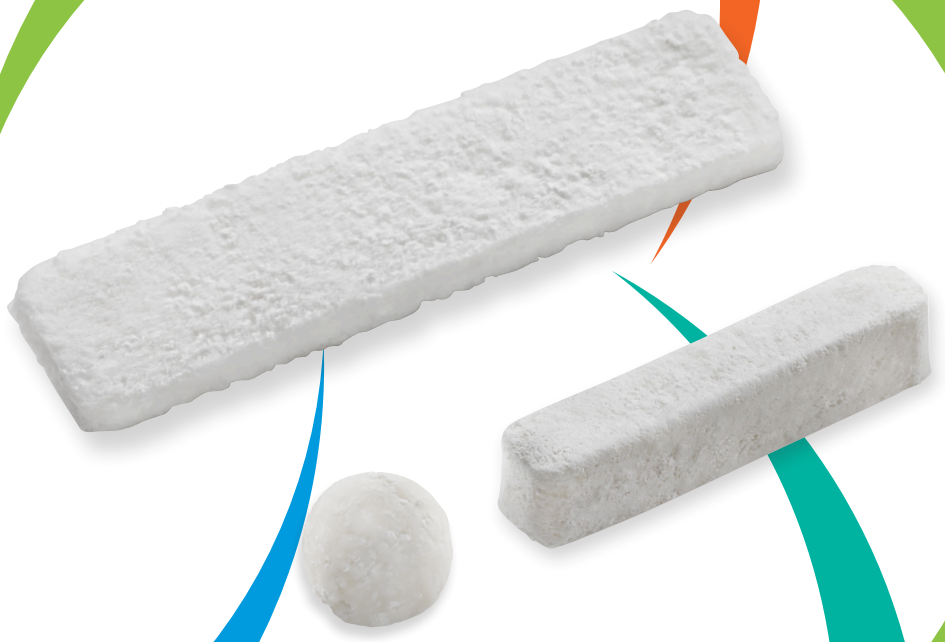
COLLAGE™

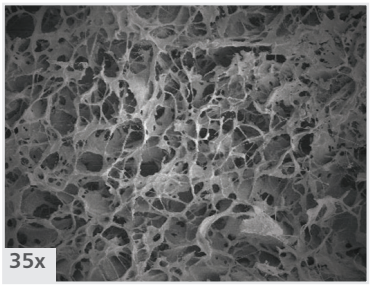
Osteoconductive Scaffold



COLLAGE™
Osteoconductive Scaffold

Advanced Engineering

Collage® Osteoconductive Scaffold is comprised of 20% Type-I collagen and 80% highly purified Beta-Tricalcium Phosphate (β-TCP) and was developed to resemble the composition and pore structure of natural human bone.[1]



Designed Features

- Collagen technology is based on over 20 years of development expertise and have been used in over 10 million patients[1,5]
- β-TCP supplies mineral components necessary for bone growth while providing a porous scaffold
- Offered in a variety of sizes and configurations

Key Advantages

- Designed to optimize safety, handling, and performance[1]
- Purification and biocompatibility minimizes the potential for immune response[1]
- Osteoconductive scaffold that allows for rapid fluid absorption, cellular ingrowth, and controlled resorption[1,2]
- Provides radiographic visualization of graft placement

Cells and Proteins Binding

Fluid Retention

With an interconnected pore structure engineered for absorbing fluids, Collage osteoconductive scaffold effectively retains bone marrow aspirate within the material.[1]

Cell Binding

With favorable influence on cellular infiltration and wound healing, higher densities of collagen provide greater protein binding sites and have been associated with more effective incorporation of bioactive proteins.[4]

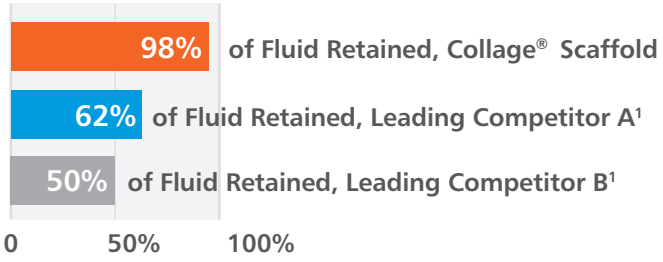
Compression Resistance[5]

Collage Osteoconductive Scaffold framework of β-TCP and cross-linked Type-I collagen allows for flexibility for various applications in the skeletal system.

- Retains bone marrow aspirate within the matrix
- Maintains graft volume and structure under compression

Compression Resistant Matrix

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



% Fluid volume retained under compression[1]

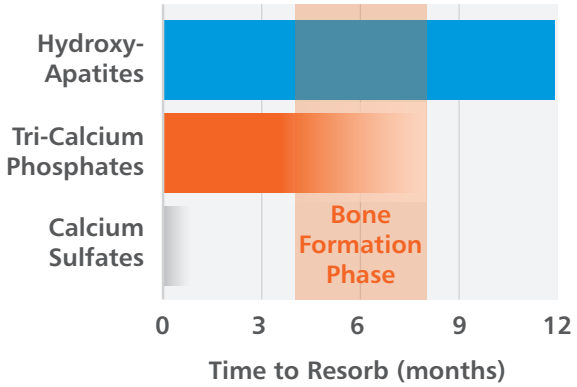
Resorption Profile

Resorption Profile Consistent with New Bone Formation

The resorption time of an osteoconductive scaffold is a crucial factor for bone healing. A short resorption profile often results in limited bone growth, while a longer resorption time can result in ineffective tissue incorporation.

The Collage scaffold is designed to support effective bone resorption and new bone formation.[3]

ß-TCP vs. Competing Graft Components[3]



Radiographic Visualization

Collage Osteoconductive Scaffold's β-TCP balances radiopacity, residence time, and structure which provides radiographic visualization after the graft has been placed.

Configurations Tailored to Surgical Needs

Collage Osteoconductive Scaffold is offered in both putty and strip configurations to meet various applications and surgeon preferences.

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[4]

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 ß-TCP granules

Configuration Benefits:

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

Clinical Evidence[2]

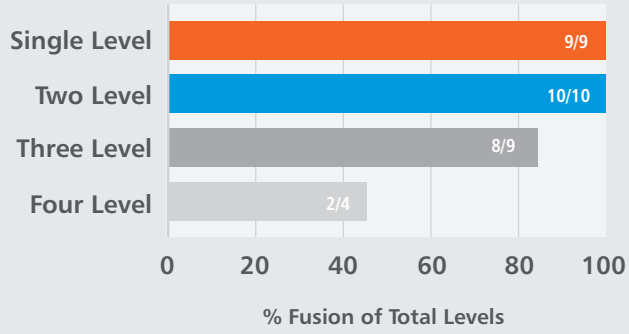
Collage Osteoconductive Scaffold demonstrated equivalent fusion rate to autograft in a retrospective study on posterolateral lumbar fusion, which included patients with comorbidities such as smoking, diabetes, and osteoporosis.

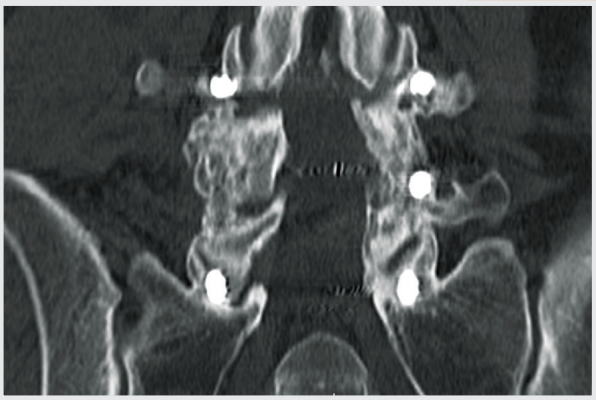
Successful fusion was defined as uninterrupted bridging of mineralized trabecular bone by CT at 12 months by an independent radiologist. At 12 months, 100% (14 patients) fusion was seen in all single and two-level procedures, with an overall fusion rate of 90.3% (28/31) across all levels.

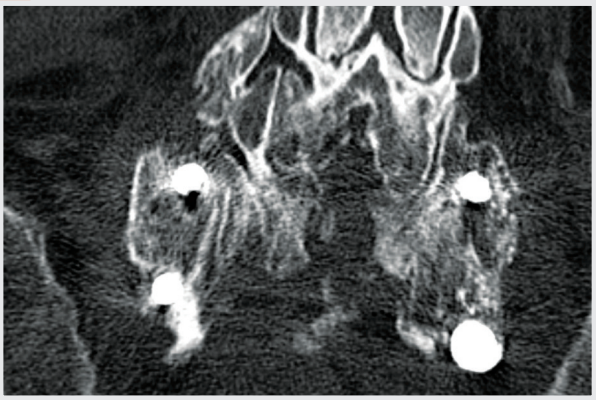
- Included patients with comorbidities such as smoking, diabetes, and osteoporosis
- Collage Scaffold applied as indicated with bone marrow aspirate alone, no mixing of additional autograft or allograft
- Spinal fusion comparisons performed in each patient individually
  - Collage Scaffold was applied to the symptomatic side
  - Autograft applied to the contralateral side

Clinical Performance – 90% Overall Fusion[2]

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







CT-scans from two patients at 12 months post-op.[5]

Ordering Information

Domestic (Inside US)

Collage Putty

Part #	Size
710005	5cc
710010	10cc
710015	15cc

Collage Strip

Part #	Size
711010	10cc (100 x 25 x 4mm)
711015	15cc (100 x 25 x 6mm)

International (Outside US)

Collage Putty, International

Part #	Size
710005ITL	5cc
710010ITL	10cc
710015ITL	15cc

Collage Strip, International

Part #	Size
711010ITL	10cc (100 x 25 x 4mm)
711015ITL	15cc (100 x 25 x 6mm)

Bone Marrow Aspiration Kits (US & OUS)

Reference	Description	Size
21-5000	Bone Marrow Aspiration Needle Kit	8 Gauge
21-5011	Bone Marrow Aspiration Needle Kit	11 Gauge

References

1.Data on File with Isotis

2.White Paper. Mataragas, Nicholas. Radiographic analysis of fusion success with Isotis Collagen Ceramic Matrix, as compared to autograft use, in posterolateral lumbar spine arthrodesis. 2010.

3.Ogose, Akira, et. al. Comparison of Hydroxyapative and Beta Tricalcium Phosphate as Bone Substitutes after Excision of Bone Tumors. J Biomed Mater Res B Appl Biomater. 2005 Jan 15; 72(1):94-101.

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

5.Isotis D0000481A 3-2016

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