English Instructions for use: Straumann® Emdogain® FL

Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.

1. Product Description

Straumann® Emdogain® is a resorbable, implantable material and supports periodontal regeneration, which takes place over more than a year. It consists of hydrophobic enamel matrix proteins extracted from developing embryonal enamel of porcine origin in a propylene glycol alginate carrier. The gel has a suitable viscosity to facilitate application directly onto root surfaces into pockets following scaling and root planing. Once applied onto an exposed root surface the protein self assembles into an insoluble three-dimensional matrix and creates a suitable environment for selective periodontal cell migration and attachment, which re-establishes lost tooth supporting tissues. Subsequent to formation of new attachment, alveolar bone can also be regenerated due to the osteogenic capacity of the restored periodontal ligament. Emdogain® is degraded by enzymatic processes of normal wound healing.

Straumann® Emdogain® is supplied in pre-filled, ready-to-use sterile syringes and available in two sizes (0.15 ml and 0.3 ml of the gel). The different filling sizes allow adapting the amount to the size and number of defects in one single patient as part of one treatment session. Each (pre-filled) syringe is meant for single use in one patient only.

The following procedure packs are offered for customer convenience:

- Straumann® Emdogain® FL: combination of one syringe of Straumann® Emdogain® (either 0.15 ml or 0.3 ml filling volume) together with 1 syringe of Straumann® PrefGel®.

2. Intended use

Straumann® Emdogain® FL is intended for topical and subgingival application in conjunction with scaling and root planning procedures to provide for regeneration of tooth / implant support lost due to periodontal / peri-implant disease.

Emdogain® may be used to support oral soft tissue wound healing processes.

3. Indications

- Emdogain® FL has been shown to be effective in residual pockets with probing depths from 5mm to 9mm with no furcation involvement in patients with adequate plaque control.
- Emdogain® has also been shown to enhance the early healing of periodontal soft tissue wounds resulting from the instrumentation of periodontal pockets.
- Adding Straumann® Emdogain® FL to the remedial therapy of peri-implant disease supports the non-surgical treatment of peri-implant mucosal inflammation.

4. Contraindications

Based on the results of the risk analysis the following patient population are contraindicated: patients with disorders or conditions including, but not limited to the following: uncontrolled diabetes or other uncontrolled systemic diseases, disorders or treatments that compromise wound healing, chronic high dose steroid therapy, bone metabolic diseases, radiation or other immuno-oppressive therapy and infections or vascular impairment at the surgical site.

5. Side effects, interactions and precautions; complications with Straumann products

In rare cases, clinical studies have reported the occurrence of general, procedure-related adverse events including but not limited to gingival bleeding, hematoma, infection, root (hyper)sensitivity, small wound dehiscence, mucosal irritation (soreness, pain, swelling), aphta-like lesions and gingival recession.

6. Warnings

Immunological studies suggest that a small number of patients may become sensitized to Emdogain® as a result of repeated use. Please use caution in patients predisposed to allergic reactions and follow patients receiving repeated use closely. Post-market experience has indicated that the sensitization adverse reaction rate is low. Required treatment has ranged from no intervention needed to analgesics and/or antihistamines. The safety and effectiveness of Emdogain® has not been established in patients undergoing anticoagulant therapy. Careful consideration should be given before using Emdogain® for these patients. Gain of tooth support occurs only to the level of the root surface covered by the repositioned oral soft tissue. Therefore, Emdogain® should be used in areas where there is adequate tissue for root coverage. Emdogain® should be used only after plaque and calculus have been removed from the diseased site.

7. Caution/Precautions

- Do not use if sterile package is opened or damaged. To prevent possible cross contamination discard or return damaged package and the enclosed device.
- Syringe and application device are single use items. Do not re-sterilize or reuse syringe or application device. Each (pre-filled) syringe is intended for use in one patient only. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury or serious illness of the patient.
- The product should be stored at 2–8 °C upon arrival.
- Site-specific anatomy, flapless and surgical management, wound stabilization during healing, and post treatment oral hygiene are critical factors for success.
- Be aware that bending the cannula when it is attached to the syringe may cause breakage of the syringe.

8. Note

Separation of Straumann® Emdogain® may occur. Separation of Straumann® Emdogain® is identified as a non-homogeneous gel. Homogenization of the separated material can be achieved by shaking down the gel from the top to the bottom of the syringe, turn around the syringe and repeat the procedure ten to fifteen times until homogenization returns.

9. Procedure

1. Take out Emdogain® / PrefGel® from cold storage approx. 30 minutes before use and allow it to assume ambient temperature.
2. Depending on the production lot, Emdogain® and PrefGel® might either be supplied in a syringe with tamper-evident closure system or with a screw cap closure system. The tamper-evident closure system can be opened by holding the syringe upright on the ribbed part of the white closure system. Gently tilt back and forth the cap to break the seals and remove by pulling upright. Avoid rotation. In case of screw cap closure system: open the syringe by unscrewing the tip cap counter clock wise and gently remove the closure cap by pulling it.
3. Carefully attach the supplied application cannula.
4. Use the Emdogain® and PrefGel® within 2 hours after opening and discard any remaining product
5. Anaesthetize the area selected for periodontal treatment by block and/or infiltration anesthesia using an anesthetic containing a vasoconstrictor such as adrenaline. Anesthesia should be placed apical to the pocket and pointing away from the pocket. Avoid injection with a vasoconstrictor into the interdental papilla or marginal gingiva.

6. Perform mechanical debridement to remove subgingival plaque and calculus from the root surface. It is very important that the root surface is as clean as possible for Emdogain® to work properly.
7. Thoroughly rinse the area with sterile saline to remove any blood and or saliva.
8. Remove remaining smear layer by cleansing the root surface with Straumann® PrefGel® (EDTA) for 2 min. Rinse thoroughly with sterile saline. Avoid contamination of the treated area with saliva or blood after the final rinse.
9. Dry the root surface as much as possible: If excessive bleeding from periodontal pockets is noted, hemostatic measures, like the application of pressure with a sterile gauze onto the gingival margin followed by continued rinsing may be used to stop it before the application of Emdogain®.
10. Immediately apply Emdogain® into the cleaned pocket onto the root surface, starting at the most apical part of the periodontal defect. Apply Emdogain® to fully cover the root surface until an overflow of material from the pocket occurs. Control of excessive bleeding of the periodontal pockets to be treated with Emdogain® is recommended in order to prevent that Emdogain® is rinsed out from the pocket after application.
11. Optimal soft tissue adaptation is essential. Gently compress the gingival margin using sterile gauzes until pocket marginal closure is attained.
12. The patients should be advised to rinse daily with an antiseptic mouth rinse (e.g. 0.1–0.2 % chlorhexidine solution) until 1 – 2 weeks after the treatment. Antibiotics may also be used if deemed appropriate based on the clinician's judgement.
13. The patient should be instructed not to brush in the treated area for 1-2 weeks following the treatment. Then only gentle brushing on buccal and lingual surfaces using the "roll-stroke" method is recommended. No sulcular or interproximal tooth cleaning must be performed until 2-3 weeks following the treatment.

In conjunction with peri-implant mucosal inflammation (peri-mucositis) non-surgical treatment

1. Instruct patients to use an effective dental care program at home, prior the treatment.
2. If more than one implant in a patient is involved, provide the same protocol for all implants.
3. Carry out mechanical subgingival debridement.
4. Perform specific actions to remove the subgingival biofilm (e.g. Apply PrefGel® in the pockets for 2 minutes, then use saline solution to rinse it thoroughly).
5. Apply Emdogain® FL subgingivally in affected sites, using a flapless approach.
6. Recommend to your patients to avoid brushing and flossing for 7 days after treatment. After 1 week, brushing is resumed. The use of chlorhexidine 0.12% is recommended 2 times per day.

Patients should be reinstructed in proper oral hygiene measures as needed.

Healing of clinical attachment and alveolar bone has been shown to continue for more than a year, and care should be taken not to interfere with this process. Probing, scaling and root planing and insertion in the treated area of any instrumentation should be avoided for the first 6 months following the treatment.

10. Healing phase

Please refer to the specific procedure part at section 9.

11. Further Information

Please refer to Straumann website for additional information.
Clinicians should contact Institut Straumann AG directly or any affiliate, local subsidiary or any 3rd party distributor through which the product may have been supplied in case of unwanted or unexpected effects that may be observed during or after use of the product.

12. Please note

Practitioners must have knowledge of Periodontology and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these 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 Product is 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 for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann, any such use will void any warranty or other obligation, express or implied, of Straumann.

13. Validity

Upon publication of these instructions for use, all previous versions are superseded.

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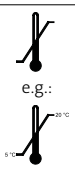
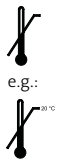
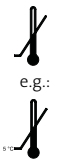
14. Availability

Some items of the Straumann® regenerative portfolio are not available in all countries.

Symbols

The following table describes the symbols that may be printed on the packaging label.
Please refer to the packaging label for the applicable symbols related to the product.

Symbol	Symbol Description	Symbol Source
	Consult instructions for use *Follow the link to the eIFU: ifu.straumann.com*	ISO 15223-1
	Manufacturer	ISO 15223-1
	Date of manufacture	ISO 15223-1
CE	CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC legislation. *Where applicable: The identification number of the Notified Body shall follow this symbol.*	MDR (EU) 2017/745
EC REP	Authorized representative in the European Community	ISO 15223-1
EC IMP	Indicates the entity importing the medical device into the European Union	Institut Straumann AG
REF	Catalogue number	ISO 15223-1
LOT	Batch code	ISO 15223-1
SN	Serial number	ISO 15223-1
MD	Medical device	Institut Straumann AG
	Do not re-use	ISO 15223-1
	Do not use more than 10 times	Institut Straumann AG
	Do not use more than 20 times	Institut Straumann AG
	Non-sterile	ISO 15223-1
	Sterilized using irradiation	ISO 15223-1

Symbol	Symbol Description	Symbol Source
	Sterilized using ethylene oxide	ISO 15223-1
	Sterilized using aseptic processing techniques	ISO 15223-1
	Single sterile barrier system	ISO 7000
	Single sterile barrier system with protective packaging inside	ISO 7000
	Double sterile barrier system	ISO 7000
	Do not resterilize	ISO 15223-1
	Do not use if package is damaged	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
Rx only	U.S. federal law restricts this device to sale by or on the order of a dental professional.	21 CFR 801.109(b) (1)
Qty.:	Quantity	Institut Straumann AG
Pat.:	Patent Marking *Follow the link to the patent information: pat.straumann.com*	Institut Straumann AG
	Use-by date	ISO 15223-1
e.g.: 	Temperature limit (e.g.: min 5 °C / max. 20 °C)	ISO 15223-1
e.g.: 	Upper limit of temperature (e.g.: max. 20 °C)	ISO 15223-1
e.g.: 	Lower limit of temperature (e.g.: min. 5 °C)	ISO 15223-1
	Keep dry	ISO 15223-1
	Caution	ISO 15223-1
	Contains hazardous substances	ISO 7000
	Contains biological material of animal origin	ISO 7000
custom-made device	Custom-made device	MDR (EU) 2017/745