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.

SYMBOLS

MATL:	MATERIAL	**CoCr:**	COBALT CHROMIUM ALLOY
MADE IN:	MADE IN <<COUNTRY>>	**TI:**	TITANIUM ALLOY
QTY:	QUANTITY	**SS, SST:**	STAINLESS STEEL
	DO NOT REUSE (SINGLE USE)		CAUTION or ATTENTION, SEE INSTRUCTIONS FOR USE
	USE BY (EXPIRATION DATE)		CONSULT INSTRUCTIONS FOR USE
LOT	BATCH CODE		MANUFACTURER
STERILE EO	STERILIZED USING ETHYLENE OXIDE		TEMPERATURE LIMITATION
STERILE R	STERILIZED USING IRRADIATION	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
NON STERILE	NON STERILE PRODUCT		DO NOT USE IF PACKAGE IS DAMAGED
REF	CATALOG NUMBER		

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 Setscrews.

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 Setscrews
- System specific instrumentation

Note: All references contained in this document pertaining to Distal Radius Nails, Metacarpal Nails, Connectors, Setscrews, Unicortical Screws and other instrumentation are specific to the IMPLATE® WAN System by Skeletal Dynamics.

Indications:
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.

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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.

⚠Warnings:

- Every Connector must be secured to the construct using two (2) Setscrews (one at each end for Metacarpal and Distal Radius Nails). If either of the Setscrews 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.
- Potential IMPLATE® WAN 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.
- DO NOT REUSE any of the IMPLATE® WAN System implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection which may result in patient injury.

⚠Precautions:

- Protect the IMPLATE® WAN System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the IMPLATE® WAN 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 intended to be used for provisional fixation of the IMPLATE® WAN System construct.
- The IMPLATE® WAN System has not been evaluated for safety and compatibility in the MR environment; nor has it been tested for heating or migration in the MR environment.
- The Skeletal Dynamics Wrist Arthrodesis Nail System is to be used only with Skeletal Dynamics instruments, implants and accessories.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within $\pm$ 0.25mm.
- Caution should be taken for interference to pacemakers during the use of a electrocautery or uncertified drills.
- Seek medical help immediately if implant malfunctions.
- To maintain traceability of the IMPLATE® WAN System 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.

Directions for Use:
The IMPLATE® WAN System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the IMPLATE® WAN System during wrist arthrodesis procedures based on their experience with the IMPLATE® WAN System.

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).

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Cleaning:
The IMPLATE® WAN System instrumentation must be cleaned to achieve sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

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.

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.

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 minutes (wrapped)	20 minutes
Gravity Autoclave	270°F (132°C)	15 minutes (wrapped)	20 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Usage of an FDA approved wrap or sterilization container 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.

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Disclaimer of Warranty and Limited Remedies:

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IMPLATE® WAN System Ordering Information: IMP-WAN-SYS

Catalog #	Nomenclature
Implants	
IMP-MCN-M40	IMPLATE Nail, Metacarpal, Mini, 4.0mm, Ti
IMP-MCN-S40	IMPLATE Nail, Metacarpal, Std., 4.0mm, Ti
IMP-MCN-S46	IMPLATE Nail, Metacarpal, Std., 4.6mm, Ti
IMP-DRN-SHT	IMPLATE Nail, Distal Radius, Short, Ti
IMP-DRN-LNG	IMPLATE Nail, Distal Radius, Long, Ti
IMP-WC-0200	IMPLATE Connector, 2mm x 0°, Ti
IMP-WC-0207	IMPLATE Connector, 2mm x 7.5°, Ti
IMP-WC-0215	IMPLATE Connector, 2mm x 15.0°, Ti
IMP-WC-0222	IMPLATE Connector, 2mm x 22.5°, Ti
IMP-WC-0700	IMPLATE Connector, 7mm x 0°, Ti
IMP-WC-0707	IMPLATE Connector, 7mm x 7.5°, Ti
IMP-WC-0715	IMPLATE Connector, 7mm x 15.0°, Ti
IMP-WC-0722	IMPLATE Connector, 7mm x 22.5°, Ti
IMP-WC-1200	IMPLATE Connector, 12mm x 0°, Ti
IMP-WC-1207	IMPLATE Connector, 12mm x 7.5°, Ti
IMP-WC-1215	IMPLATE Connector, 12mm x 15.0°, Ti
IMP-WC-1222	IMPLATE Connector, 12mm x 22.5°, Ti
Screws	
STSC-30020-CS	Set Screw, 3.0mm x 2.0mm, CoCr
UCNL-28040-TS	Unicortical Screw, 2.8mm x 4.0mm, Ti
UCNL-28050-TS	Unicortical Screw, 2.8mm x 5.0mm, Ti
UCNL-28060-TS	Unicortical Screw, 2.8mm x 6.0mm, Ti
UCNL-28070-TS	Unicortical Screw, 2.8mm x 7.0mm, Ti
UCNL-28080-TS	Unicortical Screw, 2.8mm x 8.0mm, Ti
UCNL-28100-TS	Unicortical Screw, 2.8mm x 10.0mm, Ti
UCNL-28120-TS	Unicortical Screw, 2.8mm x 12.0mm, Ti
UCNL-28140-TS	Unicortical Screw, 2.8mm x 14.0mm, Ti
System Instrumentation	
IMP-DUC-0341	IMPLATE Drill, Unicortical 3.0mm x 41mm
IMP-UDG-LKSC	IMPLATE Lock Screw, Unicortical Drill Guide
IMP-UDG-DRMC	IMPLATE Unicortical Drill Guide, DRMC Nails
IMP-UDG-DSLV	IMPLATE Drill Sleeve, Unicortical Drill Guide
IMP-UDG-DGAU	IMPLATE Depth Gauge, Unicortical Drill Guide
IMP-WAN-MGG	IMPLATE Minimum Gap Gauge
IMP-WAN-SPDR	IMPLATE Spreader, Wrist Arthrodesis Nails

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IMP-WAN-MR1	IMPLATE Metacarpal Reamer 1, 2.7mm x 87mm
IMP-WAN-MR2	IMPLATE Metacarpal Reamer 2, 3.4mm x 87mm
IMP-WAN-MR3	IMPLATE Metacarpal Reamer 3, 4.0mm x 87mm
IMP-WAN-MR4	IMPLATE Metacarpal Reamer 4, 4.5mm x 87mm
IMP-WAN-MR5	IMPLATE Metacarpal Reamer 5, 5.0mm x 87mm
IMP-WAN-RR1	IMPLATE Radial Rasp 1, 5.5mm x 70mm
IMP-WAN-RR2	IMPLATE Radial Rasp 2, 7.0mm x 70mm
IMP-WAN-AWL	IMPLATE Awl, Universal
IMP-FAT-RASP	IMPLATE Rasp, Flaring & Trough Tool
General Instrumentation	
KWIR-STD-15127	K-Wire, Standard Tip, 1.5mm x 127mm, SS
HNDL-UQC-FXD	Handle, Universal QC, Fixed
HNDL-MQC-FXD	Handle, Mini QC, Fixed
DRVR-MQC-T07	Driver, Mini QC, T-7
Sterilization Trays	
IMP-WAN-TRAY	IMPLATE® Caddy & Instrument Tray

Customer Care Center:
Skeletal Dynamics, LLC
7300 N. Kendall Dr. / Suite 400
Miami, FL 33156
1-877-753-5396

EC REP

Emergo Europe,
Prinsessegracht 20,
2514 AP, The Hague,
The Netherlands

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