Smith+Nephew

The LEOS◊ Cannulated Screw System Instructions for Use

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

DESCRIPTION OF THE MEDICAL DEVICE

The implants – delivered non-sterile – are:

- Trauma Screws existing in different diameters and lengths
- Screws having a recess for engaging a driver
- Screws designed to be implanted into bone

The implants are made out of Titanium alloy within the frame of the standard NF ISO 5832-3 and ASTM F136.

INDICATIONS FOR USE

The LEOS◊ Cannulated Screw System implants are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

MATERIAL

The LEOS◊ Cannulated Screw System implants are manufactured from a Titanium alloy (ISO 5832-3 and ASTM F136). The specialized instruments are made of surgical grade stainless steel (ISO 7153-I and ASTM F899).

HOW SUPPLIED

The LEOS◊ Cannulated Screw System implants are delivered **non-sterile** as specified by the packaging.

The LEOS◊ Cannulated Screw System instruments are provided **non-sterile** as specified by the packaging. **Non-sterile** instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

WARNINGS and POTENTIAL RISKS

The LEOS◊ Cannulated Screw System implants are designed for **single patient use only and must never be reused.** As with all other orthopedic implants, the LEOS◊ Cannulated Screw System components should never be re-implanted under any circumstances.

The LEOS◊ Cannulated Screw System implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis; demonstrates physiological or anatomical anomalies; has immunological responses, sensitization, or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery, and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of screw systems should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized.

The LEOS◊ Cannulated Screw System should never be used with dissimilar materials.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans, and other radiological studies. Only patients that meet the criteria described in the INDICATIONS FOR USE section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation, and/or degree of physical activity should be considered.

Note: This system includes an optional washer that should only be used with the headed screw and should not be used with the headless screw.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage, and/or fracture of orthopedic prostheses.

IMPORTANT: The guide wires included in the LEOS◊ Cannulated Screw System are not intended as implants. The guide wires are only intended for use as instruments to facilitate screw insertion.

POSSIBLE ADVERSE EFFECTS

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Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation, and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort, or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Non-clinical testing has demonstrated the LEOS◊ Cannulated Screw System implants are MR Conditional. A patient with these devices can be safely scanned in an MRI system meeting the following conditions:

MR

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the LEOS◊ Cannulated Screw System implants are expected to produce a maximum temperature rise of 8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the LEOS◊ Cannulated Screw System implants when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

DIRECTIONS FOR USE

To implant the LEOS◊ Cannulated Screw System implants, use only the specialized LEOS◊ Cannulated Screw System instrumentation. Do not use implants or instruments from any other system or manufacturer.

The LEOS◊ Cannulated Screw System implants are provided non-sterile. The LEOS◊ Cannulated Screw System instruments are provided non- sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document. All The LEOS◊ Cannulated Screw System device system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage, or irregularities. Damaged or broken The LEOS◊ Cannulated Screw System devices must not be used or processed and should be returned to The LEOS◊ Cannulated Screw System for evaluation.

Before using the LEOS◊ Cannulated Screw System for the first time, the surgeon should be thoroughly familiar with the LEOS◊ Cannulated Screw System Surgical Technique Manuals as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all LEOS◊ Cannulated Screw System implants and instruments, please refer to the LEOS◊ Cannulated Screw System Surgical Technique Manuals (available at no charge upon request).

CARE AND HANDLING

LEOS◊ Cannulated Screw Implants and Instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing

Repeated processing has minimal effect on these implants 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 instruments.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Where instruments interface with other devices, disassemble prior to cleaning.

Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush,

enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the instruments 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, (precleaning is not required for implants) place in the automated washer, making sure the samples do not touch each other - load instruments in such a way that the parts can drain.
- Use a standard cycle with the following parameters (at a minimum):

Enzyme Wash	Hot (40 - 65 ºC) (104 - 149 ºF) for 3 minutes
Neutral pH Wash	60 ºC (140 ºF) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 ºC (194 ºF) for 1 minute
Dry	82 ºC (180 ºF) 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.
- Final Rinse shall be performed in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.

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 instruments (precleaning is not required for implants) 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.
- Bathe the instruments or non-sterile implants in the enzymatic solution for 5 minutes; where appropriate, the instrument 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 instruments with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified 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 instruments for complete removal of any debris. If necessary, repeat manual cleaning.

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation.

[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

After Cleaning

Where instruments have been disassembled prior to cleaning, reassemble prior to use.

Maintenance and Repair

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection, and length of operative procedures.

Warning: Do not attempt to repair any Tyber Medical instrument.

If your Tyber Medical instrument requires repair or maintenance, return the instrument in the Tyber Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Tyber Medical, LLC
89 South Commerce Way
Bethlehem, PA 18017
Attn: Tyber Medical Technical Services

Note: Instruments returned to Tyber Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored, or damaged instruments.

Packaging

Instruments may be loaded into the specified LEOS◊ Cannulated Screw System 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 approved for pre-vacuum steam sterilization.

STERILIZATION

Components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: The LEOS◊ Cannulated Screw System does not recommend 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

Smith+Nephew recommends following 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

The LEOS◊ Cannulated Screw System instruments 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 The LEOS◊ Cannulated Screw System customer service for return of removed implants.

CUSTOMER SERVICE

For further information regarding the LEOS◊ Cannulated Screw 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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SYMBOL	MEANING
Rx	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference Number
LOT	Lot Number
MATL	Material
	Date of Manufacture
	Expiration Date
QTY	Quantity
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Consult Instructions for Use
	Caution
	Non-Sterile
DIST. BY	Distributed by
	Manufacturer
UDI	Unique Device Identifier
MR	MR Conditional
MD	Medical Device
	Hazardous Substance