IMPLATE® Wrist Arthrodesis Nail System
INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

Basic UDI: 00841506102320

℞: 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 alloy connectors in various lengths and angles
- Titanium alloy unicortical screws
- Cobalt chrome set screws
- 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.

IFU-00430-00 V.2 – February 2026

- 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.

MR Safety Information

The IMPLATE® WAN 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 the IMPLATE® WAN System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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* (MKT-00001-00) 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 products please refer to cleaning and sterilization instructions for use (IFU-04056-00). Please refer to the *IMPLATE® WAN Surgical Technique Guide* (MKT-00001-00) 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.

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.

Disclaimer of Warranty and Limited Remedies

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IFU-00430-00 V.2 – February 2026

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
	5.2.6 Do not resterilize	Indicates a medical device that is not to be resterilized
	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
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	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
	5.7.7 Medical device	Indicated the item is a medical device
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured

IFU-00430-00 V.2 – February 2026

IMPLATE® WAN System
Inventory Control Sheet

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

IFU-00430-00 V.2 – February 2026

IMPLATE® WAN System

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Unicortical Screws (Ti)	
Unicortical Screw, 2.8mm x 4.0mm UCNL-28040-TS (01)00841506103631  (01) 00841506103631	Unicortical Screw, 2.8mm x 8.0mm UCNL-28080-TS (01)00841506103679  (01) 00841506103679
Unicortical Screw, 2.8mm x 5.0mm UCNL-28050-TS (01)00841506103648  (01) 00841506103648	Unicortical Screw, 2.8mm x 10.0mm UCNL-28100-TS (01)00841506103686  (01) 00841506103686
Unicortical Screw, 2.8mm x 6.0mm UCNL-28060-TS (01)00841506103655  (01) 00841506103655	Unicortical Screw, 2.8mm x 12.0mm UCNL-28120-TS (01)00841506103693  (01) 00841506103693
Unicortical Screw, 2.8mm x 7.0mm UCNL-28070-TS (01)00841506103662  (01) 00841506103662	Unicortical Screw, 2.8mm x 14.0mm UCNL-28140-TS (01)00841506103709  (01) 00841506103709
Single Use (Disposable) Instruments	
K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504  (01) 00841506102504	

IFU-00430-00 V.2 – February 2026