

## Threaded Hand Nail System

INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

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**R:** For use by physicians only. Federal Law restricts this device to sale by or on the 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 Threaded Hand Nail System.

### **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
- 2.0 cannulated threaded nails: 12mm – 28mm in 2mm increments
- 2.0 cannulated threaded nails: 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.

### **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, sepsis, osteoporosis, 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.

### **⚠ 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, 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, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to post operative 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.
- 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 of the respective components Lot numbers in the patient records post implantation.

### **MR Safety Information**

The Threaded Hand Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Threaded Hand Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

### **Potential Adverse Events**

Possible adverse effects associated with Threaded Hand Nails are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

### **Directions for Use**

The Threaded 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 Threaded Hand Nail System based on their clinical experiences.

The surgeon should select the type and size implant to best meet 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 responsibility of the surgeon to be familiar with the procedure before use of this device. Additionally, it is the responsibility of the surgeon to be familiar with relevant publications regarding the procedure prior to 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.

### **Cleaning, Sterilization, and Inspection**

For instructions on cleaning, disinfection, sterilization and inspection of the Threaded Hand Nailing System products please refer to cleaning and sterilization instructions for use (IFU-04056-00). Refer to the *Threaded Hand Nail Surgical Technique Guide* (MKT-00297-00) for proper kitted tray arrangement.

### **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.

### **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 damage 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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## 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

Symbol	Symbol Reference Number and Title	Description
	<p>5.1.2 Authorized Representative in the European Community</p>	<p>Indicates the authorized representative in the European union. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol</p>
	<p>Authorized Representative in the United Kingdom</p> <p>*Note not found in BS EN ISO 15223-1</p>	<p>Indicates the authorized representative in the United Kingdom. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol</p>
	<p>5.2.8 Do Not Use if Package is Damaged</p>	<p>Indicates a medical device that should not be used if the package has been damaged or opened</p>
	<p>5.1.4 Use-by-date</p>	<p>Indicates the date after which the medical device is not to be used</p>
	<p>5.7.10 Unique Device Identifier</p>	<p>Indicates a carrier that contains unique device identifier information</p>

## Threaded Hand Nail System Inventory Control Sheet

2.0mm Non-Cannulated Threaded Hand Nail	
Threaded Hand Nail, 2.0mm x 12mm, Ti RHS-20012 (01)00841506134062  <small>(01) 00841506134062</small>	Threaded Hand Nail, 2.0mm x 26mm, Ti RHS-20026 (01)00841506134123  <small>(01) 00841506134123</small>
Threaded Hand Nail, 2.0mm x 14mm, Ti RHS-20014 (01)00841506134079  <small>(01) 00841506134079</small>	Threaded Hand Nail, 2.0mm x 28mm, Ti RHS-20028 (01) 00841506117393  <small>(01) 00841506117393</small>
Threaded Hand Nail, 2.0mm x 16mm, Ti RHS-20016 (01)00841506134086  <small>(01) 00841506134086</small>	Threaded Hand Nail, 2.0mm x 32mm, Ti RHS-20032 (01)00841506117409  <small>(01) 00841506117409</small>
Threaded Hand Nail, 2.0mm x 18mm, Ti RHS-20018 (01)00841506134093  <small>(01) 00841506134093</small>	Threaded Hand Nail, 2.0mm x 36mm, Ti RHS-20036 (01 )00841506117416  <small>(01) 00841506117416</small>
Threaded Hand Nail, 2.0mm x 20mm, Ti RHS-20020 (01)00841506134109  <small>(01) 00841506134109</small>	Threaded Hand Nail, 2.0mm x 40mm, Ti RHS-20040 (01)00841506117423  <small>(01) 00841506117423</small>
Threaded Hand Nail, 2.0mm x 22mm, Ti RHS-20022 (01)00841506134116  <small>(01) 00841506134116</small>	Threaded Hand Nail, 2.0mm x 44mm, Ti RHS-20044 (01)00841506117430  <small>(01) 00841506117430</small>
Threaded Hand Nail, 2.0mm x 24mm, Ti RHS-20024 (01)00841506117386  <small>(01) 00841506117386</small>	Threaded Hand Nail, 2.0mm x 48mm, Ti RHS-20048 (01)00841506117447  <small>(01) 00841506117447</small>
2.0mm Cannulated Threaded Hand Nail	
Threaded Hand Nail, 2.0mm x 12mm, Cannulated, Ti RHS-20012C (01)00841506146546  <small>(01) 00841506146546</small>	Threaded Hand Nail, 2.0mm x 26mm, Cannulated, Ti RHS-20026C (01)00841506146614  <small>(01) 00841506146614</small>
Threaded Hand Nail, 2.0mm x 14mm, Cannulated, Ti RHS-20014C (01)00841506146553  <small>(01) 00841506146553</small>	Threaded Hand Nail, 2.0mm x 28mm, Cannulated, Ti RHS-20028C (01)00841506146621  <small>(01) 00841506146621</small>
Threaded Hand Nail, 2.0mm x 16mm, Cannulated, Ti RHS-20016C (01)00841506146560  <small>(01) 00841506146560</small>	Threaded Hand Nail, 2.0mm x 32mm, Cannulated, Ti RHS-20032C (01)00841506146638  <small>(01) 00841506146638</small>
Threaded Hand Nail, 2.0mm x 18mm, Cannulated, Ti RHS-20018C (01)00841506146577  <small>(01) 00841506146577</small>	Threaded Hand Nail, 2.0mm x 36mm, Cannulated, Ti RHS-20036C (01)00841506146645  <small>(01) 00841506146645</small>
Threaded Hand Nail, 2.0mm x 20mm, Cannulated, Ti RHS-20020C (01)00841506146584  <small>(01) 00841506146584</small>	Threaded Hand Nail, 2.0mm x 40mm, Cannulated, Ti RHS-20040C (01)00841506146652  <small>(01) 00841506146652</small>

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Threaded Hand Nail, 2.0mm x 22mm, Cannulated, Ti RHS-20022C (01)00841506146591  (01)00841506146591	Threaded Hand Nail, 2.0mm x 44mm, Cannulated, Ti RHS-20044C (01)00841506146669  (01)00841506146669
Threaded Hand Nail, 2.0mm x 24mm, Cannulated, Ti RHS-20024C (01)00841506146607  (01)00841506146607	Threaded Hand Nail, 2.0mm x 48mm, Cannulated, Ti RHS-20048C (01)00841506146676  (01)00841506146676
<b>3.0mm Cannulated Threaded Hand Nail</b>	
Threaded Hand Nail, 3.0 x 20mm, Ti RHS-30020 (01)00841506134314  (01)00841506134314	Threaded Hand Nail, 3.0 x 50mm, Ti RHS-30050 (01)00841506116723  (01)00841506116723
Threaded Hand Nail, 3.0 x 25mm, Ti RHS-30025 (01)00841506116679  (01)00841506116679	Threaded Hand Nail, 3.0 x 55mm, Ti RHS-30055 (01)00841506117348  (01)00841506117348
Threaded Hand Nail, 3.0 x 30mm, Ti RHS-30030 (01)00841506116686  (01)00841506116686	Threaded Hand Nail, 3.0 x 60mm, Ti RHS-30060 (01)00841506117355  (01)00841506117355
Threaded Hand Nail, 3.0 x 35mm, Ti RHS-30035 (01)00841506116693  (01)00841506116693	Threaded Hand Nail, 3.0 x 65mm, Ti RHS-30065 (01)00841506117362  (01)00841506117362
Threaded Hand Nail, 3.0 x 40mm, Ti RHS-30040 (01)00841506116709  (01)00841506116709	Threaded Hand Nail, 3.0 x 70mm, Ti RHS-30070 (01)00841506117379  (01)00841506117379
Threaded Hand Nail, 3.0 x 45mm, Ti RHS-30045 (01)00841506116716  (01)00841506116716	
<b>3.5mm Cannulated Threaded Hand Nail</b>	
Threaded Hand Nail, 3.5 x 25mm, Ti RHS-35025 (01)00841506113494  (01)00841506113494	Threaded Hand Nail, 3.5 x 50mm, Ti RHS-35050 (01)00841506113548  (01)00841506113548
Threaded Hand Nail, 3.5 x 30mm, Ti RHS-35030 (01)00841506113500  (01)00841506113500	Threaded Hand Nail, 3.5 x 55mm, Ti RHS-35055 (01)00841506113555  (01)00841506113555
Threaded Hand Nail, 3.5 x 35mm, Ti RHS-35035 (01)00841506113517  (01)00841506113517	Threaded Hand Nail, 3.5 x 60mm, Ti RHS-35060 (01)00841506113562  (01)00841506113562
Threaded Hand Nail, 3.5 x 40mm, Ti RHS-35040 (01)00841506113524  (01)00841506113524	Threaded Hand Nail, 3.5 x 65mm, Ti RHS-35065 (01)00841506113579  (01)00841506113579

## Threaded Hand Nail System Inventory Control Sheet

Threaded Hand Nail, 3.5 x 45mm, Ti RHS-35045 (01)00841506113531  (01) 00841506113531	Threaded Hand Nail, 3.5 x 70mm, Ti RHS-35070 (01)00841506113586  (01) 00841506113586
<b>4.5mm Cannulated Threaded Hand Nail</b>	
Threaded Hand Nail, 4.5 x 25mm, Ti RHS-40025 (01)00841506116839  (01) 00841506116839	Threaded Hand Nail, 4.5 x 50mm, Ti RHS-40050 (01)00841506116884  (01) 00841506116884
Threaded Hand Nail, 4.5 x 30mm, Ti RHS-40030 (01)00841506116846  (01) 00841506116846	Threaded Hand Nail, 4.5 x 55mm, Ti RHS-40055 (01)00841506116891  (01) 00841506116891
Threaded Hand Nail, 4.5 x 35mm, Ti RHS-40035 (01)00841506116853  (01) 00841506116853	Threaded Hand Nail, 4.5 x 60mm, Ti RHS-40060 (01)00841506116907  (01) 00841506116907
Threaded Hand Nail, 4.5 x 40mm, Ti RHS-40040 (01)00841506116860  (01) 00841506116860	Threaded Hand Nail, 4.5 x 65mm, Ti RHS-40065 (01)00841506116914  (01) 00841506116914
Threaded Hand Nail, 4.5 x 45mm, Ti RHS-40045 (01)00841506116877  (01) 00841506116877	Threaded Hand Nail, 4.5 x 70mm, Ti RHS-40070 (01)00841506116921  (01) 00841506116921
<b>Single Use (Disposable) Instruments</b>	
K-Wire, 0.9mm x 152mm, Single Trocar KWIR-ST-09152 (01)00841506115283  (01) 00841506115283	K-Wire, HCS, 1.4mm x 203mm, Single Trocar KWIR-ST-14203 (01)00841506116938  (01) 00841506116938
K-Wire, 0.9mm x 203mm, Single Trocar KWIR-ST-09203 (01)00841506117553  (01) 00841506117553	K-Wire, 0.7mm x 152mm, Single Trocar KWIR-ST-07152 (01)00841506141428  (01) 00841506141428
K-Wire, 1.4mm x 171 mm, Double Trocar, 316 LVM KWIR-DT-14171 (01)00841506141060  (01) 00841506141060	