BEAST™

DEMINERALIZED BONE MATRICES

Hospital Registration Packet

Exclusively foot & ankle Paragon 28®

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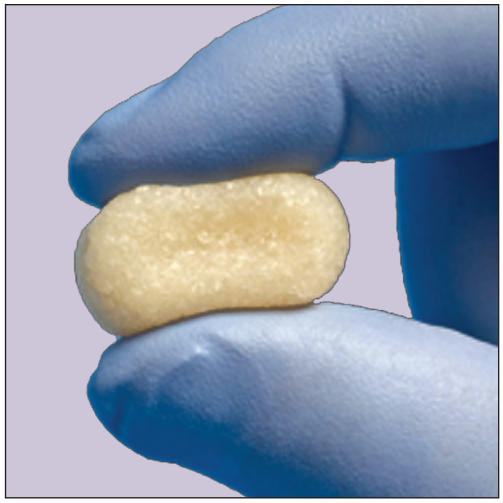
BEAST™

DEMINERALIZED BONE MATRICES

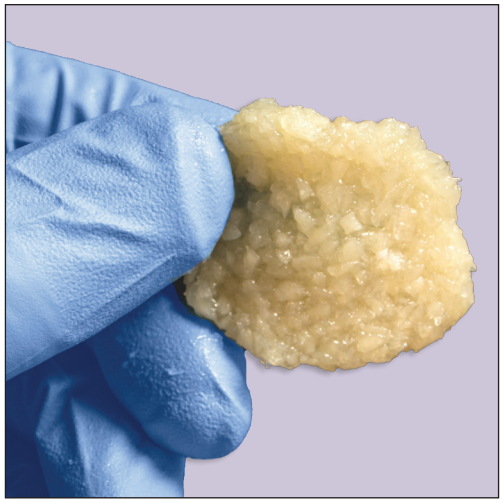
The Product Development team is pleased to announce additions to Paragon 28®'s BEAST™ Demineralized Bone Matrix (DBM) portfolio, with the release of BEAST™ Injectable Putty, BEAST PLUS™ Putty, and BEAST™ OsteoBiologic Sponge (BOB™).

BEAST™ DBMs are highly osteoconductive, with a high osteoinductive potential due to proprietary processing that preserves the native Bone Morphogenetic Proteins (BMPs). BEAST™ products are uniquely sterilized to device level standards and are tested in vivo to assure peak osteoinductive potential.

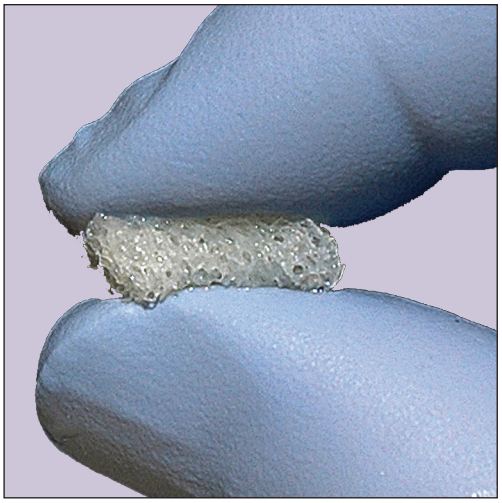
- ✓ Patented processing preserves native Bone Morphogenetic Proteins (BMPs)
- ✓ Terminally sterilized to device level standards (sterility assurance 10^{-6})
- ✓ Tested in vivo and assayed after terminal sterilization to assure high osteoinductive potential.
- ✓ Resists migration under direct irrigation



BEAST™ Injectable Putty



BEAST PLUS™



BEAST™ OsteoBiologic Sponge (BOB™)

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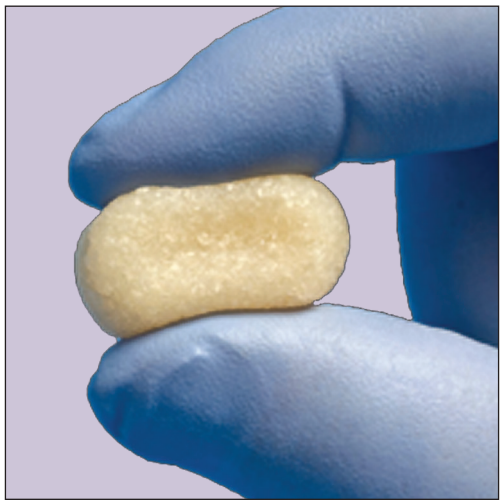
BEAST™ DEMINERALIZED BONE MATRICES

BEAST™ Injectable Putty

BEAST™ Injectable Putty is a 510(K) approved DBM putty that is pre-packaged in a syringe to cater to surgeon implant preferences. It can be injected, or packed and molded. BEAST™ Injectable Putty is derived from cortical bone.

BEAST™ INJECTABLE PUTTY
DEMINERALIZED BONE MATRIX

- Resists migration under direct irrigation
- Demonstrates consistent results of bone growth during in vivo testing, following terminal sterilization (premier indicator for high osteoinductive potential)
- Preserved native Bone Morphogenetic Proteins
- Biocompatible carrier of Carboxymethyl Cellulose (CMC) - acts as a delivery vehicle for growth factors and provides cohesive and malleable handling properties



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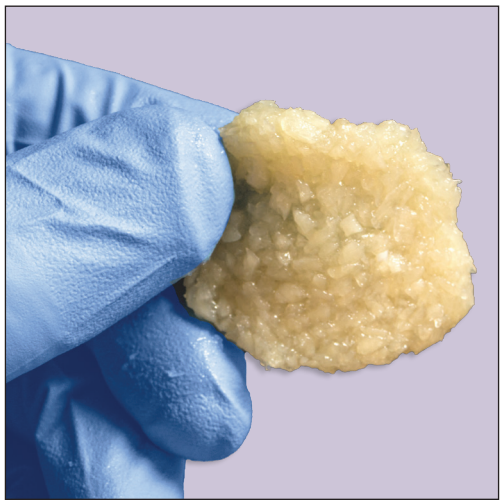
BEAST™ DEMINERALIZED BONE MATRICES

BEAST PLUS™ Putty

BEAST PLUS™ Putty is a 510(K) approved DBM putty mixed with 1-4 mm cortical chips. It can be injected, or packed and molded. BEAST PLUS™ is derived from cortical bone.

BEAST+™ DEMINERALIZED BONE MATRIX

- **Mixed with 1-4 mm cortical chips for enhanced bone regeneration and impressive handling characteristics**
- **Resists migration under direct irrigation**
- **Demonstrates consistent results of bone growth during in vivo testing, following terminal sterilization (premier indicator for high osteoinductive potential)**
- **Preserved native Bone Morphogenetic Proteins**
- **Biocompatible carrier of Carboxymethyl Cellulose (CMC) - acts as a delivery vehicle for growth factors and provides cohesive and malleable handling properties**



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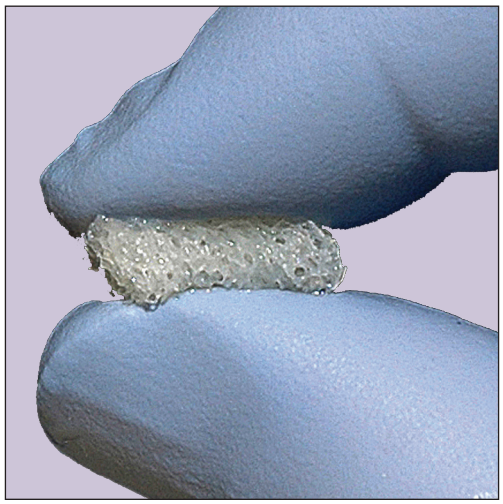
BEAST™ DEMINERALIZED BONE MATRICES

BEAST™ OsteoBiologic Sponge (BOB™)

BEAST™ OsteoBiologic Sponge (BOB™) is demineralized 100% human cancellous bone allograft. BEAST™ (BOB™) has an interconnected porosity that enables cellular proliferation and homogeneous remodeling.

BOB
BEAST™ OsteoBiologic Sponge

- Compressible sponge with shape memory
- Can be hydrated with Bone Marrow Aspirate (BMA) to achieve osteogenic grafting element
- Can absorb and retains its weight in fluid
- Sterilized to device-level sterility standards (sterility assurance level 10^{-6})
- Conforms to incongruent surfaces of patient anatomy



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BEAST™
DEMINERALIZED BONE MATRICES

Publications: BEAST™ Injectable Putty

Publication
Kiely PD, Brecevich AT, Taher F, et al. Evaluation of a new formulation of demineralized bone matrix putty in a rabbit posterolateral spinal fusion model. Spine J. 2014;14(9):2155-63.

Materials and Methods
Uninstrumented single-level PLF in rabbits. Putty vs. ICBG Fusion assessed at 12 weeks using X-ray, micro-CT, mechanical testing, manual palpation, and histology.

Results Summary
Equivalency to gold standard (iliac bone crest autograft). Histologic evaluation revealed endochondral ossification in both groups, but the fusion masses were more mature in the DBM group

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Publication
Schallenberger M, Lovick H, Locke J, et al. The effect of temperature exposure during shipment on a commercially available demineralized bone matrix putty. Cell Tissue Bank. 2016;17(4):677-687.

Materials and Methods
Shipping data acquired from 72 independent shipments were analyzed for temperature exposure, shipment times and shipping event durations. The model extrapolated worse-case scenario high temp spike of 52.9C for 12h and 14 min.

Results Summary
After five weeks of continuous exposure to 50C and 12 simulated worst-case one-way shipments did not adversely affect the handling characteristics or the in vivo osteoinductivity of the product.

Publication
Schallenberger MA, Rossmeier K, Lovick HM, et al. Comparison of the osteogenic potential of BEAST™ demineralized bone matrix putty to NovaBone calcium-phosphosilicate synthetic putty in a cranial defect model. J Craniofac Surg. 2014;25(2):657-61.

Materials and Methods
Paired, bilateral critical size defects (10mm) in the craniums of rabbits with BEAST™ putty on one side and a synthetic (bioglass) on the other. Assessment of bone formation at 6 weeks and 13 weeks using semi-quantitative histology and quantitative histomorphology.

Results Summary
Superior bone formation. Approximately 30% more bone at 6 weeks and 13 weeks with BEAST™.

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BEAST™ DEMINERALIZED BONE MATRICES

Publications: BEAST™ OsteoBiologic Sponge (BOB™)

Publication
Brigido SA, Bleazey ST, Protzman NM, D'Angelantonio A III, Schoenhaus HD. A retrospective analysis evaluating allogenic cancellous bone sponge for foot and ankle arthrodesis. J Foot Ankle Surg. 2013; 52:28-31.

Materials and Methods
Retrospective series of 47 patients (78 joints) who underwent foot and ankle arthrodesis with 6 month and 12 month follow-up.

Results Summary
97.5% fusion rate (total joints); 96% fusion rate (45/47patients) at 12 months. Statistically significant improvement in pain and function at 6 and 12 months (47 patients).

Publication
Chopko BW. Percutaneous thoracolumbar decompression combined with percutaneous pedicle screw fixation and fusion: a method for treating spinal degenerative pain in a biplane angiography suite with the avoidance of general anesthesia. J Spine Surg 2016;2(2):122-127.

Materials and Methods
13 patients under local or mild sedation underwent image guided percutaneous thoracolumbar fusion - utilizing pedicle screw fixation, local bone, BOB™ soaked in BMA and BEAST™ inserted onto the facet region through the pedicle screw access path

Results Summary
Statistically significant reduction of pain seen at both 2 week post op and 40 weeks. CT images notes solid fusion mass medial to screw head (Fig 3).

Publication
Girasole G, Muro G, Mintz A, et al. Transforaminal lumbar interbody fusion rates in patients using a novel titanium implant and demineralized cancellous allograft bone sponge. Int J Spine Surg 2013;7(1):e95-e100..

Materials and Methods
Single-level TLIF with BOB™+BMA in Titan cage (exposes more surface area of graft). Independent fusion analysis using CT in two separate follow-up groups, one at 6 months and one at 12 months.

Results Summary
97%+ fusion rate at 12 months for interbody fusion (37 of 38 patients fused).

Publication
Miller LE, Jacofsky DJ, Kirker KR. Rationale, characteristics, and clinical performance of the BOB™; A novel allograft for treatment of osseous defects. Orthop Res Rev 2012; 4:9–17.

Materials and Methods
Athymic nude mouse transplantation model of BOB™ at 2 and 4 weeks 2) Prospective series of 45 patients undergoing ACDF with BOB™ 3) Prospective randomized study of 28 patients comparing BOB™ + BMA to rhBMP-2 in posterior lumbar cage

Results Summary
Week 2 BOB™ had neovascularization and early bone healing, Week 4 showed new bone formation and osteoinductivity. Solid fusion achieved in all patients at 2 year followup. BOBT™ with BMA performed similarly to rhBMP-2 in achieving anterior fusion at 2 years

Publication
Protman NM, Galli MM, Bleazey ST, Brigido, SA. Biologic Augmentation of Foot and Ankle Arthrodesis with an Allogenic Cancellous Sponge. Orthopedics. 2014;37(3):e230-6..

Materials and Methods
Prospective series of 25 patients (45 joints) undergoing foot and ankle arthrodesis with 6 month and 12 month follow-up.

Results Summary
97.8% fusion rate (total joints); 96% fusion rate (24/25 patients) at 6 months and 12 months. Statistically significant improvement in pain and function at 6 and 12 months.

Publication
Yoon BV, Schroeder JE, Abjornson C, et al. Demineralized bone sponges and concentrated bone marrow: A Fusion Augmenter in the Posterior Spine. Paper #S2.13.Philadelphia Spine Research Symposium, Nov. 9-12, 2015, Philadelphia.

Materials and Methods
Fusion rates using BOB™ DBM in 122 patients who underwent posterolateral lumbar fusion and they used 2.73 sponges, on average, per patient and available, morcelized local bone from the surgical preparation.

Results Summary
115 patients of the 122 patients achieved solid fusion for a 94.26% fusion rate as evaluated by standard radiographic films, comparable to published fusion rates with autograft. The VAS scale data reveals a statistically significant reduction in pain at last follow-up time point.

P01-BEAST-HRM RevA
(2021-06-18)

For the IFU on this product, please visit:
www.paragon28.com/ifus

BEAST™ Injectable Putty, BEAST PLUS™, and BEAST™ OsteoBiologic Sponge (BOB™) are produced by Xtant Medical and distributed by Paragon 28® in Foot and Ankle orthopedic markets

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For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device specific instructions for use at http://www.paragon28.com/ifus