

## IMPORTANT INFORMATION

Please read prior to use.

### ORTHOFIX INC. ISKD™ SYSTEM

#### INTRAMEDULLARY SKELETAL KINETIC DISTRACTOR

(Internal Limb Lengthener)  
RX ONLY



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#### INDICATIONS FOR USE

The ISKD System is intended for limb lengthening of the tibia and femur.

#### DESCRIPTION

The ISKD System is an internal limb lengthening device designed to achieve gradual lengthening of the tibia and femur. The System consists of a telescoping Internal Limb Lengthener, Locking Screws, Instrumentation and an external hand-held Monitor. As the patient performs small rotational oscillations of the limb, the ISKD Internal Limb Lengthener gradually distracts. The rate of distraction can be varied by changing the patient's activity level or by manually manipulating the limb. The hand held Monitor contains a magnetic sensor that detects the small magnet sealed inside the Lengthener. As the Lengthener distracts, the magnet inside rotates. When positioned correctly over the magnet, the Monitor tracks and records the poles of the magnet; then converts pole changes into millimeters of distraction. With the ISKD System, both the physician and patient can regularly monitor the amount of distraction achieved.

Proper preoperative planning is essential to the successful use of the ISKD System. Please refer to the appropriate Operative Technique for instructions regarding X-ray technique, limb measurement, proper ISKD implant selection, etc.

Refer to the ISKD Monitor Manual for instructions concerning the use of the Monitor.

#### CONTRAINDICATIONS

- Cases in which there is an active infection or irregular bone diameter that would prevent the insertion of the ISKD Internal Limb Lengthener.
- Cases in which the ISKD Internal Limb Lengthener would cross joint spaces or open epiphyseal growth plates such as in skeletally immature patients.
- Cases in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
- Patients with poor bone quality or metabolic bone disorders such as severe osteopenia, osteoporosis, osteomyelitis, poorly controlled diabetes mellitus, Paget's disease, etc.
- Patients with malignancy or tumor of the bone to be lengthened.
- Patients unwilling or incapable of following postoperative care instructions.
- Cases requiring the use of magnetic resonance imaging (i.e., MRI) while the ISKD Internal Limb Lengthener is implanted. **Do Not Subject Patients Implanted with an ISKD Internal Limb Lengthener to MRI.**

#### WARNINGS

- The ISKD Internal Limb Lengthener and Locking Screw assembly cannot withstand the stresses of full weight bearing. The patient should utilize external support and/or restrict activities until consolidation occurs.
- Use of the ISKD System in patients with cardiac pacemakers is not recommended due to the presence of the magnet sealed inside the ISKD Internal Limb Lengthener. It is possible that the limb implanted with an ISKD Lengthener could come in close proximity to the implanted pacemaker.
- Use of the ISKD System in patients with gross obesity is not recommended.
- The ISKD System may not be appropriate for patients with poly-trauma.
- Use of the ISKD System in patients with an active non-union of the tibia or femur is not recommended.
- Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect on the bone regenerate during the lengthening process.

#### PRECAUTIONS

- Examine all ISKD System components carefully PRIOR TO USE to assure proper working condition. If you believe an ISKD System component to be faulty, damaged or suspect DO NOT USE.
- Once implanted, the ISKD Internal Limb Lengthener will not stop distracting until it reaches the length pre-determined by the physician. Refer to the appropriate Operative Technique for instructions regarding X-ray technique, limb measurement, and proper ISKD implant selection.
- It is essential that proper operative technique be followed for ISKD implantation. Refer to the appropriate ISKD Operative Technique.

#### POSSIBLE ADVERSE EFFECTS

- Nerve or vessel damage resulting from insertion in the intramedullary canal.
- Edema or swelling, possible compartment syndrome, wound or bone infection.
- Premature bone consolidation during distraction osteogenesis if lengthening occurs too slowly or a lack of osteogenic distraction if lengthening occurs too rapidly.
- Failure to achieve desired limb length or the potential to over-lengthen.
- Poor quality bone regenerate which fails to consolidate satisfactorily.
- Fracture of regenerate bone.
- Bending or breaking of the Internal Limb Lengthener; loosening, bending or breakage of Locking Screws.
- Reoperation to replace or remove the Internal Limb Lengthener or Locking Screw(s).
- Metal sensitivity.
- Delayed or nonunion at the osteotomy site.
- Pulmonary embolism and thrombophlebitis due to increased intramedullary pressures. These effects may be avoided by venting the intramedullary canal. (See operative techniques)
- Wound hematomas and avascular necrosis.
- Intrinsic risks associated with anesthesia and surgery.
- Risks associated with the lengthening process (e.g., soft tissue tension, muscle tightness, joint stiffness, temporary loss of motion, contracture, loss of alignment or loss of range of motion, etc.).
- Intractable pain.

#### IMPORTANT

A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure that require surgical re-intervention to remove or replace the Lengthener or Locking Screws. Proper implant and patient selection and the patient's ability to comply with postoperative care instructions will greatly affect the results.

#### MATERIALS

The ISKD Internal Limb Lengthener and Locking Screws are made from implant grade titanium alloy. The ISKD Instruments are comprised of medical grade stainless steel.

#### STERILITY

The ISKD Internal Limb Lengthener and Locking Screws are provided STERILE. Sterilization is achieved by exposure to ethylene oxide gas. Contents of package(s) are STERILE unless opened or damaged. DO NOT USE if packaging is opened or damaged.

The ISKD Internal Limb Lengthener and Locking Screws are intended for **SINGLE USE ONLY**.

**NOTE: The ISKD Internal Limb Lengthener has many small spaces that cannot be adequately cleaned after exposure to tissue or blood. ANY exposure, including partial insertion, will result in contamination of the device.**

The ISKD Instrumentation is provided NON-STERILE. Sterilization is required prior to use.

The recommended validated sterilization cycle is:

Methods	Cycle	Temperature	Exposure Time
Steam	Pre-Vacuum	132°- 135°C [270° - 275°F]	Minimum 10 minutes

Validation and routine monitoring should be performed as per AAMI recommended practice ANSI/AAMI ST46, "Good Hospital Practice: steam sterilization and sterility assurance" and AAMI (ANSI) standard ST19, "Biological indicators for saturated steam sterilization processes in health care facilities". Other cycles may be used as long as they comply with the above practices and provide a sterility assurance level of 10<sup>-6</sup>.

#### SERVICE

Contact Orthofix at 800-266-3349 or 469-742-8801 for return goods authorization or . If outside the U.S.A. contact your local distributor. Please note that alterations, repair or modifications of these devices may jeopardize patient safety.

Symbol	Definition
②	Single Use Only
STERILE EO	Sterilized by Ethylene Oxide
LOT	Lot Number
Ref.	Catalog Number
⚠	See Instructions For Use
⌚	Use Before date
T	Titanium and its Alloys
CE	CE Mark
RX Only	Federal (U.S.A) Law restricts this device to sale by or on the order of a physician
⊘	Diameter
→	Length; Range of Lengths