

OsteoGen® Plug, OsteoGen® Strip & OsteoGen® Block Product Insert

(Impladent Ltd OsteoTape® Product Family)

PRODUCT DEVICE DESCRIPTION:

OsteoTape® is an OsteoGen® with Collagen Resorbable Bone Graft Matrix in porous preformed bone grafting shapes comprised of highly purified Type I bovine Achilles tendon collagen, combined with crystals of the product OsteoGen®, a synthetic bioactive resorbable graft of the non-ceramic hydroxylapatite category. OsteoTape® simulates the natural collagen matrix and mineral porous structure of human bone. OsteoTape® eliminates the need for secondary surgery that is required to remove non-resorbable (PTFE) membrane. OsteoTape®, bone graft in preformed shapes, is designed to prevent the problematic migration of particulate bone graft products to major anatomical landmarks (e.g., mandibular canal, sinus perforations, trigeminal nerves and mental foramen). The OsteoGen® Bone Grafting Plug, OsteoGen® Strip and OsteoGen® Block are different shapes/forms of OsteoTape®, all are a composite material composed of OsteoGen® and Type I collagen.

OsteoGen®, a synthetic bioactive resorbable graft, is an osteo-conductive, non-ceramic form of hydroxylapatite, the major mineral component of bone and dental enamel. OsteoGen® [$\text{Ca}_5(\text{PO}_4)_3\text{OH}$] has been used for the augmentation and repair of bone defects since 1984. OsteoGen® is a highly crystalline material, with higher purity and crystallinity than ceramic HA as specified by ASTM standards.^{1,3} OsteoGen® has no \hat{a} tricalcium phosphates, amorphous phases, or bone inhibiting pyrophosphates, as found in ceramic HA products which are devoid of the hydroxyl group, due to their sintering process.^{1,3} However, the hydroxyl group is found in human bone and OsteoGen®. By x-ray diffraction, OsteoGen® has been shown to meet and exceed ASTM standards and specifications. OsteoGen® bone graft, by dental x-ray, will show as radiolucent the day of placement in defect sites. Four to six months later, the defect site will be radiopaque depending on vascularity, patient's age and quantity of product delivered. In many animal and clinical studies, OsteoGen® has been shown to control migration of connective tissue.⁴⁻¹²

INDICATIONS FOR USE:

OsteoTape®, an OsteoGen® with Collagen Resorbable Bone Graft Matrix in porous preformed shapes, is indicated for periodontal and maxillofacial use in surgical procedures, to be placed in sockets for the insertion of dental implants after healing; for the containment of OsteoTape® bone graft cubes after tooth extraction; repair of periodontal infrabony defects and ridge preservation; buccal onlay grafting in conjunction with OsteoTape® cubes and/or strips; to augment the sinus; and, for guided bone regeneration (GBR) techniques. The non-ceramic material can also be used for wound healing post-dental implant surgery and over titanium implant devices if primary closure is not attainable for guided tissue regeneration (GTR). Titanium tack-screws may be used to immobilize OsteoTape®.¹¹⁻¹²

INSTRUCTIONS FOR PRODUCT USE AND SURGICAL CONSIDERATIONS:

Do Not Bend or Fold OsteoGen® Strips Prior to Hydration

Basic surgical techniques are necessarily the surgeon's responsibility. Basic curettage, debridement and enucleation is performed to remove pathogens.

For tooth extraction, after curettage and debridement with No. 8 round bur, perforate the lamina dura with No. 2 round bur anatomically correct to accelerate and enhance blood and cells from the bone marrow for angiogenic activity.¹⁴⁻¹⁶ Avoid major landmarks during perforation (e.g., neighboring roots, mandibular canal, sinus perforations, trigeminal nerves, mental foramen, etc.). The OsteoGen® Plug is designed specifically for socket preservation following tooth extraction. If using OsteoGen® Strips in larger tooth sockets, remove a 20 mm x 40 mm OsteoGen® strip with sterile forceps. Cut necessary portion and soak with patient's blood, as a coagulum, or sterile saline. Roll the tape into a compact cylinder with forceps and deliver the OsteoGen® Strip into the socket. Press to conform into the defect site. Place the remaining pieces, if any, over the socket. Gauze is used to compact the product and remove excess blood. Suture in a crisscross fashion over tooth extractions.

For sinus elevations, Cut and soak several OsteoGen® Strips or Plugs to fill the width and length required. Fill the sinus cavity and place up against the new designated sinus floor. Cover the surgical sinus window with OsteoGen® Strip and suture.^{10,13-14}

For large buccal cortical defects, ridge augmentation, and onlay grafting, cortical bone is decorticated and roughened, and holes (bleeders) are made through the cortex to use blood with cells from the endosteum. Deliver OsteoGen® Strips dry to surgical site for better control and adaptability. Cut and deliver OsteoGen® Strip to the deepest concavity first. As blood is progressively absorbed by OsteoGen® Strip, place additional pieces to build up to desired width and height if necessary. Cover the site with a larger OsteoGen® Strip if necessary and suture. Two to four titanium screw-tacks can be used to secure the larger OsteoGen® Strips. The OsteoGen® Blocks can be used similarly and can be briefly hydrated prior to use for malleability.

POST SURGERY:

Recommend ice bags after surgery. Oral hygiene can be accomplished with warm salt water rinse twice daily, pre and post surgery and/or with antibiotics as the doctor prescribes. No topical tooth brushing is recommended at wound site. The patient should be placed on a soft food diet for two weeks or more, especially after removal of sutures. Do not use any "water jet" or waterpiks. Refrain from probing and subgingival scaling around natural teeth for 4-6 months following surgery.

HOW SUPPLIED:

OsteoGen® Plug, OsteoGen® Strip, OsteoGen® Block and OsteoTape® Bone Graft Matrix are sterile gamma irradiated bone graft substitutes in prefabricated shapes of various volumes. Products are single use only, supplied as follows:

OsteoGen® Plug Large:	10 mm diameter x 20 mm length
OsteoGen® Plug Slim:	6 mm diameter x 25 mm length
OsteoGen® Plug Extra Large:	15 mm diameter x 20 mm length
OsteoGen® Strip Large:	20 mm x 40 mm x 3 mm
OsteoGen® Strip Small:	12 mm x 20 mm x 3 mm
OsteoGen® Bone Block:	10 mm x 15 mm x 17 mm

PACKAGING:

Each box contains product in double bagged envelopes or blister trays for single use only. Do not use if packaging is damaged, open, or torn.

CONTRAINDICATIONS:

Do not use in the presence of any of the following contraindications:

1. Product contains bovine collagen material and may be contraindicated in patients with a history of severe allergies manifested by a history of anaphylaxis known to have allergies to bovine collagen.
2. Bone grafting therapy is not recommended for patients with acute infection in surgical site and/or oral wound cavity with existing acute or chronic infection, as well as any systemic or autoimmune disease or complications.
3. In surgical sites with inflammatory bone disease such as osteomyelitis.
4. In the presence of metabolic or systemic bone disorder.
5. In children and pregnant women.
6. In wound complications which may occur, including, but not limited to hematoma, edema, swelling and fluid accumulation, tissue thinning, infection or other complications that are possible with any surgery.

PRECAUTIONS:

1. Product is supplied sterile and is a single use product only.
2. Do not freeze or expose to extreme heat.
3. Product should be stored in a dry place with controlled room temperature conditions below 30°C (86°F).
4. Clinicians should be familiar with periodontal therapy, bone augmentation, and implant procedures. Improper technique may result in compromised results.
5. Preclinical cast models, x-rays, and CT scan evaluations are always recommended, especially for sinus elevation/implant placement and bone augmentation.

CAUTION:

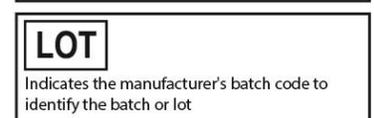
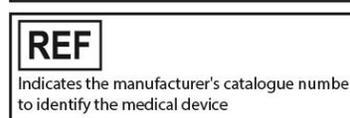
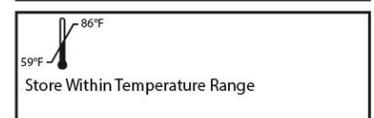
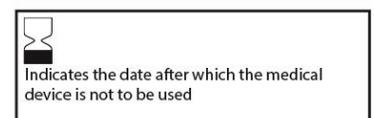
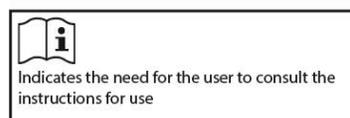
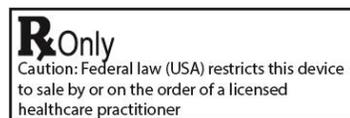
1. Federal law restricts the sale of this device to a licensed physician or dentist.
2. **DO NOT USE BEYOND INDICATED APPLICATIONS.**

MANUFACTURERS LIMITED EXPRESS WARRANTY

Impladent Ltd is a limited liability company. Impladent Ltd. warrants that reasonable care was used in the manufacture of OsteoTape® and OsteoGen® bone graft materials. Impladent Ltd. will not be liable for any consequential loss, damage or expense, directly or indirectly arising from the use or misuse of this product, other than replacement should Impladent Ltd. investigation show the product was defective at the time of shipment. The foregoing warranties are conditional and are limited and in lieu of and exclude all other warranties not expressly set forth herein, without expressed or implied warranties of merchantability of feature use. No other liability or responsibility is assumed by Impladent Ltd.

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