English

Threaded Hand Nail System

INSTRUCTIONS FOR USE (IFU) FOR THE UNITED KINGDOM & THE EUROPEAN UNION

To ensure use of the most up-to-date revision, refer to www.skeletaldynamics.com/resources/

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

This package insert is designed to provide Instructions for Use of the Threaded Hand Nail System; it is not a reference to surgical techniques. **Failure to follow instructions may lead to patient injury.**

Description

The Threaded Hand Nail System consists of the following threaded nails from medical-grade titanium alloy (ASTM F-136).

- 2.0mm non-cannulated threaded nail: 12mm – 28mm in 2mm increments
- 2.0mm non-cannulated threaded nail: 32mm – 48mm in 4mm increments
- 3.0mm cannulated threaded nail: 20mm – 70mm in 5mm increments
- 3.5mm cannulated threaded nail: 25mm – 70mm in 5mm increments
- 4.5mm cannulated threaded nail: 25mm – 70mm in 5mm increments

The Threaded Hand Nail System includes instrumentation identified for the associated surgical technique. Both the Threaded Hand Nails and instrumentation are provided non-sterile and must be sterilized in the user facility.

Intended Use

The Threaded Hand Nail System is intended for fixation, correction, and stabilization of bones or bone fragments.

Indications

The Skeletal Dynamics Threaded Hand Nail System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized threaded nail.

Contraindications

Prior to using the Threaded Hand Nail System, ensure that none of the following patient conditions are present: active or latent infection, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions. These devices are not intended for threaded nail attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Intended Patient Population

The Threaded Hand Nail System is intended for skeletally mature patients. The system should not be used in pediatric patients or patients with open growth plates.

Intended User

The Threaded Hand Nail System should only be used by surgeons familiar with this system and by facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness of using the Threaded Hand Nail System based on their clinical experience.

Expected Clinical Benefits

The expected clinical benefit of Threaded Hand Nails, when used according to instructions for use and recommended technique, is the achievement of stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-02868-32) can be found at the following link:
http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched. The summary of safety and clinical performance is available upon request. Please refer to the resources section for further information.

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Performance Characteristics of the Device

Skeletal Dynamics has established the performance and safety of the Threaded Hand Nailing System, and that they represent state-of-the-art medical devices intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies. Refer to the section Inventory Control Sheet in the scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

Device Lifetime

The expected functional lifetime of the Threaded Hand Nail is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 2-3 months in 99% of cases. The post-therapeutic lifetime of the implant is the remaining lifetime of the patient following bone consolidation. Patient factors such as weight, bone quality, activity level, and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopedic device**.**

⚠ General Warnings and Precautions

- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, malunion, non-union, device or treatment failure as a result of loose fixation and/or 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.
- The patient should be informed about the importance of following the prescribed post-operative rehabilitation protocol and to 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.
- For safe, effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the Threaded Hand Nail System may include delayed union, malunion, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading, or noncompliance with postoperative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening or migration.
- DO NOT reuse any of the Threaded Hand Nail System’s implantable components. Reuse may compromise the structural integrity of the threaded nail and/or lead to failure, which may result in patient injury.
- Protect the System’s implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Threaded Hand Nail 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 permanently implant the Skeletal Dynamics K-Wires; they are only intended to be used for provisional fixation and guidance.
- Do not mix implant components from different manufacturers for metallurgical, biomechanical, and functional reasons.
- DO NOT use threaded nail lengths that will excessively protrude through the far cortex, as it may result in soft tissue irritation or joint damage.
- 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. **Note:** To maintain traceability of the implantable components, record each component's Lot number in the patient records post-implantation.

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MR Safety Information

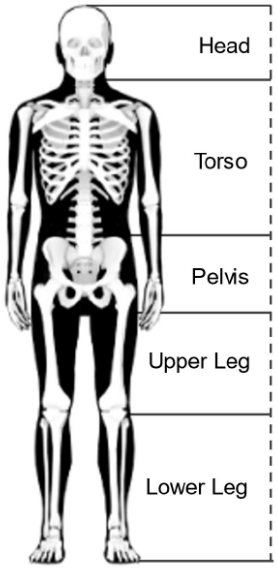
A person with the Skeletal Dynamics' Upper Extremity Systems may be safely scanned at 1.5 T or 3 T under the following conditions. MR examinations may only be performed on the upper extremities. MR use on any other anatomical region has not been evaluated and may present additional risks. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Skeletal Dynamics' Upper Extremity Systems
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**1.5 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 6.1$ µT) for up to one hour - Lower leg region: Normal Operating Mode for up to one hour **3 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 3.1$ µT) for 6 minutes of scanning, followed by a minimum cooling period of 15 minutes, up to a maximum total scanning/cooling duration of one hour - Lower leg region: Normal Operating Mode for up to one hour
Scan duration	Scan duration as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Scan Regions	Landmark restrictions as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Image Artifact	The presence of Skeletal Dynamics' Upper Extremity Systems may produce an image artifact of 5.1 cm. Some manipulation of scan parameters may be needed to compensate for the artifact
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

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MR Restricted Zone Summary

Skeletal Dynamics' Upper Extremity Systems



Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
Head	Normal Operating Mode*	Normal Operating Mode*
Torso	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 6.1$ µT	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 3.1$ µT for 6 minutes of scanning followed by a minimum cooling period of 15 minutes
Pelvis		
Upper Leg		
Lower Leg	Normal Operating Mode*	Normal Operating Mode*

Under these conditions, total scanning duration for up to one hour is permitted unless otherwise specified. When a cooling period is recommended, repeated scan/cool sequences are permitted for a total duration of up to one hour. Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate
SAR_{head}: Head averaged specific absorption rate
$B_{1+,RMS}$: RMS RF magnetic field (B_{1+})

**Normal Operating Mode limits defined by IEC 60601-2-33 Table 201.104:*
- *SAR_{wb}: 2 W/kg*
- *SAR_{head}: 3.2 W/kg*

Potential Adverse Events

Possible adverse effects associated with Threaded Hand Nails include infection, inflammation, pain, stiffness, discomfort, and nerve, joint, or soft-tissue damage from the implant or surgical trauma. The implant may break or bend due to excessive activity, prolonged loading, incomplete healing, or excessive force during insertion. It may also loosen or migrate, resulting in misalignment. Metal sensitivity, histological, allergic, or adverse foreign-body reaction resulting from implantation of a foreign material may occur. Side effects of using the implant may include cosmetic concerns of plate prominence and wound scarring. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.

Directions for Use

The Threaded Hand Nail System should be used only by surgeons who are familiar with this system. Each surgeon must evaluate the appropriateness of using the Threaded Hand Nail System based on their clinical experience.

The surgeon should select the type and size of implant that best meets the patient's needs. Although the surgeon is the medical intermediary between the company and the patient, this document contains important medical information that should be shared with the patient.

It is the surgeon's responsibility to be familiar with the procedure before using this device. Additionally, it is the surgeon's responsibility to be familiar with relevant publications on the procedure prior to its use. Please refer to the ***Threaded Hand Nail System Surgical Technique Guide*** (MKT-00297-00) to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

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Implant Removal

In case the physician decides to remove the implants, implants can be removed by using general surgical instruments.

Disposal

Any Skeletal Dynamics implant that has been contaminated with blood, tissue, or other bodily fluids/matter should never be used again and should be handled in accordance with hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of Threaded Hand Nail System products are provided in the Reprocessing IFU, ***Instructions for Reprocessing (Cleaning, Disinfection, and Sterilization) of Skeletal Dynamics Products*** **(IFU-04056-00),** available at www.skeletaldynamics.com/resources. Please refer to the ***Threaded Hand Nail System Surgical Technique Guide*** (MKT-00297-00) for the proper kitted tray configuration.

Resources

The latest version of the Instructions for Use or Summary of Safety and Clinical Performance 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.

Implant Materials

The Threaded Hand Nail System consists of several titanium-alloy implantable screws commonly used in surgical implants.

Basic UDI Code	Basic UDI #s	System Components	Material(s)	Standard(s)
THN-FAM-TI	08415061320158	Threaded Hand Nail Screws	Ti 6Al-4V ELI	ASTM F136

The titanium alloy implants conform to ASTM F136, which provides the following tolerances for the material:

ASTM F136 Chemical Composition

ement	Composition % (mass)
Nitrogen, Ni	≤ .05%
Carbon	≤ .08%
Hydrogen	≤ .015%
Iron	≤ .25%
Oxygen	≤ .13%
Aluminum	≤ 6.5%
Vanadium	≤ 4.5%
Titanium	balance*

*the percentage of Titanium is determined by the difference and is not determined or certified.

Disclaimer of Warranty and Limited Remedies

Skeletal Dynamics, Inc. makes no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the product(s) described in this publication. Skeletal Dynamics, Inc. shall not be liable under any circumstances for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has authority to bind Skeletal Dynamics, Inc. to any representation or warranty except as specifically set forth in this publication. Descriptions or specifications provided by Skeletal Dynamics, Inc. in any publication are only included to generally describe the product when manufactured and do not constitute any express warranties.

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United Kingdom

NON STERILE MD CE 2797

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Threaded Hand Nail System
Inventory Control Sheet

2.0mm Threaded Hand Nail	
Threaded Hand Nail, 2.0mm x 12mm, Ti RHS-20012 (01)00841506134062	Threaded Hand Nail, 2.0mm x 26mm, Ti RHS-20026 (01)00841506134123
Threaded Hand Nail, 2.0mm x 14mm, Ti RHS-20014 (01)00841506134079	Threaded Hand Nail, 2.0mm x 28mm, Ti RHS-20028 (01) 00841506117393
Threaded Hand Nail, 2.0mm x 16mm, Ti RHS-20016 (01)00841506134086	Threaded Hand Nail, 2.0mm x 32mm, Ti RHS-20032 (01)00841506117409
Threaded Hand Nail, 2.0mm x 18mm, Ti RHS-20018 (01)00841506134093	Threaded Hand Nail, 2.0mm x 36mm, Ti RHS-20036 (01)00841506117416
Threaded Hand Nail, 2.0mm x 20mm, Ti RHS-20020 (01)00841506134109	Threaded Hand Nail, 2.0mm x 40mm, Ti RHS-20040 (01)00841506117423
Threaded Hand Nail, 2.0mm x 22mm, Ti RHS-20022 (01)00841506134116	Threaded Hand Nail, 2.0mm x 44mm, Ti RHS-20044 (01)00841506117430
Threaded Hand Nail, 2.0mm x 24mm, Ti RHS-20024 (01)00841506117386	Threaded Hand Nail, 2.0mm x 48mm, Ti RHS-20048 (01)00841506117447
3.0mm Threaded Hand Nail	
Threaded Hand Nail, 3.0 x 20mm, Ti RHS-30020 (01)00841506134314	Threaded Hand Nail, 3.0 x 50mm, Ti RHS-30050 (01)00841506116723
Threaded Hand Nail, 3.0 x 25mm, Ti RHS-30025 (01)00841506116679	Threaded Hand Nail, 3.0 x 55mm, Ti RHS-30055 (01)0 0841506117348
Threaded Hand Nail, 3.0 x 30mm, Ti RHS-30030 (01)00841506116686	Threaded Hand Nail, 3.0 x 60mm, Ti RHS-30060 (01)00841506117355
Threaded Hand Nail, 3.0 x 35mm, Ti RHS-30035 (01)00841506116693	Threaded Hand Nail, 3.0 x 65mm, Ti RHS-30065 (01)00841506117362
Threaded Hand Nail, 3.0 x 40mm, Ti RHS-30040 (01)00841506116709	Threaded Hand Nail, 3.0 x 70mm, Ti RHS-30070 (01)00841506117379
Threaded Hand Nail, 3.0 x 45mm, Ti RHS-30045 (01)00841506116716	

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Threaded Hand Nail System
Inventory Control Sheet

3.5mm Threaded Hand Nail	
Threaded Hand Nail, 3.5 x 25mm, Ti RHS-35025 (01)00841506113494	Threaded Hand Nail, 3.5 x 50mm, Ti RHS-35050 (01)00841506113548
Threaded Hand Nail, 3.5 x 30mm, Ti RHS-35030 (01)00841506113500	Threaded Hand Nail, 3.5 x 55mm, Ti RHS-35055 (01)00841506113555
Threaded Hand Nail, 3.5 x 35mm, Ti RHS-35035 (01)00841506113517	Threaded Hand Nail, 3.5 x 60mm, Ti RHS-35060 (01)00841506113562
Threaded Hand Nail, 3.5 x 40mm, Ti RHS-35040 (01)00841506113524	Threaded Hand Nail, 3.5 x 65mm, Ti RHS-35065 (01)00841506113579
Threaded Hand Nail, 3.5 x 45mm, Ti RHS-35045 (01)00841506113531	Threaded Hand Nail, 3.5 x 70mm, Ti RHS-35070 (01)00841506113586
4.5mm Threaded Hand Nail	
Threaded Hand Nail, 4.5 x 25mm, Ti RHS-40025 (01)00841506116839	Threaded Hand Nail, 4.5 x 50mm, Ti RHS-40050 (01)00841506116884
Threaded Hand Nail, 4.5 x 30mm, Ti RHS-40030 (01)00841506116846	Threaded Hand Nail, 4.5 x 55mm, Ti RHS-40055 (01)00841506116891
Threaded Hand Nail, 4.5 x 35mm, Ti RHS-40035 (01)00841506116853	Threaded Hand Nail, 4.5 x 60mm, Ti RHS-40060 (01)00841506116907
Threaded Hand Nail, 4.5 x 40mm, Ti RHS-40040 (01)00841506116860	Threaded Hand Nail, 4.5 x 65mm, Ti RHS-40065 (01)00841506116914
Threaded Hand Nail, 4.5 x 45mm, Ti RHS-40045 (01)00841506116877	Threaded Hand Nail, 4.5 x 70mm, Ti RHS-40070 (01)00841506116921
Single Use (Disposable) Instruments	
K-Wire, 0.9mm x 152mm, Single Trocar KWIR-ST-09152 (01)00841506115283	K-Wire, HCS, 1.4mm x 203mm, Single Trocar KWIR-ST-14203 (01)00841506116938
K-Wire, 0.9mm x 203mm, Single Trocar KWIR-ST-09203 (01)00841506117553	

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