BIOHORIZONS®

SCIENCE • INNOVATION • SERVICE

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
	Sterile by gamma irradiation
	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

ENGLISH

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

This document applies to BioHorizons Site Development System.

DESCRIPTION
The Site Development System includes bone screws, tenting screws, tissue tacks, contourable titanium mesh and the associated drills and drivers for placement of these devices.

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.

The tissue tacks are intended to fixate and stabilize bioresorbable and non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in other clinical situations that require membrane use or fixation.

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 and restorative techniques 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 implant 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).

Tack Driver – After sterilizing, remove the blue driver tip from the Tack Driver. Insert the end of the Tack Driver into one of the recesses in the tack cassette and pick up a tack. You will be able to see the pointed end of the tack protruding from the nozzle tip.

Place the membrane on the defect site following the instructions for use specific to the membrane. Place the tip of the tack driver in the desired location, press against the bone and use a small mallet to seat the tack. To disengage the tack from the driver, tilt the driver away from the tack center axis.

If the tack head is not flush, reattach the blue driver tip to the tack driver (securing with dental floss), reposition over the tack head and use a mallet to seat the tack completely.

Stabilize the membrane with as many tacks as required.

Mesh - Drill through the mesh holes, prior to inserting the 2.0mm Bone Screws.

WARNINGS AND PRECAUTIONS
Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any BioHorizons Instructions for Use (IFU). Clinicians are responsible for understanding the appropriate technical use of BioHorizons prosthetic components. Additional technical information is available upon request from BioHorizons, or may be viewed and/or downloaded at www.biohorizons.com. Contact BioHorizons Customer Care or your local representative with any questions you have regarding specific IFU.

Titanium tissue tacks can be damaged in function for a number of reasons including improper loading or improper surgical placement. An adequate number of tissue tacks should be used to stabilize the membrane/ tissue. A certain percentage of tissue tacks may fail to fixate rigidly to adjacent bone and provide proper retention to the membrane. Tissue tacks demonstrating mobility should be removed. The Site Development System has not been evaluated for safety and compatibility in the MR environment. They 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 this device 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, tissue tack and mesh material; (2) screw, tissue tack, and/or mesh breakage; (3) screw, tissue tack 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) screw, tissue tack and/or mesh loosening requiring revision surgery; (9) maxillary sinus perforation; (10) labial or lingual plate perforation; and (11) bone loss possibly resulting in revision or removal.

BioHorizons titanium tissue tacks are not intended for permanent implantation and should be removed after proper healing. Tissue tack removal is performed by exposing the surgical site and using a scalpel blade, periosteal elevator, or other similar thin flat surface, prying the head of the tissue tack away from the underlying bone. Removed tissue tacks should be accounted for and discarded, and the surgical site then closed and re-sutured. In the event of tissue inflammation or evidence of infection, and at the clinician's discretion, the titanium tissue tacks may be removed.

HANDLING AND STERILIZATION

The Site Development System is NOT supplied sterile. Remove and discard any shipping material before initial sterilization. The Site Development System must be disassembled, thoroughly cleaned, reassembled and sterilized before initial use and each subsequent re-use. Remove any visible debris from the instruments and surgical kit 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 instruments in a beaker of the same solution and sonicate for 10 minutes. Rinse thoroughly. Rinse instruments with isopropyl alcohol to remove any soap residue and minerals. Blot instruments with a lint free towel and air dry completely. Disassemble the surgical kit and wash the empty tray using the same solution. Rinse with water and dry thoroughly. Return the instruments to the appropriate locations in the tray. Place product in a FDA cleared sterilization bag or wrap and run through one of the following qualified sterilization cycles: 1. Prevacuum Steam: 132°C (270°F) for five (5) minutes minimum. 2. Gravity Steam: 121°C (250°F) for sixty (60) minutes minimum.
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.