English

IMPLATE® Wrist Arthrodesis Nail System
INSTRUCTIONS FOR USE

℞: 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, sepsis, 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 prescribed in order to fully 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.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.

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- 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, nonunion, or soft tissue healing. 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 stress fractures of the bones, loosening of the construct and/or fixation, delayed fusion, non-fusion, or incomplete healing 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 and/or lead to failure or infection 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 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 implant components or system specific instrumentation from different systems or manufacturers for metallurgical, biomechanical and functional reasons.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within ± 0.25mm.
- Caution should be taken for interference to pacemakers during the use of an electrocautery or uncertified drills.
- 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 post implantation.

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.

⚠ **MRI Safety Information.**

A person with the Implate implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

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Device Name	Implate 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 my 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:
Upon receipt by the user facility, the IMPLATE® WAN 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, screws, 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 IMPLATE® WAN System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions
- IMPLATE® WAN System 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 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 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 exposure time.
4. Thoroughly rinse the 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 the 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.
   Note: When scrubbing rasps or planers, a stiff bristle brush will be required.
6. Rinse components thoroughly with deionized or purified 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 components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on the components using deionized water or purified water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization:
The accessories and instruments of the IMPLATE® WAN 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
2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Type	Temperature	Duration	Drying Time
Pre-Vacuum Autoclave	270°F (132°C)	4-5 minutes (wrapped)	40 minutes
Pre-Vacuum Autoclave	273°F (134°C)	3-5 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Immediate Use Steam Sterilization (IUSS) is 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.

Handling and Storage:
When not in use, store the clean and disinfected IMPLATE® WAN System within the Sterilization Tray.
Prior to use, inspect the instrumentation for serviceability.

Functional Checks should be performed where possible:

1. Mating devices should be checked for proper assembly.
2. Reusable devices with moving parts should be operated to check correct operation (medical grade lubricant suitable for steam sterilization can be applied as required).
3. Rotating instruments (e.g. drill bits, reamers) should be checked for straightness. This can be achieved by rolling the instrument on a flat surface.

Note: The useful life of these devices is dependent on many factors including, but not limited to the method and duration of each use and the handling of the devices between uses. Routine and careful inspection and functional testing of the device is the best method of determining the serviceable life span for the medical device.

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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MD

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IMPLATE® WAN System
Inventory Control Sheet

IMPLATE Nails (Ti)[1]					
	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) 00841506117096
	IMPLATE Nail, Metacarpal, Mini, 4.0 IMP-MCN-M40 (01)00841506102153	(01) 00841506102153			
IMPLATE Connectors (Ti)[1]					
	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)[1]					
	Set Screw, 3.0mm x 2.0mm STSC-30020-CS (01)00841506103105	(01) 00841506103105			
Unicortical Screws (Ti)[1]					
	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

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	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[1]					
	K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504	(01) 00841506102504		IMPLATE Reamer 3, Metacarpal, 4.0mm x 87mm IMP-WAN-MR3 (01)00841506102269	(01) 00841506102269
	IMPLATE Drill, Unicortical 3mm x 41mm IMP-DUC-0341 (01)00841506102139	(01) 00841506102139		IMPLATE Reamer 4, Metacarpal, 4.5mm x 87mm IMP-WAN-MR4 (01)00841506102276	(01) 00841506102276
	IMPLATE Reamer 1, Metacarpal, 2.7mm x 87mm IMP-WAN-MR1 (01)00841506102245	(01) 00841506102245		IMPLATE Reamer 5, Metacarpal, 5.0mm x 87mm IMP-WAN-MR5 (01)00841506102283	(01) 00841506102283
	IMPLATE Reamer 2, Metacarpal, 3.4mm x 87mm IMP-WAN-MR2 (01)00841506102252	(01) 00841506102252		Driver, Mini QC T-7 DRVR-MQC-T07 (01)00841506101323	(01) 00841506101323
Reusable Instruments[2]					
	Handle, Mini Quick Connect, Fixed HNDL-MQC-FXD (01)00841506102061	(01) 00841506102061		IMPLATE Rasp 1, Distal Radius, 5.5mm x 70mm IMP-WAN-RR1 (01)00841506102290	(01) 00841506102290
	IMPLATE Lock Screw, Unicort. Drill Guide IMP-UDG-LKSC (01)00841506102214	(01) 00841506102214		IMPLATE Rasp 2, Distal Radius, 7.0mm x 70mm IMP-WAN-RR2 (01)00841506102306	(01) 00841506102306
	IMPLATE Uni Drill Guide, DRMC Nails IMP-UDG-DRMC (01)00841506102191	(01) 00841506102191		Handle, Universal QC, Fixed HNDL-UQC-FXD (01)00841506102108	(01) 00841506102108
	IMPLATE Uni Drill Guide, Drill Sleeve IMP-UDG-DSLV (01)00841506102207	(01) 00841506102207		IMPLATE, Minimum Gap Gauge IMP-WAN-MGG (01)00841506102238	(01) 00841506102238
	IMPLATE Uni Drill Guide, Depth Gauge IMP-UDG-DGAU (01)00841506102184	(01) 00841506102184		IMPLATE Spreader, Wrist Arthrodesis Nails IMP-WAN-SPDR (01)00841506102313	(01) 00841506102313
	IMPLATE Awl, Wrist Arthrodesis Nails IMP-WAN-AWL (01)00841506102221	(01) 00841506102221		IMPLATE Rasp, Flaring and Troughing IMP-FAT-RASP (01)00841506102146	(01) 00841506102146
IMPLATE Tray[2]					
	IMPlate Sterilization Tray IMP-WAN-TRAY (01)00841506100494	(01) 00841506100494		IMPlate Sterilization Tray, Caddy IMP-TRAY-CAD (01)00841506100524	(01) 00841506100524
	IMPlate Sterilization Tray, Base IMP-TRAY-BASE (01)00841506100500	(01) 00841506100500		IMPlate Sterilization Tray, Instrument Tray Insert IMP-TRAY-INSRT (01)00841506100531	(01) 00841506100531
	IMPlate Sterilization Tray, Lid IMP-TRAY-LID (01)00841506100517	(01) 00841506100517			

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