STABILIZORTHO

STABILIZ ORTHOPAEDICS
574 WHARTON BLVD., EXTON, PA 19341

STABILIZ FIXATION SYSTEM
INSTRUCTIONS FOR USE

STABILIZ ORTHOPAEDICS – FIXATION SYSTEM
FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

INDICATIONS: The Stabiliz Fixation System is intended for fixation of fractures, osteotomies and nonunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula. 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.

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.

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 device is not designed to withstand the stress of full weight bearing or excessive activity. Damages to the plate from repeated 03bending 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.

It is especially important when using an SPL Locking Screw that the plate be contoured and compressed flush with the bone. 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.

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, 04 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 05 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: Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering or water contamination. For components provided sterile, use oldest lots first.

Pre-Vacuum	**Minimum Exposure Time**	**4 minutes**
	Minimum Temperature	**270˚ F (132˚ C)**
	Minimum Drying Time[1]	**30 minutes**

[1]Drying times may vary. The processor must validate the appropriate drying time for the sterilizer used.

The above recommended process parameters have been validated by the manufacturer for sterilization of this device only in its complete medical device case/tray. Instruments should be sterilized in the mounting configuration provided in the tray. The recommended parameters are not valid and the processor must establish new parameters if other products are added to the sterilizer.

Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches, or containers) should be used for packaging these sterilized devices.

The processor must be responsible to:
- Follow ANSI/AAMI ST77, ANSI/AAMI ST79, ANSI/AAMI ST81
- Follow the manufacturer's operating instructions and maximum load instructions.
- Ensure that sterilizer is properly installed, maintained, and calibrated.
- Perform ongoing testing to confirm inactivation of all forms of viable microorganisms.
- Validate that the processing achieves the desired result.

Any deviation by the processor from the recommendations provided must be properly evaluated for effectiveness and potential adverse consequences.