

THE CELLULAR ADVANTAGE

Allograft Cellular Bone Matrix Retaining Native Mesenchymal Stem Cells and Osteoprogenitor Cells.



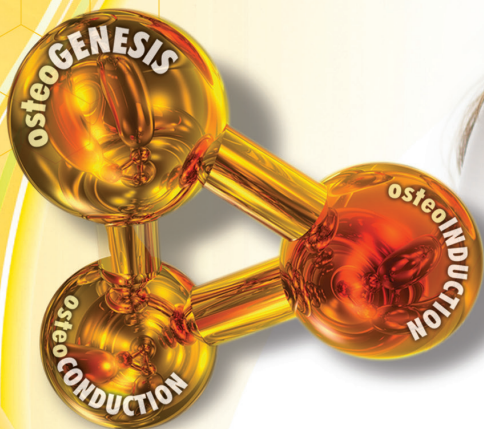
Osteocel® Plus

allograft cellular bone matrix

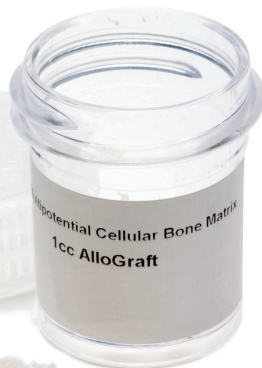
- The first product available to have the desired beneficial properties of autograft: Osteoconduction, Osteoinduction, and Osteogenesis.
- Osteocel Plus mimics the biological profile of autograft. The proprietary processing technology that produces Osteocel Plus results in a viable bone matrix product preserving the native MSCs and Osteoprogenitors found in marrow-rich bone.
- Provide patients a solution that minimizes the risk and cost of a secondary procedure.

Osteocel® Plus

**The Cellular
ADVANTAGE.**



Osteocel Plus mimics the biological profile of autograft. The proprietary processing technology used to produce Osteocel Plus results in a viable bone matrix that preserves the native Mesenchymal Stem Cells (MSCs) and Osteoprogenitors found in marrow-rich bone. It is the first product to have the desired beneficial osteoconductive, osteoinductive and osteogenic properties of autograft. Osteocel Plus allows surgeons to offer a complete solution without the added risk and cost of performing a secondary autograft procedure.



OSTEOCEL PLUS

Osteocel Plus provides all 3 components for bone formation:

Osteoconductivity: Mineralized cancellous scaffold

Osteoinductivity: MSC growth factor production, BMP production and demineralized cortical bone

Osteogenicity: Viable MSCs and osteoprogenitor cells

- Physiological: mimics biologic profile of autograft
- Consistent: each lot tested for cell concentration, cell viability, and cell activity (osteogenic potential)

Low Immunogenicity

Mesenchymal stem cells are immune privileged cells that do not stimulate a cellular immune response. Osteocel Plus does not activate T cell proliferation, as shown in vitro from Mixed Lymphocyte Reaction (MLR) testing.¹

Histologic Evidence

Histology from a human sinus augmentation study using Osteocel Plus shows high vital bone content at 16 weeks, with very low residual graft material.²

Bone Formation

MSCs contained in Osteocel® Plus are capable of differentiating into bone-forming cells (osteoblasts).³ Every lot of Osteocel Plus is tested for bone-forming potential.

Viable Cell Content

The osteogenic potential arises from the mesenchymal and osteoprogenitor cells in Osteocel Plus. Following processing of marrow-rich bone, release testing demonstrates osteogenic potential according to the following criteria:

- Rich supply of osteopotent cells: Greater than 250,000 cells/cc
- Viability: Greater than 70% cell viability
- Positive osteogenicity: In vitro cell culture assay

OSTEOCEL® PLUS

Safety Profile

- Aseptic tissue processing
- Antimicrobial treatment of tissue
- Sterility cultures performed on every lot
- Selective immunodepletion process
- No evidence of ectopic tissue formation or inflammatory cellular response with experimental high doses of MSCs cells ⁴

Donor Testing

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody
- Rapid Plasma Reagin or Serological Test for Syphilis (RPR or STS)
- HIV/HCV/HBV (NAT) Nucleic Acid Test (as required)

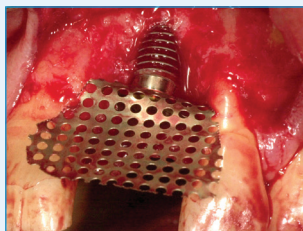
Donor Screening

- Medical and social history evaluation
- Physical examination
- Medical record evaluation, including autopsy report (if performed)
- Licensed physician review and release of every donor record

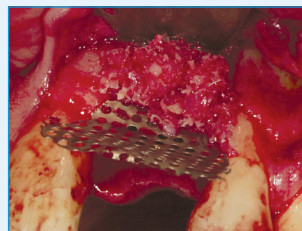
Quality Assurance

- GTP compliant according to FDA regulations
- All applicable state licensure/registrations
- Processed at an AATB® accredited tissue bank

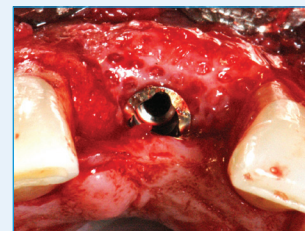
RIDGE AUGMENTATION CLINICAL CASE



BEFORE: exposed implant

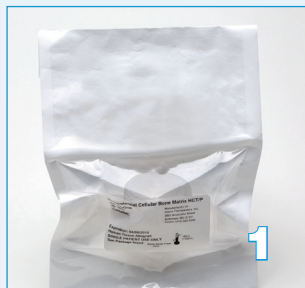


Bone graft in place prior to mesh fixation

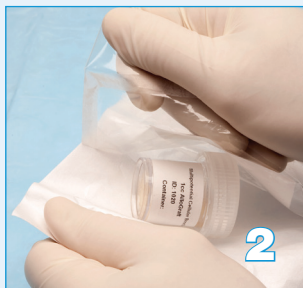


AFTER: 4 months after mesh removal

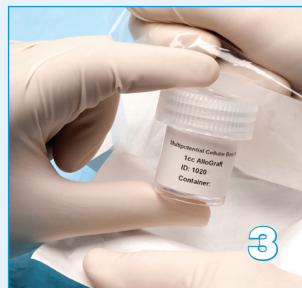
TUTORIAL: OSTEOCEL PLUS PREPARATION



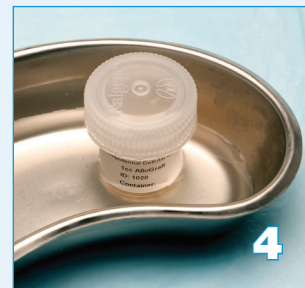
1
Upon obtaining Osteocel Plus from frozen storage, remove peel pack from protective covering. Note: Osteocel Plus cannot be refrozen.



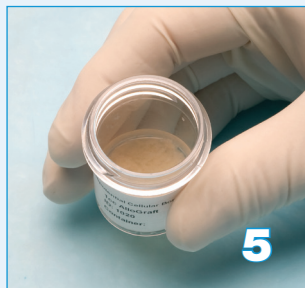
2
Designated person opens sterile peel pack utilizing standard sterile technique.



3
A sterile scrub person removes the Osteocel Plus container from the peel pack without compromising sterility.



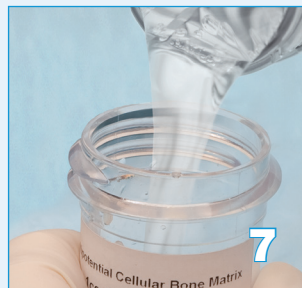
4
The Osteocel Plus container is placed into a basin of saline at physiological temperature (95-102°F / 35-39°C). Depending on size of container, Osteocel Plus will take 15-20 minutes to thaw. It can also be thawed at ambient temperature for 1 hour. Note: Do not warm above 102°F/39°C.



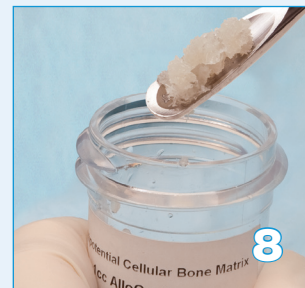
5
Once thawed, Osteocel Plus will be at the bottom of the container with the cryopreservation cell saving liquid on the top.



6
The cryopreservation cell saving liquid should be decanted and discarded.



7
Add warm (95-102°F / 35-39°C) sterile saline to fully immerse Osteocel Plus. Osteocel Plus can be maintained in saline for up to 4 hours.



8
Pour off saline prior to use. Note: Do not allow the cells to dry out. Osteocel Plus is now ready for use.

Osteocel® Plus

allograft cellular bone matrix

Consider the benefits of having a freezer in your office.

ACE SOUTHERN CRYOGENIC FREEZER PROGRAM

- Save on Osteocel Plus shipping charges
- Maximize treatment planning options
- Safely store Osteocel Plus for up to 5 years
- Fits under counter tops
- Inquire for complete program details
- Freezer storage specifications:
Temperature: -50° to -122°F (-45° to -86°C)
Dimensions: 29"h x 20"w x 22"d
Capacity: 1 cubic foot storage



Osteocel Plus

2080067	Cellular Allograft Bone Matrix	1cc vial
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Important Ordering Information

Due to the nature of the product, the order and delivery of Osteocel Plus needs to be carefully coordinated. Osteocel Plus is not available for purchase online. Osteocel Plus requires Priority Shipping and Handling which is in addition to prices shown. Please call ACE SOUTHERN for ordering instructions.

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For the most up-to-date pricing, please contact ACE SOUTHERN or visit our website at www.acesouthern.com.

Footnote References:

- 1 Mesenchymal Stem Cells Avoid Allogeneic Rejection. – Ryan, Barry, Murphy, Mahon. – Journal of Inflammation, July 2005
- 2 Histologic Evaluation of a Stem Cell Based Sinus Augmentation Procedure: A Case Series. – McAllister, Haghighat, Gonshor. – Journal of Perio., April 2009
- 3 Data on file with NuVasive, Inc.
- 4 Data on file with Osiris Therapeutics



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