



Emdogain® and PrefGel™
Instructions for use

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For additional information on Emdogain®, please refer to:

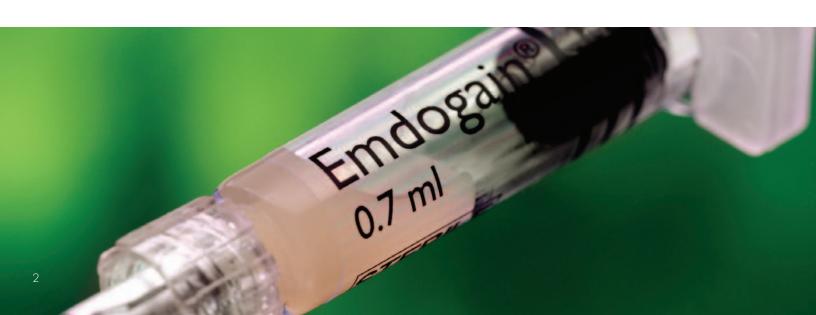
- Emdogain® the reliable solution for periodontal treatment (USLIT 199)
- Emdogain® referral booklet (USBIO 015)
- Emdogain® list of publications (152.287)
- Emdogain® treating recession defects flyer (USBIO 016)



This brochure presents step-by-step instructions for the use of Emdogain and PrefGel. Further information can be found in the package inserts enclosed in each product package.

Emdogain® is a resorbable, implantable material consisting of enamel matrix proteins that is intended as an adjunct to periodontal surgery for topical application onto exposed root surfaces. Once applied to the cleaned root surface, Emdogain forms an insoluable protein matrix that initiates the process of periodontal tissue regrowth.

PrefGel™ is a pH neutral, 24% EDTA root surface conditioner, which offers an effective, yet gentle removal of the "smear layer" during periodontal surgical procedures.



PrefGel™ – instructions for use

PrefGel is contained in a 1 ml sterilized, single-use pipette. It is available in a package of 10 pipettes or co-packaged with Emdogain® (3 units of Emdogain and 3 pipettes of PrefGel).

- 1. The pipette is opened by twisting the wing.
- 2. Press out the contents into a sterile dappen dish and apply the gel using a gauze, a small sterile instrument (e.g. a plastic instrument) or a sterile syringe with a blunt ended cannula. Alternatively withdraw the contents directly from the pipette into a syringe.
- 3. Remove remaining plaque and/or calculus as well as blood from root surfaces exposed during periodontal surgery.
- 4. Apply PrefGel onto exposed root surfaces and leave for 2 minutes. Active rubbing ("burnishing") is not recommended.
- 5. Rinse thoroughly with sterile saline.
- 6. Avoid recontamination of the conditioned root surfaces after the final rinse and prior to treatment with Emdogain.
- 7. After application, discard any residual gel.



Debridement of root surface



Application of PrefGel™



Rinsing with sterile saline before Emdogain® use

Application in intrabony defects

1. Anesthetize the area selected for surgery by block and/or infiltration anesthesia. Avoid injection of local anesthetic with a vasoconstrictor into the interdental papilla or marginal gingiva.



2. Make intra-crevicular incisions. Then, if judged appropriate, make one or two vertical releasing incisions extending out into the alveolar mucosa. Raise full-thickness (mucoperiosteal) flaps on the buccal and palatal/lingual surfaces of the teeth. Preserve as much of the gingival connective tissue in the flap as possible. Maintain viability of periondontal cells by hydration of the soft tissue with saline.



3. Only **remove the granulation tissue** adherent to the alveolar bone and any associated osseous defects necessary to provide full access and visibility to the root surfaces. Remove subgingival plaque and calculus.



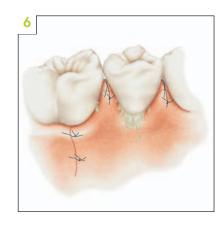
4. Remove the "smear layer" by conditioning the root surface with PrefGel[™] for two minutes. Rinse thoroughly with sterile saline solution. Avoid contaminating the cleaned and conditioned root surface with blood or saliva after the final rinse.



5. Apply Emdogain® immediately on the exposed root surface. Start at the most apical bone level and apply Emdogain so that it covers the whole root surface.



6. Complete coverage of the interproximal area and optimal soft tissue adaptation are essential. If deemed appropriate, a periosteal fenestration at the base of the flap may be used to facilitate coronal repositioning of the soft tissue. Suture materials appropriate for extended stable closure are preferred.



7. To maintain the stability of the healing wound, do not probe surgically treated areas for 6 months after Emdogain treatment.



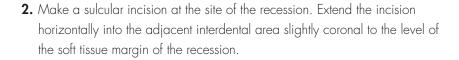


Application in recession defects

 Anesthetize the operative area. Scale and plane the exposed root surface to remove plaque, calculus, root surface irregularities and, if judged appropriate, to reduce prominence.

Extensive root planing is recommended when (i) root caries lesion has been diagnosed or (ii) when a reduced root prominence has been judged beneficial for tissue regeneration.

The presence of a restoration does not preclude the possibility for root coverage, but restoration should ideally be removed prior to covering the root with the soft tissue flap.



Make two vertical divergent releasing incisions at the mesial and distal line angle connected to the horizontal incision.

Raise a full-thickness (mucoperiosteal) flap until the mucogingival junction is passed.

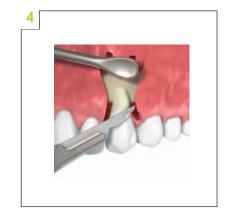
3. Make a cut through the periosteum and continue to **raise a split-thickness flap** by means of a blunt dissection. The aim is to eliminate any muscle tension on the flap margins and allow for a passive and tension-free coronal positioning of the flap at the level of the CEJ.

4. De-epithelialize the buccal aspect of the interdental papillae to create a connective tissue bed for suturing the coronally advanced flap.

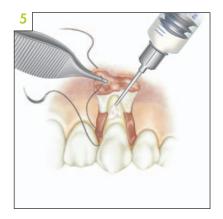








5. Remove the "smear layer" by conditioning the root surface with PrefGel[™] for two minutes. Rinse thoroughly with sterile saline solution. Avoid contaminating the cleaned and conditioned root surface. Try to minimize bleeding.

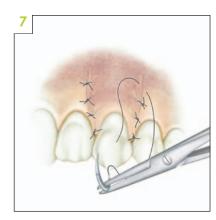


6. Apply Emdogain® immediately on the exposed and conditioned root surface.



7. Advance the flap coronally and secure it at the level of the cementum enamel junction (CEJ) by suturing the flap into the recipient bed, i.e. the deepithelialized papillae. Also close the vertical incisions with lateral sutures.

Use suture materials for extended and stable closure. No pressure should be applied to the flap after suturing.



Application in Class II mandibular furcations

1. Class II mandibular furcation defect with minimal interproximal bone loss.

Anesthetize the operative area.



2. Make intra-crevicular incisions, and if judged appropriate, make one or two vertical releasing incisions extending out into the alveolar mucosa. Raise full-thickness (mucoperiosteal) flaps on the buccal and palatal/lingual surfaces of the teeth. Preserve as much of the gingival connective tissue in the flap as possible. Maintain viability of periodontal cells by hydration of the soft tissue with sterile saline.



3. Reflect soft tissue to expose the periodontal defect.



4. Remove only the granulation tissue adherent to the alveolar bone and any associated osseous defects necessary to provide full access and visibility to the root surfaces. Remove subgingival plaque and calculus.



5. Remove the "smear layer" by conditioning the root surface with PrefGel[™] for two minutes. Rinse thoroughly with sterile saline solution. Avoid contaminating the cleaned and conditioned root surface with blood or saliva after the final rinse.



6. Apply Emdogain® immediately on the exposed root surface. Start at the most apical bone level and apply Emdogain so that it covers the whole root surface.



7. Complete coverage of the interproximal area and optimal soft tissue adaptation are essential. If deemed appropriate, a periosteal fenestration at the base of the flap may be used to facilitate coronal repositioning of the soft tissue. Suture materials appropriate for extended stable closure are preferred. Overflow of surplus material during flap closure and suturing should occur.







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