Stratum™

Foot Plating System

SYMBOL LEGEND LOCATED AT END OF DOCUMENT

Instructions for Use
Stratum™ Foot Plating System
Sterile Implants and Instruments

Please read this information carefully before using the Stratum™ Foot Plating System

DESCRIPTION

The Stratum™ Foot Plating System consists of a multi-component bone fixation implant including a plate and non-locking, locking, and/or multi-directional locking screws. Plates are provided sterile. Screws are provided in sterile and non-sterile versions. The system also includes a sterile set of accessory instruments and indivually packaged drill bits designed for preparation of the implant site and insertion of devices into the bone. The plates, sterile screws, instrument kits, and drill bits are all packaged individually in separate sterile packaging. Instructions for Use for the non-sterile screws are provided in IFU-1399.

SYSTEM COMPONENTS:

STRATUM™ Plate
Implantable Ti-6Al-4V ELI

STRATUM™ Locking Screw
STRATUM™ Non-Locking Screw
Implantable Ti-6Al-4V ELI

STRATUM™ MDS Screw
Implantable Co-Cr-Mo

STRATUM™ Instrument Kit
Stainless Steel (SS), IXEF Polyarylamide (PARA), Polycarbonate, K-Resin

STRATUM™ Drill Bit with Guide
Stainless Steel (SS)

INDICATIONS FOR USE

The Nextremity Solutions Stratum™ Foot Plating System is a plate and screws construct indicated for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments, particularly in osteopenic bone.

CONTRAINDICATIONS

- Patient conditions including insufficient quantity or quality of bone.
- Blood supply limitations and previous or active infections that may inhibit healing.
- Surgical procedures other than for the indications listed.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.

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POTENTIAL ADVERSE EFFECTS

- Infection, deep and superficial, with possible sepsis
- Nerve damage due to surgical trauma
- Loosening or migration of the implant
- Bending or fracture of the implant
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Foreign body reactions, allergies or other reactions to implant materials
- Nonunion or delayed union which may lead to breakage of the implant
- Inadequate healing
- Thrombosis and embolism

PRECAUTIONS

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective surgical technique and implants used. A detailed surgical technique in print and/or electronic formats can be obtained by contacting a Nextremity Solutions™ sales representative or online at www.nextremitysolutions.com/Stratum.
- Surgical instruments and implants may only be used for surgeries for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damage prior to use. In case of the implant or its packaging being damaged or deformed, it is not to be used.
- Only Nextremity Solutions, Inc. specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.
- The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
- Where material sensitivity is suspected, appropriate testing should be performed and sensitivity ruled out prior to implantation.
- The Stratum™ Foot Plating System requires placement of posts, when present on the underside of the plate, as well as fixation screws into bone. For optimum fixation strength, the posts and screws should be fully encapsulated in the bone and plate. The device may be unsuitable for patients with small, thin, bifurcated, split, fractured, or otherwise abnormal bone.
- The Stratum™ Foot Plating System must be used only with the provided insertion instrumentation.
- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.

- This device should only be used by physicians with training in and a thorough understanding of orthopaedic surgery.
- The Stratum™ Foot Plating System is for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE IMPLANTS OR INSTRUMENTS THAT ARE PROVIDED STERILE.
- The Stratum™ Foot Plating System has not been tested to withstand the forces needed for partial or full weight bearing or excessive activity until healing has occurred. The post-op regimen prescribed by the physician should be strictly followed to avoid stresses applied to the implant. Weight-bearing post operatively should be at the discretion of the surgeon.
- A minimum of one screw is to be implanted on each side of the fixation site. Plate posts are not intended to be sole fixation on single side of the fixation site.
- Any decision to remove the device should take into consideration the potential risk to the patient.

WARNINGS

Although the surgeon is the learned intermediary between the company and the patient, the important information conveyed in this document should be conveyed to the patient. The patient must be cautioned about the use, limitations and possible adverse effects of these implants including the potential for these devices failing as a result of loosening, stress, excessive activity, and/or load bearing particularly when the implants experience increased loads due to a delayed union, non-union or incomplete healing. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.

MRI SAFETY INFORMATION

- The Stratum™ Foot Plating System has not-been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration or image artifact in the MRI environment. The safety of the Stratum™ Foot Plating System in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

Warning: The Stratum™ Foot Plating System should only be used with the supplied, dedicated instruments. See the Stratum™ Foot Plating System surgical technique for an illustrated description of the technique.

NOTE: All Alignment Caps and Compression Ramp(s) that are pre-assembled to the plate must be removed during the surgery regardless of whether all slots/screw hole(s) are utilized for screw fixation. DO NOT IMPLANT a Compression Ramp or Alignment Cap.

HOW SUPPLIED

The Stratum™ Foot Plating System sterile plates and sterile screws are individually packaged. A dedicated Stratum™ Foot Plating System Instrument Kit is also sterile packaged. Dedicated drill bit with drill guide, if applicable, is sterile packaged together. The components of the Stratum™ Foot Plating System are for single use only. DO NOT RE-STERILIZE IMPLANTS OR INSTRUMENTS THAT ARE PROVIDED STERILE. DO NOT REUSE. Re-use and

reprocessing (cleaning and resterilization) of a device labeled for single use only may result in the transmission of infectious material from one patient to another or to the user. This could result in serious injury or death. In addition, re-use or reprocessing may weaken or damage the implants and/or instruments, leading to mechanical failure and/or devices not functioning as intended. This could also result in death or serious injury to the patient or user.

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments. Keep away from direct sunlight. Prior to use, inspect product packaging for signs of tampering and/or damage.

PACKAGING AND LABELING

1. Nextremity Solutions devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL LEGEND

Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements			
Symbol	**Symbol Reference No**	**Title of Symbol**	**Description of Symbol**
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.
	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use by date	Indicates the date after which the medical device is not to be used.

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Symbol	Symbol Reference No	Title of Symbol	Description of Symbol
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	5.2.8	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damage or opened.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instruction for use
	5.4.4	Caution	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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Symbol	Symbol Reference No	Title of Symbol	Description of Symbol
Rx only	21 CFR 801.109	The symbol statement for Prescription Device	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109)
CE	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	Conformité Européene or European Conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

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IFU – 1398 Rev 01 CE 0459