

# Straumann® Emdogain® and Straumann® Emdogain® FL

## Patient Information Leaflet

### Why is this information necessary?

Health care providers are obliged to inform their patients of the implant device being considered to treat their medical condition.

### What is Straumann® Emdogain®/Emdogain® FL?

Straumann® Emdogain®/Emdogain® FL is a sterile protein gel manufactured from porcine (from pigs) developing teeth. The device is a resorbable implant that is naturally broken down by the body's own metabolic processes and therefore does not need to be removed.

### What is it used for?

Straumann® Emdogain®/Emdogain® FL is used to help the gums grow back, support bone growth and promote healing after surgical procedures performed in the mouth.

### When is the use of Straumann® Emdogain®/Emdogain® FL recommended?

Straumann® Emdogain®/Emdogain® FL is recommended when there is loss of bone around teeth or when gums are retracting due to gum disease. It is also recommended after surgery to improve the gum healing.

### What does Straumann® Emdogain®/Emdogain® FL do?

Straumann® Emdogain®/Emdogain® FL guides the growth of gum tissue and bone in the defect area and improves gum healing.

### What are the possible side effects?

The gel in Straumann® Emdogain®/Emdogain® FL has been safely used in dental procedures for over 25 years. The use of the product has a very low complication rate and the possible side effects are generally the same as those applicable to for any dental procedure.

Possible complications that can occur with any dental procedure include infection, swelling of the intraoral tissue, sensitivity to hot and/or cold, recession of gum tissue, excessive bleeding of the gums, flap sloughing, pain, or complications associated with anaesthesia. Minor discomfort may occur for a few days.

### What must I generally be aware of after the treatment?

Seek medical advice on post-treatment hygiene based on the clinical situation, and discuss your individual protocol with your dentist.

### When Straumann® Emdogain® is used surgically:

- Rinse daily with the mouth rinse recommended by your dentist until 3–6 weeks after the surgery.
- Antibiotics may also be used at the dentist's discretion.
- Do not brush in the area where surgery has been performed until 3 weeks after the surgery. Then, only gentle brushing is recommended. No interdental cleaning (dental floss, interdental brushes, toothpicks) is allowed until 6 weeks post-surgery.

### When Straumann® Emdogain®FL is used without surgery:

- Rinse daily with the mouth rinse recommended by your dentist until 1-2 weeks after the treatment.
- Antibiotics may also be used if deemed appropriate by the dentist.
- Do not brush in the treated area for 1-2 weeks following the treatment. Then, only gentle brushing is recommended. No interdental cleaning (dental floss, interdental brushes, toothpicks) is allowed until 2-3 weeks following the treatment.

### Other recommendations:

- Heavy smoking and poor oral hygiene can have harmful effects on the outcome of the therapy.
- Inform your health care provider without delay if any allergies and/or adverse effects occur.

### What precautions should I consider?

As with all surgical procedures, caution should be exercised if you have any medical conditions that preclude surgery. Inform your health care provider if any of the following conditions apply to you.

- You are receiving long-term steroid therapy or are currently taking anticoagulants.
- You have a clinically significant systemic illness, a history of anaphylactic reactions, an autoimmune disease, uncontrolled diabetes or a disease that compromises healing.



### Further information

<b>Model:</b>	075.127W, 075.101W, 075.102W, 075.114W, 075.116W, 075.098W, 075.130, 075.131 Please refer to your patient Implant Card for the model number of your implant.
<b>Manufacturer:</b>	Institut Straumann AG Peter Merian-Weg 12 CH-4002 Basel/Switzerland www.straumann.com
<b>Local Representative:</b>	Straumann Pty Ltd/Straumann New Zealand Limited 93 Cook Street, Port Melbourne VIC 3207, Australia AU Toll Free: 1800 660 330 NZ Toll Free: 0800 408 370 customerservice.au@straumann.com www.straumann.com.au www.straumann.co.nz

Any serious incident that occurs in relation to the device should be reported directly to the local representative or the manufacturer at the email address listed above, as well as the Therapeutic Goods Administration at [www.tga.gov.au](http://www.tga.gov.au).

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