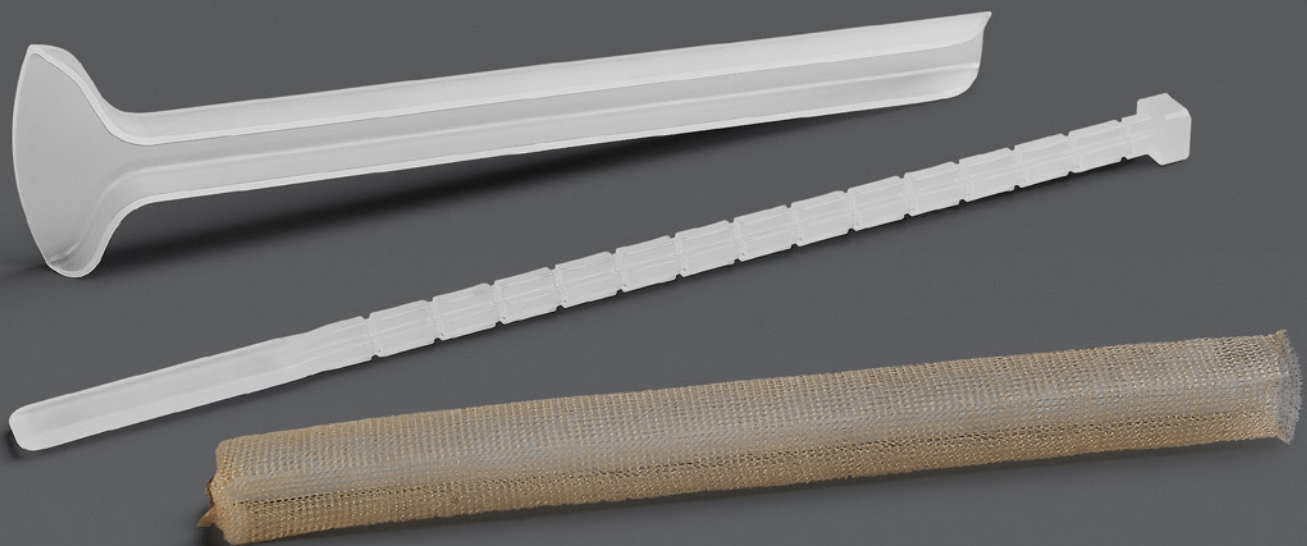




OSTEOBALLAST[®] MT

FILLABLE RESORBABLE MESH POUCH & ACCESSORIES
SALES BROCHURE

DESIGN RATIONALE

OsteoBallast® MT is a customizable graft for posterolateral fusions. Fill the resorbable mesh pouch with autograft and tailor the length and fill volume specifically for patient anatomy and desired handling or pliability. The mesh pouch allows for cellular infiltration while restricting graft migration.



GRAFT CONTAINMENT SHOWN TO IMPROVE FUSION IN PRECLINICAL MODELS

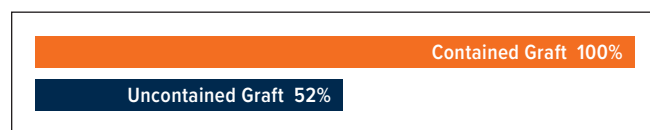
Bone graft displacement due to mechanical disturbance during irrigation or from dislodging by paraspinal muscles during closure is a clinical problem in Posterolateral Fusion [Barrow Neurological Institute, Bohl 2018].¹

Potential unintended consequences of migration and/or displacement include:

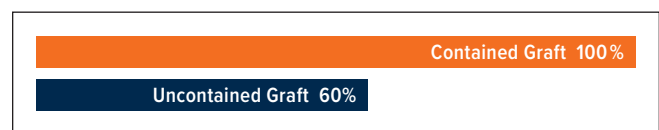
- Non-union
- Unwanted bone graft in epidural space or neural foramina
- Reduction in volume of graft that contributes to arthrodesis
- Fusion at unintended levels

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 model²



Fusion results for contained autograft vs. uncontained in rat PLF model³

Graft containment = larger fusion mass

- More robust quality of fusion and quantity of bone mass at 6 months post-op in 5 PLF patients¹
- Significant increase in fusion mass volume in rabbit and rat PLF models³⁻⁵

OSTEOBALLAST® MT

FILLABLE RESORBABLE MESH POUCH & ACCESSORIES

CUSTOMIZE AND CONTAIN

Use the supplied spatula and filling tube to create a patient specific graft that restricts migration, maintains position, and is easily placed in the posterolateral spine.



CUSTOMIZED GRAFT

- Fill with autograft
- Pack to desired cc volume
- Tailor to preferred handling
- Trim to desired length based on patient needs



RESORBABLE MESH

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

OSTEOBALLAST® MT

FILLABLE RESORBABLE MESH POUCH & ACCESSORIES



RESORPTION OF THE OSTEOBALLAST® MESH POUCH

The resorbable PLGA, poly (lactic-co-glycolic acid), mesh effectively delivers graft to the site, restricts migration, and does not inhibit bone formation.

In rabbit PLF fusion model⁶:

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

★ Marrow

↗ New bone

○ PLGA

OsteoBallast MT Ordering Information

Part #	Description
56100000	OsteoBallast MT, 150 x 11mm (1 pack)
56110000	OsteoBallast MT, 150 x 11mm (2 pack)

Pre-filled OsteoBallast Options Ordering Information

Part #	Description
56800060	45 x 11mm
56800095	45 x 17.5mm
56800115	85 x 11mm
56800180	85 x 17.5mm
56800160	115 x 11mm

¹Bohl 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.

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

³Shin 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.

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

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

⁶Walsh 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. ©2017 SeaSpine Orthopedics Corporation.



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](http://www.seaspine.com)
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