# Cytrans® Granules

SYNTHETIC BONE GRAFT MATERIAL

Prior to use, carefully read the instructions for use.

## INDICATIONS FOR USE

1. Augmentation or reconstructive treatment of the alveolar ridge.
2. Filling of periodontal defects.
3. Filling of defects after root resection, apicoectomy, and cystectomy.
4. Filling of extraction sockets to enhance preservation of the alveolar ridge.
5. Elevation of the maxillary sinus floor.
6. Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
7. Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

## CONTRAINDICATIONS

1. Do not re-use
2. Do not re-sterilize

## PRECAUTIONS

I. Precautions for use (care must be taken during use for the following patients)
   1. Patients with a history of hypersensitivity to drugs, foods, accessories, chemicals, etc.
   2. Patients on dialysis
   3. Patients with blood disorder(s)
   4. Patients with abnormal bone target hormone metabolism
   5. Patients with abnormalities in calcium metabolism system organs such as kidney and digestive organs
   6. Patients suspected of having a collagen disease
   7. Patients on steroids
   8. Diabetic patients who have not been treated or improved/stabilized by medication
   9. Patients with fever and other infectious diseases
   10. Patients with immunodeficiency
   11. Patients with serious complications (heart disease)
   12. Patients undergoing or have a history of radiation therapy
   13. Patients being treated with or with a history of bisphosphonates
   14. Patients with uncontrolled hypertension / hypotension
   15. Patients with hyperthyroidism
   16. Patients with liver damage or abnormal liver function tests

Ⅱ. Additional basic precautions
   1. Sufficient care should be taken when mixing with artificial bone of a different brand, as safety and efficacy have not been confirmed.
   2. When suturing, the device is covered with gingival flap completely, and pay attention to infection.
   3. When using this device, if there is lesion tissue containing infective granulation in the affected area, remove it completely before use.
   4. Stabilize the graft site with a membrane or periosteum so that it does not collapse.
   5. When using this device, handle it with sterilized instruments to avoid contamination and infection. At the same time, the material should be mixed with patient blood or sterile saline and care should be taken not to touch the affected area with unsterilized material.
   6. Since this product is a sterilized product, it should be used immediately after opening the container and should be used only once.
   7. Do not use for purposes other than those stated in [Indication for use].
   8. Follow-up visits should be scheduled in a manner to avoid post-operative infection of the site.
   9. Avoidance of early plaque control to avoid dislodging of the product.
   10. Consider the use of a systemic antibiotic in those patients who may have reduced healing capacity.

Ⅲ. Defects and adverse events
   Other adverse events
   1. Swelling of the cheeks
   2. Movement of the device
   3. Postoperative infection

Ⅳ. Use for pregnant women, parturient women, lactating women, and young children, etc.
   Do not use for pregnant and lactating patients and patients who may be pregnant.

## DIRECTIONS FOR USE

1. Prior to use of the product, establish the status of the application site by periapical radiograph, dental CT or panoramic radiograph to determine whether or not mixing with autogenous bone is necessary, and to select the granule size and determine the quantity desired/required.
2. Check for any damage in packaging materials and confirm the product size.
3. Open the packaging and remove the product aseptically. The product can be mixed with the patient's blood or sterilized saline to facilitate maneuverability during filling.
4. Wash the application site with sterile saline, remove excess moisture and blood, and fill with the product. To avoid infection through contamination, ensure that the product does not come into contact with saliva during the filling process. Refer to the following table when applying the product to the bone defect site.

| Application | Method |
|---|---|
| When filling a site where there is a bone defect | Fill the site of the bone defect with the product, ensuring not to damage the bone surface or periodontal tissue. |
| When filling the site with an exposed implant | Fill with the product so that the exposed part of the implant is covered. |
| When filling the surrounding area at the immediate implant placement | Place implant and then fill in gaps. During this process, ensure that the implant has been initially fixed. The non-loading period for the implant (period until the implant and the bone is attached) is at least six months. However, if the amount or quality of the bone is deemed to be insufficient, the non-loading period is extended. For sinus floor augmentation, the minimum bone thickness required is at least 3.7 mm[1]. Surgery is suspended if the mucous membrane of the maxillary sinus is perforated.<br><br>1) Kudoh K, Fukuda N, Kasugai S, Tachikawa N, Koyano K, Matsushita Y, et al. Maxillary sinus floor augmentation using low crystalline carbonate apatite granules with simultaneous implant installation: first-in-human clinical trial. J Oral Maxillofac Surg 2019;77:985.e1-11. |
| When bone augmentation is required prior to implant placement (two-stage reconstruction) | Identify the gap at the site where bone augmentation is required and fill it with the appropriate amount. The waiting period for the implant (period after the bone is filled before the implant can be placed) is at least six months. However, if the amount or quality of the bone is deemed to be insufficient, the waiting period is extended. For sinus floor augmentation, the minimum bone thickness required prior to surgery is 1 mm. Surgery is suspended if the mucous membrane of the maxillary sinus is perforated. |

5. Make sure that there is adequate blood supply to the site to facilitate healing e.g. intramarrow penetration/decortication.
6. Close the wound with sutures after filling.
7. If the surrounding area is filled at the same time as implant placement, confirm that there has been a sufficient healing period with a periapical radiograph, dental CT or panoramic radiograph
8. If bone augmentation is required prior to implant placement (two-stage reconstruction), confirm that there has been a sufficient healing period with a dental CT or panoramic X-ray, etc. before proceeding with implant placement.

## STORAGE AND HANDLING

Ⅰ. Storage method
Store at room temperature away from heat, moisture and direct sunlight. Ensure appropriate storage and management to prevent persons other than dental professionals from coming into contact with the product.

Ⅱ. Period of Use
This product is for single use only and should be disposed of after each single treatment of a single patient. If mixed with patient blood, the discarded material is considered biohazardous waste.

Ⅲ. Expiration
The product should be used by the expiry date indicated on the packaging*.
*For example, "EXP. 2020-02" means the expiry date is February 2020.

## PACKAGE

| Package sizes / Sizes (Granule sizes) | 0.25 g | 0.5 g | 2 g |
|---|---|---|---|
| S (0.3~0.6 mm) | + | + | |
| M (0.6~1.0 mm) | + | + | + |

+ = pack sizes available

Caution: U.S. Federal Law restricts the device to sale by or on the order of a dentist or physician.

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