

## A Product Description

OSTEON 3 Sinus is a synthetic osteoconductive bone graft substitute composed of 60% hydroxyapatite (HA) and 40% beta-Tricalcium phosphate (β-TCP).

OSTEON 3 presents well interconnected porous structure, similar to that of human cancellous bone. It is supplied sterile by gamma irradiation.

## B Indication for use

The use of OSTEON 3 Sinus may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

Case selection and use of appropriate surgical procedure are at the discretion of the physician.

## C Contraindication

OSTEON 3 Sinus should not be used in patients with:

- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia).
- Chronic high doses therapy with corticosteroids.
- Osteomyelitis at the surgical site.
- Vascular impairment at the implant site.
- Severe renal dysfunction, liver disease.

## D Directions for use

OSTEON 3 Sinus should be hydrated with proper amount of physiological saline to prevent osmotic damage before use. If desired, OSTEON 3 Sinus may be mixed with patient's own blood following hydration with physiological saline

- After exposure of the bony defect with a mucoperiosteal flap, all inflammatory tissue and debris must be carefully removed using curettes.
- The surgical site should be cleansed with sterile water or sterile saline and aspirated to prepare the bone for the placement of OSTEON 3 Sinus.
- Fill a sterile dappen dish with sterile saline solution or patient's own blood.
- Slightly retract the plunger on syringe and gently tap to loosen particle, then gently push plunger back into place.
- Place syringe into sterile dappen dish and retract plunger to draw liquid into syringe. To facilitate delivery, OSTEON 3 Sinus should be wetted and loosened sufficiently.
- Expel excess liquid by pushing plunger gently. When hydrated, OSTEON 3 is easily expelled from the syringe. Before injecting OSTEON 3 Sinus, separate cap from the syringe.
- Deliver OSTEON 3 Sinus directly in the surgical site with the syringe while being careful not to break OSTEON 3 Sinus particles.
- In case of bone graft jamming, put on the cap and suck the saline and gently tap to loosen particle.
- When you use OSTEON 3 Sinus, be careful not to be jammed, dropped, broken and compressed.
- Overfilling of the defects should be avoided.
- The mucoperiosteal flaps should be sutured to achieve primary closure.
- A surgical dressing may be placed over the wound for one to two weeks.

## E Precaution

- Effect on pediatric patients is not known.
- Effect on patients with a preexisting disease condition is not known.

## F Warning

- Single use only. Do not resterilize or reuse.
- Not intended for immediate load-bearing.
- Do not leave defect open.
- Do not compromise blood supply to the defect area.
- Do not apply excessive force when implanting OSTEON 3 at the surgical site.

- Do not use if package is opened or damaged or if expiration date has been exceeded.
- It is recommended to cover the implant site with a membrane when using OSTEON 3.
- Use this product in well vascularized bone.
- Product should be protected from contamination due to touching patient's tongue or saliva.

## G Adverse effect

No adverse reactions have been reported.

- Local complication could appear such as edema, numbness, bleeding after surgery, ulcer of soft tissue, infection etc.

## H Symbols

| REF | Catalogue number                                                  | LOT | Batch code                   |
|-----|-------------------------------------------------------------------|-----|------------------------------|
|     | Do not reuse                                                      |     | Date of manufacture          |
|     | Caution                                                           |     | Use by date                  |
|     | Temperature limit                                                 |     | Manufacturer                 |
|     | Do not use if package is damaged and consult instructions for use |     | Do not resterilize           |
|     | Fragile, handle with care                                         |     | Sterilized using irradiation |

## I Storage

Store in room temperature away from sunlight (1~30°C)

## J Expiration data

The expiry date is described on the container and packaging.

## K Articles

| REF        | Volume(cc) | Particle size(mm) |
|------------|------------|-------------------|
| 3G0510050S | 0.5        | 0.5 ~ 1.0         |
| 3G1020050S | 0.5        | 1.0 ~ 2.0         |

### Instruction for **OSTEON™ 3 Sinus**

- ① Slightly retract the plunger on syringe and gently tap to loosen particle, then gently push plunger back into place.
- ② Place syringe into sterile dappen dish and retract plunger to draw liquid into syringe.
- ③ To facilitate delivery, OSTEON 3 should be wetted and loosened sufficiently.
- ④ Expel excess liquid by pushing plunger gently.
- ⑤ When hydrated, OSTEON 3 is easily expelled from the syringe. Before injecting OSTEON 3, separate cap from the syringe.
- ⑥ Deliver OSTEON 3 directly in the surgical site with the syringe.

Made in KOREA, REPUBLIC OF MS-P1100/IFU-DB1308S(Rev.28,2607)



**GENOSS Co., Ltd.**

Head Office : 12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea,  
1201-1207, Gwanggyo Business Center, 156, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea  
Tel. +82-31-888-5100, [www.genoss.com](http://www.genoss.com)