Straumann® BoneCeramic™

Patient Information Leaflet

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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® BoneCeramic™?

Straumann® BoneCeramic™ is a sterile synthetic dental bone graft to replace missing bone. The product is manufactured in particulate form from fully synthetic materials. It is composed of biphasic calcium phosphate, which is a mixture of 60% hydroxyapatite (HA) and 40% the beta form of tricalcium phosphate (beta-TCP). Whether the bone loss is the result of tooth loss, gum disease, trauma or simply deterioration over time, a bone graft can help reverse the effects of dental bone loss and provide a strong foundation for a dental implant.

What is it used for?

Straumann® BoneCeramic™ is used to replace missing bone. It helps provide a strong foundation for a dental implant while supporting and promoting natural bone growth over time.

When is the use of Straumann® BoneCeramic™ recommended?

Straumann® BoneCeramic™ is recommended when there is loss of bone or insufficient bone. During the surgery, your dentist will fill the defect with BoneCeramic™ as completely as possible.

What does Straumann® BoneCeramic™ do?

Straumann® BoneCeramic™ is an aid to bone regeneration. It allows vital bone growth while preserving the bone volume in the defect area.

What are the possible side effects?

Straumann® BoneCeramic™ has been safely used in dental surgery for over 15 years. The use of the product has a very low complication rate. Possible complications that can occur after any dental surgery include infection, swelling of the intraoral tissue, sensitivity to hot and/or cold, excessive bleeding of the gums, lack of bone integration, pain, or complications associated with anaesthesia. Minor discomfort may occur for a few days.

What must I generally be aware of after surgery?

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

- For the first two weeks, when brushing your teeth avoid the area that was operated on and use an antimicrobial mouthwash. After this, you may gently brush the area with a soft toothbrush. Dental floss, interdental brushes and toothpicks should not be used for the first 4 weeks.
- Avoid smoking for 2 to 3 days after surgery. This allows for better healing.
- Heavy smoking and poor oral hygiene can have harmful effects on the outcome of the therapy.
- Antibiotics may also be used if deemed appropriate by the dentist.
- A healing time of at least 6 months is recommended for Straumann® BoneCeramic™. The healing period allows bone to form and mature in defect areas where BoneCeramic™ is used.
- Depending on the patient and individual conditions, the appropriate healing time may be different, and must be determined by the dentist based on the patient's individual situation.
- The wound should be completely closed, and the soft tissue coverage should be free of tension. Inform your dentist if the wound is exposed.
- Inform your dentist 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 dentist 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.
- You have an infection in the mouth. The dentist should be confident that any active or recent infection has been properly treated prior to the use of Straumann® BoneCeramic™.

Further information

Contents:	The implantable device is made of biphasic calcium phosphate (100% synthetic).
Model:	070.198, 070.199, 070.200, 070.203, 070.204, 070.205 Please refer to your patient Implant Card for the model number of your implant.
Manufacturer:	Institut Straumann AG Peter Merian-Weg 12 CH-4002 Basel/Switzerland www.straumann.com
Local Representative:	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.

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