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.