Important tips and guidelines when using **OSSIX**TM **Bone**

After a thorough review of the Instructions for Use, these supplemental guidelines can help you succeed while using OSSIX™ Bone.

- 1 Carefully elevate a full-thickness buccal or lingual tissue flap (not necessary when used following tooth extraction), remove all soft or granulomatous tissue, and release the periosteum until primary, tension-free closure can be achieved.
- 2 Open the sterile package, hold the device with sterile forceps, trim with sterile scissors, and place the device in the defect. It is recommended to hydrate with patient's blood from the implantation site until completely soaked.

NOTE: Use OSSIX[™] Bone only when hydrated—do not manipulate device dry. Do not hydrate OSSIX[™] Bone with saline solution.

- In extraction sockets, place without compression 1 mm apical to the bony crest (no membrane required).
- Push gently into the socket until fully submerged. Position OSSIX™ Bone so it is level with the original bone crest.
- 5 Suture over with minimal tension.
- 6 When you reopen the site, you will see the device partially or completely ossified (chalky, white appearance). **Do not remove remnants**, as the device will completely ossify over time. Recommended timing: 15–19 weeks for small sockets, and at least 22 weeks for large sockets.

NOTE: During drilling, OSSIX[™] Bone will be less resistant to drilling than mature bone or conventional bonegrafting materials.

- 7 Perform radiography/CBCT. OSSIX™ Bone will be visible in the radiograph and lightly radiopaque (not like dense bone).
- 8 If prematurely exposed, re-suture if the flaps are mobile. Have the patient rinse with chlorhexidine and avoid hard or hot food. Remember, the device is the ossification substrate. If exposed and resorbed, you may expect less or no new bone or soft tissue.

IMPORTANT: When an implant is placed in a healed OSSIX™ Bone site or immediately (post-extraction) placed in OSSIX™ Bone, make sure that your implant is properly stabilized in original bone (>5 mm) for standard osseointegration time.

SOCKET PRESERVATION WITHOUT A MEMBRANE

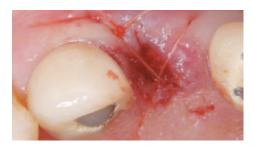
Use OSSIX[™] Bone for a simple, cost-effective socket preservation procedure.



OSSIX™ Bone soaked in blood



OSSIX™ Bone in socket



Suturing

POST-OPERATIVE RECOMMENDATIONS FROM THE MANUFACTURER

- Antibiotic treatment: 1.5 grams per day amoxicillin or equivalent for those allergic to penicillin.
- Rinse with salt water for one week (1 teaspoon salt in a small glass of lukewarm water), and avoid hard or hot food (similar to standard post-extraction instructions).



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Build bone with ease without a membrane or particulate remnants

RECOMMENDED USES FOR OSSIX™ BONE

- Socket preservation—no membrane required
- Sinus elevation (crestal approach)—no membrane required
- Lateral/vertical augmentation (only in cases with sufficient supporting bone)*
- Missing buccal bone/implant dehiscence defects*
- Ossification scaffold in guided tissue regeneration (GTR)*

*Requires OSSIX® PLUS membrane for stabilization.

SIZED FOR SPECIFIC APPLICATIONS (Actual size shown)

Alter

5x5x5 mm (0.125 cc)

- Single-rooted tooth socket preservation
- One implant transcrestal (osteotome) sinus elevation
- Single-rooted tooth immediate implant with a gap to bony walls
- Single tooth or implant bone defect
- Single tooth concavity

5x5x10 mm (0.25 cc)

- Multi-rooted tooth socket preservation
- Two implants transcrestal (osteotome) sinus elevation
- One or two teeth or implants lateral ridge augmentation



5x10x10 mm (0.5 cc)

- Large-size bony defect following removal of teeth, implants, or cysts
- Large-span lateral bone augmentation



INDICATION:

OSSIX Bone is a sterile, biocompatible bone grafting material aimed to fill, augment, or reconstruct periodontal and bony defects of the maxillo-facial complex.

IMPORTANT SAFETY INFORMATION:

- OSSIX Bone must not be used in:
- Patients with known collagen hypersensitivity.
- Patients with a sensitivity to porcine-derived materials.
- Patients suffering from autoimmune diseases and connective tissue diseases, such as: systemic lupus erythematosus, dermatomyositis, etc.
- Patients with acute or chronic infection (osteomyelitis) at the surgical site.
- Patients with vascular impairment at the implant site.
- Patients with uncontrolled periodontal disease.
- Patients that have received or are currently receiving treatment with bisphosphonates.
- OSSIX Bone should not be used in the presence of infected wounds at the site of implantation.
- OSSIX Bone is intended for a single use only. Do not resterilize or reuse.
- As OSSIX Bone contains collagen, allergic reactions (e.g. erythema, swelling, induration and/or pruritus at treatment site) may not be entirely excluded.

Please see Instructions for Use at OSSIXUSA.com.

OSSIX[™] Bone

To order, contact your OraPharma sales representative or call

866-273-7846

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