English

IMPLATE® Wrist Arthrodesis Nail System

INSTRUCTIONS FOR USE (IFU) FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

To ensure use of the most up-to-date revision, refer to www.skeletaldynamics.com/resources/

℞: For use by physicians only. Federal Law restricts this device to sale by or on the order of a physician.

This package insert is designed to provide Instructions for Use of the IMPLATE® Wrist Arthrodesis Nail (WAN) System. **Failure to follow instructions may lead to patient injury.**

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 with unicortical bone screws and then assembled into a completed construct with 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.

Intended Use

The IMPLATE® WAN System is intended for wrist arthrodesis.

Indications

The IMPLATE® WAN System 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.

Intended Patient Population

The IMPLATE® WAN System is intended for skeletally mature patients. The system should not be used in pediatric patients or patients with open growth plates.

Intended User

The IMPLATE® WAN System should only be used by surgeons who are familiar with this system and facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness of using the IMPLATE® WAN System based on their clinical experience.

Expected Clinical Benefits

The expected clinical benefits of internal fixation devices of the IMPLATE® WAN System, when used according to instructions for use and recommended technique is achievement of stabilization of bones and bone fragments to support bone consolidation.

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A summary of safety and clinical performance (IFU-00430-32) can be found at the following link: http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched. The summary of safety and clinical performance is available upon request. Please refer to the resources section for further information.

Performance Characteristics of the Device

Skeletal Dynamics has established the performance and safety of IMPLATE® WAN System and that the system represents state-of-the-art medical devices intended for the fixation and fusion of the wrist. Refer to the section Inventory Control Sheet in the scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

Device Lifetime

The expected functional lifetime of the IMPLATE® WAN System is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 3 months in 96% of cases. The post-therapeutic lifetime of the implant is the remaining lifetime of the patient following bone consolidation. Patient factors such as weight, bone quality, activity level, and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

⚠ 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 is 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 with 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.

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- Caution should be taken for interference to pacemakers during the use of electrocautery or uncertified drill power sources.
- Seek medical help immediately if the implant malfunctions.
- To maintain traceability of the system's implantable components, you must record each of the respective components' LOT numbers into patient records.



⚠ MR 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.

Parameter	Condition
Device Name	Skeletal Dynamics' Upper Extremity Systems
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**1.5 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 6.1$ µT) for up to one hour - Lower leg region: Normal Operating Mode for up to one hour **3 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 3.1$ µT) for 6 minutes of scanning, followed by a minimum cooling period of 15 minutes, up to a maximum total scanning/cooling duration of one hour - Lower leg region: Normal Operating Mode for up to one hour
Scan duration	Scan duration as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Scan Regions	Landmark restrictions as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Image Artifact	The presence of Skeletal Dynamics' Upper Extremity Systems may produce an image artifact of 5.1 cm. Some manipulation of scan parameters may be needed to compensate for the artifact
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

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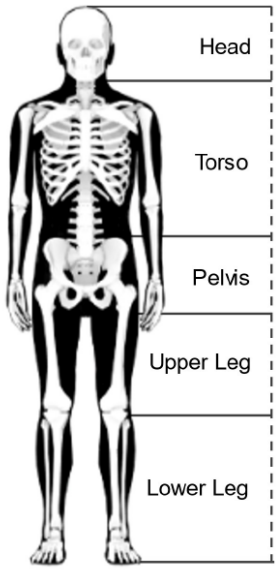
MR Restricted Zone Summary

Skeletal Dynamics' Upper Extremity Systems



Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
Head	Normal Operating Mode*	Normal Operating Mode*
Torso	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 6.1$ µT	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 3.1$ µT for 6 minutes of scanning followed by a minimum cooling period of 15 minutes
Pelvis		
Upper Leg		
Lower Leg	Normal Operating Mode*	Normal Operating Mode*

Under these conditions, total scanning duration for up to one hour is permitted unless otherwise specified. When a cooling period is recommended, repeated scan/cool sequences are permitted for a total duration of up to one hour. Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate
SAR_{head}: Head averaged specific absorption rate
$B_{1+,RMS}$: RMS RF magnetic field (B_{1+})

**Normal Operating Mode limits defined by IEC 60601-2-33 Table 201.104:*
- *SAR_{wb}: 2 W/kg*
- *SAR_{head}: 3.2 W/kg*

Potential Adverse Events

The following are potential risks associated with wrist fusion surgery: infection, nonunion, persistent pain, stiffness, bone, nerve, or soft-tissue damage, loosening, bending, or migration of the implants, resulting in hardware removal, malalignment, or revision surgery. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.

Directions for Use

The system should only be used by surgeons who are familiar with this system. Each surgeon must evaluate the appropriateness of using the system based on their clinical experience.

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).

You must maintain traceability of the IMPLATE® WAN System implantable components. Please record each component's LOT number in the patient's medical records post-implantation.

Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of IMPLATE® WAN products are provided in the Reprocessing IFU, ***Instructions for Reprocessing (Cleaning, Disinfection, and Sterilization) of Skeletal Dynamics Products*** (IFU-04056-00), available at www.skeletaldynamics.com/resources. Refer to the ***IMPLATE® WAN System Surgical Technique Guide*** (MKT-00001-00) for proper kitted tray arrangement.

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Resources

The latest version of the Instructions for Use or Summary of Safety and Clinical Performance 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 the user's request or upon delivery of the device, if 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.

Implant Materials

The IMPLATE® WAN System consists of several Titanium Alloy implantable nails, screws, connectors, and Cobalt Chrome alloy screws commonly used for surgical implants.

Basic UDI Codes	Basic UDI #s	System Components	Material(s)	Standard(s)
IMN-FAM-TI	0841506145716K	IMPLATE® Intramedullary Nail	Ti 6Al-4V ELI	ASTM F136
CS-FAM-TI	0841506142405R	IMPLATE® Connector	Ti 6Al-4V ELI	ASTM F136
CS-FAM-CC	0841506142435X	IMPLATE® Set Screw	CoCrMo	ASTM 1537
SCW-FAM-TI	08415061423866	Unicortical Screw	Ti 6Al-4V ELI	ASTM F136

The Titanium implants conform to ASTM F136, which provides the following tolerances for the material:

ASTM F136 Chemical Composition

Element	Composition % (mass)
Nitrogen, Ni	≤ .05%
Carbon	≤ .08%
Hydrogen	≤ .015%
Iron	≤ .25%
Oxygen	≤ .13%
Aluminum	≤ 6.5%
Vanadium	≤ 4.5%
Titanium	balance*

*The percentage of Titanium is determined by the difference and is not determined or certified.

Cobalt Chrome Set screws conform to ASTM F1537, which provides the following tolerances for the material:

ASTM F1537 Chemical Composition

Element	Composition % (mass)
Carbon	≤ 0.14%
Chromium	≤ 30%
Molybdenum	≤ 7.0%
Nickel*	≤ 1.0%
Iron	≤ 0.75%
Silicon	≤ 1.0%
Manganese	≤ 1.0%
Nitrogen	≤ 0.25%
Cobalt	balance**

* Nickel, classified as skin sensitizer 1: sensitization or allergic reactions to users and/or patients. Classification based on applicable EU legislation for chemical substances

** The percentage of Cobalt is determined by the difference and is not determined or certified.

 Cobalt	Cobalt Chrome ASTM 1537	This device contains Cobalt in a concentration above 0.1% weight by weight. Current scientific evidence supports medical devices manufactured do not show any significant incidence of adverse events due to the presence of Cobalt.

Set screws will contain nickel and should not be used on any patient with a known allergy.

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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) 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)[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

IFU-00430-07 V.2 - August 2026
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IMPLATE® WAN System
Inventory Control Sheet

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[1]	
K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504 (01) 00841506102504	

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