IsoTis

BALLAST®

DEMINERALIZED BONE MATRIX IN RESORBABLE MESH

SALES BROCHURE

DESIGN RATIONALE

Filled with 100% DBM, Ballast® is a highly osteoinductive bone graft for use in posterolateral fusion procedures. DBM is contained within a resorbable mesh pouch that allows for cellular infiltration while restricting graft migration.

GRAFT CONTAINMENT SHOWN TO IMPROVE FUSION IN PRECLINICAL MODELS

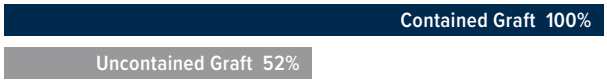
Bone graft displacement due to mechanical disturbance during irrigation or from dislodging by paraspinal muscles during closure is a clinical problem in Posterolateral Fusion [Barrow Neurological Institute, Bohl 2018].[1]

Potential unintended consequences of migration and/or displacement include:

- Unwanted bone graft in epidural space or neural foramina
- Reduction in volume of graft that contributes to arthrodesis
- Fusion at unintended levels
- Non-union

Contained grafts offer a simple procedural solution for Posterolateral Fusion (PLF), providing higher fusion rates, more robust quality of fusion and quantity of bone mass.[1-5]

Graft containment = higher fusion rates



Fusion results for contained autograft vs. uncontained in rabbit PLF model[2]

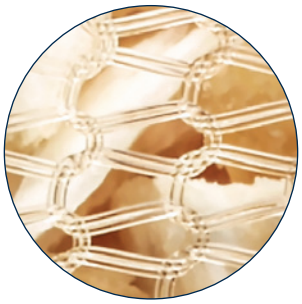
Fusion results for contained autograft vs. uncontained in rat PLF model[3]

Graft containment = larger fusion mass

- More robust quality of fusion and quantity of bone mass at 6 months post-op in 5 PLF patients[1]
- Significant increase in fusion mass volume in rabbit and rat PLF models[3-5]

POSTEROLATERAL GRAFT SOLUTION

- Delivers a large, consistent volume of graft (6-9cc per level per side)
- Withstands compressive forces of the paraspinal muscles and does not flatten or displace
- Maximizes osteoinductive potential with 100% DBM, within the mesh pouch, in a challenging application
- Contours around spinal hardware and anatomy
- Simple to deliver and position in the posterolateral gutters



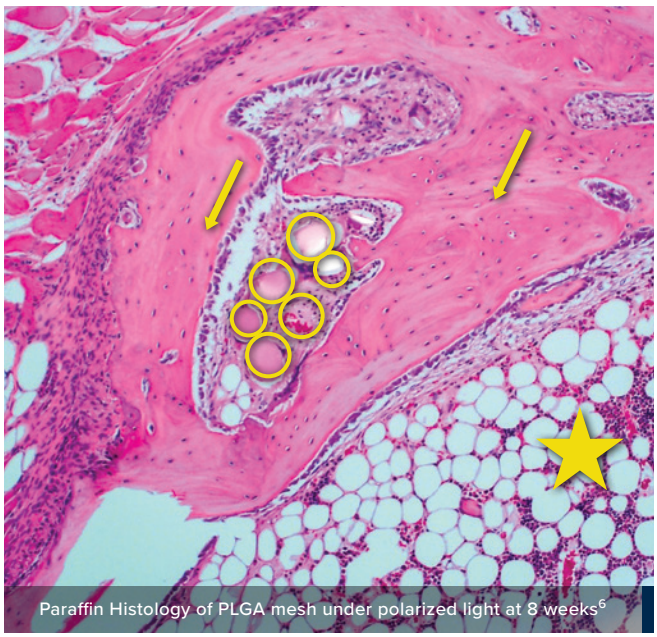
100% DBM

- No added fillers for maximum DBM content
- DBM chips provide osteoconductive properties and compression resistance
- Every lot tested to confirm osteoinductive potential

RESORBABLE MESH

- Acts as a physical barrier to restrict the migration of DBM
- Mesh pore size allows for unimpeded cellular infiltration
- Biocompatible PLGA material
- Resorbs in approximately 8 weeks

BALLAST®



Paraffin Histology of PLGA mesh under polarized light at 8 weeks[6]

RESORPTION OF THE BALLAST® MESH POUCH

The resorbable PLGA, poly (lactic-co-glycolic acid), mesh effectively delivers DBM to the graft site, restricts migration, and does not inhibit bone formation. In rat PLF fusion model:[6]

- PLGA is surrounded by new bone and marrow
- PLGA did not illicit a negative inflammatory response
- PLGA nearly 100% resorbed

★ Marrow

/ New bone

○ PLGA

Ballast Ordering Information

Part #	Description
02-8000-060	45 x 11mm
02-8000-095	45 x 17.5mm
02-8000-115	85 x 11mm
02-8000-180	85 x 17.5mm
02-8000-160	115 x 11mm

[1]Bohl M.A., Xu D.S., Daniels L., et al. The Barrow Innovation Center case series: early clinical experience with novel, low-cost techniques for bone graft containment in the posterolateral fusion bed. *World Neurosurgery* 2018;116:285-95.

[2]Bawa M., Schimizzi A.L., Leek B., et al. Paraspinal muscle vasculature contributes to posterolateral spinal fusion. *Spine* 2006; 31:891-896.

[3]Shin D., Yang B.M., Tae G., et al. Enhanced spinal fusion using a biodegradable porous mesh container in a rat posterolateral spinal fusion model. *Spine Journal*. 2014; 14:408-15.

[4]Rao R.D., Bagaria V., Gourab K., et al. Autograft containment in posterolateral spine fusion. *T Spine J*. 2008; 8:563-69.

[5]Poynton A.R., Zheng F., Tomin E., et al. Resorbable posterolateral graft containment in a rabbit spinal fusion model. *J Neurosurg* 2002; 97:460-63.

[6]Walsh W., Jalota S., Oliver R., et al. Preclinical evaluation of a resorbable mesh device containing demineralized bone matrix particles in a rabbit posterolateral fusion model.

For more information or to place an order, please contact:
TEL 866.942.8698 | FAX 877.558.6227
customerservice@seaspine.com | **seaspine.com**

IsoTis OrthoBiologics, Inc.
2 Goodyear, Irvine CA 92618
TEL 800.550.7155 | FAX 800.471.3248 | WEB seaspine.com
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