SURGIPLASTER INSTRUCTION FOR USE CE 0426

SURGIPLASTER **is a bone filler material. By following a few simple procedures it will permit the correct use of the product and allow the clinician to achieve predictable clinical results.**

PACKAGING

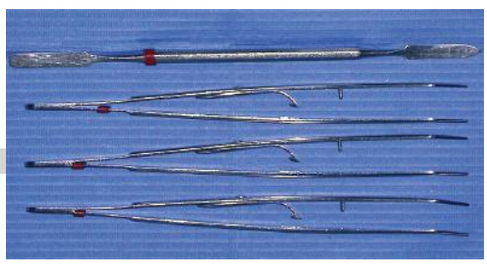
The package contains:
P30: 1 bottle with 2 g of Calcium sulfate in porous microgranules, compact and without any sharp surfaces; 1 bottle with 400 mg hemihydrated Calcium Sulfate powder; 1bottle with 1 ml REGULAR liquid;1bottle with 1 ml FAST liquid; accessories (2 mixing dappens, 1 dropper and 1 spatula).
G170: 1 bottle with 2 g of Calcium sulfate in porous granules, compact and without any sharp surfaces; 1 bottle with 400 mg hemihydrated Calcium Sulfate powder; 1bottle with 1 ml REGULAR liquid; 1 bottle with 1 ml FAST liquid; accessories (2 mixing dappens, 1 dropper and 1 spatula).
SINUS: 1 syringe with 2,5 g of Calcium sulfate in porous granules, compact and without any sharp surfaces.

INDICATIONS

- **SURGERY**
  - For filling post-extraction sockets
  - In residual bone cavities after surgery
  - Impacted third molars
- **PERIODONTOLOGY**
  - For intraosseous defects and in forcations
- **ENDODONTIA**
  - In periradicular and apical surgeries
  - As a matrix in root preforations (the product is pushed through the perforation before applying the definitive sealer with an appropriate material)
  - With open apexes (it is extruded through the apex and then the canal is prepared and closed)
- **IMPLANTOLOGY**
  - Periimplantitis
  - Minor maxillary sinus lift
  - Major maxillary sinus lift
  - Split crest
  - In procedures for increasing bone diameters
  - Immediate implants
  - As a space maintainer used with a membrane
  - Treating donor sites used for autologous bone grafts
  - Correction of dehiscence's and fenestrations

ISTRUCTIONS

- **INSTRUMENTATION REQUIRED**
  - Tweezers with stop
  - Sterile gauze tampons made of TNT (tissue-non-tissue)



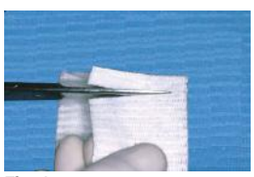


Fig. 1


Fig. 2


Fig. 3


Fig. 4

• **How to prepare the application site**
The receiving bone site must first be perfectly clean, without any contaminant materials such as tartar, granulation tissues and portions of very thin bone which, if not properly vascularized, can become necrotic: therefore it is very important to use curettes, rotary instruments at low RPM's and possibly even bone forceps of an appropriate size to clean the receiving site in the bestpossible way. At the end of the treatment, the bone cavity must be clean and the walls sufficiently thick without any roughness; any exposed roots must be completely decontaminated and polished: for this an etching solution such as supersaturated solution of citric acid can be used on the root. If there appears to be little bleeding at the site, after it has been cleaned, use a round bur to curettage the walls which will increase the presence of medullar blood rich with osteoblastic cells.

MIXING AND APPLICATION: layering technique

P30

Pour a quantity of granules sufficient enough for the regenerative needs, into the small mixing tray provided in the package and make sure to tightly close the bottle containing any remaining material. Upon contact with air and humidity, calcium sulfate hemihydrate is transformed into calcium sulfate dihydrate, resulting in a loss of many of its therapeutic characteristics. Using the dropper, withdraw some REGULAR liquid from the vial. Pour the granules into the second mixing tray and mix with a small amount of liquid until a mixture resembling "wet sand" is obtained, continue mixing until it has a dense creamy consistency. While mixing, small quantities of powder or liquid can be added to improve the consistency, or if there is any excess of liquid it can be removed by using dry sterile gauze made of TNT.
It is recommended to tampon the receiving site with sterile gauze in order to control any bleeding. Using a spatula, introduce into the cavity the first part of the mixture that was just prepared, compacting it with a small square of sterile TNT gauze (Fig. 1-4) placed on a pair of tweezers with stop. This first amount has a mechanical haemostatic effect.
Complete filling the defect with additional material by applying it in layers 2-3mm thick, using moderate pressure applied with precision and care to compress each layer, this will prevent leaving any spaces between the layers. The last layer must overfill the defect and is tamponed with a small square of sterile TNT gauze moistened with FAST liquid which will accelerate hardening.

G170

Pour a quantity of granules sufficient enough for the regenerative needs, into the small mixing tray provided in the package and make sure to tightly close the bottle containing any remaining material. Upon contact with air and humidity, calcium sulfate hemihydrate is transformed into calcium sulfate dihydrate, resulting in a loss of many of its therapeutic characteristics. Using the dropper, withdraw some REGULAR liquid from the vial. In order to place the material in the best position in the receiving site, the product must be moistened with REGULAR liquid, mixing it with a spatula to facilitate its aggregation. Thanks to the fact that 25% of the material is calcium sulfate hemihydrate, the granules adhere to each other and can easily be applied to the defect with a spatula. To obtain a more compact mixture, the powder, contained in the vial supplied with the package, may be added. On top of the granules a layer of P30 can be placed ("MIXING AND APPLICATION OF P30") or a regeneration membrane.



SINUS

Particularly indicated for **major maxillary sinus lifts** and for **minor lifts via the alveolus**.
Once access to the maxillary sinus is obtained, slant la syringe towards the receiving cavity while exerting pressure on the syringe plunger in order to extrude the product. To avoid leaving any empty spaces, adapt the material to the site condensing it with a small square of sterile gauze (fig. 1-4) placed on a pair of tweezers with stop. Finish filling the cavity with additional applications of material. Apply the P30 as the last layer to prevent any granules from escaping during respiration.

- **How to perform a correct postoperative recovery**

After surgery the patient must be warned about the possible appearance of various degrees of swelling and tenderness, generally in proportion to the severity and extensiveness of the surgery. Generally the treatments are limited to the use of a Chlorhexidine based mouth rinse, initially at 0,2% for the first week, followed by 0,12% three times per day substituting daily brushing, which is prohibited for the first 7/10 days at the surgical site. Only if necessary should analgesics and anti-inflammatory medications be administered, while antibiotics should not be prescribed as a routine therapy, except in cases when a membrane is used or when the surgeon feels it is necessary. Between the seventh and tenth day the sutures may be removed afterwards the patient can resume using a soft toothbrush. A follow-up of the progress of the regeneration can be made at a later date but is at the discretion of the surgeon. However is recommended that a radiograph 6-8 months postoperative be taken, this is considered sufficient time for a complete regeneration to take place and an addition follow-up of the patient is also recommended at 12 and 18 months.

WARNING: Product must not be re-sterilized. If the sticker on the inner package, which indicates that the product is sterile is NOT red, DO NOT use the product. If any irregularities are noticed with the packaging, isolate the non-conforming product and dispose of it as "special waste".
Any material that is not used and remains in the syringe must be disposed of after the treatment in order to avoid the risk of cross contamination due to use with other patients. As cited in the European Directive 93/42 and subsequent amendments the dentist is responsible for guaranteeing the traceability of the product, to be more precise, he must be able to trace back to the patient into which the product was implanted.
It is recommended to attach the label of the product to the patient's clinical chart.

CONTRAINDICATIONS

There are no generalized contraindications for the use of SURGIPLASTER except in those patients who have been shown to be intolerant or particularly sensitive towards any of the components. Instead, all the general contraindications associated with oral and maxillofacial surgery remain valid. The use of this product is therefore contraindicated in the presence of acute or chronic infections at the surgical site, during treatments with immunosuppressant dugs and in immunodepressed patients. The product is not intended for use in babies, pregnant women and/or women who are breastfeeding.

SIDE EFFECTS

Can cause edema at the implant site in particularly predisposed individuals.

WARNINGS AND CONSERVATION:

- Do not use after the expiration date which is indicated on the package.
- The product can be stored at room temperature.

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The product was created for use in dentistry and must be used in the manner indicated by the prescribing information. The manufacturer declines any liability for damage or harm caused by different and improper use of the product. It is the user's personal responsibility to ensure that the product is suitable for the uses to which he or she intends for it, especially if such uses are not indicated in the prescribing information.
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