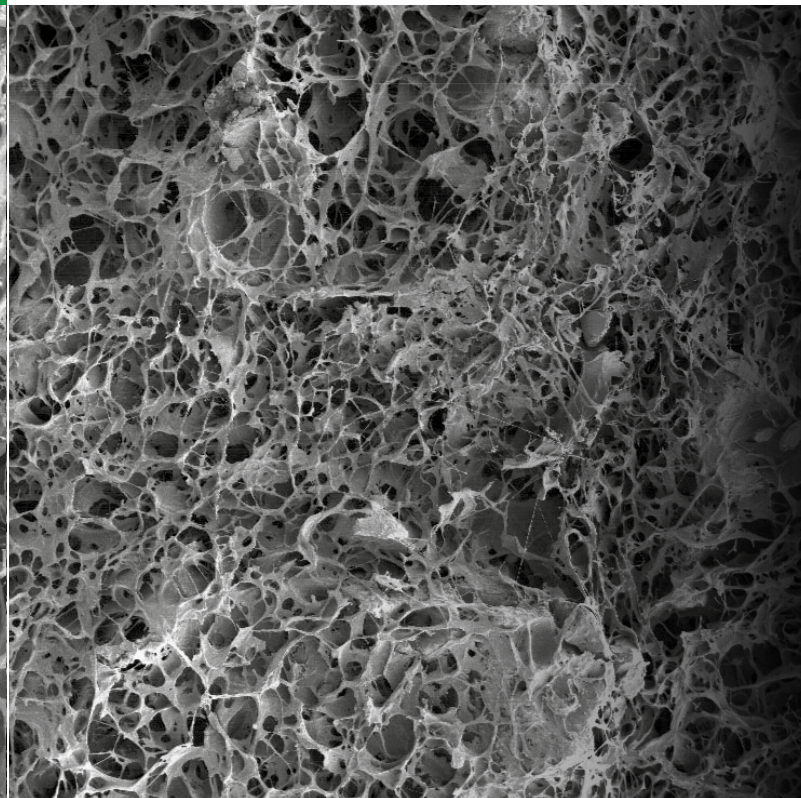
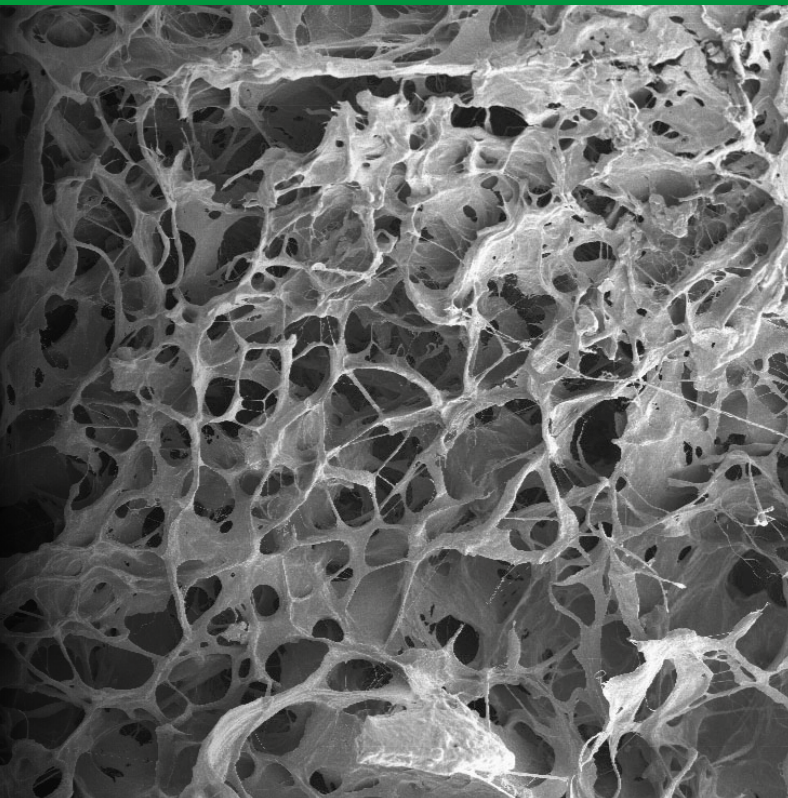


Integra™ Spine & Biologics

Integra™ Collagen Ceramic Matrix
Bone Graft Solutions

CASE STUDIES



INTEGRA™
LIMIT UNCERTAINTY

Case study 1

Multi-Level Lumbar Fusion with Integra™ Collagen Ceramic Matrix

Procedures performed and cases provided by: Nicholas R. Mataragas, M.D., Spinal Surgeon.
The Spine Center of Dupage Medical Group, Naperville, Illinois, USA.

Diagnoses: Grade I spondylolisthesis of the L4 on L5, bilateral neural foraminal stenosis & central stenosis impacting the L3-4, L4-5, L5-S1 levels.

Location of Fusion: L3-S1

Patient: 65 year-old female

Pre-Operative Radiographs



Coronal View



Sagittal View

Symptoms

The following case involves a 65 year-old female with a 1 1/2 year history of severe low back pain. She was unresponsive to an extensive amount of conservative treatment, which included medical treatment, multiple sessions of physical therapy, epidural steroid injections, and chiropractic care.

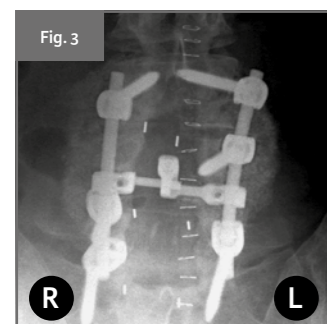
Diagnosis

The underlying pathology of the patient's condition was assessed using radiographs (Figs. 1 & 2) and MRI imaging. These imaging studies indicated severe disc space narrowing of the L3-4 disc with neuroforaminal narrowing at that level, grade I spondylolisthesis of the L4 on the L5 vertebrae, and disc space narrowing of the L5-S1 disc with neuroforaminal narrowing.

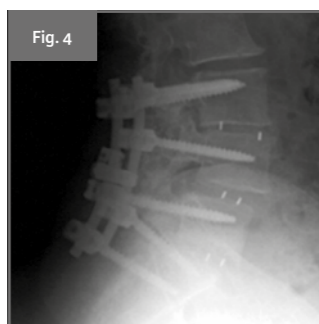
Surgical Treatment

The spinous processes and midline structures were removed from L3 to S1. The lateral recesses were decompressed and foraminotomies were performed on the L3 to S1 neuroforaminae bilaterally. Pedicle screws were placed from L3 to S1 bilaterally. Posterior interbody fusions were then performed at L3-4, L4-5, and L5-S1. PEEK cages packed with BMP-soaked collagen sponges were used to facilitate the interbody fusions. The transverse processes were decorticated and a posterolateral fusion was performed using autograft on the right side and Integra™ Collagen Ceramic Matrix supplemented with bone marrow aspirate (BMA) on the left side. Approximately 15cc of Integra™ Collagen Ceramic Matrix Strip was used for each level on the left side and roughly 1cc of Bone Marrow Aspirate was added to each 1cc of strip (1: 1 ratio of BMA: Strip Volume).

Post-Operative Radiographs at 1 Month



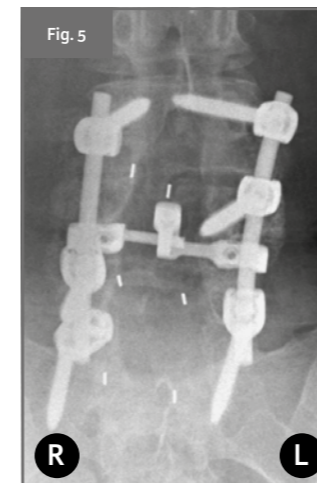
Coronal View



Sagittal View

Post-operative follow-up at 1 month. Radiographs (Figs. 3 & 4) indicate excellent position of the screws, rods, bone grafts, and interbody cages. The coronal image shows that some of the β -TCP granules in the Integra™ Collagen Ceramic Matrix Strip are still present.

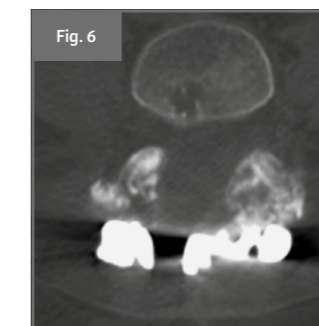
Post-Operative Radiograph at 12 Months



Coronal View

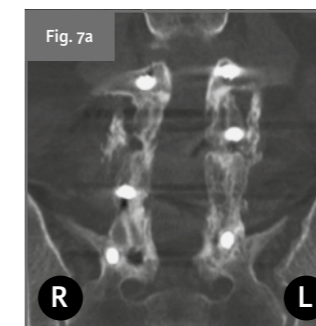
Post-operative follow-up at 1 year. At 1 year the patient reports a high level of satisfaction with her procedure, stating that all of her pre-operative pain is relieved. She has returned to full, normal activities without any restrictions and continues to do well. The coronal radiograph (Fig. 5) indicates that excellent position of the screws, rods, and interbody cages have been maintained. Additionally, these imaging studies show evidence of bridging bone formation bilaterally across the L3-4, L4-5, and L5-S1 levels in the posterolateral gutters. The image also shows that the ceramic morsels contained within the Integra™ Collagen Ceramic Matrix have been resorbed and remodeled into bone.

Post-Operative CT-Radiographs at 17 Months

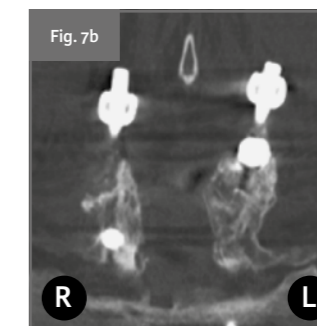


Axial View

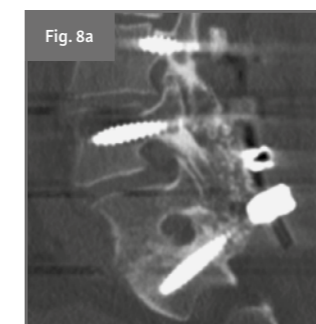
CT-Radiographs (Figs. 6-8) show no evidence of instrumentation failure. The images also show bilateral fusion across the three levels as demonstrated by the coronal and sagittal images (Figs. 7 & 8). Additionally, the images show more robust bone formation on the left side than the right side of the posterolateral fusion masses.



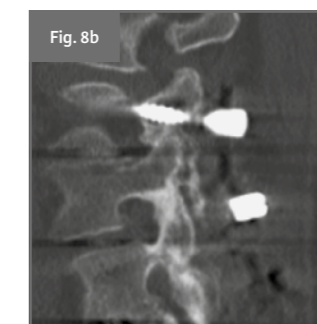
Coronal View / Upper CT image



Coronal View / Lower CT image



Left Sagittal View



Right Sagittal View

Case study 2

Multi-Level Lumbar Fusion with Integra™ Collagen Ceramic Matrix

Procedures performed and cases provided by: Nicholas R. Mataragas, M.D., Spinal Surgeon.
The Spine Center of Dupage Medical Group, Naperville, Illinois, USA.

Diagnoses: Herniated L3-4 disc impinging the right L3 nerve root.
Location of Fusion: L3-L4
Patient: 55 year-old male

Pre-Operative Radiographs



Coronal View



Sagittal View

Symptoms

The following case involves a 55 year-old male with a 4 month history of severe right anterior thigh pain and reduced strength of the right quadriceps. The patient relates a history of difficulty ascending stairs secondary to significant weakness of the right thigh muscle.

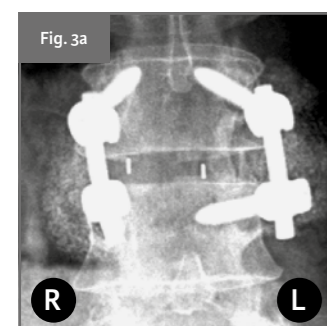
Diagnosis

The underlying pathology of the patient's condition was assessed using radiographs (Figs. 1 & 2) and MRI imaging. MRI images indicate a foraminal L3-4 disc extrusion anterior to the right L3-4 facet joint that is impinging against the right L3 nerve root. Because of the location of the patient's disc extrusion, the patient was advised that a facetectomy followed by fusion might be required to allow complete removal of the disc as well as adequate decompression of the L3 neuroforamen.

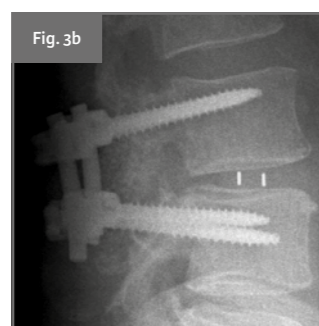
Surgical Treatment

The midline structures were removed at the L3-4 level, allowing entry into the spinal canal. The lateral recesses were decompressed and a foraminotomy of the L3 neuroforamen was performed. A facetectomy of the L3-4 facet joint on the right side was performed to allow access to the disc herniation and to completely decompress the L3 nerve root was free of any impingement. The disc extrusion was removed in several pieces and following completion of the facetectomy, the L3 nerve root was free of any impingement. Pedicle screws were inserted at the L3 and L4 pedicles bilaterally. An interbody fusion was performed at L3-4 using BMP-soaked collagen sponges in a PEEK cage. Local autograft bone was placed into the right gutter, after decortication of the transverse processes. A single Integra™ Collagen Ceramic Matrix Strip was placed in the left gutter after it was soaked in 15 cc of bone marrow aspirate that had been drawn from the iliac crest.

Post-Operative Radiographs at 1 Month



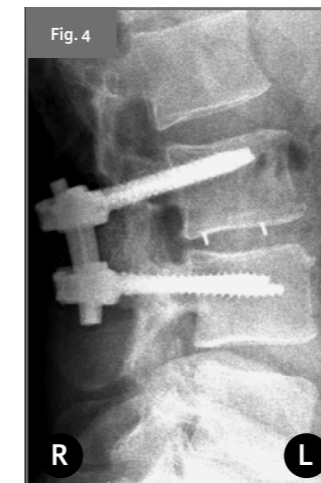
Coronal View



Sagittal View

Post-operative follow-up at 1 month. Radiographs (Figs. 3a & 3b) indicate excellent position of the screws, rods and bone graft in the posterolateral space. The coronal image shows that some of the β -TCP granules in the Integra™ Collagen Ceramic Matrix strip are still present.

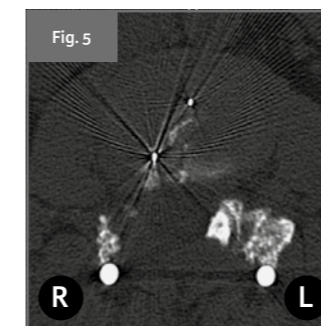
Post-Operative Radiograph at 12 Months



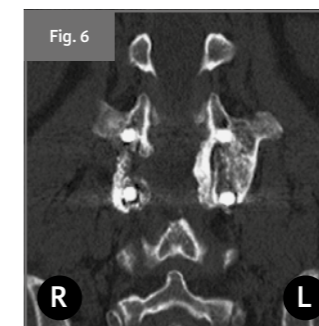
Sagittal View

Post-operative follow-up at 1 year. At 1 year the patient reports that he is free of any of his pre-operative pain and strength has returned to his right quadriceps. He has returned to his active lifestyle without noticing any residual pain or weakness at this time. The radiograph (Fig. 4) indicates that excellent position of the screws and rods have been maintained. Additionally, the radiograph shows evidence of bridging bone formation across the L3-4 level in the posterolateral gutters. The image also shows that the ceramic morsels contained within the Integra™ Collagen Ceramic Matrix have been resorbed and remodeled into bone.

Post-Operative CT-Radiographs at 12 Months



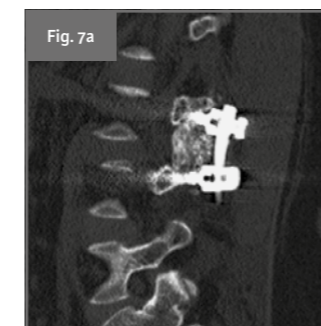
Axial View



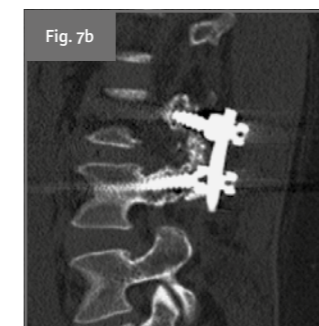
Coronal View

CT-Radiographs (Figs. 5-7) show no evidence of instrumentation failure. The images also show bilateral fusion across the single level as demonstrated by the coronal, sagittal, and axial images (Figs. 5-7).

Additionally, the posterolateral fusion appears to have healed as evidenced by abundant fusion bone formation on the left side (Integra™ Collagen Ceramic Matrix side), as compared to that of the side fused with local autograft bone.



Left Sagittal View



Right Sagittal View

Case study 3

Multi-Level Lumbar Fusion with Integra™ Ceramic Matrix

Procedures performed and cases provided by: Nicholas R. Mataragas, M.D., Spinal Surgeon.
The Spine Center of Dupage Medical Group, Naperville, Illinois, USA.

Diagnoses: Multi-level scoliosis with spondylosis of the lumbar spine & severe stenosis of the L3-4 and L4-5 levels.
Location of Fusion: L3-S1
Patient: 81 year-old female

Pre-Operative Radiographs



Coronal View

Symptoms

The following case involves an 81 year-old female with a 1 year history of right lower extremity pain that she experiences more when standing for a significant period of time or walking more than a block. She also complains of right foot weakness and requires an ankle-foot-orthosis (AFO) for ambulation in addition to her cane. Her pain is improved with sitting and with forward flexion (as with leaning over a shopping cart).

Diagnosis

The underlying pathology of the patient's condition was assessed using radiographs (Fig. 1) and MRI imaging. X-rays of the lumbar spine indicate a dextroconvex scoliosis in the lumbar spine associated with multilevel degenerative disc disease and multilevel spondylosis. MRI images indicate severe spinal stenosis of the L3-4 and L4-5 levels.

Surgical Treatment

The midline structures were removed from L3 to L5, allowing entry into the spinal canal. Next, the lateral recesses were decompressed, followed by foraminotomies of the L3, L4, and L5 neuroforaminae bilaterally. At the completion of the decompression there were no signs of impingement of the neural elements. The transverse processes were then decorticated from L3 to L5 bilaterally. Next, each of the two Collagen Ceramic Matrix Strips were imbibed with 15 cc's of bone marrow aspirate from the iliac crest and placed into the posterolateral gutters on both sides and augmented by local autograft bone that had been harvested during the procedure.

Post-Operative Radiographs at 1 Month



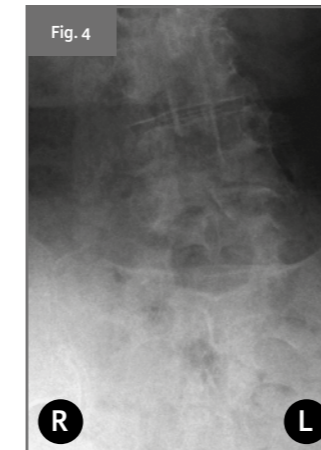
Coronal View



Sagittal View

Post-operative follow-up at 1 month. Radiographs (Figs. 2 & 3) indicate excellent position of the bone grafts and no further deterioration of spine stability.

Post-Operative Radiographs at 12 Months



Coronal View



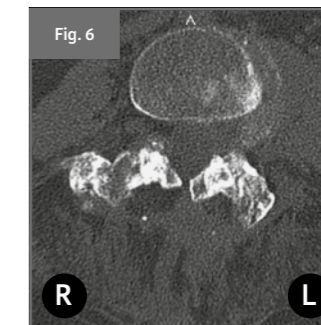
Sagittal View

Post-operative follow-up at 1 year. At 1 year after surgery, the patient notes a significant improvement in her walking tolerance as she can now walk nearly a mile. Additionally, the strength of her right foot has been improving gradually over time. She has mild soreness of the paraspinal muscles with prolonged standing, but notes that her endurance has been improving.

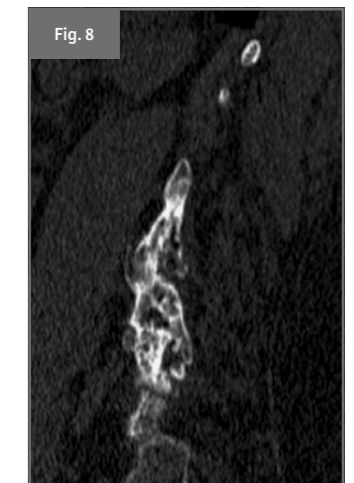
Radiographs (Figs. 4 & 5) again indicate no further deterioration of spine stability as well as formation of bone in the posterolateral gutters.

Post-Operative CT-Radiographs at 12 Months

CT-Radiographs (Figs. 6-8) show abundant bone fusion masses in the lateral gutters indicative of successful non-instrumented fusion even in the setting of an elderly patient with significant osteoporosis. The fusion mass on the left side seems to have formed in a more circuitous path than that on the right side where CT slices in both the coronal and sagittal planes show continuous bone from L3 to S1.



Axial View



Right Sagittal View



Coronal View

Overview

Autologous bone is generally accepted as the gold standard for repair of osseous defects and fractures.

However, a limited supply of patient autologous bone and long term morbidity associated with harvest sites has prompted the development of alternative bone graft substitutes. Autogenous, allogeneic, and synthetic graft materials have been used clinically with varying degrees of success.

Extensive preclinical and clinical data have demonstrated the value of Type-I collagen based carriers in binding and delivery of growth factors such as rhBMP-2 as an alternative to autologous bone. In addition, due to its inherent cell binding capacity and high biocompatibility, Type-I collagen has been shown to be a favorable scaffold for delivery of cells including bone marrow aspirate. However, alone, protein-based implants tend to lack resistance to compression from surrounding tissues and are therefore subject to a reduction in volume which can compromise both their capacity to retain fluids, cells and to yield predictable bone volumes.

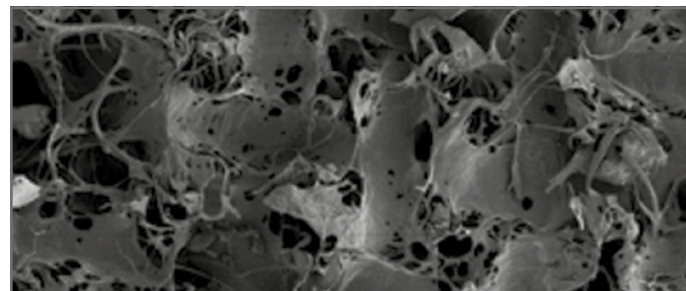
Highly purified tricalcium phosphate (TCP)-based ceramic granules have shown promise as bone graft substitutes and autograft extenders but can be difficult to effectively retain in the defect space. The development of a collagen/ceramic composite has shown significant promise by exploiting the beneficial properties of both materials.

The following 3 case studies demonstrate that the Integra Collagen Ceramic Matrix:

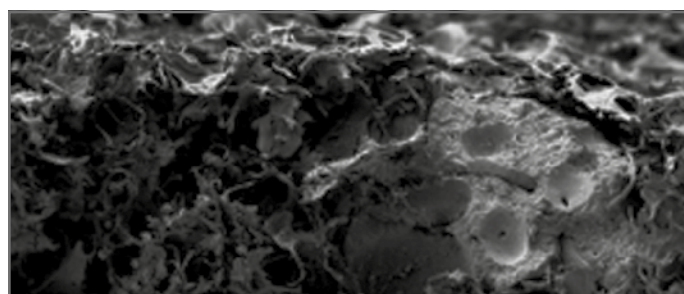
- May be used in a variety of patients as a bone grafting material.
- Facilitates the formation of bone in the posterolateral gutters.
- Leads to the formation of as much or more bone than autograft in the described case.

Reference

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



Surface of Integra Collagen Ceramic Matrix



Cross-Section of Integra Collagen Ceramic Matrix

Product Information

The Integra™ Collagen Ceramic Matrix is a synthetic bone void filler from the leader in regenerative technology. It is engineered to mimic the composition and porosity of natural human cancellous bone, resorbed at a rate consistent with the formation of new bone. Its pure ingredients improve the biocompatibility of the implant, minimizing the potential for immune response.

The Integra Collagen Ceramic Matrix consists of 80% highly purified β -TCP granules and 20% highly purified Type-I collagen. The β -TCP granules provide defect filling volume and allow for radiographic visualization of bone graft placement. They also contain mineral components necessary for bone growth. Type-I collagen from Integra has been used in over 10 million procedures and has a strong history of purity, safety, and biocompatibility. Fluids are absorbed through the Scaffold's interconnected pore structure, providing sites for cell binding, along with rapid and complete absorption of bioactive proteins.¹

The Collagen Ceramic Matrix strip is compression resistant, effectively retaining bone marrow aspirate within the matrix, resulting in guided bone fusion. It also maintains the graft volume under compression and bends to conform to uneven surfaces.

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