Smith+Nephew

The LEOS◊ Non-Sterile Single-Use K-wire Package Insert

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

DESCRIPTION OF THE MEDICAL DEVICE

The k-wires are provided non-sterile.

INDICATIONS FOR USE

The k-wires are instruments to facilitate screw insertion.

MATERIAL

The K-wires are made of surgical-grade stainless steel (ASTM F138).

HOW SUPPLIED

The k-wires are provided **non-sterile** as specified by the packaging. **Non-sterile** k-wires must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

The k-wires should not be used in a patient who currently has, 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 k-wires are designed for single-use only and must not be reused.
- The k-wires are not intended to be used as implants.

PRECAUTIONS

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

- These k-wires should be used by experienced surgeons only.
- Care should be used in handling and storage of the k-wires. The k-wires should not be scratched or otherwise damaged. K-wires should be protected during storage, especially from corrosive environments.

IMPORTANT: The k-wires are not intended as implants and are only intended as single-use k-wires to facilitate screw insertion.

POSSIBLE ADVERSE EFFECTS

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

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 k-wires;
- 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

The k-wires have not been evaluated for safety and compatibility in the MR environment. The k-wires have not been tested for heating or migration in the MR environment. The safety of the k-wires in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

Refer to an appropriate surgical technique guide for preparation, insertion, and removal of the k-wires.

CARE AND HANDLING

The k-wires 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.

Point of Use

Before being used for the first time, the instructions outlined below should be followed to ensure safe handling of biologically contaminated k-wires.

Preparation for Cleaning

Remove excess soil with a clean, lint-free, disposable, absorbent Kimwipe, cloth, or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the k-wires by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each k-wire for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other - load k-wires 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 k-wires are dry. If they are not dry, dry with a soft, clean, lint-free cloth.
- After drying, check k-wires for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace any device that cannot be cleaned.

Cleaning (Manual)

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 k-wires by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each k-wire for at least one minute.
- Bathe the k-wires in the enzymatic solution for 5 minutes; where appropriate, the k-wire 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 k-wires with a soft bristle brush while submerged in the detergent.
- Rinse the k-wires 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 k-wires for complete removal of any debris. If necessary, repeat manual cleaning. Replace any device that cannot be cleaned.

- [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.

STERILIZATION

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

Warning: It is not recommended that the k-wires be sterilized by Flash, EtO, or Chemical sterilization. When sterilizing multiple k-wires 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

The k-wires 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.

DISPOSAL

Observe internal hospital/institution procedures, practices, and guidelines, and/or government regulations for proper handling of the LEOS◊ Non-Sterile Single-Use K-Wires.

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.

Tyber Medical, LLC
83 S Commerce Way, Suite 310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933
Fax: +1 (866) 889-9914

Smith+Nephew, Inc.
1450 Brooks Road
Memphis, TN 38016 USA

CE 2797
EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
Phone: (+49) 511-6262-8630
Fax: (+49) 511-6262-8633

SYMBOL GLOSSARY

SYMBOL	MEANING
℞	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
	Distributed by
	Manufacturer
UDI	Unique Device Identifier
MD	Medical Device
CE 2797	Indicates device is in conformity with European Device Directive
EC REP	Indicates the authorized representative in the European Community/ European Union.

LBL-SN202306 – Rev. B-01 (2025-10-17)