

Xenograft PARTICULATES Instructions for Use

SYMBOLS			

Distributed By:
Community Tissue Services
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QC-605-F-83 V3.0

- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)

INSTRUCTION FOR PREPARATION
The clinician must inform the patient of the animal content, anorganic bovine bone, of the device prior to the procedure.

Site Preparation

- Raise the mucoperiosteal flap and remove the inflammation of the bony defect region using a curette.
- Clean the site using saline or distilled water.
- Content of syringe or vial is STERILE by prior exposure to gamma irradiation unless opened or damaged.
- Read expiration date before use. Do not use if expiration date has been exceeded.

Proper Placement and Containment of the Device

Vial Packaging

- Remove vial from package and dispense desired quantity of Maxxeus Dental xenograft particulates into a sterile dish with aseptic technique.
- Wet and mix Maxxeus Dental xenograft particulates with sterile saline or patient's blood.
- Granules should be sufficiently wet.
- Deliver Maxxeus Dental xenograft particulates to the surgical site using sterile instruments.
- Loosely pack Maxxeus Dental xenograft particulates into voids using sterile instruments.

Syringe Packaging

- Begin by filling a sterile dappen dish

with sterile saline solution or patient's blood.

- Slightly retract the plunger on syringe and gently tap to loosen granules, then gently push plunger back into place.
- Place syringe into sterile dappen dish and retract plunger to draw liquid into syringe. To facilitate the delivery, Maxxeus Dental xenograft particulates should be wetted and loosened sufficiently.
- Expel excess liquid by pushing plunger slightly. When hydrated, Maxxeus Dental xenograft particulates are easily expelled from the syringe. Before injecting Maxxeus Dental xenograft particulates, separate cap from the syringe.
- Deliver directly into the surgical site with the syringe while being careful not to break Maxxeus Dental xenograft particulates.
- If granules jam, replace the cap and draw sterile saline or blood into the syringe and gently tap to loosen granules.
- When using syringe, be careful not to jam, drop, break or compress. Do not overfill the defects.
- Maxxeus Dental xenograft particulates should be placed into well vascularized bone cavity with sufficient contact.
- The flap should be sutured to achieve primary closure without any tension.

Site Closure

- Cover the flap then suture the site firmly so that implantation site will not be exposed.
- Double suturing is strongly recommended due to the anticipated postoperative swelling.
- It is recommended to cover Maxxeus Dental xenograft particulates with a membrane barrier.

Patient Care Following Treatment

- Apply a surgical dressing on the surgical area for 1 to 2 weeks.
- Dentist should instruct patients not to apply pressure to the surgical site during a bone healing process.
- Dentist should inspect and evaluate patients for any allergic response due to the implant.
- A recommended 6 months healing time should be observed before implant placement.

CONTRAINDICATIONS

Conditions representing contraindications include:

- Acute or chronic infection (e.g. osteomyelitis) at the surgical site or surrounding area
- Patients with liver disease and/or kidney disorders
- Degenerative bone disease (e.g. osteoporosis)
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia) or systemic bone disorders
- Patients with vascular diseases
- Common user of steroid (High dose therapy with corticosteroids)
- Autoimmune disease
- Previous radiotherapy to the region of the operation site
- Current or previous use of medication that affect bone turnover (such as bisphosphonates)

ADVERSE EFFECTS

Possible adverse effects include but not limited to:

- Allergy to bone graft
- Hematoma
- Adverse tissue reaction
- Infection
- Swelling at the surgical site

- Flap sloughing
- Bleeding
- Local inflammation
- Bone loss

STERILIZATION

Maxxeus Dental xenograft particulates are sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised. Maxxeus Dental xenograft particulates is non-pyrogenic.

PRECAUTIONS

- Effects on pediatric patients is not known.
- Effects on patients with pre-existing disease conditions (metabolic bone disorder, cardiovascular disease, radiation) is not known.
- Safety and effectiveness during pregnancy has not been established.

WARNINGS

- Single use only. If the product is used more than once, sterility is not guaranteed and adverse reaction can occur. Do not re-sterilize or reuse.
- Not intended for immediate implant (advisable implantation is 6 months).
- When using the syringe product, be aware that there is a detachable inner filter component.
- Do not overfill defects.
- Do not leave defect open
- Do not compromise blood supply to the defect area.
- The device should be secured to prevent motion and migration, use in areas where the graft can be adequately contained.
- Do not use excessive force on granules during delivery into the void. This can destroy the porous structure of Maxxeus Dental xenograft particulates
- Maxxeus Dental xenograft particulates are intended for use by trained qualified persons familiar with bone grafting and have read this instruction for use.
- Do not use if package is opened or damaged or if expiration date has been exceeded.
- Special caution is required to use in patients who smoke heavily.

Caution Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.

MR statement: The Maxxeus Dental xenograft particulates by SigmaGraft, Inc. has not been evaluated for safety and compatibility in the MR environment. The Maxxeus Dental xenograft particulates have not been tested for heating or migration in the MR environment.

Rx Only

STORAGE

Maxxeus Dental xenograft particulates should be stored in a dry, clean and well ventilated place at ambient temperature (15-25°C/59-77°F). Keep the product stored aseptically until ready to use.

EXPIRATION DATE: 3 years

Manufactured by
SigmaGraft, Inc.
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Fullerton, CA 92831, USA

DEVICE DESCRIPTION

Maxxeus Dental xenograft particulates are an anorganic hydroxyapatite bone substitute sourced from protected bovine herds. This bone substitute provides a mineralized osteoconductive structure, similar to human bone, that has been cleaned using a proprietary multi-step purification process. Following placement in the bony voids or gap, Maxxeus Dental xenograft particulates act as an osteoconductive scaffold for the ingrowth of adjacent viable bone. Maxxeus Dental xenograft particulates gradually resorb and are replaced with bone during the healing process. Maxxeus Dental xenograft particulates are available in granules and packaged in vials and/or syringe.

INDICATION FOR USE

Maxxeus Dental small particulates are recommended for:

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

Maxxeus Dental large particulates are recommended for:

- Augmentation or reconstructive treatment of alveolar ridge

