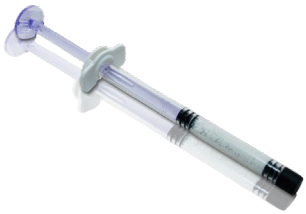
NEOBONE™ Gel

INJECTABLE BONE SUBSTITUTE

PATIENT INFORMATION LEAFLET



MANUFACTURER'S CONTACT DETAILS
Biomatlante SA ZA Les Quatre Nations 5, rue Edouard Belin 44360 Vigneux de Bretagne - FRANCE ☎ +33(0)2 28 02 00 09 🖷 +33(0)2 28 02 00 10 contact@biomatlante.com

⚠ CONTACT FOR THE REPORT OF SERIOUS INCIDENTS ⚠
Manufacturer's contact details materiovigilance@biomatlante.com **Competent Authority's contact details** https://www.tga.gov.au/

PRINCIPLE OF SPINE SURGERY: ARTHRODESIS

An arthrodesis is a surgical intervention using to treat osteoarthritis, i.e. wear and tear on the discs and/or joints of the vertebrae of the spine which is responsible for pain.

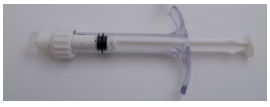
The operation consists in avoiding the movement of these damaged vertebrae allowing the treatment of the pain caused by the motion or instability of the spine.

Spinal fusion is a surgery designed to decrease back pain by stopping the motion at a vertebral segment. The procedure involves placing a bone graft to an area of the spine to set up the natural process that causes the bone graft to grow between the two vertebral segments.

This fusion is usually achieved around 1 year.

Follow-up visits are usually performed by the surgeon at 3, 6 and 12 months to evaluate the evolution of bone fusion.

MODEL OF BONE SUBSTITUTE USED FOR THE SURGERY

	REFERENCES	DESIGNATIONS	ILLUSTRATION
☐	**INJ-BS-0.5**	Injectable Bone Substitute 0,5mL	
☐	**INJ-BS-1**	Injectable Bone Substitute 1mL	
☐	**INJ-BS-2.5**	Injectable Bone Substitute 2,5mL	
☐	**INJ-BS-5**	Injectable Bone Substitute 5mL	
☐	**INJ-BS-10**	Injectable Bone Substitute 10mL	

INFORMATION ON THE INJECTABLE BONE SUBSTITUTE

WHAT IS THE INJECTABLE BONE SUBSTITUTE?

The Injectable Bone Substitute 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) associated with hydrogel (excipient vehicle of pharmaceutical grade quality (hydroxypropylmethylcellulose in an aqueous solution)).

It is a resorbable product which means that it gradually degrades over time and is replaced by new architectured bone. The total resorption of the product depends on numerous factors such as its volume, the location of the surgery, and the health status of the patient. It is admitted that an optimal bone fusion 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 note respected.

WHAT IS THE ROLE OF THE DEVICE FOR SPINE SURGERY?

The Injectable Bone Substitute is used to reconstruct bony voids or bone gaps of the skeletal system (e.g. extremities, spine, pelvis).

In spinal fusion, the performances of the Injectable Bone Substitute are the bony ingrowth from local osseous tissue onto the surface of the product (osteoconduction process) between the vertebral segments.

FOR WHOM KIND OF PATIENT THE DEVICE IS INTENDED TO BE USED?

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

SPECIAL OPERATING INSTRUCTIONS FOR THE USE OF THE DEVICE

The Injectable Bone Substitute is intended for use by physician familiar with bone void filling and rigid fixation techniques. The Injectable Bone Substitute is to be used 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 contra-indications provided from the manufacturer.

Adequate post-operative immobilization is necessary to prevent movement that may lead to soft tissue ingrowth.

Until healing is complete this device may not withstand weight bearing. Post-surgery discharge is necessary.

The patient must follow the recommendations given by the physician.

WHAT ARE THE UNDESIRABLE SIDE-EFFECTS?

- Post-operative discomfort
- Haematoma
- Irritation
- Risk of allergy
- Infection
- Foreign body reaction
- Pain
- Fever
- Inflammatory reaction
- Adverse effects on blood coagulation and blood components
- Thrombosis
- Necrosis
- Leakage or flow out of the cavity implantation
- Non-union/pseudoarthrosis due to displacement product or fibrous encapsulation
- Organs degradation

During each follow-up visit, the surgeon will check the evolution of the spinal fusion.

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.

⚠ **Any serious incident occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration (please find the contact details on the first page of this patient information leaflet.**