English

Locking Hand Nail System

INSTRUCTIONS FOR USE FOR THE UNITED STATES

℞: For use by physicians only. Federal Law (USA) restricts this device to sale by or on order of a physician.

Failure to follow instructions may lead to patient injury.

This package insert is designed to provide Instructions for Use of the Locking Hand Nailing System.

Description

The Locking Hand Nail System, comprised of single-use, permanent nail and screw implants and an instrumentation platform, is designed for minimally invasive intramedullary fracture fixation of the metacarpals and proximal phalanges. The nails offer added stability for rotationally and axially unstable fracture patterns through a locking mechanism with two locking compression screws that are placed vertically (from dorsal to volar) at proximal and distal locations of the nail.

In addition, a transfixion screw can be placed in the lateral aspect of the phalanx nail based on localized head fractures. Each metacarpal and phalanx nail includes two additional holes (vertically oriented) for temporary K-Wire fixation. The implants interface with instrumentation which helps guide insertion and reduce user error.

The Locking Hand Nail System contains:

- Titanium alloy intramedullary nails and screws, color anodized
- Cobalt-chrome (Co-Cr) locking compression and transfixion screws
- System specific instrumentation

The system is provided non-sterile and is sterilized in the user facility.

Indications

The Skeletal Dynamics Locking Hand Nail System is indicated for the fixation of extra-articular fractures of the long bones of the hand, including the metacarpals and the proximal phalanges.

Contraindications

The Locking Hand Nail System should not be used if the following are present: active or latent infection, insufficient quantity or quality of bone and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following post-operative care instructions. The Locking Hand Nail System should not be used for fractures with inadequate sizing for fixation or for intra-articular fractures.

Warnings and Precautions

- DO NOT mix system specific instrumentation from different systems or manufacturers for metallurgical, biomechanical and functional reasons.
- The information in this document should be shared with the patient.
- The patient must be cautioned about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the implant, and associated instruments.

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- Failure to carefully follow the Surgical Technique Guide may result in a delay in the surgical procedure, injury to the patient, and/or an ineffective treatment.
- Before using the system, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department.
- Do NOT use open or damaged packages.
- Protect the system's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Instruments should be assembled and used according to the Surgical Technique Guide to prevent user error, device misuse, surgical complications, and/or postoperative complications.
- Reusable components should be sterilized prior to and after use to prevent immunogenicity.
- The use of power tools for the installation of the screws is not recommended and may lead to cross threading and damage to the screws and/or the intramedullary nails.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are only intended to be used during provisional fixation.
- DO NOT use screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- Exercise care not to entangle or rupture any tendons or muscles during the procedure. Tissue and/or tendons may need to be split or retracted to avoid these complications and for access to the bone. Therefore, the use of power tools for reaming is not recommended.
- Do not use Awl under power, use the provided manual handle.
- Do not ream under power, use the provided manual handle. Use caution and an oscillatory hand motion to protect nearby soft tissue and tendons.
- Failure to re-tighten Drill Guide Locking Screw after Hand Nail insertion with Drill Guide may compromise guidance.
- Ensure K-Wires being inserted are not bent and those installed with the Drill Guide are inserted perpendicular with respect to the entry surface of Drill Guide Assembly. Do not flex/bend K-Wires from any side when inserting and targeting Hand Nail hole as this may compromise K-Wire alignment into Hand Nail hole.
- Ensure with fluoroscopy that K-Wires are placed into corresponding Nail holes before inserting screws.
- Ensure with fluoroscopy that all Locking Compression Screws are threaded into the nail.
- Ensure with fluoroscopy that all Phalanx Coronal Transfixion Screws (if necessary) are bicortical and pass through the nail.
- To maintain traceability of the system's implantable components, record each of the respective components lot numbers in the patient records post implantation.
- Use of the implants past the medullary canal in the epiphysis may impair bone growth in pediatric patients.
- Both Locking Compression Screws and Phalanx Coronal Transfixion Screws must be implanted and fully tightened into the Hand Nail to maintain the integrity and strength of the finished device. If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Non-reusable components and instruments should be discarded after use so that compromised material is not used in future procedures.
- DO NOT re-sterilize, reprocess, or reuse implantable components. The device is intended for single use, and non-adherence may result in device failure and/or injury to the patient. Reuse, reprocess or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including the transmission of infectious disease(s) from one patient to another.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures.

- Potential construct failures such as implant breakage, loosening, fixation failure, instability, delayed soft tissue healing, soft tissue irritation, delayed union, or non-union may occur as a result of noncompliance to post-operative rehabilitation, excessive activities, or construct overloading.
- Avoid weight bearing or other stress bearing at the fracture fixation site until healing is confirmed.
- The device is not designed to withstand the stress of excessive weight bearing, load bearing, or physical activity. Improper application of the device during implantation may also increase the possibility of loosening, or migration.
- The patient must be informed about the importance of following the post-operative rehabilitation procedures and instructions prescribed in order to fully understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- Seek medical help immediately if implant malfunctions.

Potential Adverse Effects

The following are potential risks that have been associated with hand surgery: infection, nonunion, persistent pain, stiffness of the fingers, loosening or migration of the implants resulting in misalignment.

MRI Safety Information

The devices included in the Locking Hand Nail System have not been evaluated for safety and compatibility in the MRI environment. They have not been tested for heating, migration, or image artifact in the MRI environment. The safety of the Locking Hand Nail System in the MRI environment is unknown. Scanning a patient who has this device implanted may result in patient injury.

Directions for Use

The Locking Hand Nail System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the Locking Hand Nail System based on their clinical experiences.

Please refer to the Locking Hand Nail System's Surgical Technique Guide to review the surgical approach as described by Jorge L. Orbay, M.D. of the Miami Hand and Upper Extremity Institute located in Miami, Florida, USA.

Cleaning, Sterilization, and Inspection

Instructions on cleaning, disinfection, sterilization and inspection of the Locking Hand Nail System products are located within the cleaning and sterilization instructions for use (IFU-04056-00). The recommended disassembly instructions are set forth below. Refer to the Locking Hand Nailing System Surgical Technique Guide (MKT-00193-00) for proper kitted tray arrangement.

1. Completely disassemble all removable components from the Metacarpal and Phalanx Drill Guides before processing, including K-Wire Drill Sleeves, Locking Screws & Phalanx Transfixion Screw Guide, if used (shown below). Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients.

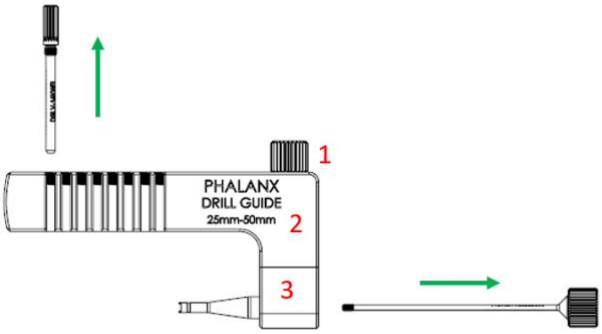

Figure 1: Drill Guide Assembly components for Phalanx and Metacarpal

Note: Phalanx and Metacarpal Drill Guides include a top connecting screw (#1), black plastic (PEEK) component (#2) and bottom metal component (#3), that should not be disassembled. Any remaining instruments, as shown, should not be assembled to Drill Guide and must be removed before cleaning & sterilization. See Figure 1.

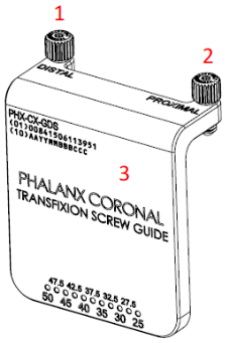

Figure 2: Phalanx Transfixion Screw Guide with non-removable screws

Note: Phalanx Transfixion Screw Guide include two top connecting screws (#1 & #2) that are not removable (captured screws) from the black plastic (PEEK) component (#3) and therefore, should remain assembled to Guide as shown. See Figure 2.

2. Visual Inspection Criteria: Once all components have been disassembled, a visual inspection for wear and tear should be conducted on the following:
    a) Drill Guide mating feature: Key tabs must be free from wear and not deformed. Cannula must be clear and free of debris. See Figure 3.

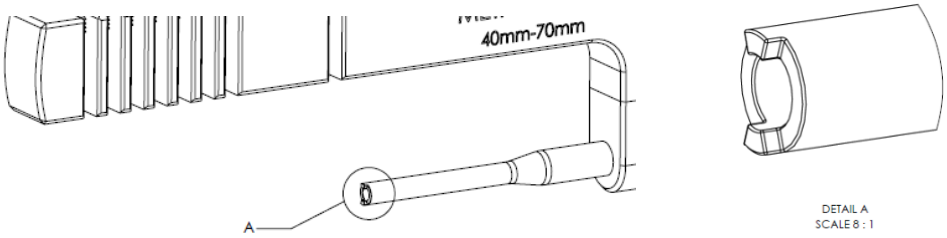

Figure 3: Drill Guide mating feature

    b) Drill Guide Locking Screw: Threads must be free from wear, not deformed or cross threaded. The shaft of the screw must not be bent. See Figure 4.

Figure 4: Drill Guide Locking Screw

c) Drill Guide Threads/ K-Wire Sleeve/ Drill Sleeve: Threads & Cannulas must be free of debris

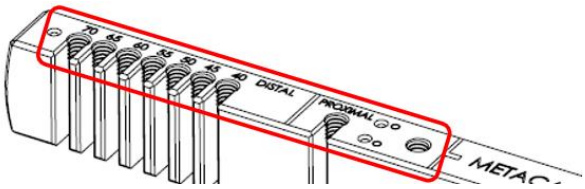

Figure 5: Instruments for Drill Guide

Resources

The latest version of the Instructions for Use may be requested in a physical format by email (orders@skeletaldynamics.com) or by phone (+1-877-753-5396). The physical copy will be provided within 7 calendar days of receiving a request from the user or at the time of delivery of the device, if so, requested at the time of order.

For the most current instructions for use visit www.skeletaldynamics.com/resources. Instructions for Use should always be reviewed before using or implanting a device.

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EC REP
Emergo Europe
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The Netherlands

NON STERILE

MD

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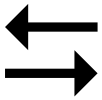
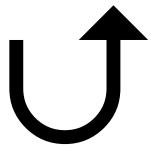
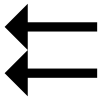
SYMBOLS GLOSSARY

Symbols that follow BS EN ISO 15223-1 / Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Symbol Reference Number and Title	Description
	5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.1.6 Catalogue number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use
	5.1.5 Batch code	Indicates the manufacturer's batch code or lot can be identified
	5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured

	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.1.2 Authorized representative in the European Community	Indicates the authorized representative in the European union. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol
	5.2.8 Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information

Locking Hand Nail System
Inventory Control Sheet

3.0mm Phalanx Intramedullary Nails	
Phalanx Intramedullary Nail, 3.0mm x 22.5mm, Ti IHFN-PHX-30022 (01)00841506142784 (01) 00841506142784	Phalanx Intramedullary Nail, 3.0mm x 37.5mm, Ti IHFN-PHX-30037 (01)00841506131795 (01) 00841506131795
Phalanx Intramedullary Nail, 3.0mm x 25mm, Ti IHFN-PHX-30025 (01)00841506113210 (01) 00841506113210	Phalanx Intramedullary Nail, 3.0mm x 40mm, Ti IHFN-PHX-30040 (01)00841506113241 (01) 00841506113241
Phalanx Intramedullary Nail, 3.0mm x 27.5mm, Ti IHFN-PHX-30027 (01)00841506131771 (01) 00841506131771	Phalanx Intramedullary Nail, 3.0mm x 42.5mm, Ti IHFN-PHX-30042 (01)00841506131801 (01) 00841506131801
Phalanx Intramedullary Nail, 3.0mm x 30mm. Ti IHFN-PHX-30030 (01)00841506113227 (01) 00841506113227	Phalanx Intramedullary Nail, 3.0mm x 45mm. Ti IHFN-PHX-30045 (01)00841506113258 (01) 00841506113258
Phalanx Intramedullary Nail, 3.0mm x 32.5mm, Ti IHFN-PHX-30032 (01)00841506131788 (01) 00841506131788	Phalanx Intramedullary Nail, 3.0mm x 47.5mm, Ti IHFN-PHX-30047 (01)00841506131818 (01) 00841506131818
Phalanx Intramedullary Nail, 3.0mm x 35mm, Ti IHFN-PHX-30035 (01)00841506113234 (01) 00841506113234	Phalanx Intramedullary Nail, 3.0mm x 50mm, Ti IHFN-PHX-30050 (01)00841506113265 (01) 00841506113265
Metacarpal Intramedullary Nails	
3.0mm Metacarpal Intramedullary Nail	
Metacarpal Intramedullary Nail, 3.0mm x 40mm, Ti IHFN-MC-30040 (01)00841506114736 (01) 00841506114736	Metacarpal Intramedullary Nail, 3.0mm x 60mm, Ti IHFN-MC-30060 (01)00841506113081 (01) 00841506113081
Metacarpal Intramedullary Nail, 3.0mm x 45mm, Ti IHFN-MC-30045 (01)00841506114743 (01) 00841506114743	Metacarpal Intramedullary Nail, 3.0mm x 65mm, Ti IHFN-MC-30065 (01)00841506113098 (01) 00841506113098
Metacarpal Intramedullary Nail, 3.0mm x 50mm. Ti IHFN-MC-30050 (01)00841506113067 (01) 00841506113067	Metacarpal Intramedullary Nail, 3.0mm x 70mm. Ti IHFN-MC-30070 (01)00841506113104 (01) 00841506113104
Metacarpal Intramedullary Nail, 3.0mm x 55mm, Ti IHFN-MC-30055 (01)00841506113074 (01) 00841506113074	
3.5mm Metacarpal Intramedullary Nail	
Metacarpal Intramedullary Nail, 3.5mm x 40mm. Ti IHFN-MC-35040 (01)00841506114750 (01) 00841506114750	Metacarpal Intramedullary Nail, 3.5mm x 60mm. Ti IHFN-MC-35060 (01)00841506113135 (01) 00841506113135
Metacarpal Intramedullary Nail, 3.5mm x 45mm, Ti IHFN-MC-35045 (01)00841506114767 (01) 00841506114767	Metacarpal Intramedullary Nail, 3.5mm x 65mm, Ti IHFN-MC-35065 (01)00841506113142 (01) 00841506113142

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Metacarpal Intramedullary Nail, 3.5mm x 50mm, Ti IHFN-MC-35050 (01)00841506113111 (01) 00841506113111	Metacarpal Intramedullary Nail, 3.5mm x 70mm, Ti IHFN-MC-35070 (01)00841506113159 (01) 00841506113159
Metacarpal Intramedullary Nail, 3.5mm x 55mm, Ti IHFN-MC-35055 (01)00841506113128 (01) 00841506113128	
4.0mm Metacarpal Intramedullary Nail	
Metacarpal Intramedullary Nail, 4.0mm x 40mm, Ti IHFN-MC-40040 (01)00841506114774 (01) 00841506114774	Metacarpal Intramedullary Nail, 4.0mm x 60mm, Ti IHFN-MC-40060 (01)00841506113180 (01) 00841506113180
Metacarpal Intramedullary Nail, 4.0mm x 45mm, Ti IHFN-MC-40045 (01)00841506114781 (01) 00841506114781	Metacarpal Intramedullary Nail, 4.0mm x 65mm, Ti IHFN-MC-40065 (01)00841506113197 (01) 00841506113197
Metacarpal Intramedullary Nail, 4.0mm x 50mm, Ti IHFN-MC-40050 (01)00841506113166 (01) 00841506113166	Metacarpal Intramedullary Nail, 4.0mm x 70mm, Ti IHFN-MC-40070 (01)00841506113203 (01) 00841506113203
Metacarpal Intramedullary Nail, 4.0mm x 55mm, Ti IHFN-MC-40055 (01)00841506113173 (01) 00841506113173	
Locking Compression Screw, 1.8 mm, CoCr	
Locking Compression Screw, 1.8mm x 4.0mm, CoCr CMP-18004-CC (01)00841506140230 (01) 00841506140230	Locking Compression Screw, 1.8mm x 9.0mm, CoCr CMP-18009-CC (01)00841506134956 (01) 00841506134956
Locking Compression Screw, 1.8mm x 5.0mm, CoCr CMP-18005-CC (01)00841506140247 (01) 00841506140247	Locking Compression Screw, 1.8mm x 10.0mm, CoCr CMP-18010-CC (01)00841506134963 (01) 00841506134963
Locking Compression Screw, 1.8mm x 6.0mm, CoCr CMP-18006-CC (01)00841506134925 (01) 00841506134925	Locking Compression Screw, 1.8mm x 11.0mm, CoCr CMP-18011-CC (01)00841506134970 (01) 00841506134970
Locking Compression Screw, 1.8mm x 7.0mm, CoCr CMP-18007-CC (01)00841506134932 (01) 00841506134932	Locking Compression Screw, 1.8mm x 12.0mm, CoCr CMP-18012-CC (01)00841506134987 (01) 00841506134987
Locking Compression Screw, 1.8mm x 8.0mm, CoCr CMP-18008-CC (01)00841506134949 (01) 00841506134949	
Phalanx Coronal Transfixion Screw, 1.5mm, CoCr	
Phalanx Coronal Transfixion Screw, 1.5mm x 6.0mm, CoCr PTS-15006-CC (01)00841506135014 (01) 00841506135014	Phalanx Coronal Transfixion Screw, 1.5mm x 11.0mm, CoCr PTS-15011-CC (01)00841506135069 (01) 00841506135069

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Phalanx Coronal Transfixion Screw, 1.5mm x 7.0mm, CoCr PTS-15007-CC (01)00841506135021 (01) 00841506135021	Phalanx Coronal Transfixion Screw, 1.5mm x 12.0mm, CoCr PTS-15012-CC (01)00841506135076 (01) 00841506135076
Phalanx Coronal Transfixion Screw, 1.5mm x 8.0mm, CoCr PTS-15008-CC (01)00841506135038 (01) 00841506135038	Phalanx Coronal Transfixion Screw, 1.5mm x 14.0mm, CoCr PTS-15014-CC (01)00841506135083 (01) 00841506135083
Phalanx Coronal Transfixion Screw, 1.5mm x 9.0mm, CoCr PTS-15009-CC (01)00841506135045 (01) 00841506135045	Phalanx Coronal Transfixion Screw, 1.5mm x 16.0mm, CoCr PTS-15016-CC (01)00841506135090 (01) 00841506135090
Phalanx Coronal Transfixion Screw, 1.5mm x 10.0mm, CoCr PTS-15010-CC (01)00841506135052 (01) 00841506135052	Phalanx Coronal Transfixion Screw, 1.5mm x 18.0mm, CoCr PTS-15018-CC (01)00841506135106 (01) 00841506135106
Single Use (Disposable) Instruments	
K-Wire, 1.4mm/1.6mm x 171mm, Double Trocar, Stepped KWDT-1416-171 (01)00841506141367 (01) 00841506141367	K-Wire, Single Trocar, 1.4mm x 152mm KWIR-STL-14152 (01)00841506117751 (01) 00841506117751
K-Wire, Single Trocar, Laser, 1.1mm x 127mm KWIR-STL-11127 (01)00841506117768 (01) 00841506117768	
Reusable Instruments	
Drill Adapter Screw SCRW-DRLL-ADP (01)00841506115870 (01) 00841506115870	

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