

A blue-tinted, semi-transparent microscopic image of a human spine, showing the vertebrae and intervertebral discs, serving as a background for the top half of the page.

MAGNUS[®]
VIABLE CELLULAR ALLOGRAFT



**ROYAL
BIOLOGICS**

YOU ASKED FOR AN EASY-TO-USE, STREAMLINED PREPARATION PROCESS, AND WE HEARD YOU!

Magnus[®] Bio Form allograft is the next generation solution for bone formation to support a variety of potential clinical applications. The allograft is delivered in an easy-to-use syringe with minimal preparation time of under 15 minutes. Royal Biologics preserves the native bone cells in a DMSO-free (free of dimethyl sulfoxide) cryoprotectant, Royal Coat[™], requiring no rinsing or decanting — just thaw and use!



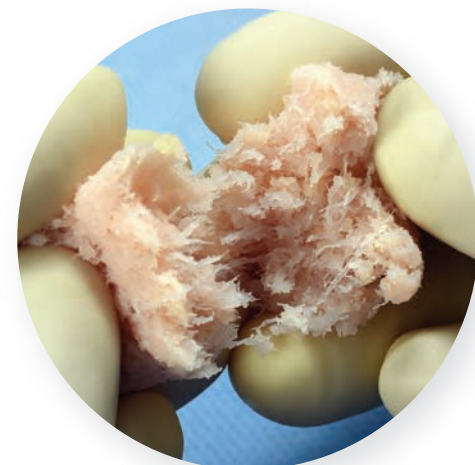
MAGNUS[®] BIO FORM PROVIDES THE THREE KEY ELEMENTS IDEAL FOR BONE FORMATION

- An osteoconductive three-dimensional scaffold with cortical and cancellous components.
- A demineralized cortical bone scaffold. Demineralized cortical bone has been identified to have osteoinductive potential.¹
- Viable endogenous bone cells to support osteogenic healing processes.



BONE SCAFFOLD DELIVERS OSTEOCONDUCTIVE AND OSTEOINDUCTIVE POTENTIAL

Magnus[®] Bio Form provides an osteoconductive bone scaffold composed of mineralized cancellous bone along with demineralized cortical fibers. Bone fibers offer superior osteoconductivity when compared to powder due to the increased ability for cells to migrate along fibers, creating “cellular highways” for bone formation.³ In contrast, particulate-based demineralized bone matrices (DBMs) have gaps between the particles that osteoblasts cannot always bridge across.³ The demineralized cortical fibers are supplemented with cancellous chips to deliver a 100% human-derived product that mimics the particulate structure of native bone.



CELLS PROTECTED BY PROPRIETARY ROYAL COAT[™] CRYOPROTECTANT

- Protective coating preserves allograft and prevents crack propagation and membrane lysis²
- Retains over 80% cell viability after thaw²
- Non-cytotoxic, non-DMSO
 - Reduces concerns about cytotoxicity and negative effects on cell differentiation^{4,5,6}
 - Does not require rinsing or decanting

ROYAL COAT[™]

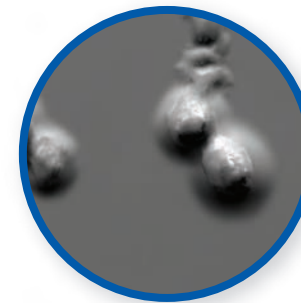


Figure 1:
Cells protected with Royal Coat to prevent crystalline damage (frozen)

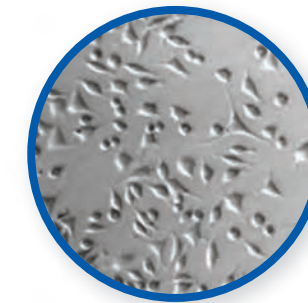


Figure 2:
Viable endogenous cells are preserved with the use of Royal Coat (frozen)

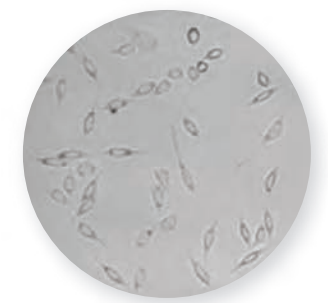


Figure 3:
2.5% DMSO-compromised cells showing reduced viability (thawed)

Proper preservation of cellular allografts requires strict adherence to recovery and processing protocols. To manufacture Magnus[®] Bio Form, viable endogenous bone cells are collected from the donor and preserved with the use of a next-generation DMSO-free cryoprotectant, Royal Coat, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis² (Figure 1). Industry standard DMSO penetrates the cell and prevents crystal formation from within (Figure 3). At room temperature, DMSO-based cryoprotectants raise concerns about cytotoxicity and negative effects on cell differentiation.^{4,5,6}

Royal Biologic’s patented and proprietary Royal Coat cryoprotectant is a differentiated technology that is applied to a number of products in our portfolio. The Royal Coat technology provides our products with distinct advantages over DMSO-based cryoprotectant technology used in competitive products. As an added bonus, because Royal Coat is DMSO-free, it does not require the multiple rinsing and decanting steps of DMSO-based cryoprotectants. Rinsing steps can diminish both the cell viability and the inherent regenerative properties of allografts.

Royal Coat provides a surgical procedure advantage over other cryoprotectants containing DMSO. Allografts treated with Royal Coat experience minimal cell loss and retain, on average, over 80% cell viability after thaw² (Figure 2). Royal Coat also allows for usage up to four hours after thawing and Magnus Bio Form allografts can be stored for up to one year at or below -65°C.

The bone cells are endogenous to the cancellous bone, remaining attached throughout the donor tissue processing event. Strict donor criteria and quality control processes verify a viable cell population for osteogenic supplementation as a viable structural allograft.

OPERATING ROOM EASE OF USE

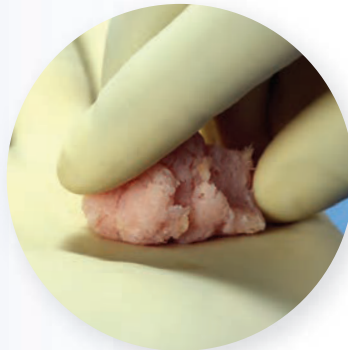
- No rinsing or decanting steps required
- Average cell viability exceeds 80% post-thaw²
- Minimum of 150,000 viable cells per cc of allograft²
- Four-hour working window for implantation after thaw without loss of cell viability

▶▶ IT ALL ADDS UP

- Improved storage container streamlines preparation: thaw product in provided syringe and use
- A natural, 100% tissue scaffold of demineralized cortical bone fibers coupled with chips rich with endogenous bone cells provides an optimal microenvironment for osteogenesis and excellent handling
- A proprietary DMSO-free cryoprotectant, Royal Coat, that protects and allows for consistent delivery of viable allograft to the patient
- A viable cell population for osteogenic supplementation as a viable structural allograft

▶▶ ORDERING INFORMATION

CODE	DESCRIPTION	SIZE
MG-25	Magnus® Bio Form	2.5cc
MG-5	Magnus® Bio Form	5cc
MG-10	Magnus® Bio Form	10cc



Royal Biologics will use reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.

1. Gruskin, E. et al., Demineralized bone matrix in bone repair: history and use. *Advanced Drug Delivery Reviews*, 2012. 64:1063-1077
2. Data on file at VIVEX Biologics, Inc.
3. Martin GJ Jr, Boden SD, Titus L, Scarborough NL, "New formulations of demineralized bone matrix as a more effective graft alternative in experimental posterolateral lumbar spine arthrodesis;" *Spine*. 1999 Apr 1;24(7):637-45.
4. Best, Benjamin. P. Cryoprotectant Toxicity: Facts, Issues, and Questions. *Rejuvenation Research*, 2015. Vol. 18, No. 5.
5. Renzi, S., et al., Mesenchymal stromal cell cryopreservation. *Biopreservation and Biobanking*, 2012. 10(3): p. 276-281.
6. Asghar, W., et al., Preserving human cells for regenerative, reproductive, and transfusion medicine. *Biotechnology Journal*, 2014. 9: p. 895-903.



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