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

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

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 qualified sterilization cycles: 1. Prevacuum Steam: 132°C (270°F) for five (5) minutes minimum. 2. Gravity Steam: 121°C (250°F) for twenty (20) 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.