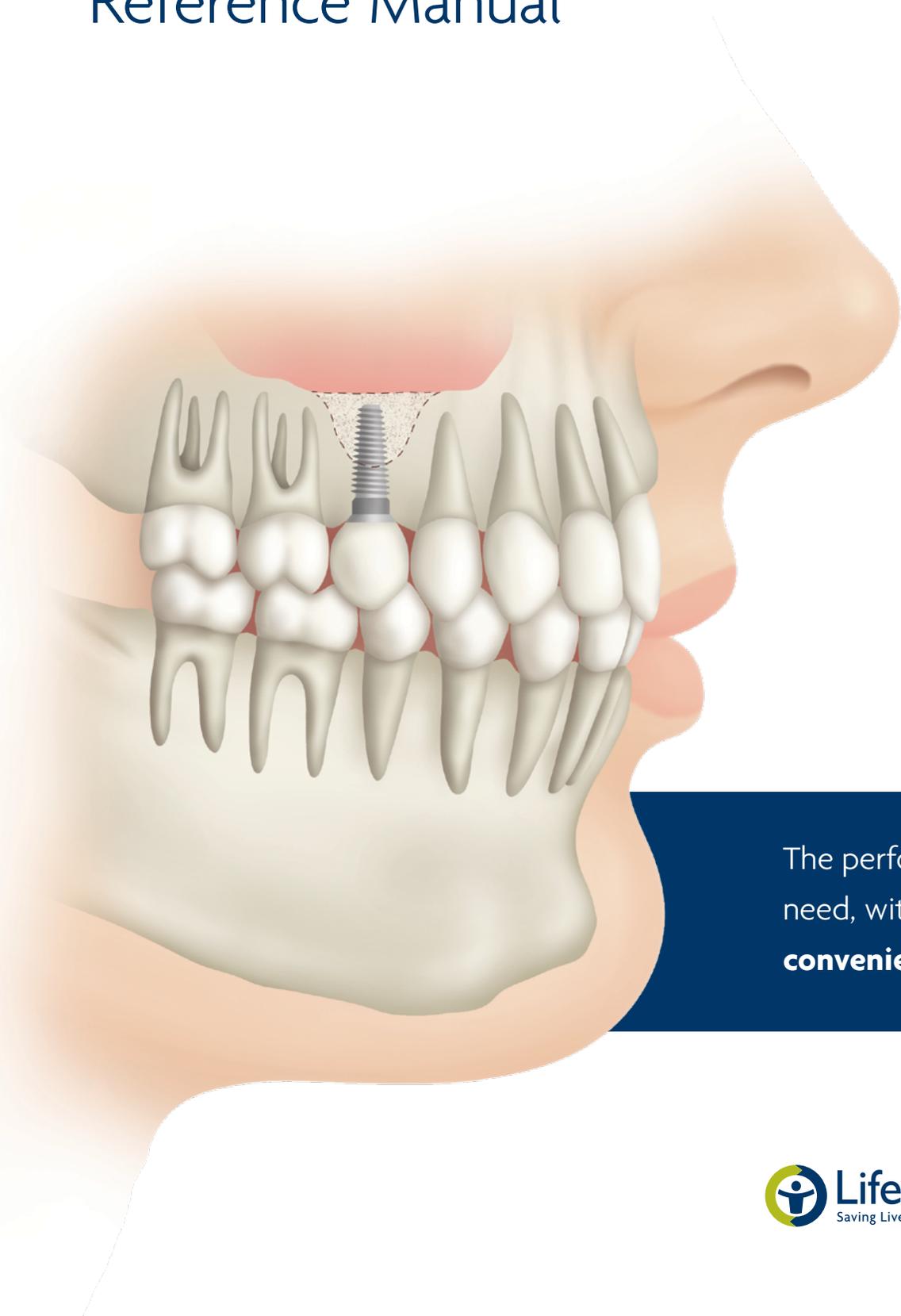


# Dental & Cranio-Maxillofacial Allograft Implant Reference Manual



The performance you  
need, with the **safety** and  
**convenience** you depend on.



## THE **VALUE** OF WORKING WITH LIFENET HEALTH

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*Thanks to your family's generous donation of bone tissue, I was able to receive a bone graft. This bone graft will allow for me to have a dental implant that looks just like the real thing! I am scheduled to start the implantation process in a month. With your small act of kindness, I can look forward to getting my smile back!*

– Erin

---

### Safety:

For over 30 years, we have refined and defined safety in the allograft industry. Our processes, quality systems, and proprietary cleaning and sterilization technologies are designed to ensure the utmost safety for your patient – **reducing the probability of infection that could be caused by an allograft implant.** Since 1995, over five million bio-implants processed using Allowash technology have been distributed by LifeNet Health with no disease transmission.

**The thread of safety is woven through every step of the donation process, including:**

- Stringent Donor Screening and Review
- Bacteria & Serology Testing
- Controlled Processing & Terminal Sterilization
- Final MD Review & Release
- Nationwide Recovery Network
- Physical Examination & Recovery Protocols

### Quality:

LifeNet Health's controlled tissue processing environment is designed to ensure bio-implant quality and safety. Through the consistent application of quality systems, quality control, and design control processes, LifeNet Health is both a medical device company and a tissue bank and our bio-implants are designed and manufactured to ensure the highest possible quality. **LifeNet Health grafts consistently perform as they should, allowing dentists to focus on the procedure, and patients to focus on healing.** Year after year, this dedication to quality is validated internally, and vetted by your peers, as well as government and industry regulators.

- Extraordinary Design Control Processes
- Validated Processes
- Quality Control Post-Processing Testing

### Innovation:

Because LifeNet Health leads the industry, and our innovations bring both clinicians and patients the most up-to-date technologies, **choosing LifeNet Health means choosing a partner able to consistently provide you with products, technologies, and services designed to improve safety, clinical effectiveness, ease of use and, ultimately, cost.** Since opening its doors in 2012, the LNH Institute of Regenerative Medicine has been a hub of research and development activity, and can **supply you with the products to meet your needs now – and in the future.**



## ABOUT LIFENET HEALTH

*Before my dental procedure, I was embarrassed to smile or have a photo taken; thank you from someone who now smiles all the time.*

– Barbara

Since 1982, LifeNet Health has helped to save lives and restore health for thousands of patients each year. It is the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

Our full line of allograft bio-implants provides surgeons with the tools they need to improve the lives of patients. Furthermore, we provide exemplary service by making the finest quality allograft implants easily accessible. With LifeNet Health as your primary bio-implant supplier, you are investing in the best possible value to ensure the well being of your patients and your reputation.

Every year LifeNet Health distributes nearly 500,000 allograft bio-implants to meet the urgent needs of patients around the world. Our record of safety is unmatched. And our philosophy is simple: When partnering with a bio-implant supplier, your decision should not be based solely on fee, but rather on the overall value you and your patients expect and deserve.

### LifeNet Health Timeline

- 1982 Eastern Virginia Tissue Bank established.
- 1989 Eastern Virginia Tissue Bank becomes LifeNet.
- 1995 Allowash® cleaning technology introduced by LifeNet.
- PAD® Demineralization technology introduced by LifeNet.
- 2000 LifeNet merges with Virginia's Organ Procurement Agency.
- 2001 First VertiGraft® VG2® Cervical spine allograft bio-implant is implanted.
- 2006 LifeNet merges with Florida Tissue Services, Inc. to become LifeNet Health of Florida.
- 2007 LifeNet becomes LifeNet Health.
- Preservon® ambient storage, fully-hydrated preservation technology introduced by LifeNet Health.
- 2008 CardioGraft® Cardiac Patch with Matracell® receives Food & Drug Administration (FDA) clearance.
- Skin & Wound Allograft Institute is established.
- OsteoCleanse® Autograft Cleaning System launched.
- 2009 LifeNet Health Regenerative Medicine Institute established.
- 2010 Record year in LifeNet Health allograft bio-implant distribution (over 300,000).
- ArthroFlex®, Dermacell® and Oracell® decellularized dermis is launched.
- 2012 Northwest Tissue Services merges with LifeNet Health to become LifeNet Health Northwest.
- 2014 Introduced the ViviGen® Cellular Bone Matrix, a differentiated cellular allograft.
- 2015 Celebrated the 20th Anniversary of allograft sterility with our patented Allowash technology.



Global Headquarters located in Virginia Beach, VA



# INNOVATION



Choosing LifeNet Health means choosing a partner able to consistently provide you with products, technologies, and services designed to improve safety, clinical effectiveness, ease of use and, ultimately, cost for the facility. Since opening its doors in 2012, the LNH Institute of Regenerative Medicine has been a hub of research and development activity, and can supply you with the products to meet your needs now – and in the future.

## Innovation in Sterilization Processes

Our patented Allowash XG sterilization process renders allograft bio-implants sterile, without compromising biomechanical or biochemical properties.



## Innovation in Preservation Technology

Our proprietary Preservon® technology allows bio-implants to be stored in a fully hydrated state at ambient temperature. This eliminates the need for lengthy rehydration and saves valuable OR time.



## Innovation in Demineralization Technology

Patented PAD® Demineralization technology provides precise bone demineralization to target the ideal residual calcium level of 1 – 4 percent. This controlled process protects bone morphogenetic proteins (BMPs) while ensuring optimal osteoinductivity.



## Innovation in Decellularization Technology

Matracell decellularization renders allograft bio-implants acellular, without compromising the biomechanical or desired biochemical properties of an allograft bio-implant for its intended surgical application.

## Innovation in Cell Technology

Our Institute of Regenerative Medicine is dedicated to the development of new cell-based technologies, designed to improve tissue and bone repair procedures.

# PERFORMANCE/CLINICAL EFFECTIVENESS

LifeNet Health provides the only allograft bio-implants backed by an entire body of published clinical data. In fact, our allograft bio-implants are proven in more applications than any other. The result? The kind of confidence that only comes with the world's most trusted provider of transplant solutions.

We have become the largest non-profit organ and tissue provider in the United States and have grown to distribute nearly 500,000 bio-implants annually.

More than 37 clinical studies document the clinical effectiveness and performance of LifeNet Health dental allografts.

### REPRESENTATIVE REPORTS USING ALLOGRAFTS AND TECHNOLOGY IN DENTAL PROCEDURES

**Particulate Grafting Studies:**

- In a study designed to test for donor-specific ChA antibodies, Christakou et al. (2002) used defects in 20 patients. The authors were unable to detect any antibodies at intervals over 7 weeks (initially successful). [\(click here for abstract\)](#)
- Calloni (2011) used both DFDBA and freeze-dried fascia lata femora to fill and protect (prevent chips). The author recommended both allograft types. [\(click here for abstract\)](#)
- Fucini et al. (1993) compared small large particle in periodontal defects. There was no statistically significant difference between the 250 to 500 µm and the 650 to 1,200 µm ranges. [\(click here for abstract\)](#)
- Chen et al. (1995) compared DFDBA with collagen membranes to the use of a collagen membrane. Both treatments promoted significant fill of the defects with no adverse reactions. [\(click here for abstract\)](#)
- Isaacs et al. (2000) concluded their study of 10 patients with support for using DFDBA for [\(click here for abstract\)](#)
- Landi and Sabatini (2001) published a technique ridge which described utilizing DFDBA mandibular ridge to prepare the location for implantation. [\(click here for abstract\)](#)
- After using OraCrown dental attached freeze-dried bone allograft (DFDBA) in a 20 patient, re-epithelialized (CE) and polytetrafluoroethylene, Ashikawa et al. (2004) concluded with DFDBA for treating intrabony defects. [\(click here for abstract\)](#)
- In a randomized, single-masked study involving 40 patients, Durinsky et al. (2004) compared enamel derived matrix (ECM) to treat intrabony periodontal defects. They concluded that when worked best, both treatments significantly improved the defect. [\(click here for abstract\)](#)
- Schwartz et al. (2006) reported positive results in a case report where DFDBA was mixed with a spiral bone defect located on the maxillary incisor. [\(click here for abstract\)](#)
- West and Oates (2007) compared implant stability in non-grafted sites vs immediate placement study showed that immediate placement with grafting is a viable option. [\(click here for abstract\)](#)
- Chhabily et al. (2005) treated a patient with alveolar ridge loss with a DFDBA and a collagen membrane. The DFDBA to augment the alveolar ridge deficiencies of 50 patients. The authors found that not all clinical results but it was essentially equivalent to the results of the allograft and autograft for [\(click here for abstract\)](#)
- Thil (2011) uses allograft to quickly correct an unanticipated defect in a ceramic milling. The case demonstrates the ease of use and predictability of allograft. [\(click here for abstract\)](#)
- Yun et al. (2011) achieved good healing, sound immediate implant placement using a polytetrafluoroethylene (PTFE) membrane. [\(click here for abstract\)](#)

### REPRESENTATIVE REPORTS USING ALLOGRAFTS AND TECHNOLOGY IN DENTAL PROCEDURES

- Sirdler AJ, Behrmaneh S, Karamali MA. Evaluation of allogenic cellular bone graft for ridge repair. *Periodontology*. 2013;26(1):25-32.
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- Went L, Oates T. Identification of stability changes for immediately placed dental implants. *J Periodontol*. 2007;78(10):1829-37.
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- Yun JH, Kim SH, Oh SH. Secondary closure of an extraction socket using the double-bar technique with immediate implant placement. *J Periodontol/Implant Sci*. 2013;84:263-268.

LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions. From organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

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**LifeNet Health**  
The LifeNet Health  
LifeNet Health, Inc.  
implant health  
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### REPRESENTATIVE REPORTS USING ALLOGRAFTS AND TECHNOLOGY IN DENTAL PROCEDURES

- Vollstiel D. Combination extraction socket grafting and horizontal augmentation of resorbed ridge. [\(click here for abstract\)](#)
- Vollstiel D. Simultaneous extraction socket grafting and horizontal augmentation of resorbed ridge. [\(click here for abstract\)](#)
- A case series by Wallace et al. (2013) in alveolar bone regeneration using histomorphometric and 3D computerized tomography analysis. Mineral and cancellous bone allograft was used to fill each socket and decellularized dermal matrix was applied over each socket site. Results showed 28.7% new bone formation using these materials. [\(click here for abstract\)](#)
- In this series, Sirdler (2014) describes the use of decellularized dentin in four separate cases. In each case, soft tissue healing and expectations for aesthetics were achieved.

**OsteoCleanse Autograft Cleaning System:**

- Graham et al. (2007) detail two successful cases using the AllonBlock XG tissue processing technique to decontaminate autologous cranial bone flaps. Two patients, one adult and one teenage, underwent cranial flap removal. The flaps were transported to LifeNet Health for processing, followed by gamma irradiation. Both patients underwent successful replacement of the AllonBlock processed flaps. At 7 and 3 months, respectively, following re-implantation of the flaps, there were no complications.
- Current salvage options for contaminated or at risk cranial bone flap autografts are inadequate due to economic, cosmetic, graft incorporation, and biocompatibility reasons. Its pilot study, Guelshuler et al. (2006) illustrated the effectiveness of OsteoCleanse® at salvaging otherwise non-implantable autografts based on clinical outcomes in 3 cases.
- Estus and Maloney (2010) present a method for decontamination and storage of autograft cranial flaps utilizing OsteoCleanse®.
- Guth et al. (2011) describe salvage options for cranial flap autografts utilizing LifeNet Health's proprietary OsteoCleanse® service. This methodology was developed for neurosurgeons and is especially useful where the autograft has been contaminated or is deemed too high risk for safe implantation. OsteoCleanse® adheres to AATB standards for recovery, packaging, labeling, and processing. Patient consent and privacy protections follow cGMP and HIPAA.

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- Christakou L, Graham RS, Carlson R, Yee G, Mischky A, Ford L, Gillin M. Salvage of contaminated cranial bone flap autografts using OsteoCleanse®. Pilot study case reports presented at Annual AATB Meeting Chicago, IL, September 6-9, 2008.

# CMF/DENTAL PORTFOLIO

LifeNet Health offers a portfolio of allograft options for both hard and soft tissue grafting designed to assist clinicians with:

- Periodontal defect correction (infrabony and furcation)
- Ridge augmentation and maintenance
- Extraction site preservation
- Sinus grafting
- Craniofacial reconstruction
- Soft tissue correction
- Conveniently packaged with a long shelf life, these products are available in many sizes to fit various applications.

LifeNet Health offers surgeons decellularized dermis for maxillofacial applications, intended for use in conjunction with guided tissue and bone regeneration, and oral soft tissue regeneration.

## General Instructions:

- Use on a single occasion for a single patient only.
- Once the package is opened, the bio-implant must be used for the current procedure or discarded.
- Inspect the bio-implant, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the bio-implant is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- Use aseptic technique at all times.
- Do not sterilize.
- Keep the bio-implant stored according to recommended storage instructions until preparing for implantation.

	Periodontal Defects	Ridge Augmentation	Extraction Site Preservation	Craniofacial Reconstruction	Sinus Grafting
Demineralized Cortical Powder	■	■	■	■	■
Cortical Particulate Mineralized	■	■	■	■	■
Cancellous Particulate Mineralized	■	■	■	■	■
Cancellous Cubes		■		■	
Cancellous Blocks		■		■	
Ilium Strips		■		■	
Iliac Crest Wedge with Preservon®		■		■	
Rib		■		■	
Large Particle Grafts		■	■	■	■
Perio Fascia Lata		■	■	■	■
Decellularized Dermis	■	■	■	■	■
Pericardium		■	■	■	■
Demineralized Cancellous Filler		■	■	■	
Demineralized Cancellous Cubes		■	■	■	
Demineralized Cancellous Strips		■	■	■	

■ Denotes appropriate product uses

Storage: Store at Ambient Temperature, shelf life is 3 years at ambient temperature.

## Graft Characteristics

GRAFT	OC	OI	HOLDS SPACE	REMODELING TIME
Demineralized Cortical (DFDBA)	Low	High	No	Fast (3-4 months)
Mineralized Cortical (FDBA)	High	-	Yes	Slow (6+ months)
Mineralized Cancellous (FDBA)	High	-	Yes	Medium (4-6 months)
Mineralized Corticocancellous (FDBA)	High	-	Yes	Medium (4-6 months)
Mineralized/Demineralized Cortical Mix	High	High	Yes	Fast (3-4 months)
Demineralized Large Particle (DFDBA)	Low	High	Minimal	Fast (3-4 months)
Structural (Can cube/block, Iliac, Rib)	High	-	Yes	Slow (6+ months)

FDBA speed of remodeling (fastest to slowest): Cancellous > C/C mix > Cortical

### OC – Osteoconductive

- Low = Scaffold is fragile due to demineralized, not likely to provide surface for creeping substitution
- Med = Scaffold moderately supports ingrowth from surrounding bone
- High = Solid scaffold will support ingrowth from surrounding bone

### OI – Osteoinductive Potential

- Low = Little chance for signaling of new cells
- Med = Moderate chance for signaling of new cells
- High = Very likely to signal new bone forming cells, leading to rapid bone regeneration

### Holds Space

- No = graft will not hold space, resorption likely
- Yes = graft will maintain the space, takes longer to turn over new bone

## Bone Volume Recommendations

PERIODONTAL DEFECTS	SUGGESTED VOLUME
Central Incisor	0.5 cc
Lateral Incisor	0.5 cc
Canine	0.5 cc
1 <sup>st</sup> & 2 <sup>nd</sup> Premolar	0.5 cc
1 <sup>st</sup> & 2 <sup>nd</sup> Molar	0.7 - 1.0 cc
3 <sup>rd</sup> Molar	0.7 - 1.0 cc

EXTRACTION SITES	SUGGESTED VOLUME
Central Incisor	0.7 - 1.0 cc
Lateral Incisor	0.5 cc
Canine	0.7 - 1.0 cc
1 <sup>st</sup> & 2 <sup>nd</sup> Premolar	0.7 - 1.0 cc
1 <sup>st</sup> & 2 <sup>nd</sup> Molar	1.2 - 2.0 cc
3 <sup>rd</sup> Molar	1.2 - 2.0 cc

SINUS GRAFTS	SUGGESTED VOLUME
Each Sinus	2.5 - 5.0 cc

## CANCELLOUS CUBES/BLOCKS



Size	Freeze-Dried	Storage Temp*	Shelf Life
10 x 10 x 10 mm	CANCUBE1	Ambient	5 years
15 x 15 x 15 mm	CCUBE-01	Ambient	5 years
15 x 15 x 8 mm	CCUBE-02	Ambient	5 years
15 x 30 x 8 mm	CCUBE-03	Ambient	5 years



## RIB

Size	Freeze-Dried	Storage Temp*	Shelf Life
60 - 115 mm	RIB	Ambient	5 years



## ILIUM STRIPS

Size	Freeze-Dried	Preservon	Storage Temp*	Shelf Life
15 x 20 mm	IS SML	ISP SML	Ambient/ Do Not Freeze	5 years
15 x 30 mm	IS MED	ISP MED	Ambient/ Do Not Freeze	5 years
20 x 40 mm	IS	ISP	Ambient/ Do Not Freeze	5 years



## COSTAL CARTILAGE

Width is greater than or equal to 7 mm

Length	Frozen	Storage Temp	Shelf Life
30 - 59 mm	CCART30	Between -40 and -80C	5 years
60 - 90 mm	CCART60	Between -40 and -80C	5 years

*\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C*

# STRUCTURAL OPTIONS

## Case Report: Block Grafting

A 25-year-old man presented with partial edentulism, the areas with missing teeth had Cawood and Howell Class 3 to Class 4 ridges. Nothing in the patient's medical history precluded planned treatment. Grafting of the atrophic area was performed using 3 mineralized human ilium block allografts, (OraGraft, LifeNet Health, Virginia Beach, Va)

Case was performed by Gian Sfasciotti.

*Selected References: (A complete compendium with hyperlinks to abstracts is available on request)*

In this case, Sfasciotti (2014) treats a severely atrophic mandible in sextants 5 and 6. Blocks formed from an ilium strip were strategically placed and secured with titanium screws. Preplanting was performed using computerized tomography and a surgical stent. Post-operative scans showed excellent early healing. A core was removed prior to implant placement and histology showed exceptional healing at 10 months. The case was successfully finished with implant placement

Nissan et al. (2011) published a follow-up to their 2008 study where they used 46 cancellous blocks to treat alveolar ridge deficiencies in 31 patients who required implants. They noted 98% implant success after a mean 34 month follow-up.

Chaushu et al. (2009) used cancellous blocks for maxilla sinus floor augmentation along with simultaneous implant placement for 28 patients. After a 27 months follow-up, the authors were encouraged by the high success rate and new bone formation.

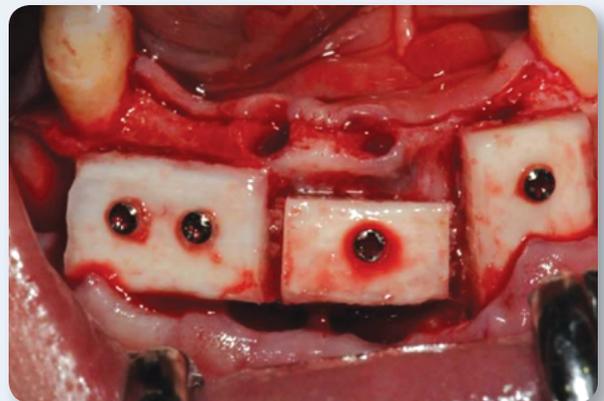
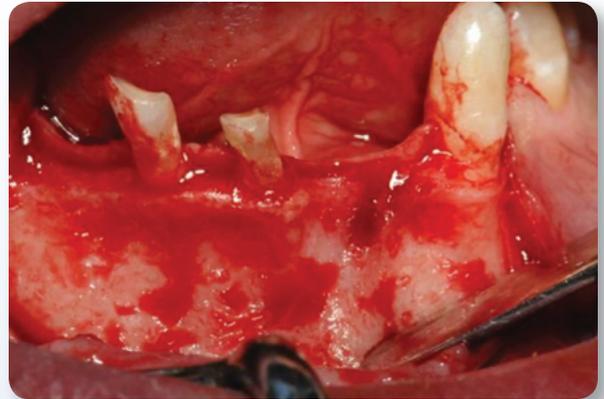


FIGURE 9. Core taken for histologic study at 10 months. Excellent healing is obvious along with adequate space for dental implantation.

**MINERALIZED CORTICAL CANCELLOUS PARTICULATE**

250 - 1000 microns



Size	Freeze-Dried	Storage Temp*	Shelf Life
0.5 cc	C/CMIX-0.5	Ambient	3 years
1.0 cc	C/CMIX-1.0	Ambient	3 years
2.0 cc	C/CMIX-2.0	Ambient	3 years

**DEMINERALIZED CORTICAL POWDER**

250 - 1000 microns



Size	Freeze-Dried	Storage Temp*	Shelf Life
0.25 cc	DGC1/20	Ambient	3 years
0.50 cc	DGC1/10	Ambient	3 years
0.70 cc	DGC1/8	Ambient	3 years
1.20 cc	DGC1/4	Ambient	3 years
2.50 cc	DGC	Ambient	3 years

**MINERALIZED CORTICAL POWDER**

250 - 1000 microns



Size	Freeze-Dried	Storage Temp*	Shelf Life
0.25 cc	GCI/20	Ambient	3 years
0.50 cc	GCI/10	Ambient	3 years
0.70 cc	GCI/8	Ambient	3 years
1.20 cc	GCI/4	Ambient	3 years
2.50 cc	GC	Ambient	3 years

*\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C*

**CANCELLOUS MINERALIZED POWDER**

250 - 1000 microns



Size	Freeze-Dried	Storage Temp*	Shelf Life
0.50 cc	O CAN-0.5A	Ambient	3 years
1.00 cc	O CAN-1.0A	Ambient	3 years
2.00 cc	O CAN-2.0A	Ambient	3 years

1000 - 2000 microns



Size	Freeze-Dried	Storage Temp*	Shelf Life
0.50 cc	O CAN-0.5B	Ambient	3 years
1.00 cc	O CAN-1.0B	Ambient	3 years
2.00 cc	O CAN-2.0B	Ambient	3 years

*\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C*



## DEMINERALIZED GROUND CANCELLOUS

1 - 8 mm

Size	Freeze-Dried	Storage Temp*	Shelf Life
5 cc	DCAN5	Ambient	5 years



## DEMINERALIZED CORTICAL

1 - 4 mm

Size	Freeze-Dried	Storage Temp*	Shelf Life
5 cc	DGC5	Ambient	5 years

*\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C*

# PARTICULATE OPTIONS

## Case Report: Ridge Augmentation

*Don Callan, DDS, Periodontist, Little Rock, AR, USA*

In this case, a 61 year old male with non-salvageable dentition is treated with bone grafting followed by implants. Other than severe periodontal disease, the patient appeared to be in good health.

The patient in question was presented with all treatment options, and full-mouth implant rehabilitation was chosen. Radiographs and diagnostic models were made and the case was planned in a restoratively driven manner. The dental team consisting of a periodontist, restoring dentist and dental technician reviewed all available data prior to beginning the case. The laboratory fabricated a set of temporary dentures (stayplates) for the patient to wear post-surgically. The patient underwent Phase I of periodontal therapy in order to control etiologic (bacteria) agents and allow for some healing of the inflamed tissues.



This patient had two issues to address: insufficient bone and insufficient soft tissue.

A complete medical and dental history was obtained and there appeared to be no contraindication to the use of IV sedation for the case. After sedation began, the oral cavity and facial areas were scrubbed with a disinfecting solution. All areas needing incisions were injected with a local anesthetic containing a vasoconstrictor. During the entire surgical procedure, the affected area was isolated with 4x4 gauzes saturated with an antibiotic solution.

In the first photo, the teeth of the maxillary arch have been removed. All granulation tissue has been removed and any unhealthy gingival tissue that surrounded the teeth. As a result, there is not enough tissue to achieve primary closure. In addition, any unhealthy bone was removed as were sharp bony prominences. You can see that the remaining bone is bleeding which is a positive sign. Sockets heal from the apex first then toward the coronal aspect. New blood vessels will feed the healing process from the socket walls.

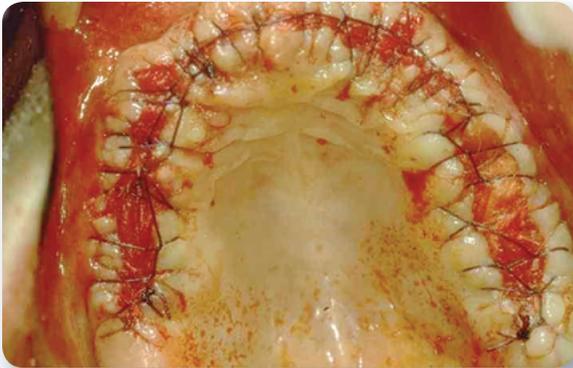
As shown in the second photo, all sockets were overfilled with demineralized freeze-dried bone (DFDBA). This graft type was chosen for its ability to provide for rapid bone healing. DFDBA would not normally be chosen, since it has limited space saving capability. The patient will be receiving a temporary denture which will protect the area and will actually mold the ridge to a desired form. It is desirable to have the ridge curved to better mimic the normal curvature in health. This will help to keep the final implants clean and healthy.



**Note:** *It is obvious that the surgical flaps cannot be approximated to allow for primary closure.*

At the time this case was presented, there were very few naturally resorbing materials that could be used in Guided Bone Regeneration procedures. The popular material of the time was e-PTFE. While popular, it did require removal. Membranes come in two types based on the characteristic of resorbability: nonresorbable and resorbable membranes. Nonresorbable membranes require an additional surgery for retrieval. The original nonresorbable membranes were made from either expanded polytetrafluoroethylene (ePTFE) produced by GoreTex or cellulose acetate such as the Millipore filter used by Nyman in 1982, the first documented GTR procedure. Nonresorbable membranes need to be retrieved after time has been allowed for tissue maturation. Murphy in 1995 completed a study that dealt with the question of when the membrane should be removed. They concluded that early removal was before six weeks and delayed removal was after six weeks. They experienced less matured bone and more recession with early retrieval and had more purulence and difficulty with removal with longer treatments. It was concluded that removal of the membrane should occur around six weeks.

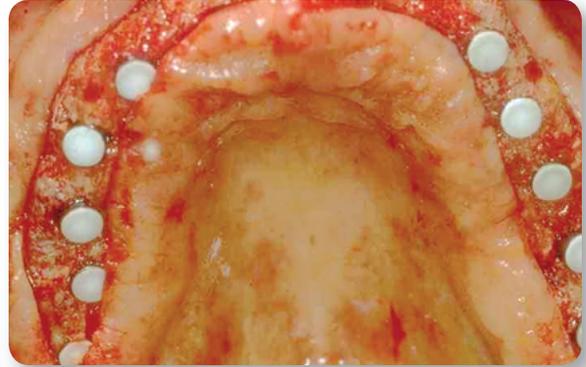
In the case at hand, because of the large area grafted, e-PTFE use would be problematic with retrieval being extremely difficult. Fascia lata was chosen instead. Fascia lata had a long track record in medicine of biocompatibility and strength. At the time the case was published, the author had used the technique on 28 other implant patients with a 100% success rate. If this case were done today, Oracell (acellular dermal matrix) would be another treatment option.



The third photo shows final suturing after the placement of the fascia lata resorbable membrane. Resorbable sutures are preferred by the Clinician and were chosen in this case. You can see areas where primary closure was not achieved, the gaps range from 5 to 7 mm. Since the patient was to wear a removal prosthetic device home, an acrylic bur was used to relieve the underside of the denture and reduce trauma to the surgical sites. Detailed instructions for wearing the prosthesis as well as oral hygiene was given and the patient was scheduled for follow up in 2 weeks.



This fourth photo shows the state of healing at 5 months. Note how smooth and rounded the ridge appears. This excellent result allows for placement of implants anywhere the clinician chooses. In this case, the dental team decided to place the implants from a restorative driven standpoint.



Hydroxyapatite coated threaded implants (Steri-Oss) were placed in the maxilla (above). The final restorations were designed by the restorative dentist and lab specialist and delivered (below).



**Note:** *Clinical judgment must be used in selecting patients who will benefit from guided tissue regeneration, selecting and implanting the appropriate configuration for the defect(s), and treating patients postoperatively. These topics are discussed widely in the literature and have been published in peer-reviewed journals.*

*Selected References: (A complete compendium with hyperlinks to abstracts is available on request)*

In a randomized trial involving 69 patients, Ogihara and Tarnow (2014) examined bony fill and soft tissue healing. The test groups were combinations of enamel matrix derivative with either demineralized freeze-dried bone allograft or mineralized freeze-dried bone allograft. Both groups showed improvement in both hard and soft tissue healing compared to the controls.

A clinical study by Eskow et al. (2013) performed histological analysis of cortical and cancellous freeze-dried bone allograft following tooth extraction and ridge preservation in a non-molar model. The study reported no significant differences in new bone formation between the two groups.

In a prospective study comparing allograft only with allograft and autograft combination treatment, Beitlitum et al. (2010) used FDDBA to augment the alveolar ridge deficiencies of 50 patients. The authors found that not only did the FDDBA alone yield good clinical results but it was essentially equivalent to the results of the allograft and autograft combination treatment.

**PERIO FASCIA LATA**



Size	Freeze-Dried	Storage Temp*	Shelf Life
15 x 30 mm Extra Small	PFL 1.5	Ambient	3 years
25 x 25 mm Small	PFL S	Ambient	3 years
25 x 55 mm Regular	PFL R	Ambient	3 years
25 x 95 mm Large	PFL L	Ambient	3 years

*\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C*

### DECELLULARIZED DERMIS

Thickness = .76 - 1.25 mm



Size	Room Temp	Storage Temp	Shelf Life
15 x 20 mm	OCELL100	15 - 30 Degree C	3 years
20 x 40 mm	OCELL101	15 - 30 Degree C	3 years
10 x 10 mm	OCELL150	15 - 30 Degree C	3 years
10 x 40 mm	OCELL151	15 - 30 Degree C	3 years

Thickness = 1.26 - 1.75 mm

Size	Room Temp	Storage Temp	Shelf Life
15 x 20 mm	OCELL200	15 - 30 Degree C	3 years
20 x 40 mm	OCELL201	15 - 30 Degree C	3 years
10 x 10 mm	OCELL250	15 - 30 Degree C	3 years
10 x 40 mm	OCELL251	15 - 30 Degree C	3 years

# SOFT TISSUE OPTIONS

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## Case Report

*Don Callan, DDS, Periodontist, Little Rock, AR, USA*

A surgery performed for implant placement at the sites of congenitally missing lateral incisors. A combination of OraGraft® mineralized cortical particulate and Oracell® decellularized dermis were required on the labial to correct for the thin bone support and to increase the soft tissue profile in these areas.



*Selected References: (A complete compendium with hyperlinks to abstracts is available on request)*

In a case report involving a maxillary implant, Mastronikolas (2014) extracts and performs site preservation on #5 [Eu. #16]. Demineralized freeze-dried bone allograft was used at the extraction site as well as a fascia lata membrane to guide bone formation. Approximately 3 months later, the patient underwent sinus augmentation at the same site utilizing freeze-dried bone allograft. Three months later, a CT scan was prescribed, which verified the successful elevation of the sinus floor.

Callan (1993) used both DFDBA and freeze-dried fascia lata femoris to fill and protect (respectively) an osseous defect in a surgical case. The author recommended both allograft types.

A case series by Wallace et al. (2013) analyzed bone regeneration using histomorphometric and 3D computerized tomography analysis. Mineralized cancellous bone allograft was used to fill each socket and decellularized dermal matrix was applied over each socket site. Results showed 28.7% new bone formation using these materials.

## OPTIUM® DBM

### GEL



Size	Freeze-Dried	Storage Temp*	Shelf Life
1 cc	TGEL01	Ambient	3 years
5 cc	TGEL05	Ambient	3 years
10 cc	TGEL10	Ambient	3 years

### PUTTY



Size	Freeze-Dried	Storage Temp*	Shelf Life
1 cc	TPUT01	Ambient	3 years
2.5 cc	TPUT02	Ambient	3 years
5 cc	TPUT05	Ambient	3 years
10 cc	TPUT10	Ambient	3 years

\*While ambient room temperature has not been defined by AATB, LifeNet Health maintains our lyophilized tissue at 10°C to 37°C

† Not available in all markets. Contact your LifeNet Health representative for availability.

**ReadiGRAFT®**

PUTTY



Size	Freeze Dried	Storage Temp	Shelf Life
0.5 cc	BF-1000-001	15 - 30 Degree C	18 months
1.0 cc	BF-1000-002	15 - 30 Degree C	18 months
2.5 cc	BF-1000-003	15 - 30 Degree C	18 months
5.0 cc	BF-1000-004	15 - 30 Degree C	18 months
10.0 cc	BF-1000-005	15 - 30 Degree C	18 months

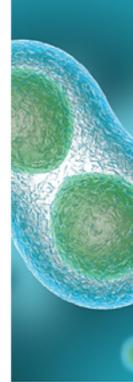
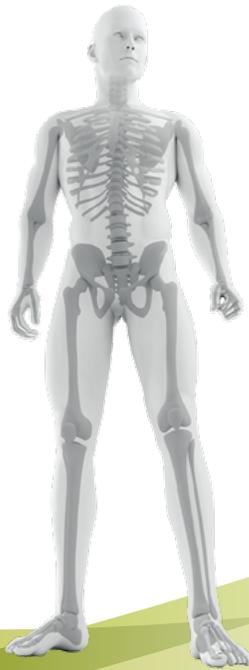
**DEMINERALIZED BONE MATRIX**

PUTTY CRUNCH



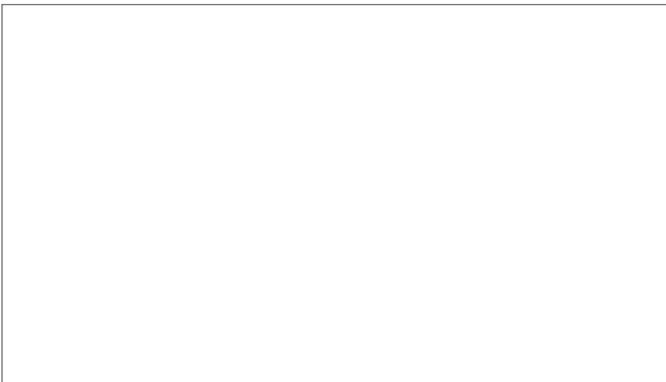
Size	Freeze Dried	Storage Temp	Shelf Life
0.5 cc	BL-1400-001	15 - 30 Degree C	18 months
1.0 cc	BL-1400-002	15 - 30 Degree C	18 months
2.5 cc	BL-1400-003	15 - 30 Degree C	18 months
5.0 cc	BL-1400-004	15 - 30 Degree C	18 months
10.0 cc	BL-1400-005	15 - 30 Degree C	18 months

† Not available in all markets. Contact your LifeNet Health representative for availability.



LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

**G** For Use: **Global Markets**



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