STABILIZORTHO

STABILIZ ORTHOPAEDICS
574 WHARTON BLVD EXTON, PA 19341

SPL LOCKING SCREW
INSTRUCTIONS FOR USE

SPL LOCKING SCREW for use with STABILIZ FIXATION SYSTEM FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

DESCRIPTION: The SPL Locking Screw is a metal locking screw with a resorbable threaded polymer collar intended exclusively for use with the Stabiliz Fixation System. The Stabiliz Fixation System includes standard straight LCP plates, metal locking screws, cortical screws, fully-threaded cancellous screws, and partially-threaded cancellous screws in various sizes and geometries.

MATERIALS: All implants are made from 316L stainless steel and polymer containing screws are over-molded with 85/15 L-lactide / Glycolide (PLGA) bioresorbable polymer.

INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support.

INDICATIONS: The Stabiliz Fixation System with SPL Locking Screw is intended for fixation of fractures, osteotomies and nonunions of the humerus, radius, ulna, distal tibia, and fibula.

CONTRAINDICATIONS: Contraindications for the system are active or latent infection; sepsis; insufficient quantity or quality of bone/soft tissue; and material sensitivity. If sensitivity is suspected, tests must be performed prior to implantation to determine metal sensitivity. Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

WARNINGS: For safe effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for the device.

The plate should be contoured and compressed flush to bone. This is especially important when using an SPL Locking Screw. The appropriate torque limiting driver should be used when inserting an SPL Locking Screw. These screws may only be fully inserted once. Loosening a fully seated SPL Locking Screw requires screw removal, disposal and replacement with the appropriate substitute screw. The device is not designed to withstand the stress of full weight bearing or excessive activity. Damages to the plate from repeated bending and/or scratches on the instruments/implants can substantially impair the strength of the product and lead to premature breakage. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.

Improper insertion of the device during implantation can increase the possibility of loosening or migration.

The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant.

The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. The implant system has not been evaluated for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.

PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Instruments should be inspected for wear or damage prior to usage.

Protect implants against scratching and nicking, as such stress concentrations can lead to failure.

ADVERSE EFFECTS: Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur.

Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

STERILITY: The SPL Locking Screw is provided sterile and cannot be re-sterilized. All other Stabiliz Fixation System components are provided non-sterile.

STORAGE INSTRUCTIONS: The SPL Locking Screws should be stored in a dry place at room temperature (60-77 F) and kept away from direct sunlight. Prior to use, inspect product package for signs of tampering or water contamination. Do not use if product exposed to temperatures higher than indicated on label. For components provided sterile, use oldest lots first.