteoconductive Scaffold and autograft.
- Success in a patient population containing many common confounding factors or 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.
- Integra Mozaik™ Osteoconductive Scaffold applied as indicated with bone marrow aspirate alone, no addition of autograft or allograft.
- Spinal fusion comparisons performed in each patient individually, Integra Mozaik™ Osteoconductive Scaffold applied to the symptomatic side and autograft to the contralateral side.

Clinical Performance

Fusion rates were equivalent to autograft, including the ability to achieve fusion in **100%** of one and two level procedures.



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

Diverse Configurations

Strip



Compression resistant matrix combines the cell binding benefits of cross-linked Type-I collagen with the volume and radiopacity of highly purified β-TCP granules.

Configuration Benefits:

- Excellent carrier for Bone Marrow Aspirate
- Bends to conform to uneven surfaces
- Maintains post operative graft volume

Putty



Moldable putty with the cell binding benefits of Type-I collagen and the volume and radiopacity of highly purified β-TCP granules.

Configuration Benefits:

- Versatile with excellent handling
- Optimal for placement in irregularly shaped defects of the spine or extremities

Integra Mozaik™ Osteoconductive Scaffold Ordering Information

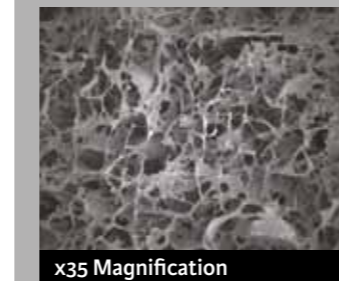


Moldable Putty

Description	Catalog number
15cc	PTY10256ITL
10cc	PTY10210ITL
5cc	PTY10155ITL
2.5cc	PTY10125ITL

Compression Resistant Strip

Description	Catalog number
15cc (100x25x6 mm)	CCM10256ITL
10cc (100x25x4 mm)	CCM10210ITL



Integra Engineered Collagen Matrix

With 30 years of experience in regenerative technology and over 10 million implants to date of products such as DuraGen® Dural Graft Matrix, Layershield® Adhesion Barrier Matrix, Integra's engineered collagen matrix carries a long history of safe and effective use.

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. 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. **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

Integra LifeSciences Services (France) SAS
Sales & Marketing EMEA
Immeuble Séquoia 2 • 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69100 Saint Priest • FRANCE
T +33 (0)4 37 47 59 00 • Fax +33 (0)4 37 47 59 99
emea.info@integrallife.com • integrallife.eu

Customer Service
International: +1 (949) 595 8710 • Fax: +1 (949) 595 8777 • irvine.customerservice@integrallife.com

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Because we are committed to limiting uncertainty, we continuously develop new biologic technologies to complete the Integra biologic product line.

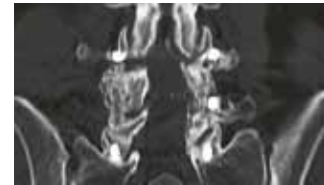
Specifications

80 % Highly Purified beta-TCP Granules

- Provides defect filling volume.
- Allows for radiographic visualization of bone graft placement.
- Contains mineral components necessary for bone growth.

20 % Highly Purified Type-1 Collagen

- Provides sites for protein binding.¹
- Biocompatibility and safety of Integra's collagen demonstrated in over 10 million implants (neurosurgery, plastic and reconstructive surgery, and orthopedic surgery).
- Rapid and complete absorption of bioactive proteins.¹



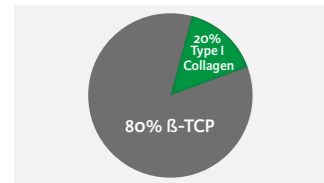
Clinically Proven

Integra Mozaik™ Osteoconductive Scaffold has demonstrated equivalent fusion performance to autograft in a retrospective study on posterolateral lumbar fusion that included patients with many 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%.¹



Diverse Configurations

The Integra Mozaik™ Osteoconductive Scaffold is offered in two diverse configurations including strip and putty to meet varying application needs and preferences. Each configuration benefits from purified components and advanced engineering while offering unique advantages to the surgeon.



Advanced Engineering

The blend of 20% Type I Collagen and 80% highly purified beta-TCP in the Integra Mozaik™ Osteoconductive Scaffold provides an exceptional osteoconductive scaffold for bone regeneration. The specialized architecture is engineered to resemble the porosity of natural human bone, and promotes successful fusion.



Carrier for Cells and Proteins

The Integra Mozaik™ Osteoconductive Scaffold has an interconnected pore structure that absorbs bone marrow aspirate, which contains cells and proteins that play an important role in bone formation. Integra's collagen technology enhances the binding of bone forming proteins and cells.



Radiographic Visualization

The beta-TCP used in the Integra Mozaik™ Osteoconductive Scaffold provides radiographic visualization of graft placement, and acts as an indicator of active resorption during healing.



Compression Resistance

The formulation of beta-TCP and cross-linked Type-I collagen in Integra Mozaik™ Osteoconductive Scaffold strip provides the material with structure and compression resistance. Integra Mozaik™ Osteoconductive Scaffold strip maintains its graft placement and three-dimensional structure while allowing for surgical flexibility in various applications.



Exceptional Resorption Profile

The beta-TCP component of the Integra Mozaik™ Osteoconductive Scaffold is engineered to resorb at a rate consistent with the formation of new bone. The residence time allows for the complete replacement of the graft material by new natural bone.³



Integra Engineered Collagen Matrix

With 30 years of experience in regenerative technology and over 10 million implants to date of products such as DuraGen® Dural Graft Matrix, Layershield® Adhesion Barrier Matrix, Integra's engineered collagen matrix carries a long history of safe and effective use.

Advanced Engineering

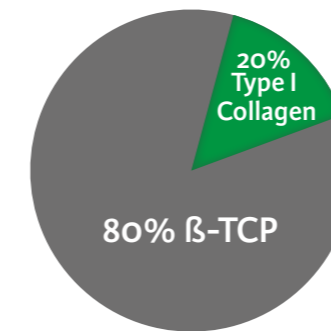
Integra Engineered Collagen Matrix and Highly Purified Beta- Tricalcium Phosphate (beta-TCP)

Engineered Collagen Matrix (ECM)

With 30 years of experience in regenerative technology and over 10 million implants to date, Integra is a leader in collagen engineering. Integra's industry leading collagen products span a broad range of clinical applications, including Integra® Dermal Regeneration Template, DuraGen® Dural Graft Matrix, Layershield® Adhesion Barrier Matrix, and NeuraGen® Nerve Guide.

Highly Purified beta-TCP

The highly purified beta-TCP component of the Integra Mozaik™ Osteoconductive Scaffold is designed for an optimal resorption profile. The porous architecture is engineered to optimize the graft's osteoconductive properties.



The Integra Mozaik™ Osteoconductive Scaffold is engineered as an exceptional osteoconductive scaffold.

Benefits of ECM in Orthopedic Applications

- Specifically engineered to provide a scaffold with a porosity resembling natural bone
- Provides binding sites for cells in Bone Marrow Aspirate, and tissue cells during the healing process
- Integra's 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

Carrier for Cells and Proteins

Fluid Retention

With an interconnected pore structure engineered for absorbing fluids, the Integra Mozaik™ Osteoconductive Scaffold effectively retains bone marrow aspirate within the matrix.



Cell Binding

With a favorable influence on cellular infiltration and wound healing, higher densities of collagen provide greater protein binding sites and have been associated with more rapid incorporation of bioactive proteins.²

Radiographic Visualization



The highly purified beta-TCP component of the Integra Mozaik™ Osteoconductive Scaffold acts as an effective radiopaque marker.

- Provides radiographic visualization of graft placement
- Indicates active resorption during healing
- Maintains three-dimensional structure throughout the healing process

The beta-TCP component of the Integra Mozaik™ Osteoconductive 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.

Compression Resistance

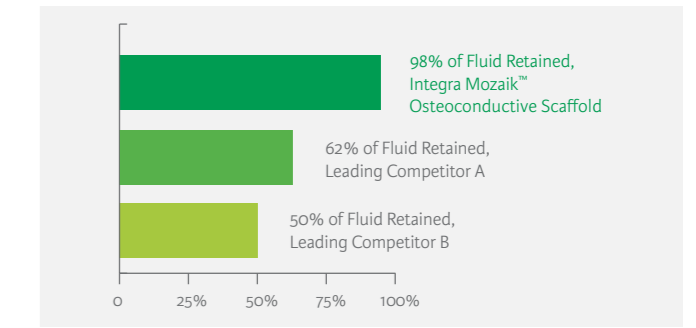
The highly purified beta-TCP along with cross-linked Type-I collagen in Integra Mozaik™ Osteoconductive Scaffold strip provides the material with structure and compression resistance while maintaining the flexibility to conform to uneven surfaces.

- Retains bone marrow aspirate within the matrix, resulting in guided 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. This structure enables robust 3-dimensional bone formation throughout the graft.



% Fluid volume retained under compression.

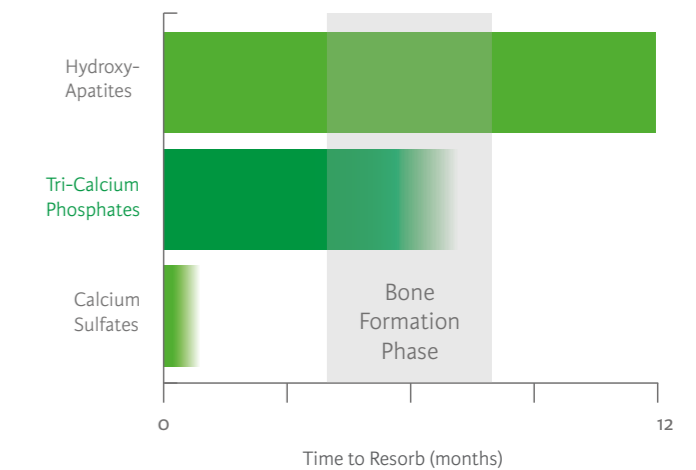
Exceptional Resorption Profile

Resorption Profile Consistent with the Formation of New Bone

The residence time of an osteoconductive scaffold is a crucial factor for bone healing. A shorter than ideal resorption profile often results in limited or weak bone growth, while an extensive profile often results in ineffective tissue incorporation, leaving the graft intact.

The composition and microarchitecture of the beta-TCP component of the Integra Mozaik™ Osteoconductive Scaffold is engineered to support the complete replacement of the graft material by new natural bone.³

beta-TCP vs. Competing Graft Components



Collagen Development Timeline

