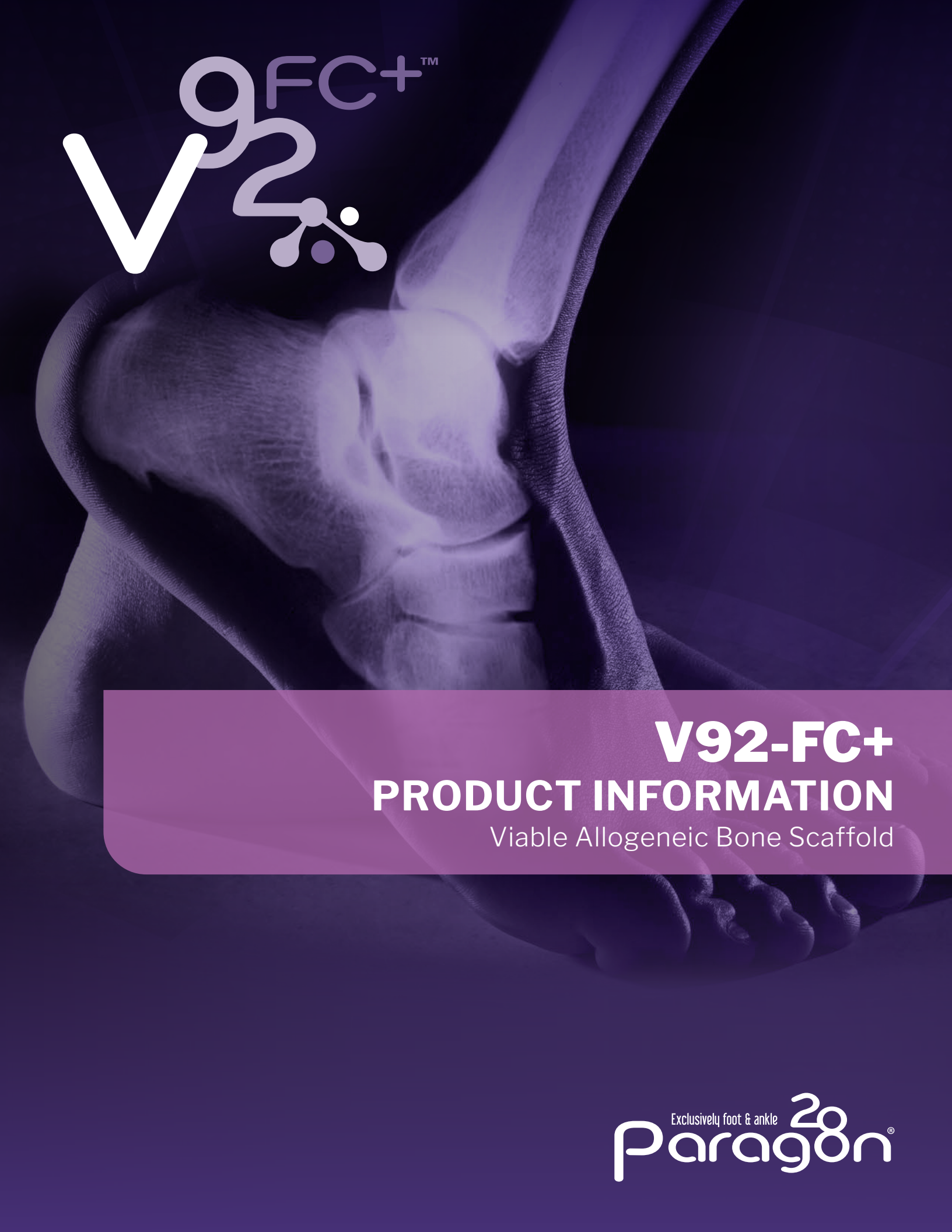


V92-FC+
PRODUCT INFORMATION
Viable Allogeneic Bone Scaffold

Exclusively foot & ankle
Paragon 28®

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

V92-FC+ 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. Paragon 28® preserves the native bone cells in a DMSO-free (free of dimethyl sulfoxide) cryoprotectant, requiring no rinsing or decanting — just thaw and use!

V92-FC+ 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

V92-FC+ 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.

OPERATING ROOM EASE OF USE

- **Packaged in easy-to-use syringe**
- **No rinsing or decanting steps required — native bone cells are preserved in a DMSO-free cryoprotectant**
- **Average cell viability exceeds 92% post-thaw[2]**
- **Average of 1.5 million viable cells per cc of allograft[2]**
- **Four-hour working window for implantation after thaw without loss of cell viability**

CELLS PROTECTED BY PROPRIETARY CRYOPROTECTANT

- **Protective coating preserves allograft and prevents crack propagation and membrane lysis[2]**
- **Retains over 92% cell viability after thaw[2]**
- **Non-cytotoxic, non-DMSO**

  - Reduces concerns about cytotoxicity and negative effects on cell differentiation[4,5,6]
  - Does not require rinsing or decanting

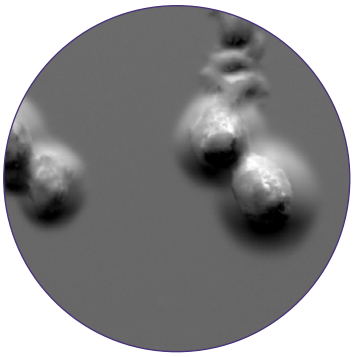


FIGURE 1

Cells protected with proprietary cryoprotectant to prevent crystalline damage (frozen) *image captured by SEM

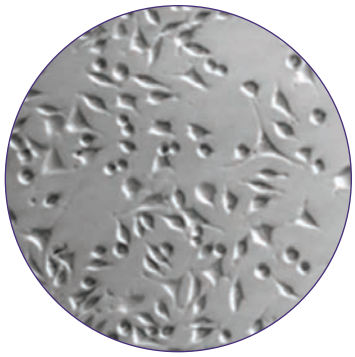


FIGURE 2

Viable endogenous cells are preserved with the use of proprietary cryoprotectant (frozen)

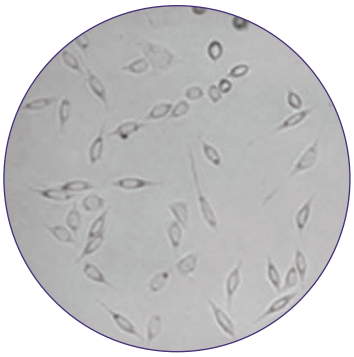


FIGURE 3

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

Proper preservation of cellular allografts requires strict adherence to recovery and processing protocols. To manufacture V92-FC+, viable endogenous bone cells are collected from the donor and preserved with the use of a next-generation DMSO-free cryoprotectant, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis[2] (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]

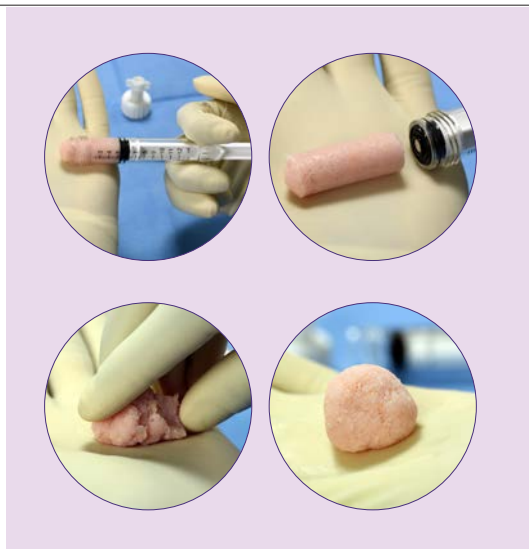
Paragon 28®'s patented and proprietary cryoprotectant is a differentiated technology that is applied to a number of products in our portfolio. The technology provides our products with distinct advantages over DMSO-based cryoprotectant technology used in competitive products. As an added bonus, because our cryoprotectant 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.

Our cyoprotectant provides a surgical procedure advantage over other cryoprotectants containing DMSO. Allografts treated with our cryoprotectant experience minimal cell loss and retain, on average, over 80% cell viability after thaw[2] (Figure 2). Our cryoprotectant also allows for usage up to four hours after thawing and V92-FC+ 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.

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 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

PART NUMBER	DESCRIPTION
P01-V92-0102	V92-FC+, BONE MATRIX, 1.0CC
P01-V92-0252	V92-FC+, BONE MATRIX, 2.5CC
P01-V92-0502	V92-FC+, BONE MATRIX, 5.0CC
P01-V92-1002	V92-FC+, BONE MATRIX, 10.0CC

V92FC+-BRO-01 Rev B
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1. Gruskin, E. et.al., Demineralized bone matrix in bone repair: history and use. Advanced Drug Delivery Reviews, 2012. 64:1063-1077
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