

# IMPLATE® Wrist Arthrodesis Nail System

## INSTRUCTIONS FOR USE

**Basic UDI:** 00841506102320

**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 IMPLATE® Wrist Arthrodesis Nail (WAN) System; it is not a reference to surgical techniques.

#### **Description:**

The IMPLATE® WAN System is designed as an intramedullary nailing platform to address wrist arthrodesis procedures utilizing a minimally invasive dorsal approach into the third metacarpal and distal radius by trained physicians. The respective nails are secured within the intramedullary canals by means of unicortical bone screws, and then assembled into a completed construct using a connector and two set screws.

The IMPLATE® WAN System is comprised of:

- Titanium alloy distal radius & metacarpal intramedullary nails (Titanium per ASTM F-136)
- Titanium alloy connectors in various lengths and angles (Titanium per ASTM F-136)
- Titanium alloy unicortical screws (Titanium per ASTM F-136)
- Cobalt chrome set screws (Cobalt Chrome per ASTM F1537)
- System specific instrumentation

**Note:** All references contained in this document pertaining to distal radius nails, metacarpal nails, connectors, set screws, unicortical screws and other instrumentation are specific to the IMPLATE® WAN System by Skeletal Dynamics.

#### **Indications for Use:**

The IMPLATE® WAN System is intended for wrist arthrodesis. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

#### **Contraindications:**

Prior to using the IMPLATE® WAN 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, or patients who are unwilling or incapable of following post operative care instructions. The system should not be used in pediatric patients or patients with open growth plates.

#### **⚠ Warnings & Precautions:**

- Every connector must be secured to the construct using two (2) set screws (one at each end for metacarpal and distal radius nails). If either of the set screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- All unicortical screws must be implanted and fully tightened into the radial and metacarpal nails to maintain the integrity and strength of the finished construct. If the unicortical screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- The information in this document should be shared with the patient.

- The patient should be informed about the importance of following the post-operative rehabilitation in order to fully understand the 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. 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.
- The device is not designed to withstand the stress of excessive weight bearing, load bearing, or physical activity. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- 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, delayed union, or non-union may occur as a result of non-compliance to post-operative rehabilitation, excessive wrist activities or construct overloading.
- Ensure sufficient space is available for proper application when used in conjunction with other implants to prevent interference. Interference with other prostheses may lead to failure of the implant or postoperative complications.
- DO NOT REUSE any of the system's implantable components. Reuse may compromise the structural integrity of the construct.
- Protect the system's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- 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 permanently implant the Skeletal Dynamics k-wires; they are only intended to be used during provisional fixation.
- DO NOT mix system specific instrumentation or implants from different systems or manufacturers for metallurgical, biomechanical and functional reasons.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Caution should be taken for interference to pacemakers during the use of an electrocautery or uncertified drill power sources.
- Seek medical help immediately if implant malfunctions.
- To maintain traceability of the system's implantable components, you must record each of the respective components LOT numbers into the patient records.

#### **Potential Adverse Events:**

The following are potential risks that have been associated with wrist fusion surgery: infection, nonunion, persistent pain, stiffness of the fingers, loosening or migration of the implants resulting in mal alignment. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.



#### 🏠 **MRI Safety Information.**

A person with the IMPLATE® WAN implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

|                                     |                                                                                                                       |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Device Name                         | IMPLATE® WAN Implants                                                                                                 |
| Static Magnetic Field Strength (B0) | 1.5T or 3.0T                                                                                                          |
| Maximum Spatial Field Gradient      | 30 T/m (3,000 gauss/cm)                                                                                               |
| RF Excitation                       | Circularly Polarized (CP)                                                                                             |
| RF Transmit Coil Type               | There are no Transmit Coil restrictions                                                                               |
| Operating Mode                      | Normal Operating Mode                                                                                                 |
| Maximum Whole-Body SAR              | 2 W/kg (Normal Operating Mode)                                                                                        |
| Maximum Head SAR                    | 3.2 W/kg (Normal Operating Mode)                                                                                      |
| Scan duration                       | 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) |
| MR Image Artifact                   | The presence of this implant may produce an image artifact.                                                           |

#### **Directions for Use:**

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

Please refer to the IMPLATE® WAN Surgical Technique Guide to review the surgical approach to minimally invasive wrist arthrodesis as described by Jorge L. Orbay, M.D. of the *Miami Hand & Upper Extremity Institute* located in Miami, Florida (USA).

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

For instructions on cleaning, disinfection, sterilization and inspection of the IMPLATE® WAN System please refer to cleaning and sterilization instructions for use (IFU-04056-07).

#### **Safety and Clinical Performance**

The IMPLATE® WAN System has information on safety and clinical performance in the Summary of Safety and Clinical Performance (IFU-00430-32) document.

#### **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](http://www.skeletaldynamics.com/resources). Instructions for Use should always be reviewed before using or implanting a device.

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# **IMPLATE® WAN System** Inventory Control Sheet

| IMPLATE Nails (Ti) <sup>1</sup>                                              |                                                                                                            |                                                                          |                                                                                                              |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| IMPLATE Nail, Metacarpal, Standard, 4.0<br>IMP-MCN-S40<br>(01)00841506102160 | <br>(01) 00841506102160   | IMPLATE Nail, Distal Radius, Short<br>IMP-DRN-SHT<br>(01)00841506102122  | <br>(01) 00841506102122   |
| IMPLATE Nail, Metacarpal, Standard, 4.6<br>IMP-MCN-S46<br>(01)00841506102177 | <br>(01) 00841506102177   | IMPLATE Nail, Distal Radius, Long<br>IMP-DRN-LNG<br>(01)00841506102115   | <br>(01) 00841506102115   |
| IMPLATE Nail, Metacarpal, Mini, 4.0<br>IMP-MCN-M40<br>(01)00841506102153     | <br>(01) 00841506102153   | IMPLATE Nail, Metacarpal, Mini, 4.6<br>IMP-MCN-M46<br>(01)00841506117096 | <br>(01) 00841506117096   |
| IMPLATE Connectors (Ti) <sup>1</sup>                                         |                                                                                                            |                                                                          |                                                                                                              |
| IMPLATE Connector 2mm x 0°<br>IMP-WC-0200<br>(01)00841506102337              | <br>(01) 00841506102337   | IMPLATE Connector, 7mm x 15.0°<br>IMP-WC-0715<br>(01)00841506102399      | <br>(01) 00841506102399   |
| IMPLATE Connector, 2mm x 7.5°<br>IMP-WC-0207<br>(01)00841506102344           | <br>(01) 00841506102344  | IMPLATE Connector, 7mm x 22.5°<br>IMP-WC-0722<br>(01)00841506102405      | <br>(01) 00841506102405  |
| IMPLATE Connector, 2mm x 15.0°<br>IMP-WC-0215<br>(01)00841506102351          | <br>(01) 00841506102351 | IMPLATE Connector, 12mm x 0°<br>IMP-WC-1200<br>(01)00841506102412        | <br>(01) 00841506102412 |
| IMPLATE Connector, 2mm x 22.5°<br>IMP-WC-0222<br>(01)00841506102368          | <br>(01) 00841506102368 | IMPLATE Connector, 12mm x 7.5°<br>IMP-WC-1207<br>(01)00841506102429      | <br>(01) 00841506102429 |
| IMPLATE Connector, 7mm x 0°<br>IMP-WC-0700<br>(01)00841506102375             | <br>(01) 00841506102375 | IMPLATE Connector, 12mm x 15.0°<br>IMP-WC-1215<br>(01)00841506102436     | <br>(01) 00841506102436 |
| IMPLATE Connector, 7mm x 7.5°<br>IMP-WC-0707<br>(01)00841506102382           | <br>(01) 00841506102382 | IMPLATE Connector, 12mm x 22.5°<br>IMP-WC-1222<br>(01)00841506102443     | <br>(01) 00841506102443 |
| IMPLATE Set Screws (CoCr) <sup>1</sup>                                       |                                                                                                            |                                                                          |                                                                                                              |
| Set Screw, 3.0mm x 2.0mm<br>STSC-30020-CS<br>(01)00841506103105              | <br>(01) 00841506103105 |                                                                          |                                                                                                              |
| Unicortical Screws (Ti) <sup>1</sup>                                         |                                                                                                            |                                                                          |                                                                                                              |
| Unicortical Screw, 2.8mm x 4.0mm<br>UCNL-28040-TS<br>(01)00841506103631      | <br>(01) 00841506103631 | Unicortical Screw, 2.8mm x 8.0mm<br>UCNL-28080-TS<br>(01)00841506103679  | <br>(01) 00841506103679 |

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|                                                                             |                                                                                                          |                                                                          |                                                                                                            |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Unicortical Screw, 2.8mm x 5.0mm<br>UCNL-28050-TS<br>(01)00841506103648     | <br>(01) 00841506103648 | Unicortical Screw, 2.8mm x 10.0mm<br>UCNL-28100-TS<br>(01)00841506103686 | <br>(01) 00841506103686 |
| Unicortical Screw, 2.8mm x 6.0mm<br>UCNL-28060-TS<br>(01)00841506103655     | <br>(01) 00841506103655 | Unicortical Screw, 2.8mm x 12.0mm<br>UCNL-28120-TS<br>(01)00841506103693 | <br>(01) 00841506103693 |
| Unicortical Screw, 2.8mm x 7.0mm<br>UCNL-28070-TS<br>(01)00841506103662     | <br>(01) 00841506103662 | Unicortical Screw, 2.8mm x 14.0mm<br>UCNL-28140-TS<br>(01)00841506103709 | <br>(01) 00841506103709 |
| <b>Single Use (Disposable) Instruments<sup>1</sup></b>                      |                                                                                                          |                                                                          |                                                                                                            |
| K-Wire, Standard Tip, 1.6mm x 127mm<br>KWIR-STD-15127<br>(01)00841506102504 | <br>(01) 00841506102504 |                                                                          |                                                                                                            |

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