

Skeletal Dynamics Headless Screw Solution Systems

INSTRUCTIONS FOR USE

Basic UDI: 00841506102054

R: 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 Headless Screw Solutions Systems' devices; it is not a reference to surgical techniques.

Description

The Skeletal Dynamics Headless Screw Solution Systems consist of the following implants made from a medical grade titanium alloy (ASTM F-136).

REDUCT® Headless Compression Screw System

- 2.5mm cannulated HCS screws
- 3.5mm cannulated HCS screws
- 4.5mm cannulated HCS screws

REDUCT® Arthrodesis Screw System

- 2.0mm non-cannulated HCS Arthrodesis screws
- 2.5mm cannulated HCS Arthrodesis screws
- 3.5mm cannulated HCS Arthrodesis screws

Threaded Hand Nailing System

- 2.0mm non-cannulated threaded nail
- 3.0mm cannulated threaded nail
- 3.5mm cannulated threaded nail
- 4.5mm cannulated threaded nail

The Headless Screw Solution Systems include instrumentation identified for the associated system's surgical techniques. Both the Headless Screw Solution Systems implants and instrumentation are provided non-sterile and must be sterilized in the user facility.

Indications

The Skeletal Dynamics Headless Screw Solution Systems' devices are intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized implant.

Contraindications

Prior to using the Headless Screw Solution Systems' 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.

⚠ Warnings

- 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 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 Headless Screw Solution Systems' implantable components. Reuse may compromise the structural integrity of the screw.
- Seek medical help immediately if implant malfunctions.

⚠ Precautions

- Protect the Headless Screw Solution Systems' 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. 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.
- 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.



⚠ MRI Safety Information.

A person with any Headless Screw Solution Systems' implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Headless Screw Solution Systems' Implants
Static Magnetic Field Strength (B_0)	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 may produce an image artifact.

Potential Adverse Events

Possible adverse effects associated with Headless Screw Solution Systems' implants are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma. 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 Headless Screw Solution Systems' implants should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of a Headless Screw Solution based on their clinical experiences.

The surgeon should select the type and size 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 provided in this document should be shared to the patient.

It is the responsibility of the surgeon to be familiar with the procedure before use of this device. Additionally, it is the responsibility of the surgeon to be familiar with relevant publications regarding the procedure prior to use. Please refer to the appropriate Headless Screw Solution System Surgical Technique Guide to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Cleaning, Sterilization, and Inspection

For instructions on cleaning, disinfection, sterilization and inspection of the Headless Screw Solution Systems' products please refer to cleaning and sterilization instructions for use (IFU-04056-07).

Safety and Clinical Performance

The Headless Screw Solution Systems have information on safety and clinical performance in the Summary of Safety and Clinical Performance (IFU-01271-32) document.

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.

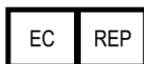
For the most current instructions for use visit www.skeletaldynamics.com/resources. Instructions for Use should always be reviewed before using or implanting a device.

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Compass House, Vision Park Histon
Cambridge CB24 9BZ
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

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

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® Arthrodesis Screw System

Inventory Control Sheet B

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® Arthrodesis Screw System

Inventory Control Sheet B

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

Threaded Hand Nailing System

Inventory Control Sheet

2.0mm Threaded Hand Nail	
Threaded Hand Nail, 2.0mm x 12mm, Ti RHS-20012 (01)00841506134062	Threaded Hand Nail, 2.0mm x 26mm, Ti RHS-20026 (01)00841506134123
Threaded Hand Nail, 2.0mm x 14mm, Ti RHS-20014 (01)00841506134079	Threaded Hand Nail, 2.0mm x 28mm, Ti RHS-20028 (01) 00841506117393
Threaded Hand Nail, 2.0mm x 16mm, Ti RHS-20016 (01)00841506134086	Threaded Hand Nail, 2.0mm x 32mm, Ti RHS-20032 (01)00841506117409
Threaded Hand Nail, 2.0mm x 18mm, Ti RHS-20018 (01)00841506134093	Threaded Hand Nail, 2.0mm x 36mm, Ti RHS-20036 (01) 00841506117416
Threaded Hand Nail, 2.0mm x 20mm, Ti RHS-20020 (01)00841506134109	Threaded Hand Nail, 2.0mm x 40mm, Ti RHS-20040 (01)00841506117423
Threaded Hand Nail, 2.0mm x 22mm, Ti RHS-20022 (01)00841506134116	Threaded Hand Nail, 2.0mm x 44mm, Ti RHS-20044 (01)00841506117430
Threaded Hand Nail, 2.0mm x 24mm, Ti RHS-20024 (01)00841506117386	Threaded Hand Nail, 2.0mm x 48mm, Ti RHS-20048 (01)00841506117447
3.0mm Threaded Hand Nail	
Threaded Hand Nail, 3.0 x 20mm, Ti RHS-30020 (01)00841506134314	Threaded Hand Nail, 3.0 x 50mm, Ti RHS-30050 (01)00841506116723
Threaded Hand Nail, 3.0 x 25mm, Ti RHS-30025 (01)00841506116679	Threaded Hand Nail, 3.0 x 55mm, Ti RHS-30055 (01)0 0841506117348
Threaded Hand Nail, 3.0 x 30mm, Ti RHS-30030 (01)00841506116686	Threaded Hand Nail, 3.0 x 60mm, Ti RHS-30060 (01)00841506117355
Threaded Hand Nail, 3.0 x 35mm, Ti RHS-30035 (01)00841506116693	Threaded Hand Nail, 3.0 x 65mm, Ti RHS-30065 (01)00841506117362
Threaded Hand Nail, 3.0 x 40mm, Ti RHS-30040 (01)00841506116709	Threaded Hand Nail, 3.0 x 70mm, Ti RHS-30070 (01)00841506117379
Threaded Hand Nail, 3.0 x 45mm, Ti RHS-30045 (01)00841506116716	

Threaded Hand Nailing System

Inventory Control Sheet

3.5mm Threaded Hand Nail	
Threaded Hand Nail, 3.5 x 25mm, Ti RHS-35025 (01)00841506113494	Threaded Hand Nail, 3.5 x 50mm, Ti RHS-35050 (01)00841506113548
Threaded Hand Nail, 3.5 x 30mm, Ti RHS-35030 (01)00841506113500	Threaded Hand Nail, 3.5 x 55mm, Ti RHS-35055 (01)00841506113555
Threaded Hand Nail, 3.5 x 35mm, Ti RHS-35035 (01)00841506113517	Threaded Hand Nail, 3.5 x 60mm, Ti RHS-35060 (01)00841506113562
Threaded Hand Nail, 3.5 x 40mm, Ti RHS-35040 (01)00841506113524	Threaded Hand Nail, 3.5 x 65mm, Ti RHS-35065 (01)00841506113579
Threaded Hand Nail, 3.5 x 45mm, Ti RHS-35045 (01)00841506113531	Threaded Hand Nail, 3.5 x 70mm, Ti RHS-35070 (01)00841506113586
4.5mm Threaded Hand Nail	
Threaded Hand Nail, 4.5 x 25mm, Ti RHS-40025 (01)00841506116839	Threaded Hand Nail, 4.5 x 50mm, Ti RHS-40050 (01)00841506116884
Threaded Hand Nail, 4.5 x 30mm, Ti RHS-40030 (01)00841506116846	Threaded Hand Nail, 4.5 x 55mm, Ti RHS-40055 (01)00841506116891
Threaded Hand Nail, 4.5 x 35mm, Ti RHS-40035 (01)00841506116853	Threaded Hand Nail, 4.5 x 60mm, Ti RHS-40060 (01)00841506116907
Threaded Hand Nail, 4.5 x 40mm, Ti RHS-40040 (01)00841506116860	Threaded Hand Nail, 4.5 x 65mm, Ti RHS-40065 (01)00841506116914
Threaded Hand Nail, 4.5 x 45mm, Ti RHS-40045 (01)00841506116877	Threaded Hand Nail, 4.5 x 70mm, Ti RHS-40070 (01)00841506116921
Single Use (Disposable) Instruments	
K-Wire, 0.9mm x 152mm, Single Trocar KWIR-ST-09152 (01)00841506115283	K-Wire, HCS, 1.4mm x 203mm, Single Trocar KWIR-ST-14203 (01)00841506116938
K-Wire, 0.9mm x 203mm, Single Trocar KWIR-ST-09203 (01)00841506117553	