

Basic information on the surgical procedures with Straumann® Emdogain® to support oral wound healing



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1. Straumann® Emdogain® – features and benefits

Straumann® Emdogain® is a clinically well proven easy-to-apply gel containing Enamel Matrix Proteins (Amelogenins). These proteins form an extracellular matrix that stimulates various cell types that are crucial for the wound healing process and therefore are able to stimulate and accelerate the healing and regeneration of soft tissue wounds and oral tissues in general. Emdogain® stimulates various cell types and cellular processes that are crucial for the healing of oral tissues^{1,2,3}. Emdogain® further enhances the cell proliferation and stimulates cells to produce extracellular matrix and growth factors that are essential for wound healing like TGF-β or angiogenesis like VEGF^{4,5}.

Preclinical and clinical studies in several indications demonstrate that the use of Emdogain® in oral surgical procedures:

- Modulates the production of inflammatory factors related to wound healing^{6,7,8,9}
- Significantly improves post-surgical revascularization^{10,11}
- Significantly accelerates early wound closure and reepithelialization¹²
- Stimulates a faster post-surgical increase in soft tissue thickness^{13,14}
- Significantly improves keratinization^{16,15}

Clinical studies have shown that besides the improvement of wound healing patients who have been treated with Emdogain® have considerably less problems with pain and swelling^{17,18,19}.

Clinical studies have shown that Emdogain® is extremely well tolerated and associated with a very low risk of post-surgical complications^{21,22}.

Straumann® Emdogain® is available in 3 different sizes:

Art. No.	Article
075.127W	1 × 0.15 ml Straumann® Emdogain®
075.101W	1 × 0.3 ml Straumann® Emdogain®
075.102W	1 × 0.7 ml Straumann® Emdogain®
075.098W	5 × 0.15 ml Straumann® Emdogain®
075.128W	5 × 0.3 ml Straumann® Emdogain®
075.129W	5 × 0.7 ml Straumann® Emdogain®

2. Indications

Straumann® Emdogain® can be used to support early soft tissue wound healing in oral surgical procedures. Straumann® Emdogain® can be used as part of flap surgeries in general comprising dental implantation and peri-implant procedures or as part of soft tissue grafting and gingivectomy procedures.

The application of Emdogain® to support soft tissue wound healing perfectly integrates in the oral surgical procedure and does not require any adaptation of the procedure.

3. General considerations and recommendations

General considerations and recommendations that need to be considered for the use of Emdogain® to support soft tissue wound healing of oral surgical procedures:

- Straumann® Emdogain® is topically applied as a gel using the included sterile, single use application cannula.
- Straumann® Emdogain® is applied on the complete wound area and wound margins including exposed bone structures and all surrounding epithelial and connective tissues of the surgical wound right before final flap closure.
- Retention of Straumann® Emdogain® under the surgical flap can be optimized by pre-suturing the flap and applying the product under the pre-sutured flap. To prevent rinse out of the product from the wound site, control of hemostasis might be necessary before application of the product. Straumann® Emdogain® might ooze out of the wound margins upon final flap closure. Product that is oozing out can be removed if considered necessary.
- Straumann® Emdogain® can be used in combination with bone graft materials and or collagen substrates.
- Straumann® Emdogain® is available in three different product sizes. The appropriate product size that fits to the implantation procedure can be estimated best based on the wound size, the requirements for additional biomaterials (bone grafts and collagen substrates) and the number of implants that will be placed.

The following recommendations might be considered:

- Straumann® Emdogain® 0.15 ml for procedures with single implants.
- Straumann® Emdogain® 0.3 ml for procedures with single to multiple (2 to 3) implants, for peri-implant procedures, for soft tissue grafting procedures or when used in combination with graft materials or membranes.
- Straumann® Emdogain® 0.7 ml for large wound areas and implant procedures with several implants. Several units might be used in case of full arch procedures.

4. Flap surgery, implantation and peri-implant procedures

Depending on the local requirements of the restorative approach soft tissue management procedures can be categorized in subgingival and transgingival procedures. Transgingival procedures are furthermore subdivided into delayed or immediate procedures. Due to the ease of application Straumann® Emdogain® can be used with any of these procedures to stimulate the early soft tissue wound healing and to improve soft tissue management.

The use of Straumann® Emdogain® can be specifically recommended in complex cases, invasive procedures and esthetic procedures and particularly when combined with early and immediate protocols.

4.1 Use of Straumann® Emdogain® as part of implantation or peri-implant procedures involving submucosal healing

As part of implantation or peri-implant procedures (e.g. mucogingival or regenerative peri-implant procedures) Straumann® Emdogain® is generally applied in the last step of the surgical procedure, i.e. after implant placement or after mechanical peri-implant debridement, and immediately before final flap closure. Submucosal healing is recommended in esthetic indications and for implantation procedures with simultaneous guided bone regeneration (see below).



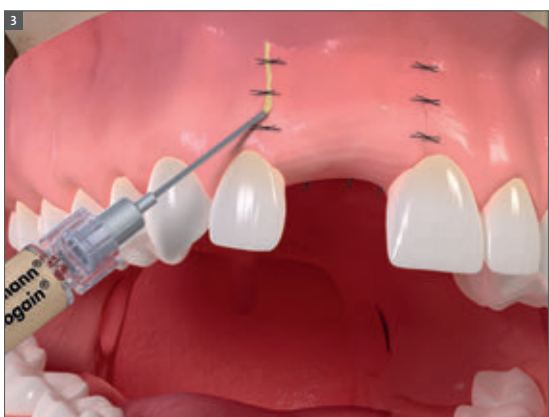
Step 1

For submucosal healing (healing under closed mucoperiosteal flap) the use of a closure cap is recommended. In order to allow maximum retention of Straumann® Emdogain® under the flap, control hemostasis and apply pre-sutures.



Step 2

Apply Straumann® Emdogain® by means of the application cannula on the complete wound area under the surgical flap, i.e. on exposed crestal bone structures and exposed epithelial and gingival tissue wound areas.



Step 3

Close the flap by primary intention. In the case of larger augmentations, special care should be given for sufficient flap preparation to ensure a tension-free flap closure. Delayed procedures require a second surgical procedure for final restoration. The use of Straumann® Emdogain® to support wound healing of oral surgical procedures can be recommended in each surgical procedure of an approach involving multiple surgeries.

4.2 Use of Straumann® Emdogain® as part of implantation or peri-implant procedures involving transgingival healing

For the use of Straumann® Emdogain® as part of procedures involving transgingival healing (delayed or immediate procedures) the same general recommendations related to handling apply, i.e. Straumann® Emdogain® is applied on the complete wound area directly under the surgical flap before final flap closure.



Step 1

To support transgingival healing and soft tissue contouring around the implant and abutment apply Straumann® Emdogain® around the collar of the abutment and implant neck by gently injecting additional Emdogain® in the space between the soft tissue and crestal bone right before final flap closure.



Step 2

Residual Emdogain® can be applied on the sutures and around the wound margins as well as around the implant collar after final flap closure.

4.3 Use of Straumann® Emdogain® in combination with bone grafting procedures

Straumann® Emdogain® can be used to support oral soft tissue wound healing as part of smaller and larger peri-implant restorative or regenerative procedures. To achieve optimum healing results Straumann® Emdogain® can be pre-mixed with bone graft materials (synthetics, xenografts, allografts or autogeneous bone) prior to the augmentation. Straumann® Emdogain® should additionally be applied on top of the bone graft material right before final flap closure to cover the bone graft material. In case of block augmentations (e.g. with maxgraft® bonebuilder or in general with allograft or autograft blocks) Straumann® Emdogain® can be applied on top of the block graft before final flap closure.



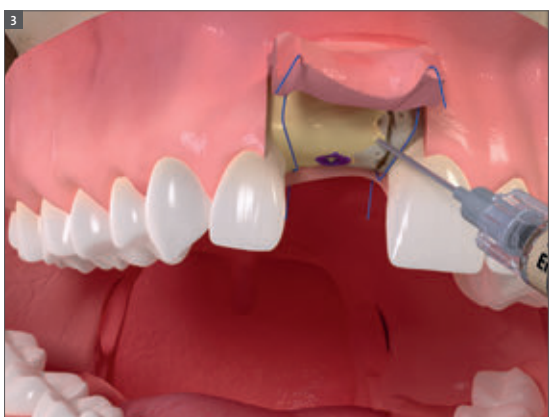
Step 1

Add Straumann® Emdogain® drop-wise to the bone substitute and mix the product with a spatula or other instruments suited for mixing until the mix gets a paste-like/wet coarse sand consistency that is suited for the application.



Step 2

Apply the mixture of Straumann® Emdogain® and bone graft material loosely into the osseous defect. Fill the defect as completely as possible.



Step 3

Apply a layer of Emdogain® on top of the bone graft substitute immediately before final wound closure. If extra mechanical stabilization of the graft is considered to be necessary, consider the use of a membrane (see Use of Straumann® Emdogain® in combination with membrane procedures).

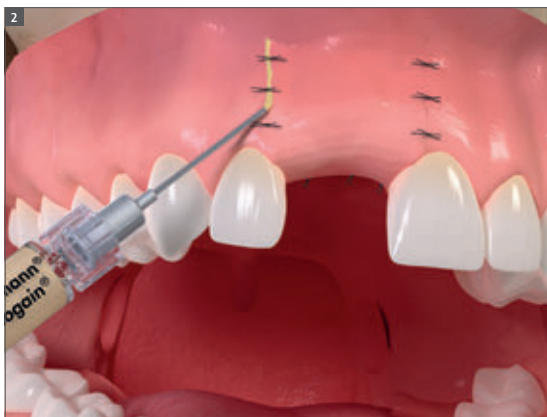
4.4 Use of Straumann® Emdogain® in combination with membrane procedures

Straumann® Emdogain® can be used to support oral soft tissue wound healing as part of augmentation procedures involving collagen membranes or other collagen substrates (e.g. fleeces or soft tissue grafts, e.g. mucoderm®). If considered appropriate, Straumann® Emdogain® can be used to pre-coat the membranes. Individual recommendations for pre-soaking given by the individual manufacturer should be considered before combination of the collagen substrates with Straumann® Emdogain®.



Step 1

After final placement of the membrane and immediately before final flap closure apply a layer of Straumann® Emdogain® evenly on top of the membrane. If considered appropriate, pinning of the membrane can be considered to improve mechanical stability of the membrane and underlying augmentate during the procedure.



Step 2

Ensure tension-free flap closure in order to prevent wound dehiscence and to ensure a successful augmentation procedure. Sufficient flap mobilization to allow tension-free flap closure should be assessed before the augmentation procedure and application of Straumann® Emdogain®.

4.5 Use of Straumann® Emdogain® in soft tissue grafting procedures and gingivectomy procedures

Emdogain® can be used to support oral soft tissue healing as part of soft tissue grafting and gingivectomy procedures. When used as part of soft tissue grafting procedures Straumann® Emdogain® can be used at the donor site and the acceptor sites.



Donor sites of subepithelial connective tissue

At harvesting/donor sites of subepithelial connective tissue grafts with surgical access by a split thickness flap apply Straumann® Emdogain® under the flap before final flap closure and suturing. Consider pre-suturing and control of hemostasis to optimize the application of Straumann® Emdogain®.



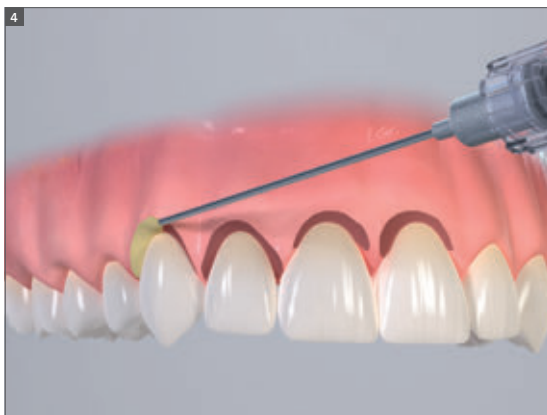
Donor sites of epithelialized free gingival grafts

At harvesting sites of epithelialized free gingival grafts apply Straumann® Emdogain® on the complete wound area. If considered necessary, the wound area can be additionally covered with a collagen fleece or connective soft tissue graft substitute (e.g. mucoder®). In this case it is recommended that Straumann® Emdogain® is applied between the wound area and the collagen graft before fixation of the graft substitute.



Acceptor sites of tissue grafts

In acceptor sites of free gingival grafts or subepithelial connective tissue grafts Straumann® Emdogain® is applied under the epithelialized free gingival graft before final closure of suture.



Gingivectomy procedures

In case of gingivectomy procedures, e.g. periodontal gingivectomy procedures that may not require suturing apply Straumann® Emdogain® on the complete wound area as the final step of the procedure. If considered necessary, treatment with Emdogain® can be repeated during the early healing phase after the procedure (e.g. up to seven days after surgery).

5. Post-surgical recommendations

The use of Straumann® Emdogain® does not necessitate any extra recommendations for post-surgical care other than those that are required by the procedure itself. General recommendations and considerations related to post-surgical care might include but are not limited to the following:

- Suture materials should be used for extended stable flap closure.
- No pressure should be applied to the flap after suturing.
- The patient should be advised not to brush in the operated area, but rinse daily with an antiseptic mouth rinse (e.g. 0.1-0.2% chlorhexidine solution) until 3 weeks post-surgery.
- Patients should also be instructed to avoid muscle traction or other trauma to the operated area for the same period.

Sutures are removed when clinical healing of the flap is stable and sutures no longer add to wound stability.

6. Important guidelines

Please note

Practitioners must have appropriate knowledge and instruction in the handling of the Straumann® CAD/CAM products or other Straumann® products (“Straumann Products”) for using the Straumann® Products safely and properly in accordance with the instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner’s responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company (“Straumann”), except if stated otherwise in this document or in the instructions for use for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann® in this document or in the respective instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann®.

Availability

Some of the Straumann Products listed in this document may not be available in all countries.

Caution

In addition to the caution notes in this document, our products must be secured against aspiration when used intraorally.

Please consider that bending of the application cannula after mounting the cannula to the syringe can cause breakage of the syringe.

Validity

Upon publication of this document, all previous versions are superseded.

Documentation

For detailed instructions on the Straumann Products contact you Straumann® representative.

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