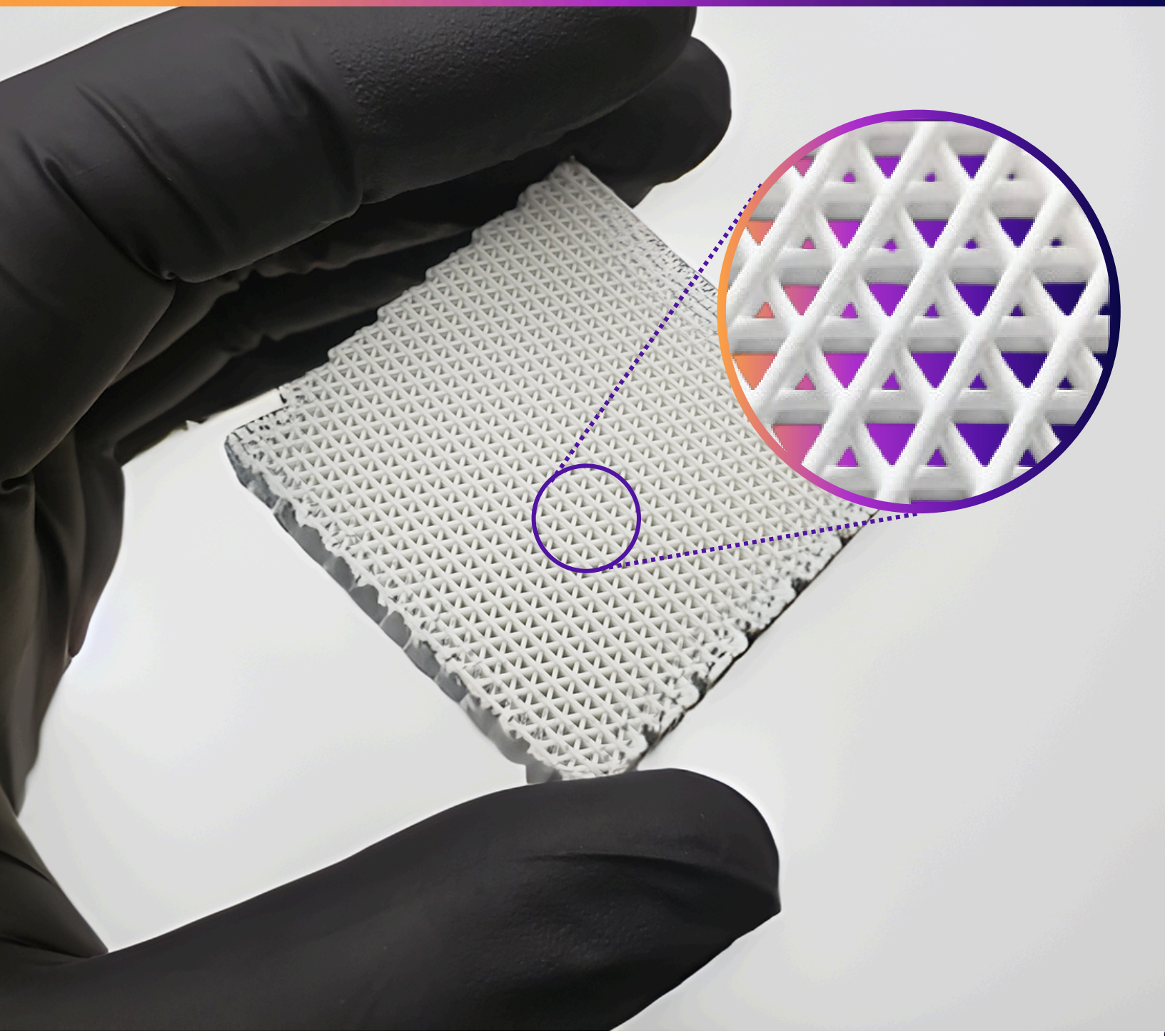
Dimension Inx



CMFlex®

3D-Printed Regenerative Bone Graft

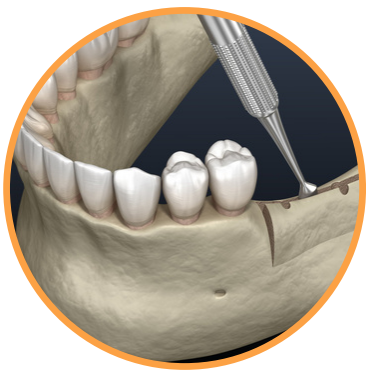
CMFlex® is an FDA 510(k)-cleared fully synthetic 3D-printed regenerative bone graft that can be used for various bony defects in oral and maxillofacial surgical applications.

CMFlex utilizes a chemistry comprised primarily of hydroxyapatite particles combined with biodegradable polylactide-co-glycolide (PLG) polymer. Both materials have an extensive history demonstrating biocompatibility with various implant applications.

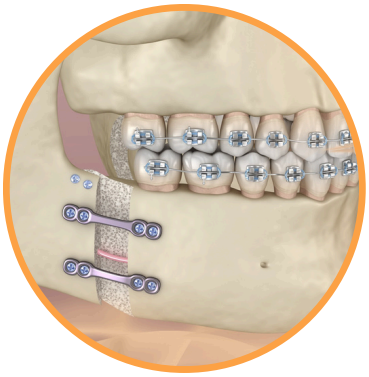
Dimension Inx combines these base materials into a proprietary microstructurally porous composite material, Hyperelastic Bone®, which is 3D-printed using a proprietary process into the microporous structure, CMFlex.

CMFlex's comprehensive micro and macroporosity support tissue integration and vascularization with surrounding tissues, allowing the device to work with the human body's cellular remodeling activity and be replaced by natural bone over time[1,2].

Targeted applications for CMFlex include:

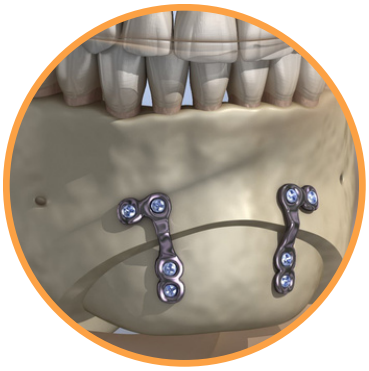


Alveolar ridge augmentation



Orthognathic surgery

Sinus elevation grafting



Facial trauma

CMFlex® represents an innovative approach to bone graft substitutes that combines the best properties of Hydroxyapatite with a 3D-printed architecture to promote bone regeneration and remodeling. Its unique properties make it a promising option for a variety of bone grafting applications.

Technology

Hyperelastic Bone is a proprietary synthetic biomaterial made of 90% hydroxyapatite and 10% biodegradable polyester. It has a distinctive microstructural surface area and innate material porosity that is ideal for cell adhesion, tissue interaction, and new hard tissue formation. Despite its high ceramic content, it maintains its mechanical strength while allowing some degree of elasticity, reducing the potential for fracture or breakage.

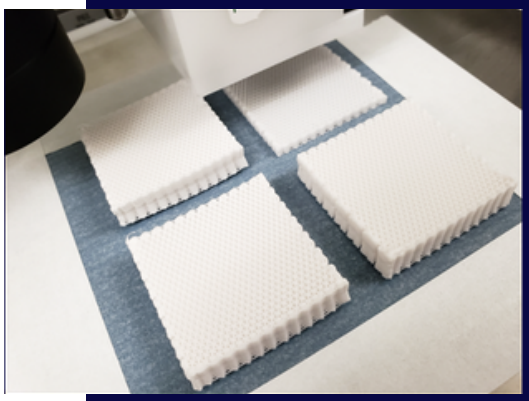
Hyperelastic Bone can be formed into 3D structures, such as CMFlex; maintaining the biological, microstructural characteristics of the base material, while adding additional structural, microporosity, and handling characteristics that assist with placement and tissue integration.

Highly Porous

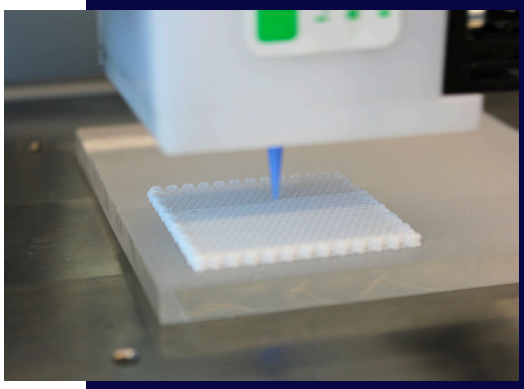
The manufacturing process of CMFlex is based on a unique multilevel product architecture design that enhances cell infiltration and adhesion. CMFlex is hydrophilic and highly porous in both macro and microstructure, resulting in increased surface area. This creates an environment that promotes cellular activity and enhances the potential for cell attachment.

Physical Characteristics

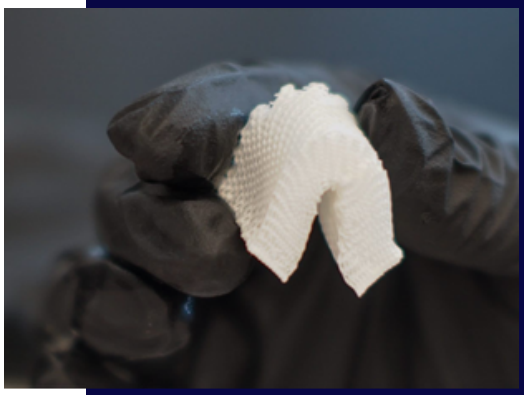
CMFlex retains a rigid yet flexible structure that maintains integrity and won't wash away during intense irrigation. To enhance its flexibility, submerge the graft in room temperature sterile saline or autologous fluid prior to implantation. The longer the graft is immersed, the greater its flexibility.



3D-printed CMFlex grafts



3D-printing in action



Flexibility after 15 minutes of submersion in fluid at about 37°C

Properties of CMFlex®

CMFlex exhibits the following features

- **Customizable Solution:** CMFlex can be easily shaped and contoured with simple tools like a sterile scalpel, eliminating the need for complex cutting devices such as bone saws or osteotomes, which can be challenging to handle, time consuming, and may not provide precise measurements for the defect site.
- **Porosity and Surface Area:** CMFlex has an overall porosity of >80% and features interconnected pores within and between the fibers. This high degree of porosity allows for cell infiltration and adhesion while maintaining its strength and avoiding brittleness.
- **Versatility and Flexibility:** CMFlex delivers exceptional benefits by harnessing its inherent flexibility, allowing for adaptation to the surrounding bone structure. Through hydration, CMFlex exhibits increased flexibility, enhancing its handling characteristics and enabling conformability to fit within various anatomical locations.
- **Hydrophilic Characteristics:** CMFlex's highly porous structure enables it to swiftly absorb and retain fluids, effectively maintaining them within its graft structure.

These distinct characteristics empower surgeons to tailor CMFlex according to their unique handling preferences.

Highly Absorbent and Rapidly Integrating Biomaterial with Increased Porosity:

CMFlex has a distinct multi-level porosity **(Figure 1)** derived from its proprietary manufacturing process, resulting in high absorbency **(Figure 2)**, rapid vascularization, and tissue integration **(Figure 3)**[1,2].

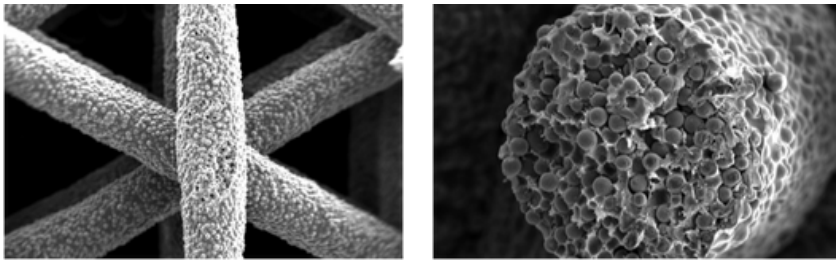


Figure 1. High magnification scanning electron microscope images of intercrossing strands, and magnification of individual strand showing individual hydroxyapatite particles.

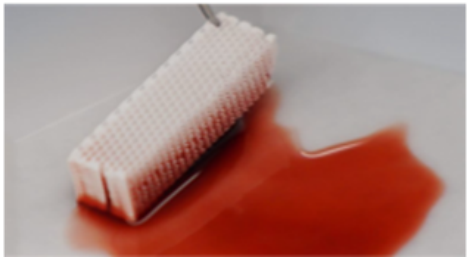


Figure 2. Multi-porous structure makes CMFlex highly absorbent.

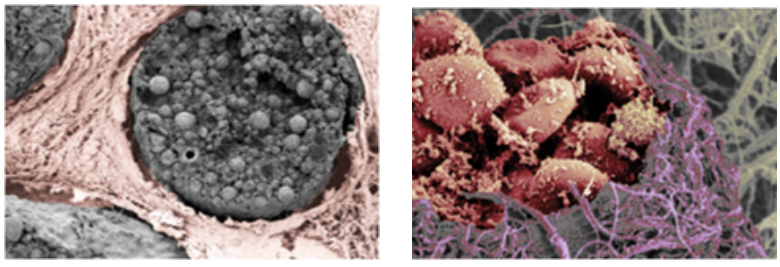
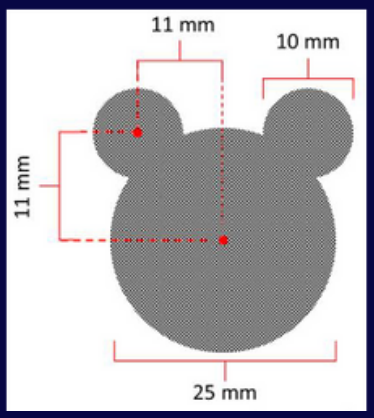


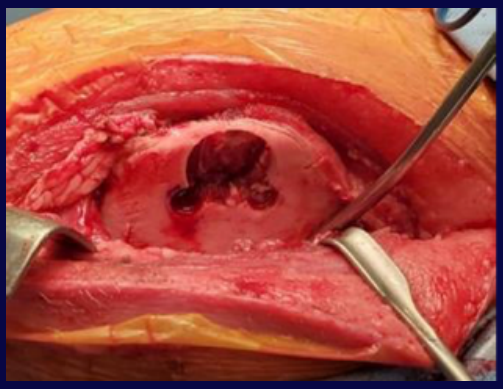
Figure 3. Scanning electron microscope (SEM) images of tissue growth occurring in between CMFlex strands and magnification of microvascular structure formation.

Scientific Data[3]

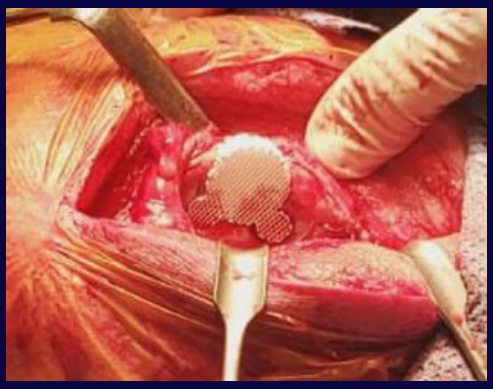
Irregular shaped (25-35mm and 11mm thickness) ramus defects in two adult pigs were treated with CMFlex or left untreated (negative control). Specimens were analyzed for new bone formation by computed tomography(CT), micro-CT scans(uCT), histology, and mechanical testing.



Est. AREA (Planar 1 side)=12.7cm²

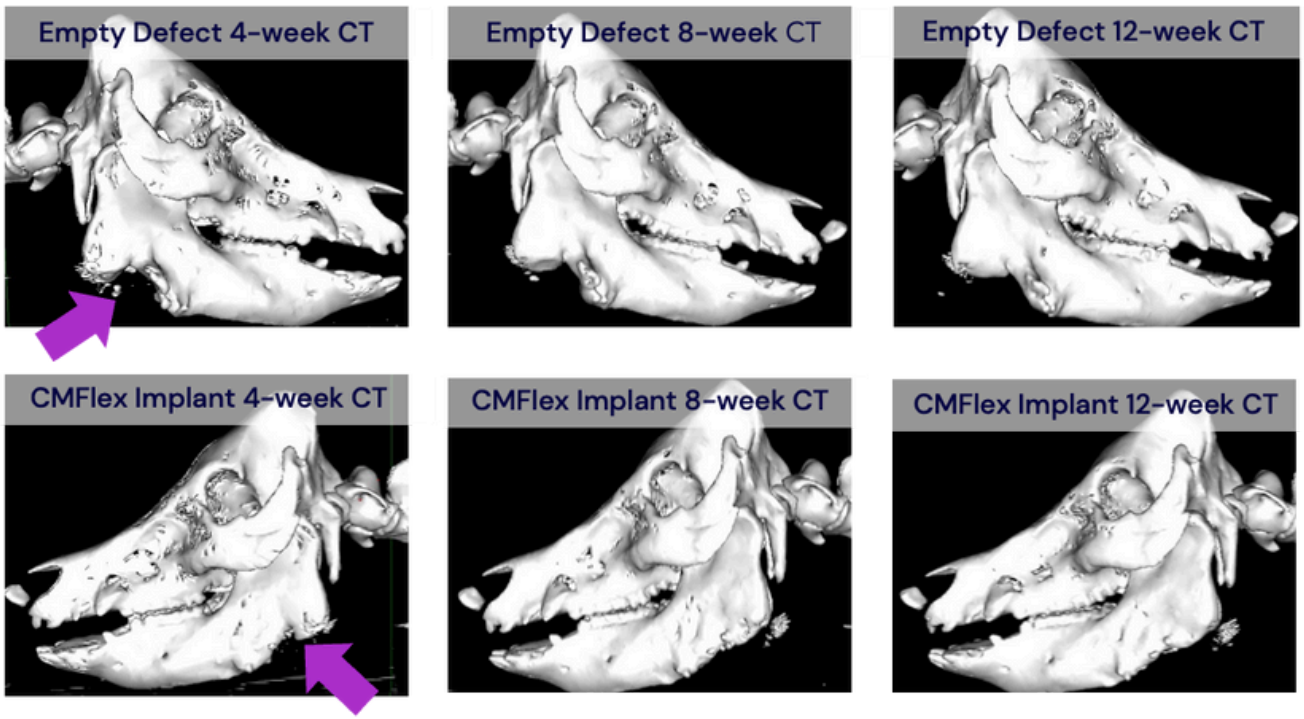


Control Empty Defect



CMFlex

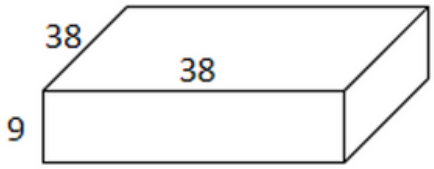
Conclusion: At eight weeks, the CMFlex treated defect demonstrated near-complete filling of new bone throughout the defect and recovery of the jaw contour in contrast to the non-treated control.



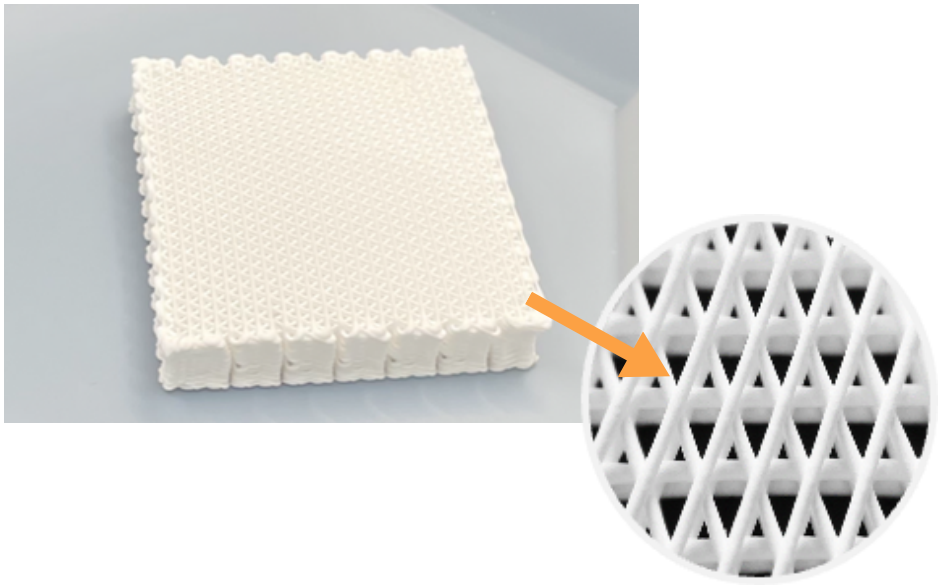
Surgical Technique

1. Pre-Op Planning

The size of CMFlex block needed for treatment should be estimated prior to the surgical intervention based on radiological and clinical examination.



NOTE: One size available: 38 mm x 38 mm x 9 mm. Additional sizes are being evaluated.



Routine surgical procedures should be used to expose the surgical site and create a soft tissue flap, if necessary.

NOTE: Once exposed, eliminate all granulation or necrotic tissue at the defect site.

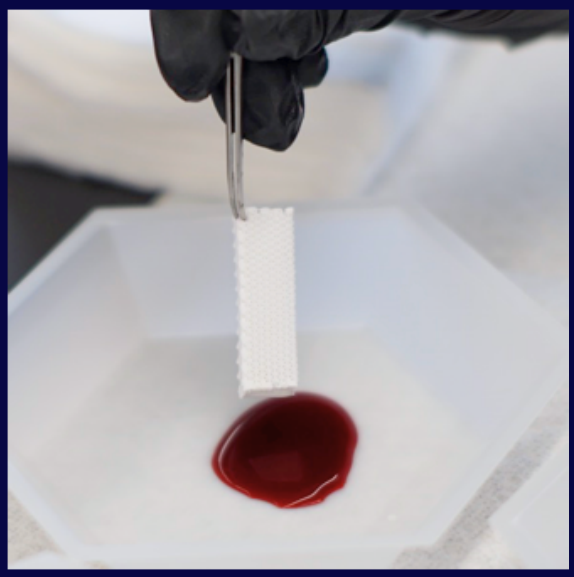
Bleeding should be observed originating from the host bone to indicate viability. Intra-marrow penetration (e.g., by perforation of cortical bone) is useful to ensure bleeding from the host bone, which aids in bone regeneration.

IMPORTANT: For complete instructions, indications, warnings, precautions, contraindications, and adverse events, please refer to the complete *Instructions for Use*.

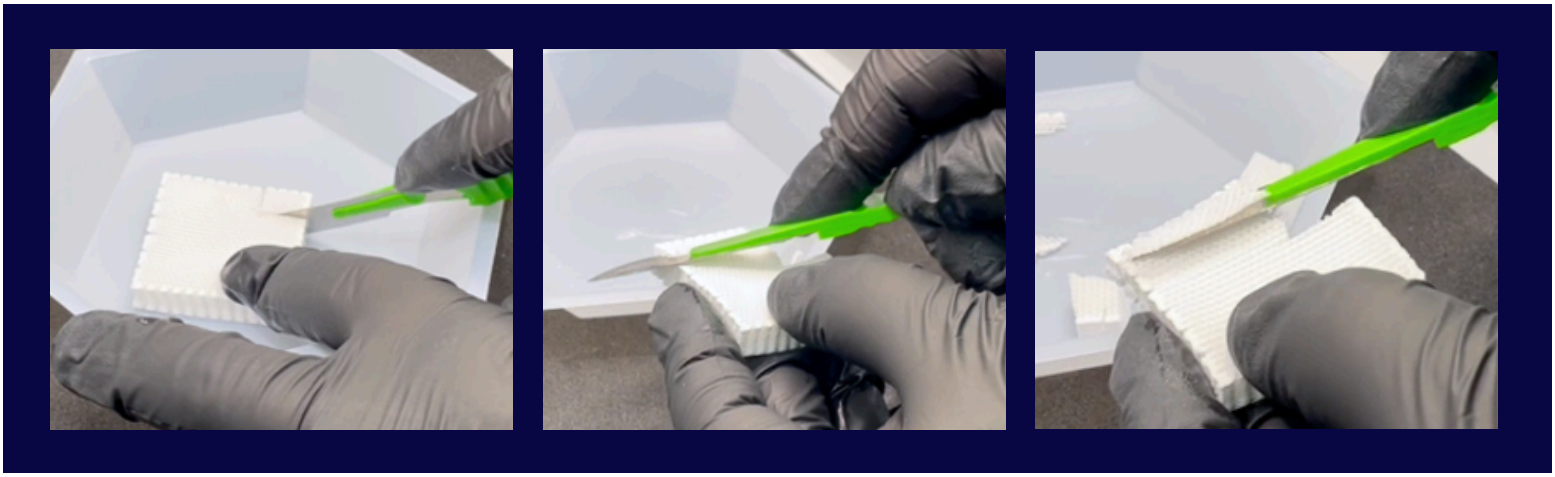
2. CMFlex® Preparation

Remove the CMFlex product from sterile packaging within the sterile field.

Prior to implantation or shaping the graft to the desired form, it is recommended to submerge CMFlex in warm sterile saline or autologous fluid. This step promotes increased pliability and flexibility of the graft, enabling it to fit the defect site more effectively.



CMFlex product may be trimmed with sterile surgical instruments (e.g., scissors or scalpel) to fit the defect site.



3. Graft Placement

Upon implantation, care should be taken to preserve the product's open pore architecture. The visible porous structure of CMFlex should not be damaged or altered (e.g., do not apply excessive compaction or crushing of the implant). Avoid overfilling of the defect to minimize tension around the wound closure. For optimal performance, CMFlex should be trimmed to fit the defect site as opposed to using excessive compaction.

CAUTION: Do not over compress the implant to the point that the open porosity is compromised during placement.

Place CMFlex in direct contact with well vascularized, bleeding bony surfaces using sterile instruments (e.g., tweezers).

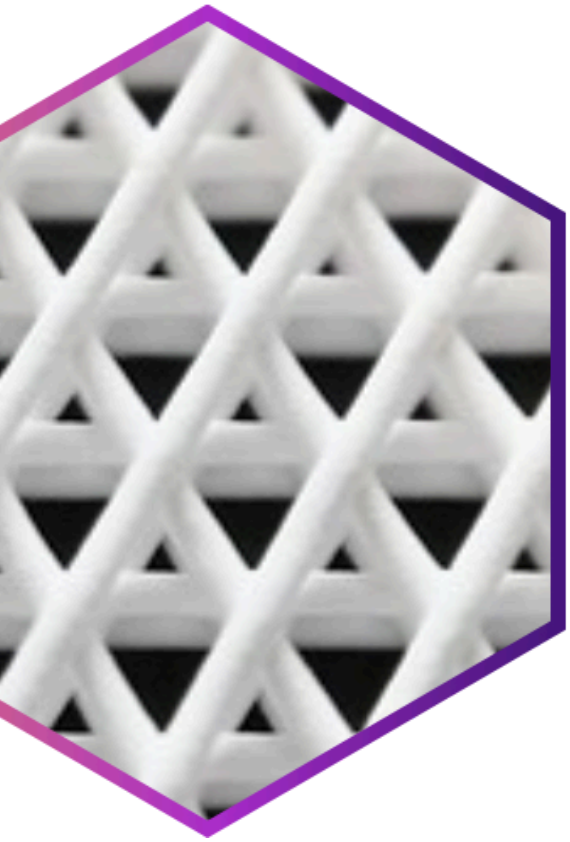
After placement into/onto the defect, any excess product that protrudes from the defect space should be trimmed with surgical tools (e.g., sterile scalpel). Saline may be used to wash away any loose pieces caused by trimming.

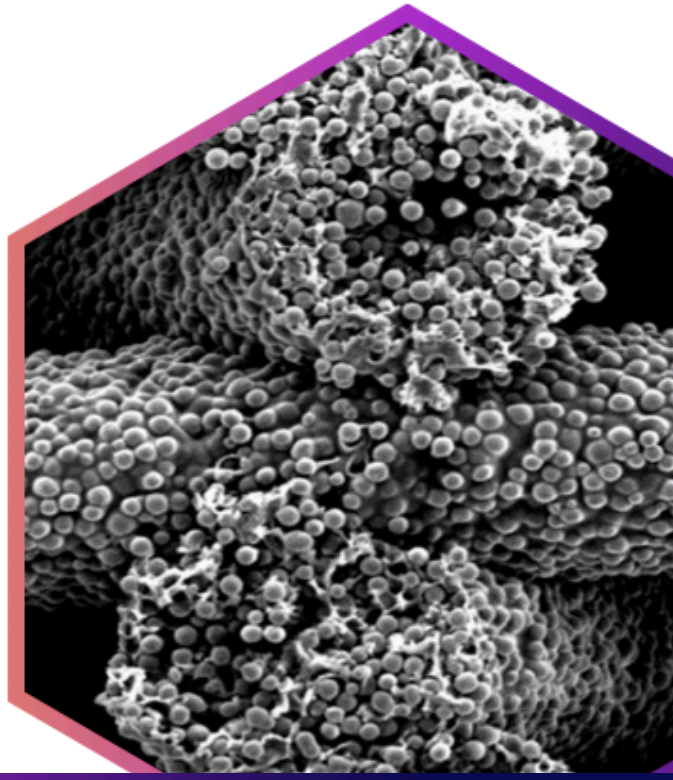
4. Surgical Site Closure

After the implant is placed into/onto the defect, secure the surgical site to prevent micro-motion or implant migration as per standard practice until primary closure is achieved. A soft tissue flap or membrane should completely cover the implanted CMFlex product.

5. Post-Op Care

Patient care following treatment is patient and indication specific and should follow the same regimen as standard surgical bone grafting procedures.





CMFlex®

3D-Printed Regenerative Bone Graft

CMFlex

Bone Grafting Device

PRODUCT DESCRIPTION

CMFlex is a sterile, non-pyrogenic, bioresorbable, biocompatible, synthetic, porous bone graft substitute for use in periodontal, oral, and maxillofacial surgery. CMFlex is comprised of Hyperelastic Bone®, a composite of synthetic hydroxyapatite bound by biodegradable poly(lactide-co-glycolide) and contains no animal or human derived substances. CMFlex is a pliable bone graft that can be easily cut to fit the shape of the defect. The multi-level porosity and high content of hydroxyapatite in CMFlex creates a unique microstructure and results in high absorbent properties. CMFlex is osteoconductive and is remodeled and replaced by natural bone. The success of the therapy depends on many factors including surgical technique as well as patient health, compliance, age, and potential for bone regeneration.

INDICATIONS FOR USE

CMFlex is indicated for filling and/or augmenting maxillofacial, mandibular, and intraoral osseous defects. Indications include:

- Intrabony periodontal osseous defects
- Furcation defects
- Bony defects or bony deficiencies of the alveolar ridge
- Intraoral, maxillofacial, and mandibular augmentation
- Bony defects of the upper or lower jaw
- Filling of tooth extraction sites
- Sinus elevation grafting

CONTRAINDICATIONS

CMFlex is not designed or sold for any use except as indicated. Do not use CMFlex in patients with:

- Existing acute or chronic infection or inflammation especially at the site of the operation
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction or presence of liver disease
- High dose corticosteroid use
- Vascular impairment at the implant site
- Irradiation treatment of the graft site
- Malignant tumors

PRECAUTIONS

- CMFlex should only be used by trained medical professionals, such as dentists, oral maxillofacial surgeons, or plastic surgeons.
- To facilitate the formation of new bone, CMFlex should be implanted in direct contact with well-vascularized bony tissue and, if necessary, microfracturation of the adjacent bone may be performed.
- If CMFlex is trimmed at the time of use, any excess trimmings or loose pieces should be removed from the product prior to implantation.
- All bone grafting procedures can experience variable results depending on various factors that should be considered including: the graft material; the applied technique; age of the patient and quality of patient bone; location, configuration, and size of the defect; adequate filling of the bone void or gap; intimate contact of viable bone and bone graft substitute; and wound closure and stabilization of the graft site to prevent migration of the graft material.
- Effect on pregnant or lactating women is not known.
- Effect on pediatric patients is not known.
- No allergic reaction against CMFlex or any of its components is known.
- CMFlex is not intended for immediate load bearing.
- Excessive compression of CMFlex upon implantation that significantly compromises the open pore structure of CMFlex may reduce performance (delayed bone integration) and increase risk of dehiscence.

WARNINGS

- CMFlex is intended for SINGLE USE ONLY. DO NOT reuse or re-sterilize.
- Do not overfill defects.
- Do not leave defect open.
- Do not compromise blood supply to the defect area.
- CMFlex should be secured to prevent motion and migration; use in areas where the graft can be adequately contained.
- CMFlex is not intended for immediate load bearing.
- Do not use CMFlex if package is opened or damaged or if product is expired.
- Do not use CMFlex if tamper seal or outer pouch is compromised.
- Do not use CMFlex if product is damaged (e.g., crushed or fragmented).

NOTES:

Dimension Inx

REFERENCES

1. Huang, Yu-Hui, et al. “Three-Dimensionally Printed Hyperelastic Bone Scaffolds Accelerate Bone Regeneration in Critical-Size Calvarial Bone Defects.” Plastic and Reconstructive Surgery, vol. 143, no. 5, 2019, pp. 1397–1407. doi:10.1097/prs.0000000000005530.
2. Jakus, AE, et al. "Hyperelastic “bone”: A highly versatile, growth factor–free, osteoregenerative, scalable, and surgically friendly biomaterial." Science Translational Medicine, vol 8, no. 358ra127, 2016. doi:10.1126/scitranslmed.aaf7704.
3. Data of file with Dimension Inx.

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