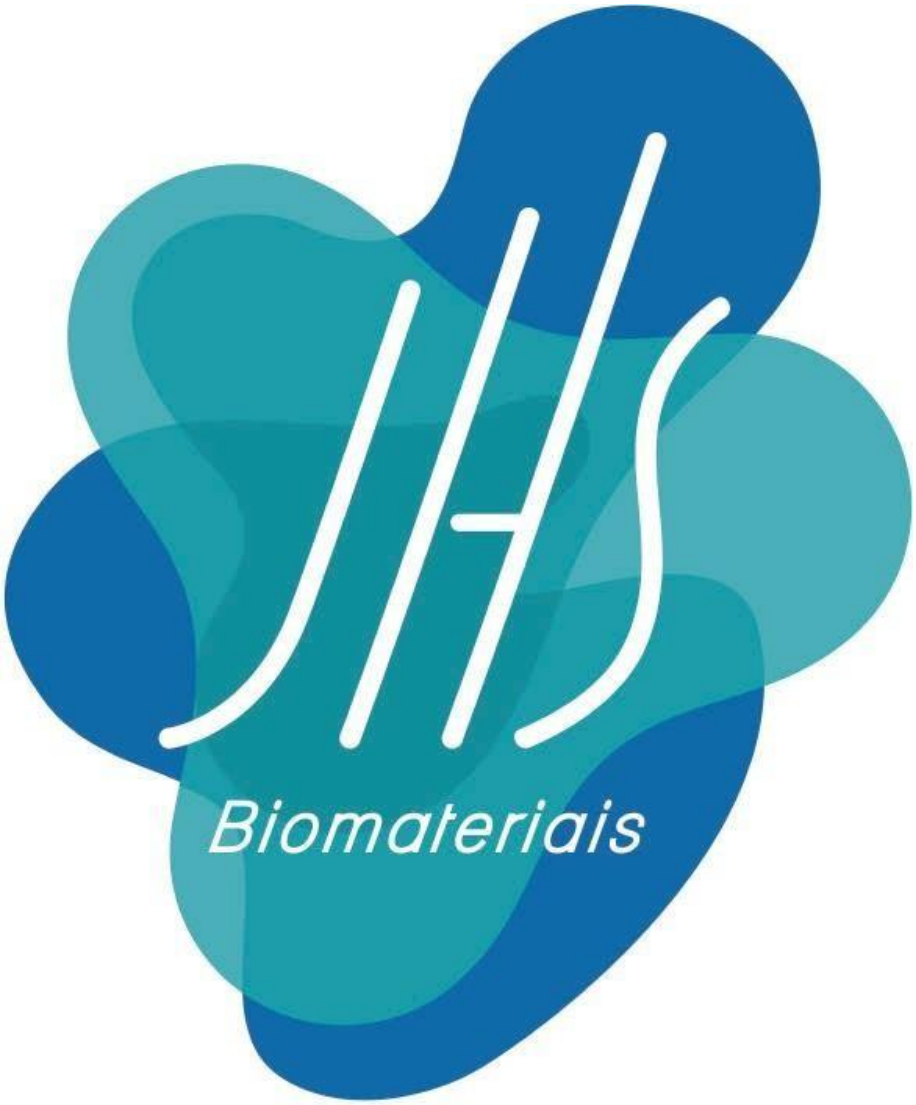

INSTRUCCIONS FOR USE

HAP-91

HAP-91®

Product Commercial Name: HAP-91 Absorbable Porous Hydroxyapatite
Technical Product Name: Bone Graft

INSTRUCTIONS FOR USE

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PRODUCT DESCRIPTION:

HAP-91 - Absorbable Porous Hydroxyapatite, hereinafter called HAP-91, is a biomaterial, synthesized from the chemical reaction of Calcium Hydroxide Ca (OH) 2 with Phosphoric Acid (H3PO4).

Hydroxyapatite has a similarity to bone tissue, since the inorganic phase of it is mostly constituted by hydroxyapatite [Ca10 (PO4) 6 (OH) 2]. Because it is biocompatible and has characteristics of osteoinduction (chemotaxis) and osteoconduction

(haptotaxy), being widely used as a bone substitute, the same being grafted in the region where bone formation is necessary.

When the HAP-91 is placed close to the bone and works as a support for bone tissue regeneration. HAP-91 allows regeneration tissue to grow within its physical structure by the presence of pores, preventing encapsulation by fibrous connective tissue and increasing the speed of tissue growth. In addition, it provides the nutritional support of the tissue within its pores, producing a continuity with the surrounding bone.

COMPOSITION:

The HAP-91 is made up of:

- ≥95% Hydroxyapatite
- ≤ 05% Calcium phosphates

RECOMMENDATION:

HAP-91 is indicated in medical and dental surgeries for recovery, partial replacement, filling and reconstruction of bone tissue, due to bone loss and deformities, extraction. Thus, it has applications and indications in the areas of dental, orthopedic and traumatological surgery, neurosurgery, buccomaxillofacial trauma surgery, craniofacial surgery, reconstructive plastic surgery and otorhinolaryngology surgery.

STERILIZATION:

HAP-91 is supplied in a sterile state in order to prevent potential contamination. It is sterilized by: Ethylene Oxide (STERILE EO)

Sterilization is only guaranteed if the packaging remains intact.

INSTRUCTIONS FOR USE:

• The product should only be used (grafted) by medical and dental professionals with knowledge in surgical and grafting techniques;

• 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;

• The region that will receive the product must be exposed and curetted, where the infected and / or necrotic tissues must have been removed;

• Direct application of HAP-91 to the site to be grafted is recommended, if it is delivered to plasma enriched with platelets (PRP), patient's blood and / or autogenous bone trim, the product obtained from this combination must be a very consistent mass , to facilitate its handling.

• Due to its physical-chemical properties and characteristics, hydroxyapatite can be used as a carrier for antibiotics, proteins, chemotherapy and others, releasing them systematically in the body.A HAP-91 não deve ser fixada com parafuso ou ser utilizada como base de sustentação.

• The HAP-91 must not be fixed with a screw or used as a support base.

PRECAUTIONS AND WARNINGS:

To ensure proper use, safety and efficacy of the HAP-91 product, care must be taken:

- Only qualified medical and dental professionals with full knowledge of the necessary surgical and asepsis techniques can use the product;
- HAP-91 is supplied in sterile conditions;
- The information provided on the product label, including product name, commercial presentation, batch number, expiration date and manufacturer's name, must be part of the patient's medical record or other equivalent document;
- Three self-adhesive control labels with product name, commercial presentation, lot number (LOT) expiration date (⌛) and manufacturer's name are located inside the package, to assist in these records, and at least one unit of them must be attached to the patient's documentation, ensuring complete product traceability.
- Use only support materials and sterile surgical instruments;

- Unused product (surplus) in the surgical procedure must be disposed of, disposed of as hospital waste.
- HAP-91 is a product manufactured in order to facilitate its handling during surgery, but it is IMPORTANT to point out that it is highly friable, liable to deformation, but its physical-chemical characteristics, as well as its biocompatibility and biofunctionality ARE NOT CHANGED, when any change in format occurs;
- The compressed, disc, wedge, parallelepiped, cube, stopper and cylinder presentations cannot be screwed and / or used as an implant support base, since they are friable and their formats have the sole purpose of facilitating their handling.
- The product HAP-91 is sold in sealed packaging.
- If the packaging is violated and / or uncharacterized, the product must be considered under the condition of non-sterile and must not be used, and must be discarded.

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

CONTRAINDICATIONS AND RESTRICTIONS:

No rejection problems have been reported with the use of the HAP-91 product.

There are no restrictions on the maximum amount of HAP-91 to be used, it must be determined previously, after the professional has analyzed the size of the surgical bed.

In case of any type of adverse reaction to the product, the company / manufacturer must be communicated together with the National Health Surveillance Agency (ANVISA).

- **STORAGE, TRANSPORT AND HANDLING CONDITIONS:**

It must be transported and stored away from direct sunlight, sources of heat and humidity;

- The product should preferably be kept at a temperature of 15-30 ° C and a maximum humidity limit of 75% RH (±5%);
- It must be stored in order to maintain the physical integrity of the packaging, without damaging it;
- No heavy object 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 removed.

DISPOSAL CONDITIONS:

HAP-91 is a calcium phosphate and according to RDC 306 of 2004 it generates Group D waste and because it is used in a surgical environment it must be disposed of in hospital waste, mischaracterizing the product.

EXPIRATION DATE:

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

WARNINGS:

The patient must be carefully examined and evaluated when undergoing a surgical procedure, in order to analyze all aspects that may influence the final result of the surgery.

Any surgical procedure is liable to complications, such as swelling at the surgical site, crusting of the flap, hemorrhage, local inflammation, bone loss, infection and pain at the site.

It is worth mentioning that in some cases particle extrusion and granule migration may occur, but that do not compromise clinical results.

It is the surgeon's job to pass on some information regarding the graft, surgical and postoperative procedure to the patient, so that he is aware of how the entire procedure will take place. It is important to inform that when necessary to physical activities, they will be restricted during the recovery period and should be evaluated according to the type of surgery, extent of the lesion and place of application. The region's functionality will be affected for a period of time, which will be determined by the doctor after surgery analysis, among other information that will vary from surgical procedure and patient.

PRESENTATION:

	Apresentação	Granulometria			Peso / Volume	Demonstração
		Mesh	µm	mm		
HAP-91 Hidroxiapatita Porosa Absorvível	Granulado	≤ 10	≥ 2000	≥ 2,0	0,5g	
					1,0g	
					2,0g	
					5,0g	
					10,0g	
					5,0cc	
					10,0cc	
					20,0cc	
		≤ 20	≥ 841	≥ 0,841	0,5g	
					1,0g	
					2,0g	
					5,0g	
		≤ 30	≥ 595	≥ 0,595	0,5g	
					1,0g	
					2,0g	
					5,0g	
	Dura	≤ 10 a 30	≥ 2000 a 595	≥ 2,00 a 0,595	5,0g	
	Apresentação	**Dimensão**			**Peso / Quantidade**	**Demonstração**
	Comprimido	≥ 2 mm			0,5g	
					1,0g	
					2,0g	
					5,0g	
	Disco	≥ 14 x 14 mm			01 unid.	
		≥ 12 x 14 mm			01 unid.	
		≥ 11 x 14 mm			01 unid.	
	Cunha P	≥ 03 x 7,5 x 15 x 20 mm			01 unid.	
	Cunha M	≥ 08 x 10 x 15 x 25 mm			01 unid.	
	Cunha G	≥ 03 x 15,5 x 15 x 35 mm			01 unid.	
	Paralelepípedo	≥ 10 x 20 x 10 mm			01 unid.	
		≥ 25 x 20 x 05 mm			01 unid.	
	Cubo	≥ 10 x 10 x 10 mm			01 unid.	
	Rolha (botão)	≥ 22 x 10 mm			01 unid.	
	Cilindro	≥ 10 x 10 mm			01 unid.	

Manufacturer
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CNPJ: 71.029.631/0001-81
Operating permit: ANVISA/MS: 10405720001
ANVISA Registration nº: 80149980012
Technical manager: Dámiana Máximo Brandão CRF/MG 26315

Sheyla Maria de Castro Máximo Bicalho
LEGAL REPRESENTATIVE

Dámiana Máximo Brandão - CRF/MG 26315
TECHNICAL RESPONSIBLE