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: 132°C (270°F) for thirty (30) minutes minimum. 3. Gravity Steam: 121°C (250°F) for sixty (60) minutes minimum. 4. Prevacuum Steam: 134°C (273°F) for three (3) minutes minimum. Dry for twenty (20) to fifty (50) minutes. Do not exceed 134°C (273°F) during sterilization or drying.

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.