Smith+Nephew

LEOS◊
Plating System

The LEOS◊ Plating System Instructions for Use

Indications for use:
The intended use of the LEOS Plating System is to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the following bone plate categories:

I. Mini-frag System:
The LEOS Mini-frag System is indicated for fixation of fractures, osteotomies, nonunions, malunions, replantations, and fusions of short bones and small fragments of bone including, but not limited to, the hand, wrist, foot, and ankle. The mini-frag system is also intended for reduction and stabilization of non-load bearing long bone fragments. The LEOS Mini-frag System is not for Spinal Use.

II. Foot System:
The LEOS Foot System is indicated for fixation of fractures, osteotomies, nonunions, malunions, replantations, and fusions of short bones and small fragments of bone in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) , and long bones and long bone multi-fragments in the foot (Phalanges and Metatarsals)in an adult patient. The LEOS Foot System is not for Spinal Use.

Contraindications Include:
- Infection.
- Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

℞ Federal law restricts this device to sale by or on the order of a physician.

Materials:
The LEOS Plating System plates and screws are manufactured from a Titanium alloy (ASTM F136). The instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899).

Adverse Effects:
In all surgical procedures, the potential for complications and adverse reactions exist. The risks and complications with these implants include:
- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and / or loosening
- Pain, discomfort, or abnormal sensations due to the presence of an implant
- Nerve damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed or nonunion of bone fragments
- Allergic reaction to the implant materials

Warnings & Precautions:
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants must not be re-used or re-sterilized
- Use only Ti-6Al-4V screws with Ti-6Al-4V devices
- Improper insertion of the device during implantation may result in implant loosening or migration
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, nonunion and incomplete healing may occur
- Bending or fracture due to applied excessive stresses and load bearing
- Failure to follow postoperative care instructions may result in post-operative complications or failure of the implant.
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition may occur

MRI Safety Information:
The LEOS Plating System is MR Conditional and may only be in an MR environment under specific conditions. The following tables provide the MR conditions for which the LEOS Plating System may be safely scanned in the MR environment. Failure to adhere to these conditions may result in injury or device malfunction.

The patient should consult with their healthcare provider prior to an MR exam and inform the MRI site personnel that they have an MR Conditional Device during the MR screening prior to MR exam.

An MR Patient Implant Card is available at https://leos-eifu.info. This should be completed using the label of the implanted device and provided to the patient as part of their postoperative care.

MRI Safety Information

MR

A patient with the LEOS Plating System (plate/screw construct) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	LEOS Plating System
Nominal value(s) of Static Magnetic Field (T)	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-received coil
Maximum Whole Body SAR [W/kg]	1.0 W/kg or 2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration - 1.0 W/kg SAR	1.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scans without breaks)
Limits on Scan Duration - 2.0 W/kg SAR	2.0 W/kg whole body average SAR for 7 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) with a 23-minute cooling period between scanning periods for an hour-long scanning session (7-minute scan followed by a 23-minute cooling period, repeated)
MR Image Artifact	The presence of this implant may produce an image artifact of 68 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Instructions for use:
1. Using standard dissection techniques, expose the surgical site.
2. Perform the intended osteotomy or identify the fracture location.
3. After reduction of the fracture, choose the proper plate based on the size and type of indication.
4. Place the plate on the fracture/osteotomy site, fix with k-wires with stop. If forming/bending the plate to fit the anatomy – use the bending irons for preparation of the proper contour. DO NOT REPEATEDLY BEND THE PLATE – as this will cause a weakened fatigue life of the plate.
5. Utilize the drill guide with proper drill according to screws size for angulation into the most secure bone structure. Drill hole for screw. Repeat hole preparation as necessary for proper fixation of the plate.
6. Utilize the depth gauge for proper length of screw in bone anatomy for firm fixation in the opposite bone cortex.
7. Insert desired size screw matching to plate size and bone anatomy. Repeat process on remaining screw(s) with angulation holes – using either locking or standard screws.

8. Remove k-wires with stop. Check plate/screw tightness on bone anatomy fracture/osteotomy site.
9. Using fluoroscopy, confirm the proper plate and screw placement on the bone anatomy. Correct as warranted & re-check.
10. Clean the surrounding area with a pulse lavage.
11. Use the surgeons preferred method for closing the surgical site.

Postoperative Management:
Provide the patient with their completed MR Patient Implant Card.
The patient is allowed to ambulate with weightbearing to tolerance on the operated fracture site within limits imposed by postoperative discomfort. The progression to normal use of the digit or limb is limited only by the persistence of postoperative swelling and discomfort.

CARE AND HANDLING
Certain Smith + Nephew components are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

Limitations on Processing:
Repeated processing has minimal effect on these implant and instruments. End of life is normally determined by wear and damage due to use.

Point of Use:
Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated devices.

Containment and Transportation:
It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning Remove excess soil with a clean, lint-free, disposable, absorbent cloth.

Disassembly of Depth Indicator:

1. Unthread proximal cap counter-clockwise until cap disengages from outer cannula of instrument.
2. Remove cap and inner cannulas from outer cannula.
3. Proceed to cleaning steps below.

The depth indicator is intended to be cleaned, sterilized, and stored disassembled. For assembly instructions, refer to the Assembly of Depth Indicator section.

Cleaning (Automated):
Equipment: Automated washer, soft bristle brush, enzymatic detergent, and neutral pH detergent.

- Preclean the devices by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other - load devices in such a way that the parts can drain.
- At a minimum, use a cycle meeting the following parameters.

Enzyme Wash	Hot (40 - 65 ℃) (104 - 149 ℉) for 3 minutes
Neutral pH Wash	60 ℃ (140 ℉) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 ℃ (194 ℉) for 1 minute
Dry	82 ℃ (180 ℉) for 6 minutes

- Determine if the devices are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace devices that cannot be cleaned.

Cleaning (Manual):
Warning: Movable components and blind holes require particular attention during cleaning.
Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the devices by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- Bathe the devices in the enzymatic solution for 5 minutes; where appropriate, the device shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the devices with a soft bristle brush while submerged in the detergent.
- Rinse the devices using reverse osmosis or distilled water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check devices for complete removal of any debris. If necessary, repeat manual cleaning. Replace devices that cannot be cleaned.

Assembly of Depth Indicator:

1. Insert inner piece into the outer body.
2. Place cap on outer body and rotate clockwise until cap is fully seated.

Inspection and Function Testing:
Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.
Check for staining, discoloration, corrosion, misalignment, burrs, bent or fractured tips.
Mechanically test the working parts to verify that each instrument functions correctly. Replace any device that is not functioning.
Verify the legibility of all markings. Replace any device that is unreadable.
Repeat cleaning and/or replace the affected devices as needed to ensure proper operation before proceeding to sterilization.

Packaging:
devices may be loaded into the specified LEOS instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared for pre-vacuum steam sterilization.

Sterilization:
For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Smith + Nephew.
WARNING: Please note that a single use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

If not specifically labeled STERILE, or if labeled NON-STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: It is not recommended that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, Smith + Nephew recommends the following parameters:

Method	**Time**	**Temper -ature**	**Dry Time**
Pre-vacuum	4 minutes	270° F (132° C)	20 minutes
	3 minutes	275° F (135° C)	
Gravity	15 minutes	270° F (132° C)	20 minutes

It is recommended to follow ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and

external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Storage:
LEOS devices must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Smith + Nephew customer service for return of removed implants.

DISPOSAL
Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the LEOS◇ Plating System.

FOR FURTHER INFORMATION
For further information regarding the LEOS Plating System, contact Customer Service at +1 800 238 7538 for calls within the continental USA and +1 901 396 2121 for international calls.

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Symbols Glossary		
Symbol	**Title/ Standard**	**Meaning**
Rx only	21 CFR 801.109b Prescription Only	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
REF	ISO 15223-1 5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified
LOT	ISO 15223-1 5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
MATL	Material	Indicates the material of the device
CC	ISO 15223-1 5.1.11 Country of manufacture	To identify the country of manufacture of products
	ISO 15223-1 5.1.4 Use-by date	Indicates the date after which the medical device is not to be used
QTY	Quantity	Indicates the quantity of devices
	ISO 15223-1 5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use
NON STERILE	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 5.1.9 Distributor	Indicates the entity distributing the medical device into the locale
	ISO 15223-1 5.1.1 Manufacturer	Indicates the *medical device manufacturer*
MD	ISO 15223-1 5.7.7 Medical Device Symbol	Indicates that the item is a medical device
UDI	ISO 15223-1 5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information
MR	ASTM F2503	Indicates that the device is MR Conditional and can be used in the MRI environment provided certain strict conditions are followed.
	ISO 15223-1 5.7.3 Patient Identification	Indicates the identification data of the patient.
	ISO 15223-1 5.7.4 Patient Information Website	Indicates a website where a patient can obtain additional information on the medical product
	ISO 15223-1 5.7.5 Health Care Centre or Doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found
31	ISO 15223-1 5.7.6 Date	Indicates the date that information was entered or a medical procedure took place