encore™ ALLOGRAFTS

OSTEOGENICS

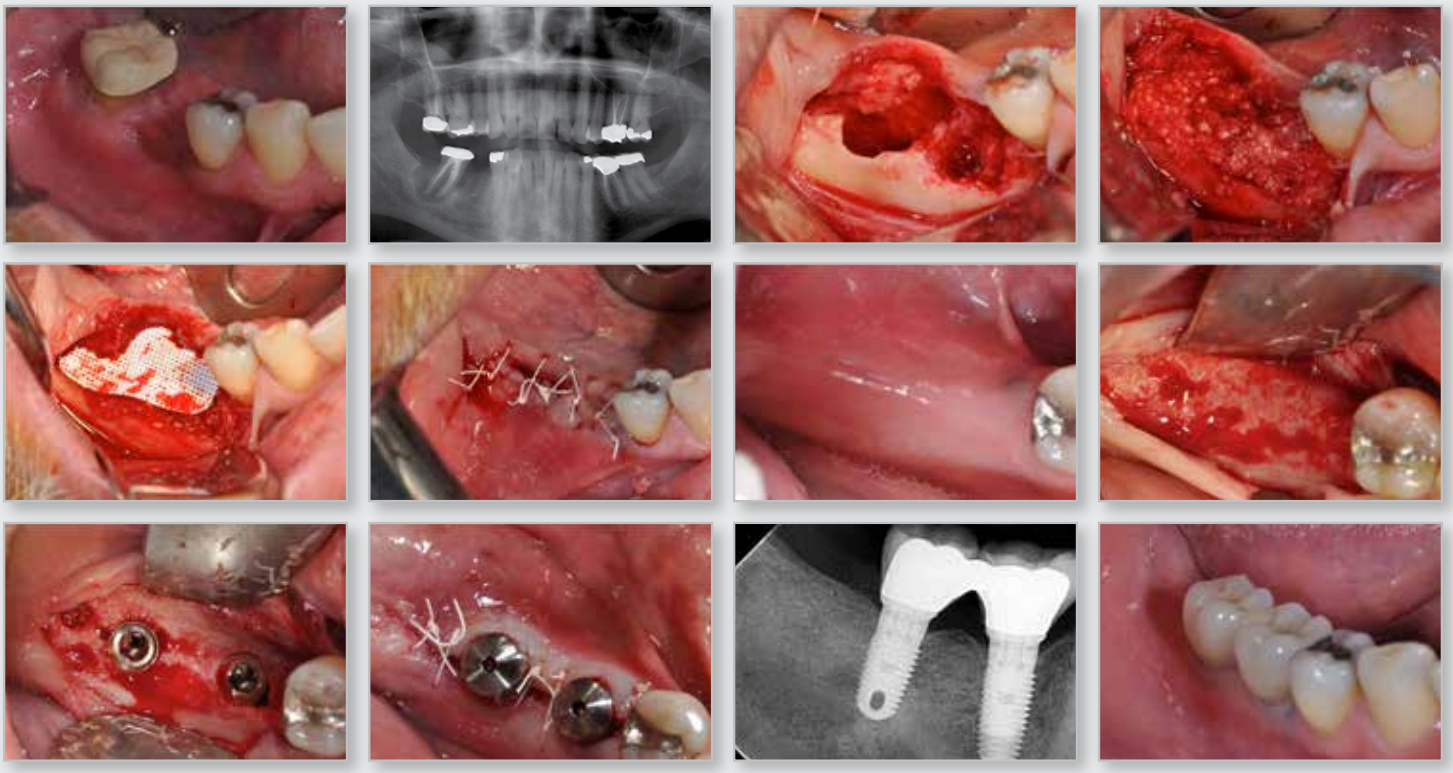
enCore® 70/30 Combination Allograft...

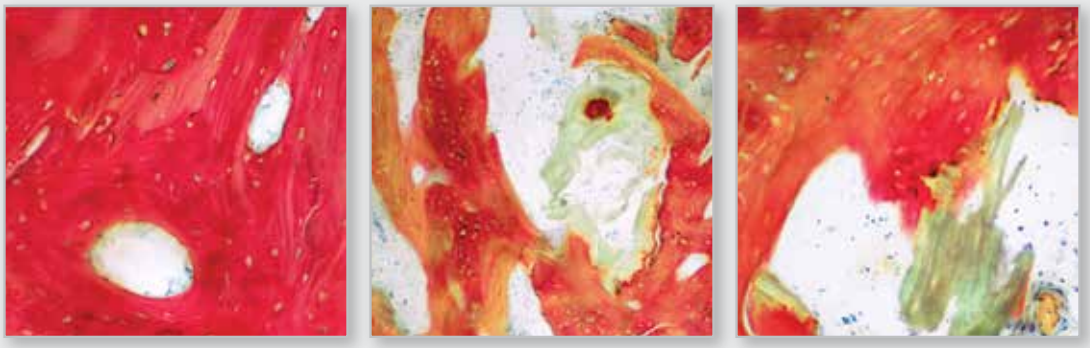
is a particulate bone grafting product combining mineralized and demineralized bone in a single bottle. Already a popular combination among many specialists, enCore® leverages the complementary benefits of space-maintaining mineralized cortical bone with osteoinductive demineralized matrix to optimize 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 in vitro to ensure it meets a BMP-2 threshold statistically validated to be osteoinductive**
- *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*

**Data on file*

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}.

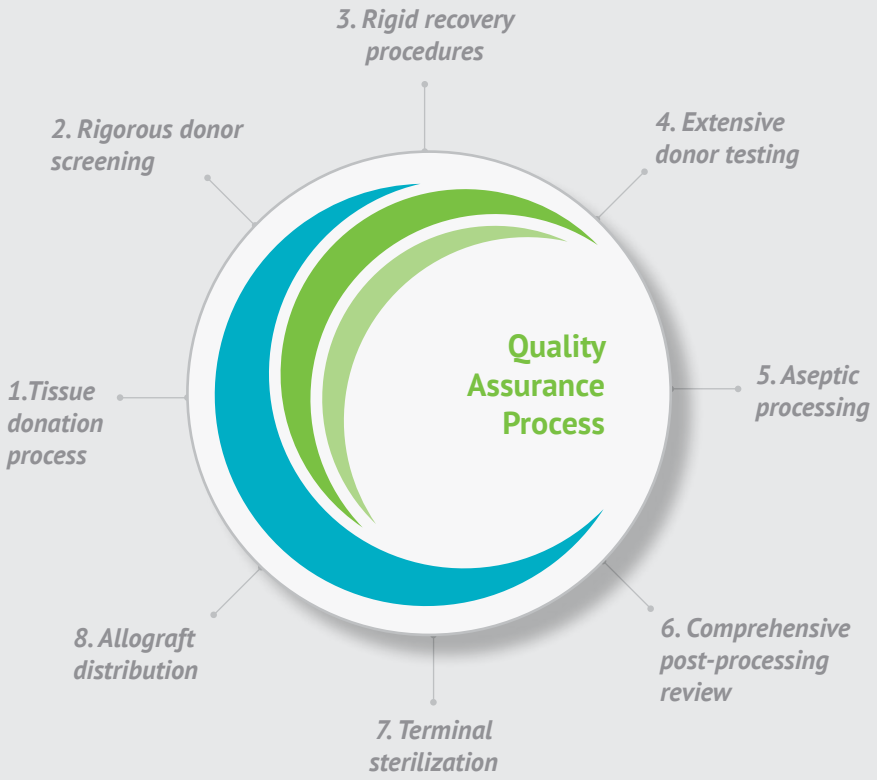
** Only demineralized portion of 70\30 combination allograft undergoes testing.*

enCore™ ALLOGRAFTS

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™ ALLOGRAFTS

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

70% Mineralized Cortical and 30% Demineralized

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 and 50% Mineralized Cancellous

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 and 70% Mineralized Cancellous

0.25 mm - 0.85 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® Cortical Allograft

100% Cortical

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 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	NAT150	(1 per box)
2.5 cc	NAT250	(1 per box)

enCore® Cancellous Allograft

100% Cancellous

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)

enCore® Demineralized Cortical Allograft

100% DemineralizedCortical

0.125 mm - 0.85 mm Particle Size

0.25 cc	DMCR025	(1 per box)
0.5 cc	DMCR050	(1 per box)
1.0 cc	DMCR100	(1 per box)
1.5 cc	DMCR150	(1 per box)
2.5 cc	DMCR250	(1 per box)

OSTEOGENICS

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