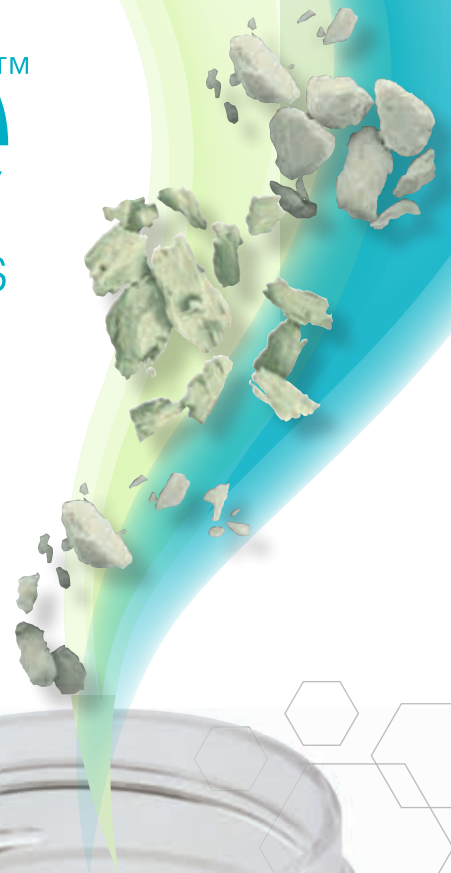


# enCore™

ALLOGRAFTS



# introducing...

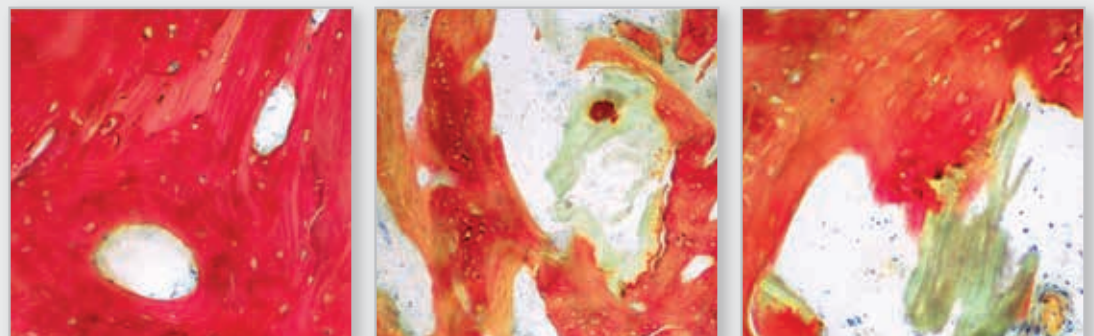
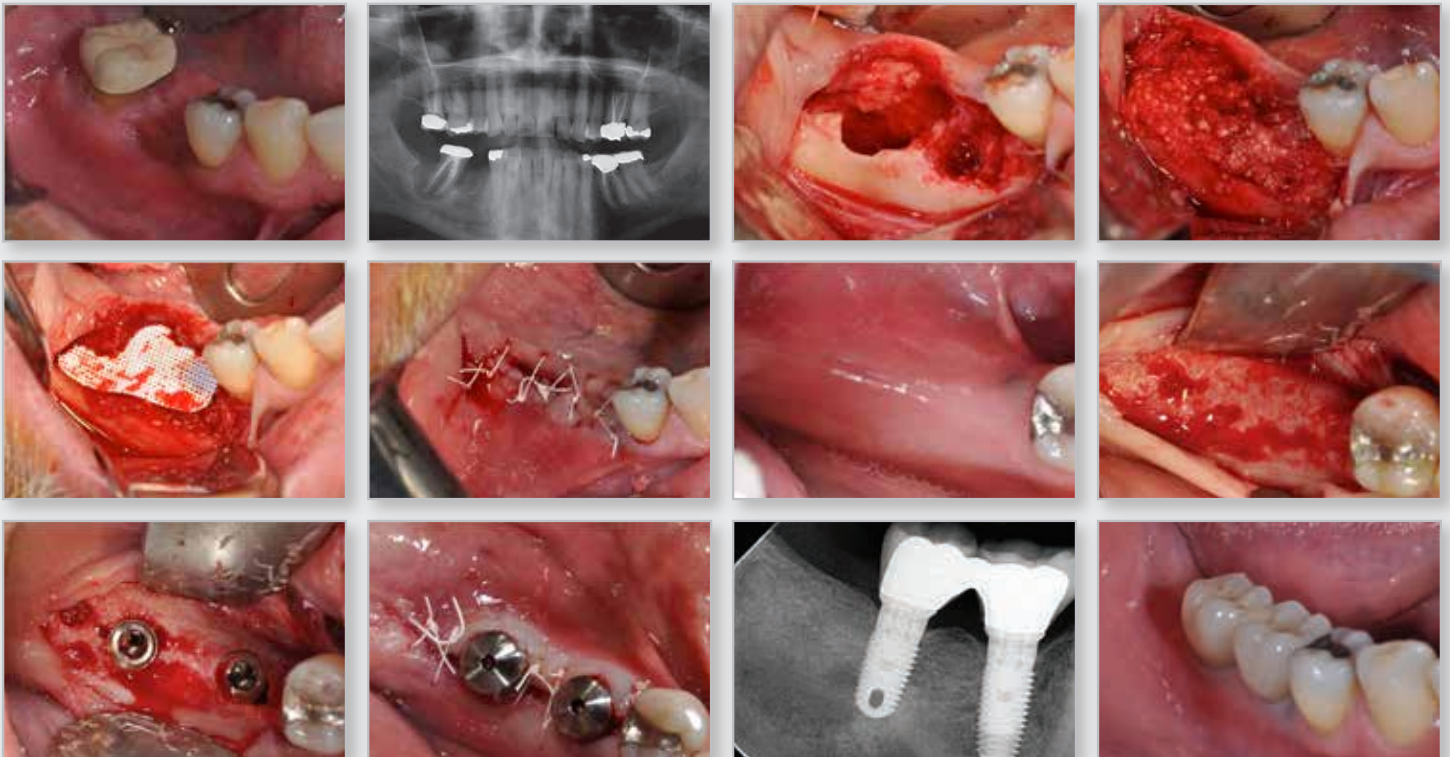
**enCore® 70/30 Combination Allograft** is a particulate bone grafting product combining mineralized and demineralized bone in a single bottle. Already a popular combination among many specialists, enCore® leverages the complementary benefits of space-maintaining mineralized cortical bone with osteoinductive demineralized matrix to optimize the environment for the regeneration of vital bone.

- *Mineralized cortical bone provides a slowly resorbing, 3-dimensional matrix for space maintenance during regeneration*
- *Every lot of demineralized bone is tested twice to ensure osteoinductivity*
- *Best practices in safety:*
  - *Tissue is processed by Allotech, an FDA-registered and AATB-accredited tissue bank*
  - *Single donor per lot*
- *Terminally sterilized by low-dose e-beam irradiation to a sterility assurance level of  $10^{-6}$*
- *Double-sterile packaged for aseptic presentation in the surgical field*
- *Chair-side efficiency:*
  - *70/30 combination graft is pre-mixed to reduce inventory and reduce chair-side preparation*
  - *Available in 0.5 cc, 1.0 cc, 1.5 cc, and 2.5 cc bottles to treat a wide range of bony defects*





## Guided Bone Regeneration Using a Combination Allograft and High-density PTFE Membrane



*Representative histology taken at 6 months from a case using 70/30 combination allograft*

**86% vital bone, 14% residual graft**  
**51% bone, 49% Marrow**

Histology by Michael Rohrer, DDS, MS,  
University of Minnesota

## Each lot of enCore® is processed with performance in mind.

Throughout the process steps are taken to not only ensure each lot is safe for your patient, but to also verify that each lot of enCore® 70/30 Combination Allograft is osteoinductive.



### Aseptic Processing

*Aseptic processing reduces or eliminates bioburden on the final product and packaging, thereby allowing the use of a very low-dose of e-beam irradiation.*

### Pre-Sterilization In Vitro BMP-2 Assay\*

*Prior to packaging and terminal sterilization, every lot of enCore® 70/30 Combination Allograft is tested for a minimum threshold of BMP-2. All lots that fail to meet this threshold are rejected.*



### Terminal E-Beam Sterilization

*In choosing a sterilization method and dose, there is a delicate balance between assuring sterility and mitigating impact on product performance. Because of aseptic processing steps, enCore® requires only a low-dose of e-beam irradiation to provide a sterility assurance level (SAL) of  $10^{-6}$ .*



### In Vivo Osteoinductivity Verification\*

*Every lot of enCore® 70/30 Combination Allograft undergoes a final in vivo post-sterilization test for verification of osteoinductive potential.*

\* Only demineralized portion of 70/30 combination allograft undergoes testing.



## Rigorous Focus on Safety

*enCore® is processed by Allotech, an FDA-registered and AATB-accredited tissue bank*

enCore® allografts are processed with multiple safeguards in place to assure allograft safety. These include:



**1. Tissue donation process** initiated by a certified organ procurement organization (OPO)

*All lots of enCore® Combination Allograft are sourced from a single donor*

**2. Rigorous donor screening** in accordance with FDA regulations and standards published by the American Association of Tissue Banks (AATB), including verification of donor medical records and social history

**3. Rigid recovery procedures** carried out by highly trained and qualified tissue recovery team

**4. Extensive donor testing**, including serological and microbiological testing, during recovery, processing and packaging

**5. Aseptic processing**

**6. Comprehensive post-processing review**, including visual inspection of final allografts

**7. Terminal sterilization** using E-beam sterilization

**8. Allograft distribution** after verification of labeling, sizing and expiration date

## enCore® 70|30 Combination Allograft (FDBA & DFDBA)

70% Mineralized Cortical Allograft and 30% Demineralized Allograft

### 0.25 mm - 1.0 mm Particle Size

0.5 cc	C73050	(1 per box)
1.0 cc	C73100	(1 per box)
1.5 cc	C73150	(1 per box)
2.5 cc	C73250	(1 per box)

## enCore® 50|50 Cortical & Cancellous Allograft

50% Mineralized Cortical Allograft and 50% Mineralized Cancellous Allograft

### 0.5 mm - 1.25 mm Particle Size

0.5 cc	CM55050	(1 per box)
1.0 cc	CM55100	(1 per box)
1.5 cc	CM55150	(1 per box)
2.5 cc	CM55250	(1 per box)

## enCore® OD 30|70 Cortical & Cancellous Allograft

30% Mineralized Cortical Allograft and 70% Mineralized Cancellous Allograft

### 0.25 mm - 1.0 mm Particle Size

0.5 cc	OD37050	(1 per box)
1.0 cc	OD37100	(1 per box)
2.5 cc	OD37250	(1 per box)

## enCore® Mineralized Cortical Allograft

100% Mineralized Cortical Allograft

### 0.25 mm - 1.0 mm Particle Size

0.25 cc	SMIN025	(1 per box)
0.5 cc	SMIN050	(1 per box)
1.0 cc	SMIN100	(1 per box)
1.5 cc	SMIN150	(1 per box)
2.5 cc	SMIN250	(1 per box)



### enCore® Natural Blend Allograft

*Cortical and Cancellous Allograft from a Single Donor*

**0.25 mm - 1.0 mm Particle Size**

0.25 cc	NAT025	(1 per box)
0.5 cc	NAT050	(1 per box)
1.0 cc	NAT100	(1 per box)
1.5 cc	NATN150	(1 per box)
2.5 cc	NAT250	(1 per box)

### enCore® Cancellous Allograft

*100% Cancellous Allograft*

**0.25 mm - 1.0 mm Particle Size**

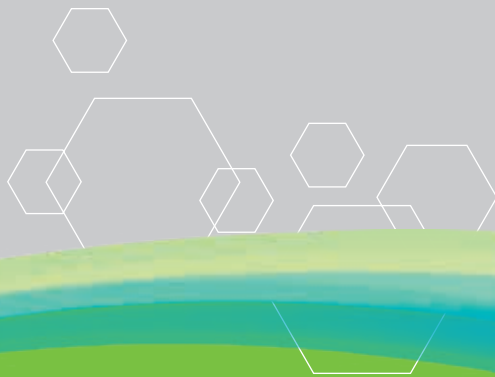
0.25 cc	MCAN025	(1 per box)
0.5 cc	MCAN050	(1 per box)
1.0 cc	MCAN100	(1 per box)
1.5 cc	MCAN150	(1 per box)
2.5 cc	MCAN250	(1 per box)





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