Patient Info

OsteoFlo-G Synthetic Bone Substitute

Signature Orthopaedics

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This brochure offers a brief overview of OsteoFlo-G, synthetic bone substitute distributed by Signature Orthopedics. This information is for educational purposes only and is not intended to replace the expert guidance of your physician.

When do you need synthetic bone substitute ?

You currently suffer from a bone defect that requires a surgical treatment. Bony voids can be surgically created or result from a traumatic injury. The aim of bone grafting surgery is to restore the bone volume, in its shape, width and height.

To that goal, the surgeon will use a bone substitute which is a synthetic product used to fill the defect and to facilitate the bone healing /reconstruction. The Synthetic Bone Substitute is intended for use to reconstruct bony voids or bone gaps of the skeletal system (e.g. extremities, spine and pelvis).

The Synthetic Bone Substitute can be used in adults excluding pregnant women and has not been tested in pediatric population.

The Synthetic Bone Substitute is intended for use by physician familiar with bone void filling and rigid fixation techniques.
The Synthetic Bone Substitute is to be handled or implanted by trained qualified physicians having read this instruction for use.
The implantation of the device on the patient must be evaluated and confirmed by the physician before surgery, considering the potential contraindications provided from the manufacturer.

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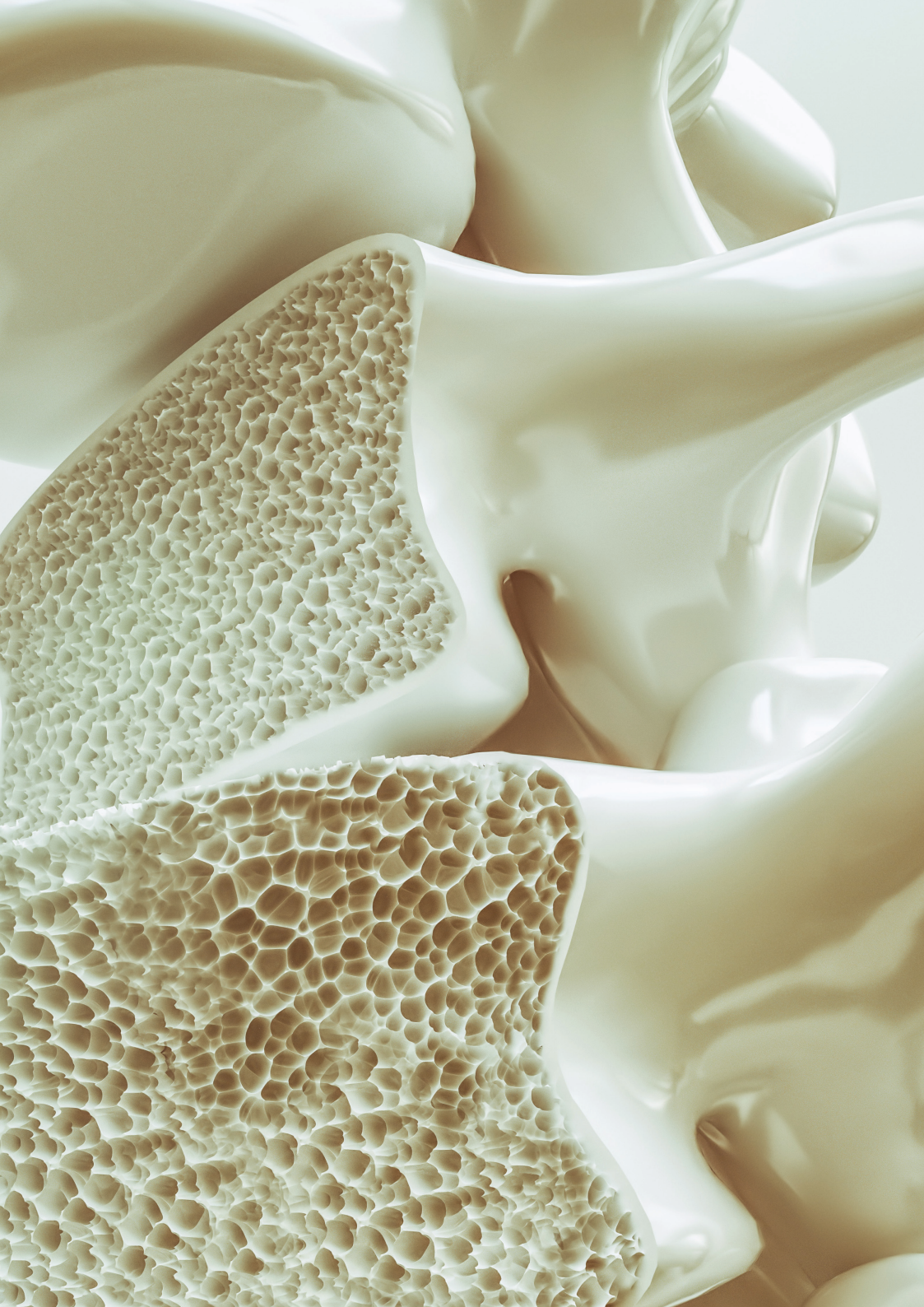
The Synthetic Bone Substitute is indicated for bony voids surgically created or osseous defects created from traumatic injury to the bone. The performances of the Synthetic Bone Substitute are the filling of bone defects and the bony ingrowth from local osseous tissue onto the surface of the product.

What Is A Synthetic Bone Substitute ?

OsteoFlo-G is a bone void filler. This product is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (ß-TCP) particles.

It is a resorbable product which means that it gradually degrades over time and is replaced by new bone.
The total resorption of the product depends on numerous factors such as its size and volume, the location of the defect, the surgical technique and the health status of the patient.
It is admitted that an optimal bone regeneration is always observed before the complete resorption of the product.

The performances of the device can be affected if the surgery is not performed following standard techniques or if post-operative recommendations given by the physician are not respected.



Adverse events and risks

OsteoFlo-G Synthetic Bone Substitute

During each follow-up visit, the surgeon will check the evolution of the bone healing /reconstruction in the surgical site. If you experience any adverse effect between two visits or after the follow-up timeline, do not hesitate to contact your surgeon or any other health professional in relation to the surgery you underwent.

It is important that patients know about the following possible risks and complications, which include but are not limited to:

- Post-operative discomfort
- Haematoma
- Irritation
- Risk of allergy
- Infection
- Foreign body reaction
- Pain
- Fever
- Inflammatory reaction
- Osmotic shock
- Adverse effects on blood coagulation and blood components
- Thrombosis
- Necrosis
- Non-union/pseudoarthrosis due to displacement product or fibrous encapsulation

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Manufacturer's contact details
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materiovigilance@biomatlante.com
Competent Authority's (TGA) contact details
https://www.tga.gov.au/reporting-adverse-events

Any serious incident occurring in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration.

OsteoFlo-G
Synthetic Bone Substitute

Adequate post-operative immobilization is necessary to prevent movement that may lead to soft tissue ingrowth. This device does not harden after implantation until healing. The patient must follow the recommendations given by the physician.

References	Designations
151-012-110	Granules 1-2 mm (10 cc)
151-012-130	Granules 1-2 mm (30 cc)
151-012-202	Granules 2-3 mm (2 cc)
151-012-205	Granules 2-3 mm (5 cc)
151-012-210	Granules 2-3 mm (10 cc)
151-012-215	Granules 2-3 mm (15 cc)
151-012-230	Granules 2-3 mm (30 cc)
151-012-512	Sticks 5x5x10 mm (x2)
151-012-514	Sticks 5x5x10 mm (x4)
151-012-522	Sticks 5x5x20 mm (x2)
151-012-524	Sticks 5x5x20 mm (x4)

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This leaflet is intended for use in Australia.
For the latest version of this leaflet, please refer to
www.signatureortho.com.au/patientinfo

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