

Skeletal Dynamics REDUCT® Headless Compression Screw System

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

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

R_x: For use by physicians only. Caution: 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 REDUCT® Headless Compression Screw System devices. **Failure to follow instructions may lead to patient injury.**

Description

The Skeletal Dynamics REDUCT® Headless Compression Screw System contains titanium alloy implantable medical devices in multiple sizes.

The Skeletal Dynamics REDUCT® Headless Compression Screw System:

- Titanium alloy REDUCT® Headless Compression cannulated screws
- Titanium Alloy REDUCT® Headless Compression arthrodesis non-cannulated and cannulated screws
- Stainless steel K-Wires (for provisional fixation, not for implantation)
- System-specific instrumentation

Both the REDUCT® Headless Compression Screw System implants and instrumentation are provided non-sterile and must be sterilized in the user facility.

Intended Use

REDUCT® Headless Compression Screw System is intended for fixation, correction, and stabilization of bones or bone fragments.

Indications

The Skeletal Dynamics REDUCT® Headless Compression Screw System devices are intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw.

Contraindications

Prior to using the REDUCT® Headless Compression Screw System devices, 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 (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions. These devices are not intended for implant attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Intended Patient Population

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

Expected Clinical Benefits

The expected clinical benefits of the REDUCT Screws, when used according to instructions for use and recommended technique, are the achievement of stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-01271-32) 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 REDUCT® Headless Compression Screw System, and that they represent state-of-the-art medical devices intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies. 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 REDUCT Screws is 2-3 months in 98% 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 orthopedic device.

⚠ Warnings & Precautions

- The patient must be cautioned about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, malunion device or treatment failure as a result of device loosening, screw prominence/protrusion, 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 patient should be informed about the importance of following the post-operative rehabilitation protocol and to 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.
- For safe, effective use of an implant, the surgeon must be thoroughly familiar with the surgical technique, implants, and associated instruments.
- The devices are 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.
- DO NOT reuse any of the REDUCT® Headless Compression Screw System implantable components. Reuse may compromise the structural integrity of the screw.
- Seek medical help immediately if the implant malfunctions.
- Protect the REDUCT® Headless Compression Screw System implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using any Skeletal Dynamics devices, 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 for provisional fixation and guidance.
- K-Wires are double trocar. The user should handle K-Wires accordingly during insertion and removal to prevent unintended K-Wire penetration or injury.
- Do not mix system-specific devices from different manufacturers for metallurgical, biomechanical, and functional reasons.
- DO NOT use implant lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation or joint damage.

- 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. **Note:** To maintain traceability of the implantable components, record each of the respective components LOT numbers in the patient records post implantation.

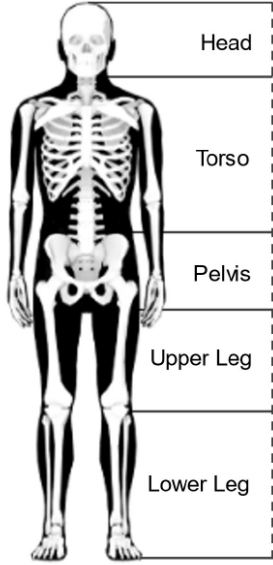


△ MR Safety Information

A person with the Skeletal Dynamics' Upper Extremity Systems may be safely scanned at 1.5 T or 3 T under the following conditions. MRI examinations may only be performed on the upper extremities. MRI use on any other anatomical region has not been evaluated and may present additional risks. 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
B_0 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.

Skeletal Dynamics' Upper Extremity Systems

		1.5 T	3 T
	Landmark Region	Scan Restriction	Scan Restriction
	Head	Normal Operating Mode*	Normal Operating Mode*
	Torso	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 6.1 \mu\text{T}$	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 3.1 \mu\text{T}$ 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

Possible adverse effects associated with REDUCT® Headless Compression Screw System implants include infection, pain, stiffness, loss of reduction, non-union, heterotopic ossification, irritation, and nerve/soft tissue damage due to implant use or surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity, histological, allergic, or adverse foreign-body reactions resulting from implantation of a foreign material may occur. 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 REDUCT® Headless Compression Screw System implants should be used only by surgeons familiar with this system. Each surgeon must evaluate the appropriateness of using a headless compression screw based on their clinical experience.

The surgeon should select the type and size of implant to best meet the patient's needs. Although the surgeon is the medical intermediary between the company and the patient, this document contains important medical information that should be shared with the patient.

It is the responsibility of the surgeon to be familiar with the procedure before use of this device. Additionally, it is the surgeon's responsibility to be familiar with relevant publications on the procedure prior to use. Please refer to the appropriate surgical technique **REDUCT® Headless Compression Screw System Surgical Technique Guide** (MKT-00079-00) or **REDUCT® Arthrodesis Screw System Surgical Technique** (MKT-00121-00) to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Implant Removal

In case the physician decides to remove the implants, implants can be removed by using general surgical instruments.

Disposal

Any Skeletal Dynamics implant that has been contaminated with blood, tissue, or other bodily fluids/matter should never be used again and should be handled in accordance with hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of REDUCT® Headless Compression Screw System 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. Please refer to the Headless Screw Solution Systems' Surgical Technique Guides: **REDUCT® Headless Compression Screw System Surgical Technique Guide (MKT-00079-00)** or **REDUCT® Arthrodesis Screw System Surgical Technique Guide (MKT-00121-00)** for proper kitted tray configuration.

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 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.

Implant Materials

The REDUCT® Headless Compression Screw System consists of several titanium-alloy implantable screws commonly used in surgical implants.

Basic UDI Codes	Basic UDI #s	System Components	Material(s)	Standard(s)
HCS-FAM-TI	0841506102054T	Headless Compression Titanium Screws	Ti 6Al-4V ELI	ASTM F136
ASC-FAM-TI	08415061165463	Arthrodesis Titanium Screws	Ti 6Al-4V ELI	ASTM F136

The titanium alloy 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*

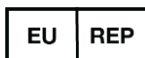
*the percentage of Titanium is determined by the difference and is not determined or certified.

Disclaimer of Warranty and Limited Remedies

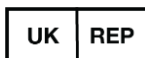
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United Kingdom



REDUCT® Headless Compression Screw System

Inventory Control Sheet

2.5mm Headless Compression Screw	
Screw, Headless Compression, 2.5mm x 10mm, Ti HCS-25010 (01)00841506101835  (01) 00841506101835	Screw, Headless Compression, 2.5mm x 18mm, Ti HCS-25018 (01)00841506101873  (01) 00841506101873
Screw, Headless Compression, 2.5mm x 11mm, Ti HCS-25011 (01)00841506115207  (01) 00841506115207	Screw, Headless Compression, 2.5mm x 20mm, Ti HCS-25020 (01)00841506101880  (01) 00841506101880
Screw, Headless Compression, 2.5mm x 12mm, Ti HCS-25012 (01)00841506101842  (01) 00841506101842	Screw, Headless Compression, 2.5mm x 22mm, Ti HCS-25022 (01)00841506101897  (01) 00841506101897
Screw, Headless Compression, 2.5mm x 13mm, Ti HCS-25013 (01)00841506115214  (01) 00841506115214	Screw, Headless Compression, 2.5mm x 24mm, Ti HCS-25024 (01)00841506101903  (01) 00841506101903
Screw, Headless Compression, 2.5mm x 14mm, Ti HCS-25014 (01)00841506101859  (01) 00841506101859	Screw, Headless Compression, 2.5mm x 26mm, Ti HCS-25026 (01)00841506101910  (01) 00841506101910
Screw, Headless Compression, 2.5mm x 15mm, Ti HCS-25015 (01)00841506115221  (01) 00841506115221	Screw, Headless Compression, 2.5mm x 28mm, Ti HCS-25028 (01)00841506101927  (01) 00841506101927
Screw, Headless Compression, 2.5mm x 16mm, Ti HCS-25016 (01)00841506101866  (01) 00841506101866	Screw, Headless Compression, 2.5mm x 30mm, Ti HCS-25030 (01)00841506101934  (01) 00841506101934
Screw, Headless Compression, 2.5mm x 17mm, Ti HCS-25017 (01)00841506115238  (01) 00841506115238	
3.5mm Headless Compression Screw	
Screw, Headless Compression, 3.5mm x 10mm, Ti HCS-35010 (01)00841506101941  (01) 00841506101941	Screw, Headless Compression, 3.5mm x 20mm, Ti HCS-35020 (01)00841506101996  (01) 00841506101996
Screw, Headless Compression, 3.5mm x 11mm, Ti HCS-35011 (01)00841506115245  (01) 00841506115245	Screw, Headless Compression, 3.5mm x 22mm, Ti HCS-35022 (01)00841506102009  (01) 00841506102009
Screw, Headless Compression, 3.5mm x 12mm, Ti HCS-35012 (01)00841506101958  (01) 00841506101958	Screw, Headless Compression, 3.5mm x 24mm, Ti HCS-35024 (01)00841506102016  (01) 00841506102016

REDUCT® Headless Compression Screw System

Inventory Control Sheet

Screw, Headless Compression, 3.5mm x 13mm, Ti HCS-35013 (01)00841506115252  (01) 00841506115252	Screw, Headless Compression, 3.5mm x 26mm, Ti HCS-35026 (01)00841506102023  (01) 00841506102023
Screw, Headless Compression, 3.5mm x 14mm, Ti HCS-35014 (01)00841506101965  (01) 00841506101965	Screw, Headless Compression, 3.5mm x 28mm, Ti HCS-35028 (01)00841506102030  (01) 00841506102030
Screw, Headless Compression, 3.5mm x 15mm, Ti HCS-35015 (01)00841506115269  (01) 00841506115269	Screw, Headless Compression, 3.5mm x 30mm, Ti HCS-35030 (01)00841506102047  (01) 00841506102047
Screw, Headless Compression, 3.5mm x 16mm, Ti HCS-35016 (01)00841506101972  (01) 00841506101972	Screw, Headless Compression, 3.5mm x 35mm, Ti HCS-35035 (01)00841506105840  (01) 00841506105840
Screw, Headless Compression, 3.5mm x 17mm, Ti HCS-35017 (01)00841506115276  (01) 00841506115276	Screw, Headless Compression, 3.5mm x 40mm, Ti HCS-35040 (01)00841506105857  (01) 00841506105857
Screw, Headless Compression, 3.5mm x 18mm, Ti HCS-35018 (01)00841506101989  (01) 00841506101989	Screw, Headless Compression, 3.5mm x 45mm, Ti HCS-35045 (01)00841506105864  (01) 00841506105864
4.5mm Headless Compression Screw	
Screw, Headless Compression, 4.5mm x 20mm, Ti HCS-45020 (01)00841506115771  (01) 00841506115771	Screw, Headless Compression, 4.5mm x 30mm, Ti HCS-45030 (01)00841506108711  (01) 00841506108711
Screw, Headless Compression, 4.5mm x 22mm, Ti HCS-45022 (01)00841506115788  (01) 00841506115788	Screw, Headless Compression, 4.5mm x 35mm, Ti HCS-45035 (01)00841506108728  (01) 00841506108728
Screw, Headless Compression, 4.5mm x 24mm, Ti HCS-45024 (01)00841506108681  (01) 00841506108681	Screw, Headless Compression, 4.5mm x 40mm, Ti HCS-45040 (01)00841506108735  (01) 00841506108735
Screw, Headless Compression, 4.5mm x 26mm, Ti HCS-45026 (01)00841506108698  (01) 00841506108698	Screw, Headless Compression, 4.5mm x 45mm, Ti HCS-45045 (01)00841506108742  (01) 00841506108742
Screw, Headless Compression, 4.5mm x 28mm, Ti HCS-45028 (01)00841506108704  (01) 00841506108704	Screw, Headless Compression, 4.5mm x 50mm, Ti HCS-45050 (01)00841506108759  (01) 00841506108759

REDUCT® Headless Compression Screw System

Inventory Control Sheet

Single Use (Disposable) Instruments	
K-Wire, 0.9mm x 152mm, Double Trocar KWIR-HCS-09152 (01)00841506109145  (01) 00841506109145	K-Wire, 1.4mm x 165mm, Double Trocar KWIR-HCS-14165 (01)00841506102481  (01) 00841506102481
K-Wire, Single Trocar, 0.9mm x 152mm KWIR-ST-09152 (01)00841506115283  (01) 00841506115283	K-Wire, Single Trocar, 1.4mm x 165mm KWIR-ST-14165 (01)00841506115290  (01) 00841506115290
K-Wire, Double Trocar, 0.9mm x 152mm KWIR-DT-09152 (01)00841506115320  (01) 00841506115320	K-Wire, Double Trocar, 1.4mm x 165mm KWIR-DT-14165 (01)00841506115337  (01) 00841506115337

REDUCT® Headless Compression Screw System

Inventory Control Sheet

2.0mm Arthrodesis Screw	
Screw, Arthrodesis, 2.0 x 20mm, Ti HCSD-20020 (01)00841506112749  (01) 00841506112749	Screw, Arthrodesis, 2.0 x 32mm, Ti HCSD-20032 (01)00841506115535  (01) 00841506115535
Screw, Arthrodesis, 2.0 x 22mm, Ti HCSD-20022 (01)00841506115498  (01) 00841506115498	Screw, Arthrodesis, 2.0 x 34mm, Ti HCSD-20034 (01)00841506115542  (01) 00841506115542
Screw, Arthrodesis, 2.0 x 24mm, Ti HCSD-20024 (01)00841506115504  (01) 00841506115504	Screw, Arthrodesis, 2.0 x 36mm, Ti HCSD-20036 (01)00841506117157  (01) 00841506117157
Screw, Arthrodesis, 2.0 x 26mm, Ti HCSD-20026 (01)00841506115511  (01) 00841506115511	Screw, Arthrodesis, 2.0 x 40mm, Ti HCSD-20040 (01)00841506108926  (01) 00841506108926
Screw, Arthrodesis, 2.0 x 28mm, Ti HCSD-20028 (01)00841506115528  (01) 00841506115528	Screw, Arthrodesis, 2.0 x 44mm, Ti HCSD-20044 (01)00841506117164  (01) 00841506117164
Screw, Arthrodesis, 2.0 x 30mm, Ti HCSD-20030 (01)00841506108902  (01) 00841506108902	
2.5mm Arthrodesis Screw	
Screw, Arthrodesis, 2.5 x 26mm, Ti HCSD-25026 (01)00841506115559  (01) 00841506115559	Screw, Arthrodesis, 2.5 x 34mm, Ti HCSD-25034 (01)00841506115580  (01) 00841506115580
Screw, Arthrodesis, 2.5 x 28mm, Ti HCSD-25028 (01)00841506115566  (01) 00841506115566	Screw, Arthrodesis, 2.5 x 36mm, Ti HCSD-25036 (01)00841506115597  (01) 00841506115597
Screw, Arthrodesis, 2.5 x 30mm, Ti HCSD-25030 (01)00841506108957  (01) 00841506108957	Screw, Arthrodesis, 2.5 x 38mm, Ti HCSD-25038 (01)00841506115603  (01) 00841506115603
Screw, Arthrodesis, 2.5 x 32mm, Ti HCSD-25032 (01)00841506115573  (01) 00841506115573	Screw, Arthrodesis, 2.5 x 40mm, Ti HCSD-25040 (01)00841506108971  (01) 00841506108971
3.5mm Arthrodesis Screw	
Screw, Arthrodesis, 3.5 x 32mm, Ti HCSD-35032 (01)00841506115429  (01) 00841506115429	Screw, Arthrodesis, 3.5 x 40mm, Ti HCSD-35040 (01)00841506109039  (01) 00841506109039

REDUCT® Headless Compression Screw System

Inventory Control Sheet

Screw, Arthrodesis, 3.5 x 34mm, Ti HCSD-35034 (01)00841506115436  (01) 00841506115436	Screw, Arthrodesis, 3.5 x 42mm, Ti HCSD-35042 (01)00841506115467  (01) 00841506115467
Screw, Arthrodesis, 3.5 x 36mm, Ti HCSD-35036 (01)00841506115443  (01) 00841506115443	Screw, Arthrodesis, 3.5 x 44mm, Ti HCSD-35044 (01)00841506115474  (01) 00841506115474
Screw, Arthrodesis, 3.5 x 38mm, Ti HCSD-35038 (01)00841506115450  (01) 00841506115450	Screw, Arthrodesis, 3.5 x 46mm, Ti HCSD-35046 (01)00841506115481  (01) 00841506115481
Single Use (Disposable) Instruments	
K-Wire, 0.9mm x 127mm, Double Trocar KWIR-DT-09127 (01)00841506109060  (01) 00841506109060	K-Wire, HCS, 1.1mm x 127mm, Double Trocar KWIR-DT-11127 (01)00841506209098  (01) 00841506209098