INTEGRA OS™

OSTEOCONDUCTIVE SCAFFOLD

THE OSTEOCONDUCTIVE SCAFFOLD
FROM THE LEADERS IN COLLAGEN TECHNOLOGY

INTEGRA™
Extremity Reconstruction

INTEGRA OS™

OSTEOCONDUCTIVE SCAFFOLD

The Foundation for Fusion

Integra OS™ Osteoconductive Scaffold, combined with bone marrow aspirate, guides new bone formation in the treatment of osseous defects.

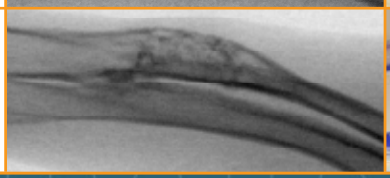
- Integra OS Putty is a resorbable bone void filler with excellent absorption and retention of fluids.
- Integra OS rapidly imbibes bone marrow aspirate, allowing the scaffold to bind cellular components and bioactive proteins.

Integra OS Putty is designed to facilitate the natural healing processes of bone regeneration and resorption.

- The Putty resorbs at a rate consistent with new bone formation.[1]
- Integra OS composed of β -Tricalcium Phosphate (β -TCP) has an ideal residence time of 6 to 12 months before resorption[1], providing mineral content to foster bone formation during the healing process.
- Ceramics that resorb more quickly, i.e. dicalcium phosphate, may not be present throughout bone-healing.
- Ceramics that resorb more slowly, i.e. hydroxyapatite, may remain in the body when no longer useful.

Integra OS Putty provides a framework for new bone formation and is ultimately remodeled into bone.

- The structure and composition of Integra OS simulate natural bone matrices.
- New bone forms in apposition to the Integra OS osteoconductive scaffold, resulting in guided bone fusion.

Integra OS Putty	X-Ray	Histology
Baseline Original defect and implanted Integra OS™		
6 Weeks Callus formation and early fusion		
12 Weeks Complete fusion and bone remodeling		

Based on studies conducted with Integra OS Putty in animal model (rabbit).

Integra: A leader in regeneration technology

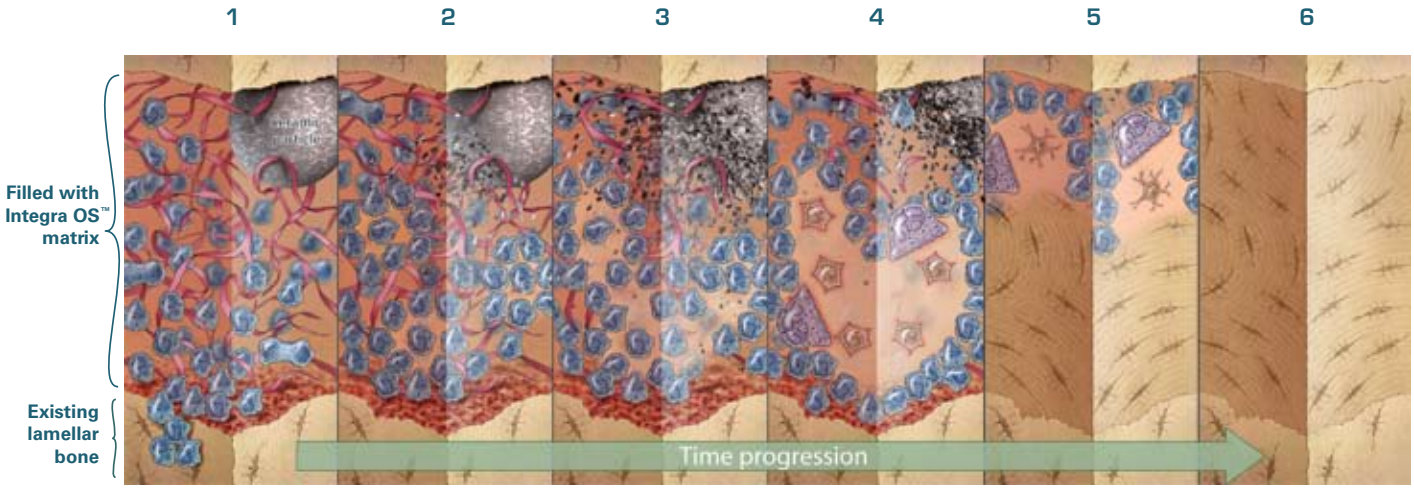
- Collagen from Integra used in over 10 million procedures.
- Major corporations trust the collagen expertise of Integra.

1970-1980's	1996
Collagen Matrix Development	Plastic & Reconstructive INTEGRA® Dermal Regeneration Template

*Developed by Integra for use with another company's product.

Pure Components Create a Natural Environment for Bone Formation

Integra OS BONE BIOLOGY



1 Cell Attachment, Migration, and Proliferation
Integra OS™ provides a framework of cell-binding proteins for rapid ingrowth of cells.

2 Cell Proliferation and Differentiation
Cells differentiate into osteoblasts and osteoclasts and begin to deposit new bone within the Integra OS™ matrix.

3 Bone Deposition and Growth
New bone clusters coalesce to form larger islands of new woven bone. Integra OS™ ceramic particles dissolve, providing minerals for bone growth.

4 Woven Bone Remodeling
New woven bone is remodeled by osteoblasts and osteoclasts. Integra OS™ ceramic continues to dissolve, providing minerals for bone growth.

5 Lamellar Bone Formation
Woven bone is remodeled to form strong lamellar bone.

6 Fused Bone

Integra OS™ Osteoconductive Scaffold is composed of 20% highly purified Type-I Collagen and 80% high purity β -Tricalcium Phosphate.

- Pure components minimize the potential for immune response to Integra OS Putty.

20% Type-I Collagen: Provides excellent handling characteristics and demonstrated biocompatibility.

- High collagen density provides strong protein binding sites, and has been associated with rapid and complete absorption of bioactive proteins.[2]
- Collagen from Integra has a strong history of safety, purity and biocompatibility.

80% β -TCP granules: Provides localized mineral content to foster bone formation.

- Serves as a unique radiopaque marker for visualization of bone graft placement.
- Allows radiographic detection of new bone formation.

2001	2002		2003	2004	2005	2006
Nerve NeuraGen® Nerve Guide	Plastic & Reconstructive INTEGRA™ Matrix Wound Dressing INTEGRA™ Bilayer Matrix Wound Dressing	Bone Absorbable Collagen Sponge with Bone Growth Factor*	Bone Collagen Ceramic Matrix Bone Graft Substitute*	Nerve NeuraWrap™ Nerve Protector	Tendon TenoGlide®	Bone Integra OS™ Osteoconductive Scaffold

Integra OS Osteoconductive Scaffold: Integral to Bone Growth

The highly purified Type-I Collagen and β-Tricalcium Phosphate in Integra OS create a natural, porous matrix to guide new bone formation.

Integra OS Putty features excellent handling characteristics and can be easily packed into a defect site: ideal for use in the extremities.

FEATURE	FUNCTION	BENEFIT
20% Collagen	Provides strong binding sites for retention of bioactive proteins[2]	Excellent handling/moldability Demonstrated biocompatibility
80% Tricalcium Phosphate	Provides minerals for bone growth	Fosters new bone formation Ideal resorption profile[1]
Integra OS Putty	Osteoconductive scaffold facilitates bone remodeling and guided bone fusion	Interconnected pore structure rapidly absorbs and effectively retains fluids

Integra OS Osteoconductive Scaffold	CATALOG #	DESCRIPTION
	IOS10125	Small (2.5cc) Putty
	IOS10155	Medium (5cc) Putty

Indications for Use: Integra OS Osteoconductive Scaffold – Putty, combined with bone marrow aspirate, is intended for use as a 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. Integra OS Putty is 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), Integra OS Putty is resorbed and replaced with bone during the healing process.

Adverse Events: As with other bone grafting materials, there are the following potential complications for Integra OS: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis. Immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. Although there is no evidence that the device will be unsafe or ineffective in such patients, the safety and effectiveness of the device in these patients has not been established. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

References:

1. Based on studies conducted with Integra Osteoconductive Scaffold Strip and Putty in an animal model (rabbit). Data on file. Integra LifeSciences Corporation, Plainsboro, NJ. 2006.

2. Geiger M., Li RH., Friess W. Collagen sponges for bone regeneration with rhBMP-2. Adv Drug Deliv Rev. 2003;55:16131629.

INTEGRA™

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