

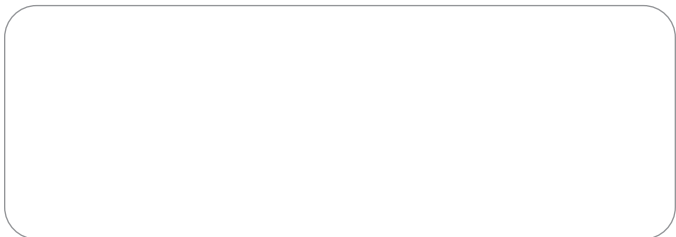
GEM 21S®

GROWTH-FACTOR ENHANCED MATRIX

Promotes faster,
better healing
and a more
predictable
outcome of your
oral procedure.



FROM THE OFFICE OF:



Your doctor has recommended GEM 21S® as part of your surgical treatment. GEM 21S® Growth-Factor Enhanced Matrix is designed to enhance your body's natural ability to heal and restore your gums and the underlying bone that has been lost as a result of periodontal disease. Healthy, intact gums and bone support are extremely important for the long-term maintenance of your oral health.

What is **GEM 21S®**?

GEM 21S® Growth-Factor Enhanced Matrix is a synthetic bone graft composed of pure, sterile bioengineered platelet-derived growth factor (PDGF) and a bone graft. PDGF is naturally found in our bodies (present in the platelets in your blood) and is often referred to as *nature's wound healing protein*. Whenever you experience a wound or surgery, your blood clots and platelets release PDGF (along with other proteins), stimulating the healing process. Unfortunately, as we grow older and with certain conditions, the amount of naturally occurring PDGF declines so we no longer heal as we did previously. GEM 21S® replenishes the amount of PDGF at the grafted site to aid in faster, better healing.

What is a periodontal defect?

When you smile, a periodontal defect might look like the picture in Figure 1. Notice that the gum line has receded from the original healthy starting position (a gingival recession defect). Underneath the gums, it is likely that bone and other structures have also been lost. These structures are necessary to anchor the tooth firmly in place.

As periodontal disease progresses further without treatment, the loss of gum tissue, bone, and other supporting structures becomes more severe. If left untreated, you may experience pain, swelling, loosening of teeth, and eventually tooth loss.

Fig. 1



Figures 2a and 2b illustrate severe bone loss around teeth where periodontal disease has gone untreated.

Fig. 2a



Fig. 2b



GEM 21S[®] Growth-Factor Enhanced Matrix promotes better healing of periodontal defects and more complete bone regeneration.

How does **GEM 21S®** promote healing?

Since GEM 21S® will be implanted under your gums, you won't be able to see the powerful effects of the treatment as it occurs. The illustrations that follow describe how GEM 21S® speeds up your body's natural healing process.



Fig. 3

Your doctor will begin by thoroughly cleaning the area to be treated. Once properly prepared, GEM 21S® is used to fill the area where bone and other supporting structures have been lost. GEM 21S® acts by signaling your body to actively begin to heal and regenerate healthy bone and soft tissues.

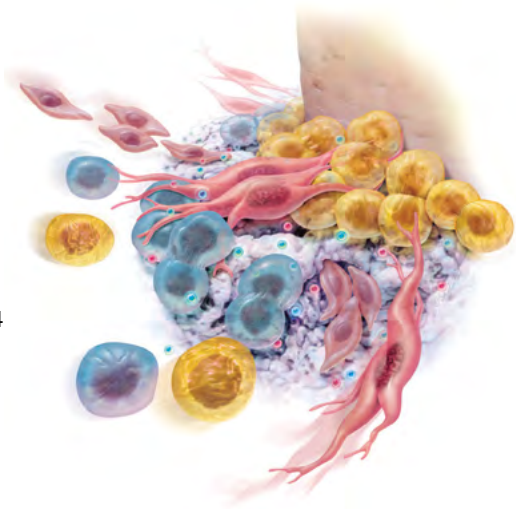
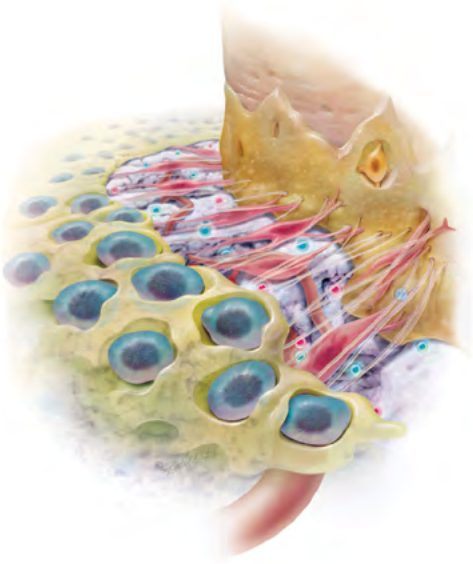


Fig. 4

GEM 21S® attracts the specific cells that your body needs to regenerate bone and the surrounding tissues, causing them to multiply in number. This increase in cellular activity results in a more rapid healing process.*

Fig. 5



GEM 21S® is gradually replaced with your own bone and other normal tissues. Several months after treatment with GEM 21S®, healing is complete.

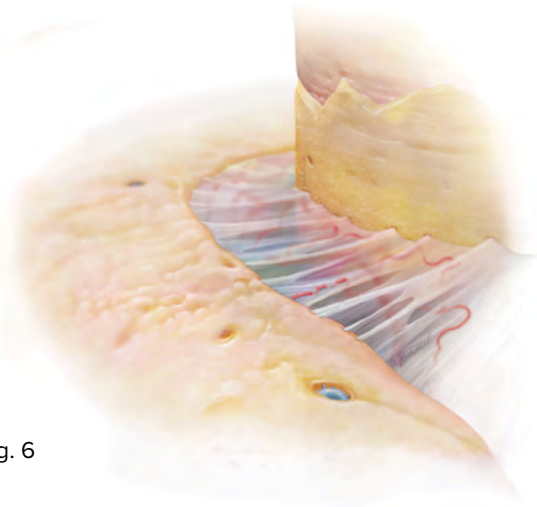


Fig. 6

* Based on in-vitro and in-vivo data; see device description on page 8 for complete information.

How long will it take to see results?

Your gums will typically heal within 1 -2 weeks. While GEM 21S® promotes rapid healing, it takes bone several months to mature into its final dense structure (Fig. 7). The goal of treatment with GEM 21S® is restoration of a normal healthy condition (complete regeneration of the bone and soft tissues).



Fig. 7

How will I benefit from treatment with **GEM 21S®**?

GEM 21S® will improve the health of the jaw bone and surrounding tissues that have been damaged as a result of periodontal disease. GEM 21S® is the only product available for use in dental surgery that contains pure PDGF to improve healing.

Is **GEM 21S**[®] FDA approved?

YES. GEM 21S[®] has been fully approved by FDA.

In addition to being the only FDA-approved product available for use in dental surgery that contains pure PDGF (*nature's wound healing protein*), your dentist is using GEM 21S[®] because it's also one of the most rigorously studied products in dentistry over the last 20 years.

GEM 21S[®] was evaluated in one of the largest, most rigorous clinical trials ever conducted in the United States for a regenerative product in dentistry. In fact, a recent scientific publication found over 60 clinical studies have been published on PDGF, the active ingredient of GEM 21S[®]!

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

Visit our web site at **LYNCHBIOLOGICS.COM** and/or ask your dentist or other oral care specialist.



LYNCH BIOLOGICS

Helping You Heal

Lynch Biologics, LLC is a biotechnology company specializing in products to accelerate healing and regeneration of human tissue.

GEM 21S[®], proven scientifically and clinically to aid faster and better healing across different types and severities of periodontal defects, is just one of the many products in our suite of complementary regenerative products.

To learn more about GEM 21S[®] or any of our other products, please visit us online or call to speak with a product specialist.

800-874-2334 | [LYNCHBIOLOGICS.COM](https://lynchbiologics.com)

IMPORTANT SAFETY INFORMATION

GEM 21S[®] Growth-Factor Enhanced Matrix is intended for use by periodontists/dentists/oral surgeons familiar with periodontal surgical techniques. It should not be used in the presence of untreated acute infections or untreated malignant cancerous growth at the site of use, where bone grafting is not advisable or tissue coverage is not possible and, in patients with a known hypersensitivity to one of its components. It must not be injected into your body, only placed into a defect around your teeth.

The safety and effectiveness of GEM 21S[®] has not been established in patients with an active malignant cancerous growth, in other non-periodontal bony locations, in patients less than 18 years old, in pregnant or nursing women, in patients with frequent/excessive tobacco use (e.g. smoking more than one pack per day). In a 180 patient clinical trial, there were no serious adverse events related to GEM 21S[®]. Adverse events that may occur are those associated with periodontal surgical procedures in general, including swelling; pain; bleeding; dizziness; fainting; difficulty breathing; eating or speaking; sinus problems; headaches; loose teeth; infection; loss of feeling; and shock. Should any of these occur, an additional surgical procedure and/or removal of the product may be required.