

Threaded Hand Nail System

INSTRUCTIONS FOR USE

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; it is not a reference to surgical techniques.

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.

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.

MRI 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 to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Cleaning

Upon receipt by the user facility, the Threaded Hand Nail System should be cleaned prior to sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Implant Cleaning

Implanted plates, threaded nails, or associated components should never be re-used. After each use, unused implants must be cleaned separately from contaminated instruments to prevent cross-contamination utilizing the cleaning instructions provided below.

Warnings & Precautions

- If the implant has been in contact with the patient, body fluids or tissues or is damaged, it may NOT be reprocessed and MUST be properly discarded.
- Users should wear appropriate personal protective equipment (PPE).
- Users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.

Instrument Cleaning

The Threaded Hand Nail System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- The System's reusable instruments and accessories, including sterilization tray and tray components, should be decontaminated immediately after completion of the surgical procedure. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying.
- Only qualified personnel with documented evidence of training and competency should clean the instruments. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.
- Avoid the use of metal brushes or scouring pads during the cleaning process.
- Instruments should be rinsed of cleaning agents to prevent residue.
- Do not use mineral oil or silicone lubricants on instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear. If the product cannot be cleaned after repeated washing or 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.

Cleaning Instructions

Cleaning should begin at the point of use prior to processing. Keep instruments moist after use to prevent soil from drying on them. An enzymatic detergent (Enzol) was used to validate the cleaning process.

1. Disassemble instrumentation, if applicable.
2. Rinse all components, including instruments, sterilization tray and tray components, thoroughly under running cool tap water. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components.
3. Soak all components in a neutral enzymatic cleaner for a minimum of ten (10) minutes. Components must be fully immersed in the cleaner. Follow the cleaner manufacturer's instructions for cleaner preparation and whenever longer exposure times are recommended.
4. Thoroughly rinse all components with cool water. While rinsing, use soft bristle brushes, pipettes or a water jet to clean out lumens, holes, and other challenging features.
5. Manually scrub all components thoroughly in newly made, clean, neutral pH enzymatic cleaner using soft bristle brushes or pipettes. All lumens, holes, hinged components, mating surfaces, and crevices, and challenging components should be thoroughly scrubbed. Actuate all moveable features and expose all areas to cleaner and to the brush or pipette.
6. Rinse all components thoroughly under reverse osmosis/deionized (RO/DI) water; using pipettes or a water jet to clean out lumens, holes, and other hard to reach or challenging features. Actuate all movable features to fully irrigate all areas.
7. Visually inspect all components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on all components using running RO/DI water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization

The Threaded Hand Nail System is provided non-sterile. This system is intended for steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray. Do not stack trays during sterilization.

2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Times for Dynamic-Air-Removal (Vacuum) Steam Sterilization Cycles

Item	Exposure time at 132°C (270° F)	Minimum Drying Time
Wrapped Sterilization Tray	4 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Immediate-Use Steam Sterilization (IUSS) not recommended.
- Usage of an FDA approved wrap is required.
- Subsequent instrument sterilization needs to be performed in the tray system provided. For reuse and sterilization, instruments should be arranged within the tray system in the manner supplied by the company.

Storage

When not in use, store the clean and disinfected Threaded Hand Nail System within the Sterilization Tray. Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect the instrumentation for serviceability.

Disclaimer of Warranty and Limited Remedies

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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	 (01) 00841506134062	Threaded Hand Nail, 2.0mm x 26mm, Ti RHS-20026 (01)00841506134123	 (01) 00841506134123
Threaded Hand Nail, 2.0mm x 14mm, Ti RHS-20014 (01)00841506134079	 (01) 00841506134079	Threaded Hand Nail, 2.0mm x 28mm, Ti RHS-20028 (01) 00841506117393	 (01) 00841506117393
Threaded Hand Nail, 2.0mm x 16mm, Ti RHS-20016 (01)00841506134086	 (01) 00841506134086	Threaded Hand Nail, 2.0mm x 32mm, Ti RHS-20032 (01)00841506117409	 (01) 00841506117409
Threaded Hand Nail, 2.0mm x 18mm, Ti RHS-20018 (01)00841506134093	 (01) 00841506134093	Threaded Hand Nail, 2.0mm x 36mm, Ti RHS-20036 (01) 00841506117416	 (01) 00841506117416
Threaded Hand Nail, 2.0mm x 20mm, Ti RHS-20020 (01)00841506134109	 (01) 00841506134109	Threaded Hand Nail, 2.0mm x 40mm, Ti RHS-20040 (01)00841506117423	 (01) 00841506117423
Threaded Hand Nail, 2.0mm x 22mm, Ti RHS-20022 (01)00841506134116	 (01) 00841506134116	Threaded Hand Nail, 2.0mm x 44mm, Ti RHS-20044 (01)00841506117430	 (01) 00841506117430
Threaded Hand Nail, 2.0mm x 24mm, Ti RHS-20024 (01)00841506117386	 (01) 00841506117386	Threaded Hand Nail, 2.0mm x 48mm, Ti RHS-20048 (01)00841506117447	 (01) 00841506117447
3.0mm Threaded Hand Nail			
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)0 0841506117348	 (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		

Threaded Hand Nail System

Inventory Control Sheet

3.5mm Threaded Hand Nail			
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, 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
4.5mm Threaded Hand Nail			
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
Single Use (Disposable) Instruments			
K-Wire, 0.9mm x 152mm, Single Trocar KWIR-ST-09152 (01)00841506115283	 (01) 00841506115283	T10 Driver, AO, Cannulated DRVR-CAN-T10 (01)00841506116990	 (01) 00841506116990
K-Wire, 0.9mm x 203mm, Single Trocar KWIR-ST-09203 (01)00841506117553	 (01) 00841506117553	Driver, Universal Quick Connect, T10 DRVR-UQC-T10 (01)00841506101330	 (01) 00841506101330

Threaded Hand Nail System Inventory Control Sheet

K-Wire, HCS, 1.4mm x 203mm, Single Trocar KWIR-ST-14203 (01)00841506116938  (01) 00841506116938	T8 Driver, AO, Cannulated DRVR-CAN-T8 (01)00841506129457  (01) 00841506129457
REDUCT Driver, 2.0 DRVR-HCS-0110 (01)00841506107288  (01) 00841506107288	Driver, Universal QC, T8 DRVR-UQC-T8 (01)00841506129464  (01) 00841506129464

Reusable Instruments	
Handle, Universal QC, Ratcheting HNDL-UQC-RTC (01)00841506106533  (01) 00841506106533	Measurement Ruler MSRT-RL (01)00841506116952  (01) 00841506116952
HCS Wire Pusher HCS-WP (01)00841506105413  (01) 00841506105413	K-Wire Exchanger GDW-EXCH (01)00841506118147  (01) 00841506118147
Depth Gauge, Hand Trauma Threaded Nail, 2.0 DGA-THN-20 (01)00841506134895  (01) 00841506134895	Depth Gauge, Threaded Hand Nails DGA-RHS (01)00841506127910  (01) 00841506127910
Countersink, 3.3mm, Cannulated RHS-CSK-33 (01)00841506129433  (01) 00841506129433	Countersink, 3.8mm, Cannulated RHS-CSK-38 (01)00841506117683  (01) 00841506117683
Reamer, 1.8mm, Cannulated RHS-RMR-18 (01)00841506118109  (01) 00841506118109	Reamer, 2.4mm, Cannulated RHS-RMR-24 (01)00841506129440  (01) 00841506129440
Reamer, 2.7mm, Cannulated RHS-RMR-27 (01)00841506118123  (01) 00841506118123	Reamer, 3.3mm, Cannulated RHS-RMR-33 (01)00841506118130  (01) 00841506118130