SCREW FOR GRAFT AND FIXATION

VALID FOR ALL COUNTRIES EXCEPT BRAZIL

PROFESSIONAL USE ONLY

Legal Manucfaturer:
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Technical Product Name: Non-Bioabsorbable Craniofacial Bone Screw, Sterile (9000085)
Trade Name: SCREW FOR GRAFT AND FIXATION
Sterilization Method: Gamma Radiation


Keep out of the sun


Keep dry


Do not use if the packaging is damaged


See instructions for use

Temperature Limit

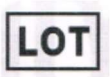

Do not reuse

Do not resterilize

Product sterilized by gamma radiation


Expiration date


Manufacturing date



Lot

Reference / code

Screw for Graft and Fixation

Screw for Graft and Fixation Family

Screw for Graft and Fixation x,*x mm Xyy,y mm*

1. DETAILED DESCRIPTION OF THE MEDICAL PRODUCT, INCLUDING THE FUNDAMENTALS OF ITS OPERATION AND ITS ACTION, ITS CONTENTS OR COMPOSITION, IF APPLICABLE, AS WELL AS LIST OF ACCESSORIES INTENDED TO INTEGRATE THE PRODUCT.

Screw for Graft and Fixation is a dental device used in bone graft surgery for fixation of bone graft block and membranes (these products do not accompany the product, are sold separately and have separate registration). **The screw is not indicated for fixation of plates for osteosynthesis, since may occur screw fracture and the lack of adaptation due to its incompatibility.**

The screws is intended to maintain the bone block graft and/or the membrane in position, providing greater stability and being easily removed. The screws are temporary and single use, their removal is concomitantly to the bone blocks and / or membrane use. Therefore, they must remain for 6 to 8 months according to the indication of use and evaluation of the professional.

The screw consist of a viable alternative clinically and scientifically proven over time for the treatment of injuries caused to bone tissue due to tumor resections and dental-maxillo-facial deformities.

In addition to providing stability to the bone block, the screw also causes greater contact between the bone block and the host surface through compression between the both.

It presents a model with different lengths and diameters that allows the choice and use appropriate and specific to each surgical procedure. It has a format developed to promote stability even in cancellous bone and maintain the membrane or bone graft in position. It is a threaded with milled, cylindrical body, conical tip self-tapping with milled, head with spherical surface and has fit to key in cross format.

The raw materials machined allow undergoing the sterilization process to gamma radiation, which is essential for use in clinical intervention procedure.

2. COMPOSITION

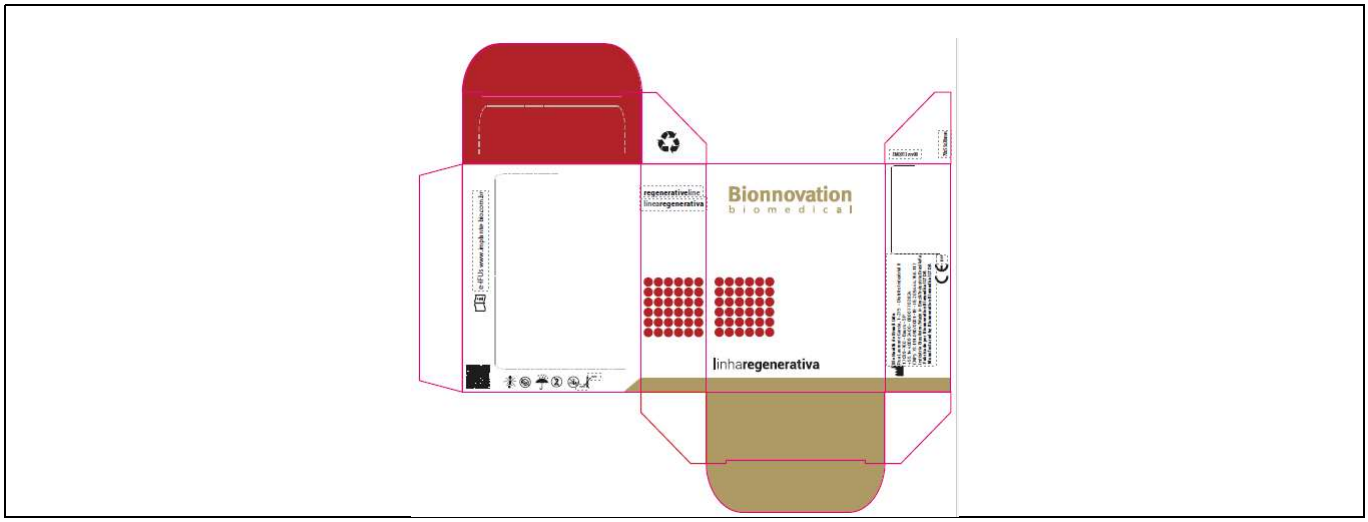
The screw is made with Titanium 6Al 4V according to EN ISO 5832-3 and ASTM F136, favoring its biocompatibility and corrosion resistance in biological environment.

3. FORMS OF PRESENTATION IN MARKET OF THE MEDICAL PRODUCT

Content: 01 Screw for Graft and Fixation x,x mm X yy,y mm, is package in blister sealed with Tyveck® as primary packaging and has an adhesive label of identification attached with information for its traceability.The Final package is composed by a Box of high grammage paperboard and two adhesive labels attached to the cover (01) and front part (01) of the box.

See annex IIIA: Screw for Graft and Fixation Models:reference code, description, diameter (*x, x mm*) and length*(yy,y mm)*.

<table>
<tr><td colspan="2">Product: Screw for Graft and Fixation</td></tr>
<tr><td colspan="2">   </td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Blister sealed with Tyveck®</td><td>Traceability labels</td></tr>
<tr><td colspan="2">Final Packing
Cardboard box</td></tr>
<tr><td colspan="2">BIO HEALTH</td></tr>
</table>



List of *Screw for Graft and Fixation*

Screw length (yy.y mm)			Diameter of Screws (x.x mm)						
	1,2	1,3	1,4	1,5	1,6	1,7	1,8	1,9	2,0
2	x	x	x	x	x	x	x	x	x
3	x	x	x	x	x	x	x	x	x
4	x	x	x	x	x	x	x	x	x
5	x	x	x	x	x	x	x	x	x
6	x	x	x	x	x	x	x	x	x
7	x	x	x	x	x	x	x	x	x
8	x	x	x	x	x	x	x	x	x
9	x	x	x	x	x	x	x	x	x
10	x	x	x	x	x	x	x	x	x
11	x	x	x	x	x	x	x	x	x
12	x	x	x	x	x	x	x	x	x
13	x	x	x	x	x	x	x	x	x
14	x	x	x	x	x	x	x	x	x
15	x	x	x	x	x	x	x	x	x

4. INDICATION, PURPOSE OR USE INTENDED FOR THE PRODUCT

The Screws for Graft and Fixation are dental devices for fixation and immobilization of bone block graft and membranes (not included with the product, sold separately) with bone reconstruction function. The screws are of single use and temporary, remaining only in the period of bone repair, for 6 to 8 months, since its purpose is to keep the bone graft or membrane in position and not of osseointegration.

The screws are used in surgeries for immobilization of bone graft, because if movements of the bone block occur during the graft repair period will result in the formation of fibrous connective tissue between the bone block and the host surface, or in the reabsorption at various levels of the graft.

It is the surgeon's responsibility to select the best options available (model, diameter and length of Screws for Graft and Fixation), according to the conditions of the affected bone portion, type of fracture and the surgical technique.

5. INSTRUCTIONS FOR USE

For the use of Screw for Graft and Fixation we recommend the following steps

1. **Screw selection:** For the selection of the screws, the professional should use measurements obtained through the imaging tests and evaluation of the size of the graft.
2. **Adapting the screw-in insertion wrench:** After accessing the screw, the surgeon must adapt the wrench by fitting it to the screw head, making a slight snap-in pressure.
3. **Graft fixation:** The screws are self-tapping, clockwise. Depending on the mechanical strength of the graft material, it can be used for the direct fixation of the graft. If the grafts are of higher density, they must be prepared with a drilling using a drill with a slightly smaller diameter of the screw.
4. **Removal of the key:** To remove the key simply perform pendulum movements associated with traction.

6. PRECAUTIONS, RESTRICTIONS, WARNINGS, SPECIAL CARE, CLARIFICATIONS ON THE USE OF MEDICAL PRODUCT, STORAGE, TRANSPORT AND PRODUCT DISPOSAL.

1. STERILE - since it kept the integrity of the packaging, shelf life and storage conditions;
2. The Screw for Graft and Fixation should be used only for the purpose intended for;
3. The Screw for Graft and Fixation is supplied in a sterile package (Gamma Radiation). Since the integrity of the packaging is not compromised in any way, it will retain the sterile product 5 years from the date of sterilization;

4. In cases of adverse effects occurring in the patient, the professional responsible should contact immediately the SAC (Customer Service) through **0800 770 3824** or email sac@implante-bio.com.br. The Products and all others involved (**dentists, patients and doctors**) are responsible for notifying the ANVISA (National Health Surveillance Agency - Brazil) on the relevant events as internal procedure for technical surveillance www.anvisa.gov.br/notivisa;

5. Should any adverse effects occur with the patient on the use of our products in the European Community, countries should contact our authorized representative Bionnovation Europe SL by phone +34 931407240 and / or contact the factory and by email sac@implante-bio.com.br.. Recalling that professionals are responsible for reporting adverse events to local authorities within the European Union, health monitoring contact points are listed on the European Commission website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm.

6. The Screw for Graft and Fixation was developed in order to prevent that its use compromises the clinical condition of patients as well their safety;

7. The sequence of drills for initial perforation of the bone graft indicated for each diameter of the graft screw is described in the table below:

Drill Sequence of Screw for Graft and Fixation				
Ø Screw for Graft and Fixation (mm)	**Helical Drill**			
	1.0mm	**1.2mm**	**1.4mm**	**1.6mm**
1.2mm	x			
1.4mm	x	x		
1.6mm		x	x	
1.8mm			x	x

NOTE 1: Drills should be replaced regularly to maintain cutting efficiency. They do not accompany the product, sold separately and have separate registration

Note 2: We recommend that the 03 (three) identification adhesive labels that accompany the product be attached to the documentation to be delivered to the patient: clinical records, Report delivered to the patient and tax invoice of sale of the product. To ensure complete traceability of the product by code and batch identification, contained in the labels, and which

allows the immediate localization of all production and product documentation kept on hold for relevant assessments and analyzes when necessary.

6.1. WARNINGS AND RESTRICTIONS:

1. PROFESSIONAL USE ONLY - The screws should be implanted only by qualified professionals and professionals with knowledge on bone grafting techniques. The use of incorrect techniques for placement of the screws may lead to its failure and substantial loss of the adjacent bone;
2. PROHIBITED TO RE-STERILISE AND REPROCESS – If re-sterilized or reprocessed may change the physicochemical properties causing foreign body reaction. The re-sterilization mainly in autoclave alters the quality of the product and also can change in the quality of the titanium alloy;
3. PROHIBITED TO REUSE – Even without damage, the screw undergoes loads when implanted, making it brittle. If reused, deformation may occur in the fitting of the installation wrench, changing the thread profile and reducing the screw fixation quality;
4. The use of the product with surgical techniques and inadequate biosafety conditions may harm the patient leading to unsatisfactory results;
5. Always sterilize surgical instruments before using them;
6. The clinical and radiographic evaluation must be done prior to the installation surgery, to assist in the correct planning of the treatment, as well determine bone quality and quantity, repairs, anatomical structures and in analysis of adjacent teeth;
7. In all operations involving the Screw for Graft and Fixation must be observed appropriate aseptic and antiseptic techniques;
8. The abuse of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of treatment;
9. It is supplied in a sterile condition and once opened should be used in aseptic conditions. It should always work with sterile fields, appropriate instruments to the procedure and in good condition in order to eliminate sources of infection and damage caused to the product by improper instrumentation;

10. If complications arise impossible to be controlled, as tissue inflammation or evidence of infection is recommended an immediate removal of the material;

11. There are no restrictions on the maximum amount of product that can be implanted. The amount will be determined by the professional after analyzing the size of the surgical bed;

12. The professional should raise suspicions and evidence of sensitivity and allergy to the metal of screw material during anamnesis and medical history. If there are any, the same should request sensitivity tests prior to implantation of the screw;

13. The surgeon should evaluate the indication in patients who are carriers of diseases or who use medications that may alter the repair metabolism;

14. If the product shows cracks or creases of great intensity, which may cause problems to operation in the product, it must be discarded and a new one must be acquired;

15. Its removal is indicated concomitantly to the membranes. For bone graft procedures, it should remain only during the period of bone regeneration, that is, from 06 to 08 months, depending on the indication. If the Screw for Graft and Fixation stays longer than indicated, its exposure may occur and causing pain and local swelling.

6.2. ADVERSE EFFECTS

All potential adverse effects should be informed in advance to the patient. The following complications associated with surgery:

1. Dehiscence, inflammation, discomfort, painful sensation, hypoesthesia, hemorrhage, localized edema and / or abnormal sensation due to the presence of the device;
2. Breakage of the fixation device due to a non-union or delayed union of the bone tissue;
3. Curvature or fracture of fixation screws;
4. Surface / deep infection;
5. Possible treatment failure due to: inadequate osteotomy, infections, systemic diseases or problems, low bone quality or quantity remaining, lack or failure of irrigation, poor oral hygiene and lack of specific training, bone loss, tissue staining allergic reaction of the product material triggering risk of anaphylaxis.

6.3. CONTRAINDICATIONS

1. The Screw for Graft and Fixation use is not indicated in the presence of inflammatory or infectious processes of intra - oral tissues;

2. It should not be used in patients who are not able under clinical point of view, to be subjected to a dental intervention. As for example, in patients with um compensated diabetes;

3. The use of Screw for Graft and Fixation is not intended for procedures where the patient does not have complete bone formation.

4. It should not be used as a means of fixing prostheses or any objects other than membranes, titanium meshes or bone blocks.

5. The use of Screw for Graft and Fixation is not indicated in the presence of an infectious or inflammatory process, allergy, inadequate bone volume or quality, serious medical problems, such as: disorders of bone metabolism, coagulation disorders, inadequate healing, hygiene inadequate oral, drug or alcohol abuse, prolonged functional disorders that resist any drug treatment, immunological disorders, use of steriods, pregnancy and degenerative diseases.

6.4. SPECIAL CONDITIONS OF STORAGE AND TRANSPORTATION, CONSERVATION AND / OR PRODUCT HANDLING

6.4.1. Storage and Transportation

Transport and store the product away from direct sunlight, and from heat. (Maximum temperature: 15 -25° C and humidity). Keep the package sealed until the moment of use. Make sure of the integrity of it before use. Do not use if sterile package be opened or damaged or validity date expired to avoid possible contamination. Disposal the product mischaracterized according legislation for medical waste or return the damaged package and the included device to the Factory.

6.4.2 Conservation and manipulation

Any change on the surface or format of Screw, the product should be disposed according to legislation for medical waste or return the damaged package and the included device to the Factory.

7. PRE– and POST-OPERATIVE CARE

In the preoperative evaluation, the correct indication of the materials and the use of techniques and compatible procedures, as well as monitoring and postoperative controls are essential to the desirable results.

Preoperative Care: All patients who will be undergo the surgical procedure should be carefully examined and evaluated in order to determine the clinical and radiographic condition, as well as bone deficit or adjacent soft tissue that may influence the outcome of the intervention.

Post-perative Care: Observe postoperative care for surgical procedures. Painkillers, antibiotics and rest for 24-48 hours may be prescribe, varying according to the procedure and the professional technical conduct.

8. PRODUCT DISPOSAL CARE

"All products and materials used in the surgery to implants/ biomaterials installation can endanger the health of those who handle them. Therefore, after surgery all materials used should be disposed of in contaminated waste and follow the procedures of storage and dispose in accordance with current legislation.

The BIO HEALTH recommends obey the environmental and current biosafety laws - Dispose of all contaminated waste material (identified as contaminated waste - white bag, resistant to rupture and leakage, impermeable according to NBR 9.191/2000 of ABNT) and follow the procedures of external storage and collection according to Conama Resolution No. 237/97."

LEGAL GUARANTEE TERMO

(According to the Protection and Defense of Consumer Code: Law 8.078 of September 11, 1990).

In compliance with Article 26 of Law 8.078, of September 11, 1990, the ***Bio Health do Brasil*** company establishes the right of the consumer to complain about apparent defects or about easy verification of all products manufactured and marketed by it for a period of 90 days from the effective date of delivery of the products.

In the case of hidden defects, the decadential period starts when the defect is evidenced, as provided in Paragraph 3 of Article 26 of Law 8.078.

In order for this Legal Guarantee Term to take effect, the consumer must observe the conditions described below:

Do not allow unauthorized persons to handle the materials in question.

Do not allow the improper use as well as misuse of the materials in question.

Follow all the guidelines for use, as well as the care described in the User Manual or Instructions for Use.

We declare true the information presented in this Model of Instructions for Use.

BIO Health do Brasil LTDA
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