BIOHORIZONS®

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English

# Site Development System IFU


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The symbol table below is for reference only. Refer to product packaging label for applicable symbols.

| Symbol | Symbol Description |
|---|---|
|  | Caution |
|  | Electronic instructions for use |
|  | Manufacturer |
|  | BioHorizons products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC |
|  | Reference/ article number |
|  | Lot/ batch number |
|  | Do not re-use |
|  | Use-by-date |
| **Non-Sterile** | Non-Sterile |
|  | Date of manufacture |
| **Rx Only** | Caution: U.S. Federal law restricts these devices for sale, distribution and use by, or on the order of, a dentist or physician |

This document supersedes all prior revisions. Original language is English.

This document applies to BioHorizons Site Development System.

**DESCRIPTION**

The BioHorizons Site Development System is a collection of Bone Screws and Tenting Screws used in conjunction with contourable Titanium Mesh to fixate and stabilize barrier membranes to adjacent bone at the surgical site and are used for tissue regeneration in the oral cavity or in other maxillofacial applications. The Bone Screw and Tenting Screws are intended to be used with Titanium Mesh to stabilize and fixate barrier membranes in the mandible or maxilla. The function of the Titanium Mesh is to limit and shape the setting of synthetic or biological materials for osteoplasty. The Bone Screws, Tenting Screws and Titanium Mesh are intended for short-term, single use. The Bone Screws portfolio will consist of two (2) diameters – 1.4mm and 2.0mm and five (5) lengths- 4mm, 6mm, 8mm, 10mm, and 12mm. The Tenting Screws portfolio will consist of one (1) diameter – 1.4mm and four (4) lengths – 8mm, 10mm, 12mm, and 14mm. The Titanium Mesh will be 0.2mm thick and will consist of two (2) sizes – 77mm x 45mm and 38mm x 45mm. The Bone Screws and Tenting Screws are produced from biocompatible Ti-6Al-4V ELI per ASTM F136. The Titanium Mesh is produced from biocompatible Grade 1 Titanium, per ASTM F67.



**INDICATIONS FOR USE**

The Site Development System is indicated for use in oral maxillofacial surgical reconstruction and dental regeneration procedures as temporary implants to stabilize and support autograft, allograft, and bone void fillers and/or fractured bone segments with or without titanium mesh in bony defects of oral maxillofacial anatomy for maintaining space during bone grafting procedures and to support soft tissue until bone formation.

**CONTRAINDICATIONS**

The Site Development System should not be used in patients who have contraindicating systemic or uncontrolled local diseases such as blood dyscrasias, diabetes, hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorder, pregnancy, collagen and bone diseases. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depending on severity.

**DIRECTIONS FOR USE**

Proper surgical procedures are the responsibility of the medical professional. Each clinician must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case at hand. BioHorizons strongly recommends completion of postgraduate dental implant education and strict adherence to the instructions and procedures for use that accompany BioHorizons products. NOTE: A pre-operative 30-second rinse with a 0.12% Chlorhexidine Digluconate solution is recommended. (The influence of 0.12% Chlorhexidine Digluconate Rinses on the Incidence of Infectious Complications and Implant Success. Lambert, Paul M., et al, J Oral Maxillofacial Surgery 55:25-30, 1997, Suppl5).

The Bone Screws and Tenting Screws are intended to be placed using Jeil bone screw instrumentation. See table below for compatible Jeil instrumentation associated with each BioHorizons screw:

| BioHorizons Part Description | Jeil Part Number | Jeil Part Description |
|---|---|---|
| 1.4mm Bone Screws | BS-MCSSFT -HND | Micro Screwdriver Shaft for Screwdriver Body |
| | BS-MCSSFT -ANG | Micro Screwdriver Shaft for latch-type handpieces |
| | BS-1MCDB-ANG | 1.0mm Micro Drill Bit for latch-type handpieces |
| 2.0mm Bone Screws | BS-MNSSFT -HND | Mini Screwdriver Shaft for Screwdriver Body |
| | BS-MNSSFT -ANG | Mini Screwdriver Shaft for latch-type handpieces |
| | BS-16MMDB-ANG | 1.6mm Mini Drill Bit for latch-type handpieces |
| | BS-16X54.8MDB-STR | 1.6 x 54.8mm Mini Drill Bit for friction-grip handpieces (Ø2.35mm) |
| | BS-16X67MDB-STR | 1.6 x 67.0mm Mini Drill Bit for friction-grip handpieces (Ø2.35mm) |
| 1.4mm Tenting Screws | BS-MNSSFT -HND | Mini Screwdriver Shaft for Screwdriver Body |
| | BS-MNSSFT -ANG | Mini Screwdriver Shaft for latch-type handpieces |
| | BS-1MCDB-ANG | 1.0mm Micro Drill Bit for latch-type handpieces |

Bone Screw and Titanium Mesh Placement

1. Cut and contour the Titanium Mesh to fit defect.
2. Place the appropriate grafting materials to cover the defect.
3. Drill pilot holes using appropriate diameter drill bit.
4. Position the Titanium Mesh over defect area.
5. Secure the Titanium Mesh by fully inserting the screw threads of the Bone Screws.
6. Complete placement of additional graft materials if necessary.
7. Close the incision with sutures.
8. Allow sufficient time for bone formation during healing before removing the screws and mesh.

Tenting Screw Placement

1. Drill pilot holes using the appropriate diameter drill bit.
2. Insert Tenting Screws and stabilize screws by fully inserting the screw threads into the bone.
3. Place the appropriate grafting materials in the socket or defect, around and under the tenting screws.
4. Close the incision with sutures.
5. Allow sufficient time for bone formation during healing before removing screws.

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**WARNINGS AND PRECAUTIONS**

The Site Development System has not been evaluated for safety and compatibility in the MR environment. Screws, and Mesh have not been tested for heating, migration or image artifact in the MR environment. The safety of BioHorizons Site Development System in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

**COMPLICATIONS AND ADVERSE EFFECTS**

The risks and complications with the Site Development System include, but are not limited to: (1) allergic reaction(s) to screw, and mesh material; (2) screw and/or mesh breakage; (3) screw and/ or mesh loosening; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/ or fibroblasts; (7) formation of fat emboli; (8) maxillary sinus perforation; (9) labial or lingual plate perforation; and (10) bone loss possibly resulting in revision or removal.

**HANDLING AND STERILIZATION**

Site Development System components are NOT supplied sterile. Remove and discard any shipping material before initial sterilization. The components must be disassembled where applicable, thoroughly cleaned, reassembled and sterilized before initial use and each

subsequent re-use. Remove any visible debris from the components using a soft bristle brush and a broad-spectrum cleaning or disinfecting agent such as Hu-Friedy's Enzymax® or equivalent. Rinse thoroughly. Place the components in a beaker of the same solution and sonicate for 10 minutes. Rinse thoroughly. Rinse components with isopropyl alcohol to remove any soap residue and minerals. Blot components with a lint free towel and air dry completely. Place product in a FDA cleared sterilization bag or wrap and run through one of the following sterilization cycles:

| Sterilization Method | Temperature | Exposure Time | Minimum Drying Time |
|---|---|---|---|
| Gravity Steam (ANSI/AAMI ST79) | 121°C (250°F) | 30min | 15-30 minutes |
| Gravity Steam (ANSI/AAMI ST79) | 132°C (270°F) | 15min | 15-30 minutes |
| PreVac Steam (ANSI/AAMI ST79) | 132°C (270°F) | 4min | 20-30 minutes |
| PreVac Steam<br>(UK DoH Health Technical Memorandum 01-01) | 134°C (273°F) | 3min | 20-30 minutes |

Attention! Improper cleaning may lead to inadequate sterilization. Failure to completely dry instruments during autoclaving may leave moisture and cause discoloration and oxidation. The use of hydrogen peroxide or other oxidizing agents will damage the surface of the instruments. Periodic testing, cleaning, and calibration of the autoclave equipment is recommended to ensure the unit remains in proper working order.