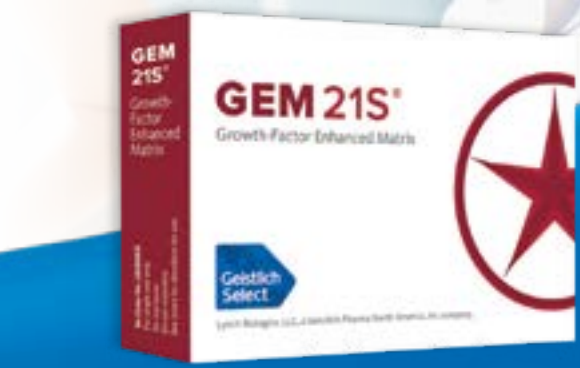
GEM 21S®

Growth-Factor Enhanced Matrix

Promotes faster, better healing and a more predictable outcome of your oral procedure.[1-3]



PATIENT INFORMATION LEAFLET

rhPDGF-BB is similar to platelet-derived growth factor naturally found in the body. In vitro and animal studies have demonstrated that PDGF has mitogenic (proliferative), angiogenic (neovascularization) and chemotactic (directed cell migration) effects on bone- and periodontal ligament-derived cells and promotes the regeneration of periodontal tissues including bone, cementum, and periodontal ligament.

Attraction

Proliferation

Regeneration

rhPDGF-BB has been used for the treatment of certain types of chronic skin wounds in the feet and legs of diabetic persons and also, combined with β-TCP, for bone grafting in foot and ankle surgery. rhPDGF-BB is designed to enhance the effects of β-TCP by promoting the ingrowth of bone-forming cells into the bone matrix and bone defect.

GEM 21S® is gradually replaced over time by new bone. Studies have shown new bone ingrowth into the defect to be between 63% - 73% after 36 months.[5]

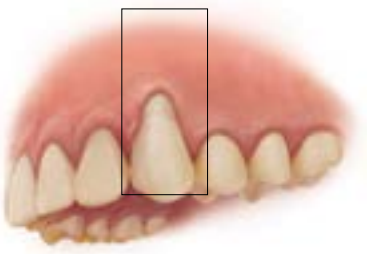
There are no residual substances from the manufacturing process that are expected to pose any risk.

Device Description and Indications:

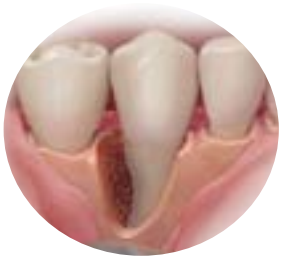
You have been diagnosed with a periodontal bone defect, a condition characterized by bony voids or gaps around teeth, typically caused by dental plaque and the body's reaction to it. Your dental practitioner would like to treat your condition using GEM 21S®. This is a two-component device consisting of a bone-like substance called β-tricalcium phosphate (β-TCP) and a bioengineered protein, recombinant human platelet-derived growth factor (rhPDGF-BB).

β-TCP is commonly used as a general bone void filler. In GEM 21S®, it has a particle size in the range 0.25 to 1.0 mm. It is designed to physically fill bone defects and provides a scaffold or framework for bone formation. By filling the defect, it also prevents collapse of gum and other soft tissues into the bone defect and helps stabilize the blood clot and promotes bone growth into the defect.

Periodontal Defect



Severe Bone Loss



Intended Performance:

GEM 21S® has been shown, by both clinical and radiographic (X-ray) measures, to be effective in treating moderate to severe periodontally related defects within six months of implantation.

Risks / Adverse Events:

No serious adverse reactions attributable to GEM 21S® were reported in a 180 patient clinical trial.[4] Patients being treated with GEM 21S® may experience any of the following adverse events that have been reported in the literature with regard to periodontal surgical grafting procedures: swelling; pain; bleeding; hematoma (bruising); dizziness; fainting; difficulty breathing, eating, or speaking; sinusitis (inflamed sinuses); headaches; increased tooth mobility; superficial (shallow) or deep wound infection; cellulitis (infection of the surrounding skin); wound dehiscence (wound reopening); neuralgia (severe nerve pain) and loss of sensation locally and peripherally; and, anaphylaxis (severe allergic reaction).

GEM21S® is sterile product; however any surgical procedure carries with it a small residual risk of infection.

Precautions and Other Advice:

Your surgeon will provide you with instructions on how to care for the affected area after surgery, such as when to change dressings and what to use, when/what to use to rinse the mouth, pain management, eating and drinking and medication.

It is important to follow those instructions carefully to give the site the best care during the healing phase.

It is important to stay well hydrated and drink 8-10 glasses of water a day after surgery. Avoid hot drinks and hot, spicy and acidic foods. Avoid foods like nuts, sunflower seeds, popcorn, gum, fried foods etc. for 7-14 days or until the wound area has healed.

If you experience any of the following symptoms, please contact your doctor or surgeon immediately; excessive swelling, persistent pain that increases despite pain medication, increased muscle stiffness beyond 5 days; increased redness after 5-7 days, difficulty swallowing or increased difficulty opening your mouth after 5-7 days; fever and chills or excessive bleeding.

Incident Reporting:

Patients should report any serious incident that occurs in relation to the device to the manufacturer: www.lynchbiologics.com/contact as well as to the Therapeutic Goods Administration: https://www.tga.gov.au/ and to Geistlich Pharma Australia & New Zealand at: info@geistlich.com.au

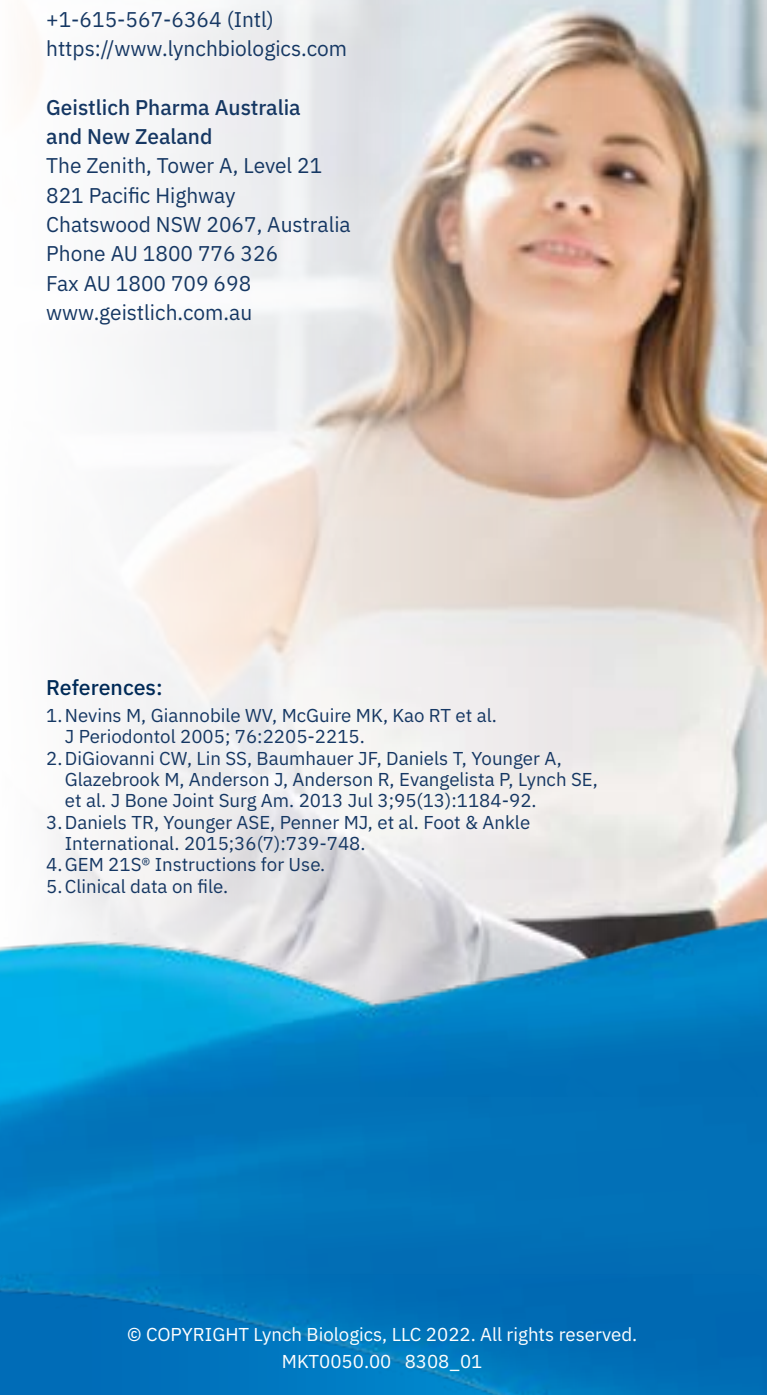
How can I find out more information about GEM 21S®?

Visit our web site at **www.geistlich.com.au/** and/or ask your dentist or other oral care specialist.

Contact Us:

Lynch Biologics, LLC
393 Nichol Mill Ln, Suite 280
Franklin, TN 37067
1-800-874-2334 (US)
+1-615-567-6364 (Intl)
https://www.lynchbiologics.com

Geistlich Pharma Australia and New Zealand
The Zenith, Tower A, Level 21
821 Pacific Highway
Chatswood NSW 2067, Australia
Phone AU 1800 776 326
Fax AU 1800 709 698
www.geistlich.com.au



References:

1. Nevins M, Giannobile WV, McGuire MK, Kao RT et al. J Periodontol 2005; 76:2205-2215.
2. DiGiovanni CW, Lin SS, Baumhauer JF, Daniels T, Younger A, Glazebrook M, Anderson J, Anderson R, Evangelista P, Lynch SE, et al. J Bone Joint Surg Am. 2013 Jul 3;95(13):1184-92.
3. Daniels TR, Younger ASE, Penner MJ, et al. Foot & Ankle International. 2015;36(7):739-748.
4. GEM 21S® Instructions for Use.
5. Clinical data on file.

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