

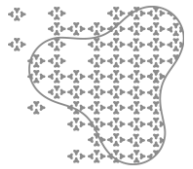
COL.HAP-91®



Commercial Name: COL.HAP-91® Bone Graft
COL.HAP-91® is a registered trademark of JHS Laboratório Químico Ltda.
Technical Name: Bone Graft
ANVISA Register n°: 10405720003
AFE/ANVISA n°: 9904LHMY57H9 (8.01499.8)
TECHNICAL RESPONSIBLE: DÁMIANA MÁXIMO BRANDÃO - CRF/MG: 26.315
Sterile product in ethylene oxide



Conditions for storage, conservation and / or handling, warnings and / or precautions, technical characteristics and instructions for use: See Instructions for Use.



PRODUCT DESCRIPTION:

The product **COL.HAP-91**[®] Bone Graft, hereinafter called **COL.HAP-91**[®], is an association of hydroxyapatite and Bovine hemostatic collagen. **HAP-91**[®] - Absorbable Porous Hydroxyapatite, hereinafter called **HAP-91**[®], used in the production of **COL.HAP-91**[®], has a grain size ≤ 50 mesh. The collagen used for the production of the bone graft, **COL.HAP-91**[®], consists of a fibrous protein, relatively soluble in water obtained from the ox's deep flexor tendon. Hemostatic collagen is obtained in the form of powder, sponge or film from a company duly licensed and authorized by the competent health agencies. The association of hydroxyapatite (**HAP-91**[®]) with hemostatic collagen promotes flexibility, hemostasis, the ability to osteoconduction and osteoinduction integrated in the same product.

COMPOSITION:

COL.HAP-91[®] é constituída de:

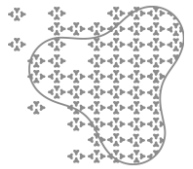
- 75% Hydroxyapatite (**HAP-91**[®] Absorbable Porous Hydroxyapatite)
- 25% Bovine Hemostatic Collagen

INDICATION:

COL.HAP-91[®] is indicated in medical and dental surgeries for recovery, partial replacement, filling, reconstruction of bone tissue and hemostasis, due to losses due to bone deformities, extraction, etc. 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:

COL.HAP-91[®] is supplied in a sterile state in order to prevent potential contamination. It is sterilized by: Ethylene Oxide (STERILE | EO) or Gamma Radiation (STERILE | R). The sterilization method is indicated on the cartridge and product labels. Sterilization is only guaranteed if the packaging remains intact.



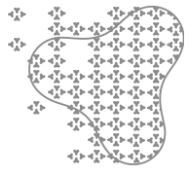
INSTRUCTIONS FOR USE:

- 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 **COL.HAP-91®** to the site to be grafted is recommended, if it is delivered to plasma enriched with platelets (PRP) or blood of the patient, the product obtained from this association must be a mass with consistency to facilitate its handling .
- Due to its physical-chemical properties and characteristics, **COL.HAP-91®** can be used as an antibiotic carrier.
- **COL.HAP-91®** must not be fixed with screws or used as a support base.

PRECAUTIONS AND WARNINGS:

To ensure the proper use, safety and effectiveness of the **COL.HAP-91®** product, some precautions must be followed:

- Only qualified medical and dental professionals with full knowledge of the necessary surgical and asepsis techniques can use the product;
- **COL.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;
- Use only support materials and sterile surgical instruments;
- Three self-adhesive control labels with product name, commercial



presentation, batch number (LOT), expiration date (⌚), type of sterilization and manufacturer's name are inside the package, to assist in these records, at least one unit of which must be attached to the patient's documentation, ensuring complete product traceability;

- Unused product (surplus) in the surgical procedure must be disposed of, disposed of as hospital waste;
- **COL.HAP-91®** must not be fixed with screws nor used as a support base;
- The **COL.HAP-91®** product 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;

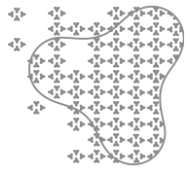
STERILE PRODUCT, SINGLE USE (⊗), DO NOT REUSE, DO NOT RESTERILIZE, DO NOT REPROCESS, DO NOT USE IF THE VALIDITY IS EXPIRED OR THE PACKAGE IS VIOLATED.

CONTRAINDICATIONS AND RESTRICTIONS:

- No problems have been reported regarding the rejection of the **COL.HAP-91®** product.
- There are no restrictions on the maximum amount of **COL.HAP-91®** to be used, it must be determined previously, after the professional has analyzed the size of the surgical bed.
- **COL.HAP-91®** has bovine hemostatic collagen in its composition, which can cause allergic reactions, so it is contraindicated for people who are hypersensitive to this constituent.
- 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 CONDITIONS, TRANSPORT AND HANDLING:

- 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 (\pm 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 its physical integrity and sterility;
- 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 has been violated, the product must be discarded and its packaging must be uncharacterized.

DISPOSAL CONDITIONS:

COL.HAP-91[®] according to RDC 222 of 2018 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:

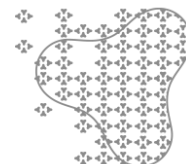
The expiration date of the product is two (2) years after the sterilization date and this information is contained on the cartridge, product label and control labels.

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, granule migration may occur, but that do not compromise clinical results.



It is the surgeon's job to pass on 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, in some cases it will not be possible to apply a load on the site, this means 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	Formato (tamanho)	Quantidade	Código de referência	Demonstração
Tiras	≈10 x 20mm	1 unidade	502511	
	≈20 x 20mm	1 unidade	502512	
	≈20 x 30mm	1 unidade	502523	
Base Piramidal (Ravioli)	≈30 x 30 x 10mm	1 unidade	502540	
Pastilha	≈10 x 10mm	1 unidade	502530	
Rolha	≈14 x 8mm	1 unidade	502560	

MANUFACTURED BY:

Nome fantasia: JHS Biomateriais
Razão Social: JHS Laboratório Químico LTDA.
CNPJ: 71.029.631/0001-81
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