OSSEOPLUS®

Technical Product Name: Bone Graft

INSTRUCTIONS FOR USE
Revision 01

PRODUCT DESCRIPTION
In order to meet the needs of the market, JHS Biomaterials has developed a product with chemical characteristics similar to those existing in living organisms.

The bone is composed of rigid inorganic matrices, strengthened by calcium salt deposits. The middle bone contains, by weight, about 30% matrix and 70% salts. The bone graft synthesized by JHS Biomaterials aims to provide calcium phosphate salts to strengthen the inorganic matrix. This synthetic bone graft commercially called OsseoPlus® was developed with the following characteristics: to be biocompatible and biofunctional. Osteo-conduction promoted by OsseoPlus® occurs due to the product's ability to be phagocyted by osteoclasts acting as a bone matrix assisting in osteogenesis, thus it is possible to verify the presence of osteoclasts and osteoblasts (bone cells), making the product a support for cell invasion. As a result, OsseoPlus® is biodegradable due to the action of osteoclasts on the product, thus leading to bone formation.

OsseoPlus® is indicated for medical and dental use with the objective of assisting bone neoformation, stimulating the action of fibroblasts, osteoclasts and osteoblasts.

The graft after implantation provides regeneration and restoration of the injured area, which is absorbed by the body. The absorption time varies from patient to patient depending also on the skeletal system to which it was grafted.

COMPOSITION
OsseoPlus® consists of:
- ≥60% Hydroxyapatite
- ≤40% Calcium phosphates

INDICATIONS:
It is indicated for filling and restoring bone losses, as well as for the maintenance of anatomical structures (bone part), maxillofacial reconstruction; filling of bone cavities in regions resulting from injuries, segmental losses, sinking, dehiscence, pseudoarthrosis, bone infectious processes, osteomyelitis, osteolysis, cysts and tumors; filling of the alveolar crest due to atrophies; filling of the maxillary sinus; base of the maxillary sinus; periodontal intraosseous injuries; periapical injuries; substitute for uninfected surgical bone defect; defects after surgical removal and corrective osteotomies; reconstructive surgery on injured bone areas; arthrodesis (vertebral arthrodesis with the help of Cage); aesthetic repairs to the bone.

Thus it has applications and indications, for bone formation, in the areas of orthopedics and traumatology, neurosurgery, surgery and traumatology, maxillofacial, bone reconstructive plastic surgery, craniofacial surgery, dental surgery, ophthalmology, otolaryngology.

WAY OF USE:
Exclusive use by qualified professionals (doctors and dentists) and with knowledge of surgical and grafting techniques;
- The patient must undergo preoperative evaluation so that the best set of materials and surgical techniques are determined for the use of the product;
- OsseoPlus® must be used in an aseptic environment;
- It is supplied in a sterile state and must be opened in an aseptic environment (surgical, ambulatory, dental office or medical clinic) at the time of application.;
- After necessary surgical techniques, prepare the recipient bed so that the product is applied in contact with the healthy and bleeding bone. Necrotic areas with infection must be treated before grafting the material;
- Use only support materials and sterile surgical instruments.
- Direct application of OsseoPlus® to the site to be grafted is recommended;
- The surgeon must adopt the classic prophylactic treatment described in the literature for immediate and late pre- and postoperative periods.
- It is recommended to use a maximum of 30.0 grams of product per procedure. In case there is a need to use a quantity greater than the recommended maximum, the trader should analyze the risk, being responsible for the adoption of the additional quantity to be used.

PRECAUTIONS:
Check the information regarding the validity of the product, as well as the integrity of the packaging;
- The product is for single use, marketed sterile ready for use, packaged so that it can be used only once, without the need to be processed for use;
- Do not use the product if it has expired;
- If the product (packaging) has been dropped, damaged, tampered with, has been poorly stored and / or handled, it must not be used and must be returned to the manufacturer or disposed of properly. However, the final judgment as to the adequacy of the graft is always the surgeon who uses it;
- The use of OsseoPlus® is restricted to qualified professionals, with knowledge of the surgical techniques and procedures indicated; since improper application may result in relative failure and / or migration of the product.
- Preoperative evaluation, the correct indication of materials and the use of compatible surgical techniques and procedures, as well as postoperative monitoring and controls, are essential for the desirable results.
- As it is a sterile product, the packaging (surgical-grade paper) should only be opened at the time of use. Its use requires appropriate asepsis techniques;
- The region that will receive the product must be exposed and curetted, where the infected and / or necrotic tissues must have been removed;
- Use only support materials and sterile surgical instruments.

STERILE PRODUCT, SINGLE USE (②), DO NOT REUSE, DO NOT RESTERILIZE, DO NOT REPROCESS, DO NOT USE IF THE VALIDITY IS EXPIRED OR THE PACKAGE IS VIOLATED.

RESTRICTIONS:
The product can only be used by professionals trained in the field of surgery (dentists and doctors).

Graft load restrictions
This product is not designed to withstand load. Repetitive efforts, stress, support / loading activities can result in fractures or damage to the implanted area. THIS PRODUCT CANNOT BE SCREWED AND / OR USED AS AN IMPLANT SUPPORT BASE.

- **Bone Support**

The product must be grafted into a healthy and bleeding bone region, the quality of the bone region must be estimated at the time of surgery. The bone region is decisive for the success of the product. The evaluation of bone support must be made by the surgeon, for each patient.

- **Combination with implants**

The product can be used with metallic implants. The need to use and combine these products is at the surgeon's discretion.

- **Use**

The product can only be used if it is within the expiration date, has been stored as intended and with its full packaging.
It is recommended to use a maximum of 30.0 grams of product per procedure. If there is a need to use a quantity greater than the stipulated one, it must be determined previously, being the responsibility of the professional to adopt the additional quantity to be used.

WARNINGS:
Only qualified medical and dental professionals with full knowledge of the necessary surgical and asepsis techniques can use the product;
The surgical techniques adopted as well as the material used are the responsibility of the surgeon;
Unused product (surplus) in the surgical procedure must be disposed of, disposed of as hospital waste.
- OsseoPlus® is a product manufactured in such a way as to facilitate the handling of the sameosurgical procedure, but it is IMPORTANT to point out that it is friable, liable to deformation, but its physical-chemical characteristics, as well as its biocompatibility and biofunctionality ARE NOT CHANGED, when any change in the its format;
- OsseoPlus® in one piece (tablet, disc, wedge, parallelepiped, cube, stopper and cylinder), cannot be screwed and / or used as an implant support base, since they are friable and their shapes are unique aim to facilitate its handling.

The patient's ability and willingness to follow medical recommendations is of paramount importance for the success of the graft. Patients affected by senility, mental illness, alcoholism, and drug abuse may be at high risk of failure of the procedure, as they are more likely to ignore the recommendations and restrictions.

OsseoPlus® has a blue-green tint, if the same is different, do not use the product and contact the manufacturer;

To patients: Physical activities are restricted during the recovery period, and should be evaluated by the surgeon, according to the type of surgery, extent of the lesion and place of application. The patient must abstain from smoking, alcoholic beverages and drugs of abuse, for a period of at least 4 weeks, with the surgeon being able to change this period.

STERILE PRODUCT, SINGLE USE (②), DO NOT REUSE, DO NOT RESTERILIZE, DO NOT REPROCESS, DO NOT USE IF THE VALIDITY IS EXPIRED OR THE PACKAGE IS VIOLATED.

CONTRAINDICATIONS :
- The product should not be used in case of infection (acute or chronic) and / or inflammation, especially at the surgery site.
- Do not use OsseoPlus® in the presence of infected and / or necrotic tissue that has not been removed.
- No tests were performed on pregnant women, nursing mothers, so use in this group is not recommended.
- Patient with immature skeletal development (bone immaturity).
- Applications to support efforts.
- Surrounding bone is not viable or unable to support or support graft.
- Metabolic and / or inflammatory disease that can prevent bone formation.
- Immunological and / or systemic disorders that hinder wound healing or calcium metabolism.
- Severe neurological or vascular diseases.
- Uncooperative patients who are unwilling or unable to follow postoperative instructions, including individuals who use drugs or alcohol.
- Smoking patients.
- Patients who use drugs and / or alcohol.
- In immunosuppressed patients, with diabetes mellitus, in corticosteroid therapy or affected by diseases that lead to bone demineralization, they may not present predictable results, due to the patient's own systemic involvement.
- The product is aimed at bone formation, studies on aesthetic surgeries (subcutaneous filling, among others) have not been carried out, so the product is not indicated and should not be used for procedures other than bone formation.
- All cases not included in the indications.

ADVERSE EFFECTS
In the safety studies, no adverse effects were found. Common complications in implant surgery (grafting) can occur as:
- Infection;
- Sepsis;
- Swelling;
- Osteomyelitis;
- Pain in the first days after grafting at the site;
- Anesthetic-related complications.

In the event of adverse effects related to the product, it is necessary to contact the manufacturer JHS Biomaterials at +55 (31) 3484-9355. It is possible to proceed, also with the notification of these in the competent sanitary organ, ANVISA.

STORAGE CONDITIONS, TRANSPORT AND MANIPULATION:
- Must be transported and stored away from direct sunlight, sources of heat and moisture;
- The product should preferably be kept at a temperature of 15-30°C and a relative humidity of 35-75% (± 5% RH);
- It must be stored in order to maintain the physical integrity of the packaging, without damaging it;
- No heavy or sharp objects should be placed on the product to avoid damaging its packaging and endangering the physical integrity and sterility of the product;
- As it is a sterile product, the packaging should only be opened at the time of use. Its use requires appropriate asepsis techniques;
- When expired or the packaging is violated, the product must be discarded and its packaging must be uncharacterized.
- Ensure that the storage environment is free of dust and weather that may affect the conservation of the stored product.

DISPOSAL CONDITIONS:

OsseoPlus® according to RDC 306 of 2004 generates group D waste and, as it is used in a surgical environment, it must be disposed of in hospital waste.

STERILIZATION AND VALIDITY:

OsseoPlus® can be sterilized by Ethylene Oxide or Gamma Radiation. The sterilization method to which the product was subjected must be checked on its labels.

The shelf life of the product is two (2) years after sterilization. This information is contained on the cartridge, product label and control labels.

The cartridge is not sterile, the sterile items are those stored inside the surgical grade paper.

TRACEABILITY

Within the packages, 5 (five) labels are provided, according to the applicable legislation through resolution nº 1804 of 11/09/2006 of the Federal Council of Medicine, and these must be filed:

- In the patient's clinical record;
- In the report delivered to the patient;
- In the tax documentation that generates the charge at the AIH, in the case of a patient attended by SUS, or in the sales invoice, in the case of a patient attended by the complementary health system;

PRESENTATIONS:

OsseoPlus® is presented in the following forms:

Presentation	Granulometry			Weight	Reference Code	Demonstration
	Mesh	µm	mm			
Granules	≤10	≈2000	≈2,00	0,5g	P05G10	
				1,0g	P10G10	
				2,0g	P20G10	
				3,0g	P30G10	
				4,0g	P40G10	
				5,0g	P50G10	
				6,0g	P60G10	
				7,0g	P70G10	
				8,0g	P80G10	
				9,0g	P90G10	
				10,0g	P100G10	
				0,5cc	P05C10	
				1,0cc	P10C10	
				2,0cc	P20C10	
				3,0cc	P30C10	
				4,0cc	P40C10	
				5,0cc	P50C10	
				6,0cc	P60C10	
				7,0cc	P70C10	
				8,0cc	P80C10	
				9,0cc	P90C10	
				10,0cc	P100C10	
				15,0cc	P150C10	
				20,0cc	P200C10	
	≤20	≈841	≈0,841	0,5g	P05G20	
				1,0g	P10G20	
				2,0g	P20G20	
				3,0g	P30G20	
				4,0g	P40G20	
				5,0g	P50G20	
				6,0g	P60G20	
				7,0g	P70G20	
				8,0g	P80G20	
				9,0g	P90G20	
				10,0g	P100G20	
				0,5cc	P05C20	
				1,0cc	P10C20	
				2,0cc	P20C20	
				3,0cc	P30C20	
				4,0cc	P40C20	
				5,0cc	P50C20	
				6,0cc	P60C20	
				7,0cc	P70C20	
				8,0cc	P80C20	
				9,0cc	P90C20	
				10,0cc	P100C20	
				15,0cc	P150C20	
				20,0cc	P200C20	
	≤30	≈595	≈0,595	0,5g	P05G30	
				1,0g	P10G30	
				2,0g	P20G30	
				3,0g	P30G30	
				4,0g	P40G30	
				5,0g	P50G30	
				6,0g	P60G30	
				7,0g	P70G30	
				8,0g	P80G30	
				9,0g	P90G30	
				10,0g	P100G30	
				0,5cc	P05C30	
				1,0cc	P10C30	
				2,0cc	P20C30	
				3,0cc	P30C30	
				4,0cc	P40C30	
				5,0cc	P50C30	
				6,0cc	P60C30	
				7,0cc	P70C30	
				8,0cc	P80C30	
				9,0cc	P90C30	
				10,0cc	P100C30	
				15,0cc	P150C30	
				20,0cc	P200C30	

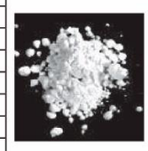
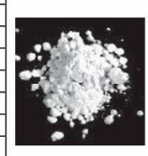
- With the company that supplied it - distributor (historical distribution record - RHD);
- With the surgeon in charge.

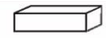
The labels contain the following information:

- Commercial name;
- Identification of the manufacturer / company logo;Código do produto;
- Lot number;
- Registration number with ANVISA;
- Product presentation.

Once the packaging has been opened, it is necessary to attach the labels to their respective locations. The surgeon must inform the patient about the existence of the labels and the information contained therein, instructing him to keep them.

NOTE: Dentists, when using the material, should proceed as described above. Product traceability depends on the labels mentioned above.

Presentation	Granulometry			Weight	Reference Code	Demonstration
	Mesh	µm	mm			
Dura	≤10 a 30	≈2000 a ≈595	≈2,00 a ≈0,595	0,5g	P05GD	
				1,0g	P10GD	
				2,0g	P20GD	
				3,0g	P30GD	
				4,0g	P40GD	
				5,0g	P50GD	
				6,0g	P60GD	
				7,0g	P70GD	
				8,0g	P80GD	
				9,0g	P90GD	
				10,0g	P100GD	
				0,5cc	P05CD	
				1,0cc	P10CD	
				2,0cc	P20CD	
				3,0cc	P30CD	
				4,0cc	P40CD	
				5,0cc	P50CD	
				6,0cc	P60CD	
				7,0cc	P70CD	
				8,0cc	P80CD	
				9,0cc	P90CD	
				10,0cc	P100CD	
				15,0cc	P150CD	
				20,0cc	P200CD	
Duríssima	≤10 a 30	≈2000 a ≈595	≈2,00 a ≈0,595	0,5g	P05GDR	
				1,0g	P10GDR	
				2,0g	P20GDR	
				3,0g	P30GDR	
				4,0g	P40GDR	
				5,0g	P50GDR	
				6,0g	P60GDR	
				7,0g	P70GDR	
				8,0g	P80GDR	
				9,0g	P90GDR	
				10,0g	P100GDR	
				0,5cc	P05CDR	
				1,0cc	P10CDR	
				2,0cc	P20CDR	
				3,0cc	P30CDR	
				4,0cc	P40CDR	
				5,0cc	P50CDR	
				6,0cc	P60CDR	
				7,0cc	P70CDR	
				8,0cc	P80CDR	
				9,0cc	P90CDR	
				10,0cc	P100CDR	
				15,0cc	P150CDR	
				20,0cc	P200CDR	

Presentation	Format (size)	Unit/ Weigt	Reference Code	Demonstration
Tablet	≥ 2mm	0,5g	P05GCO	
		1,0g	P10GCO	
		2,0g	P20GCO	
		5,0g	P50GCO	
		10,0g	P100GCO	
Disco	≈14 x 14mm	01 unit.	PDG	
	≈12 x 14mm	01 unit.	PDM	
	≈11 x 14 mm	01 unit.	PDP	
Wedge	≈03 x7,5 x 15 x 20 mm	01 unit.	PCP	
	≈08 x 10 x 15 x 25 mm	01 unit.	PCM	
	≈03 x15,5 x15 x 35 mm	01 unit.	PCG	
Parallelepiped	≈10 x 20 x 10 mm	01 unit.	PPT	
	≈25 x 20 x 05 mm	01 unit.	PPP	
Cube	≈10 x 10 x 10 mm	01 unit.	PCB	
Boton	≈22 x 10 mm	01 unit.	PRH	
Cylinder	≈10 x 10 mm	01 unit.	PCL	

OSSEOPLUS®

Technical Product Name: Bone Graft
ANVISA Registration nº: 80149980012
AFE/ANVISA: 8.01.499-8 (9904LHMY57H9)
TECHNICAL MANAGER:
DÁMIANA MÁXIMO BRANDÃO - CRF/MG: 26.315

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