Emdogain®

The reliable solution for periodontal treatment.

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Emdogain® benefits

Emdogain® is a biology-based product that promotes the predictable regrowth of hard and soft tissues lost due to periodontal disease. With its proven scientific documentation, its ease of use, and the flexibility required to manage areas that are difficult to treat, Emdogain is clearly the reliable solution.

Reliable in treatment

- In more than 60 clinical studies, involving more than 2,000 intrabony periodontal defects, Emdogain has been proven to be effective in stimulating the formation of new periodontal attachment in:
  - soft tissue – measured as clinical attachment level gain and probing pocket depth reduction
  - hard tissue – evidence of new alveolar bone
- Clinical studies have demonstrated an average of 60–70% defect fill measured as gain of radiographic bone, one year following treatment with Emdogain.
- Safety of Emdogain has been established in numerous clinical studies and EMD has an excellent safety profile.

Simple in application

- Treatment with Emdogain requires little or no preparation time; no mixing of materials is required and no specialized products or equipment are necessary.
- Emdogain allows for rapid placement and little time in manipulation of material into a periodontal defect, resulting in limited exposure of open tissues.
- Emdogain does not affect tissue integrity beyond that of normal flap surgery.
- Emdogain requires only one surgical procedure; no follow-up surgery is necessary.
- The simplicity of Emdogain enables you to treat periodontal defects on teeth adjacent to areas where other surgical procedures are being performed (e.g. implant placement, ridge augmentations, extraction site augmentations, and extractions) at the same time.

Versatile in practice

- Emdogain is convenient and effective to use in difficult-to-reach areas such as interproximal areas, defects distal to the second molar, defects located under bridgework, and wide defects.
- The possibility for the use of Emdogain in periodontal defects is expanding. Emdogain is indicated for:
  - 1-, 2-, and 3-wall intrabony defects
  - Class II mandibular furcation defects with minimal interproximal bone loss
  - Recession defects
The biological approach

The cellular breakthrough of Emdogain®

Emdogain found its beginnings more than a decade ago when a breakthrough in the basic biology of tooth development revealed a native complex of enamel matrix proteins and the key role they play in the development of tooth-supporting tissues. As shown below, these “matrix proteins” mediate the formation of acellular cementum on the root of the developing tooth, providing a foundation for all of the necessary tissues associated with a true functional attachment.

Emdogain is comprised of a number of proteins that self-assemble to create a matrix. The dominant protein in this matrix is amelogenin, which has been remarkably well-conserved throughout evolution and functionally consistent in many species. Therefore, although the matrix proteins in Emdogain are of porcine origin, they are considered as “self” when encountered by the human body.

The safety of Emdogain has been completely documented through a number of thorough toxicology programs.

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The product

Designed for ease of use
Emdogain® has been carefully designed to fit easily into established treatment regimens. Available in two sizes to treat single or multiple defects, Emdogain is also co-packaged with PrefGel™.

*PrefGel is a pH neutral, 24% EDTA gel solution that effectively removes the smear layer during periodontal surgery, while preserving the vitality of surrounding periodontal tissues.

The indications
Emdogain is intended as an adjunct to periodontal surgery as a topical application onto exposed root surfaces to treat intrabony defects due to moderate or severe periodontitis. It has been proven to be effective in:
- one-wall, two-wall, and three-wall intrabony defects
- class II mandibular furcation defects with minimal interproximal bone loss
- recession defects
In vitro and in vivo
Investigations were initiated to determine the ability of the proteins to promote the regain of lost periodontal supporting tissues. Additionally, studies were performed and efficacy was proven in animal models.

Human studies
Multicenter trial
Emdogain® demonstrated that out of 27 defects, 25 showed radiographic bone gain.

Histology
Emdogain satisfies the requirements for true periodontal tissue regain via human histologic evaluation. New bone, cementum, and periodontal ligament were observed coronal to a notch placed in calculus as the histologic marker (Figure 1).

Re-entry
Results included 53 re-entries one year later following Emdogain treatment. Results included probing depth reduction of 4.94 mm, percent of defect fill of 74 %, and percent of defect resolution of 83.2 % (Figure 2).

Histology
Figure 1
Shown below: Histologic evaluation of 67-year-old Caucasian man; smoker. Wide 3-wall defect on mesial aspect of mandibular left canine was treated with Emdogain and evaluated at 6 months post surgery.

Area just coronal to notch (cn) demonstrates new bone (b), acellular cementum (ac), and periodontal ligament (pdl) (40x; hematoxylin-eosin stain).

Case courtesy of Dr. James T. Mellonig
Professor and Director,
Postdoctoral Program Periodontics
The University of Texas Health Science Center at San Antonio, USA

12 month re-entry
Figure 2
Osseous defect exposed on the distal of tooth #30 treated with Emdogain. The defect measured 6.40 mm.

At 12-month re-entry, the defect fill measured 5.40 mm, representing a percent defect fill of 85 %.

Presurgical radiograph of the defect prior to Emdogain treatment.

A 12-month postsurgical radiograph prior to reentry.

Case courtesy of Dr. Stuart J. Froum
Clinical Professor, Department of Periodontics
Director of Research, Department of Implant Dentistry
New York University Dental Center, USA
Long-term results

**Bone gain/loss 3 year post-treatment**
As illustrated in the graph below, Emdogain® has been shown to promote an increase of bone over time.

![Graph showing bone gain/loss over time](image)

**Outcome at 12 months post-surgery (mean in mm):**

- PPD reduction: 5.2 mm
- PAL gain: 4.7 mm
- Radiographic bone gain: 2.9 mm

- 99 of 145 sites gained ≥ 4 mm PAL
- Only 8 of 145 sites gained ≤ 2 mm PAL


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**Baseline**
Periodontal defect showing inflammation, attachment loss and epithelial downgrowth.

**Days**
After surgical application, Emdogain proteins aggregate and form an insoluble matrix on the root surface. A coagulum now fills the defect and research suggests mesenchymal cells will attach to the protein matrix.

**Weeks**
Experimental research has shown that bone formation starts along the Emdogain treated root surface and not as appositional growth of the residual bone of the defect.

**Months**
New attachment with cementum and ligament are formed along the treated root surface, as seen by histology from experimental animal models and in a human biopsy*. In vitro research also demonstrates restriction of epithelial cell growth in the presence of Emdogain.

**One year +**
Regain of clinical attachment and new alveolar bone has been shown to continue for more than one year after treatment with Emdogain.

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* Histology obtained from one tooth in a patient with periodontal disease who was treated with Emdogain revealed regeneration; however, the long-term stability of the regenerated tissue has not been established and results may vary.
**Intrabony defects**

Within the indications for one-wall, two-wall, and three-wall intrabony defects, Emdogain® provides access to difficult-to-reach areas such as:

- Distal to the second molar
- Under bridgework
- Esthetic zone

**Esthetic zone**

Baseline

18 months later

Result: Probing Pocket Depth Reduction of 7–8 mm.

Case courtesy of: Dr. Robert F. McGrail Fredericksburg, Virginia

**Distal to the second molar**

Baseline

18 months later

Result: Probing Pocket Depth Reduction of 5–6 mm.

Case courtesy of: Dr. Susan Alexander Marietta, Georgia

**Under bridgework**

Baseline

12 months later

5 years later

Result: Probing pocket depths were reduced 7 mm, and 3.5 to 5.4 mm of radiographic bone was gained in the first year and continued to be maintained at 5 year follow-up.

Case courtesy of: Dr. Robert Horowitz, Scarsdale, New York
Emdogain® treating furcation and recession defects

**Emdogain® in Class II mandibular furcation**
Emdogain is shown to be effective in the treatment of Class II mandibular furcations with interproximal bone height at, or above, the fornix of the furcation.
- Emdogain has been shown to improve the classification and reduce horizontal depth of the furcation.
- Clinicians have reported improved wound healing and patients have reported minimal pain and swelling.

**Emdogain® in recession**
Emdogain used in conjunction with a coronally advanced flap represents a simpler procedure for the clinician and a less invasive procedure for the patient compared to treatment utilizing connective tissue.
- There is no donor site required.
- Facilitates treatment of numerous defects.
- Obviates the need for secondary gingivoplasty.
- Results of a randomized, controlled, single-center, split mouth study¹ demonstrate a mean root coverage of 95.1 % for Emdogain treated sites.
- Study results also measured 100% root coverage 89.5 % of the time with coronally advanced flap utilizing Emdogain compared to 79 % of the time with subepithelial connective tissue graft.
- Emdogain used with a coronally advanced flap resulted in similar root coverage without the morbidity or potential clinical difficulties of donor site surgery.


**Furcation**

Baseline 12 months later

Result: Excellent osseous regeneration in the furcation region.

Case courtesy of:
Dr. Anthony Polimeni, Huntington, New York, USA

**Recession**
Lateral incisor treated with a subepithelial connective tissue graft and coronally advanced flap.

Baseline 12 months later

Contra-lateral, lateral incisor treated with Emdogain® in conjunction with a coronally advanced flap.

Baseline 12 months later

Case courtesy of: Dr. Michael K. McGuire, Houston, Texas
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