English

REDUCT® Headless Compression Screw System
INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

Basic UDI: 00841506102054

℞: 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 REDUCT Headless Compression Screw System. **Failure to follow instructions may lead to patient injury.**

Description

The REDUCT® Headless Compression Screw (HCS) System consists of the following screws from medical-grade titanium alloy (ASTM F-136).

- 2.5mm cannulated HCS screws
- 3.5mm cannulated HCS screws
- 4.5mm cannulated HCS screws
- 2.0mm non-cannulated HCS Arthrodesis screws
- 2.5mm cannulated HCS Arthrodesis screws
- 3.5mm cannulated HCS Arthrodesis screws

The REDUCT® Headless Compression System includes instrumentation identified for the associated surgical techniques. Both the REDUCT® Headless Compression Screws and instrumentation are provided non-sterile and must be sterilized in the user facility.

Indications

The Skeletal Dynamics REDUCT® Headless Compression Screw System is 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, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, 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 screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

⚠ 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, 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 the implant, the surgeon must be thoroughly familiar with the surgical technique, implants, and associated instruments.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive 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's implantable components. Reuse may compromise the structural integrity of the screw.
- Seek medical help immediately if the implant malfunctions.

© 2026 Skeletal Dynamics, Inc

- Protect the System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the REDUCT® Headless Compression Screw 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 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.
- 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

The REDUCT® Headless Compression Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the REDUCT Headless Compression Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Potential Adverse Events

Possible adverse effects associated with headless compression screws 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.

Directions for Use

The REDUCT® Headless Compression Screw System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the Headless Compression Screw System based on their clinical experiences.

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 provided in this document should be shared to the patient.

It is the responsibility of the surgeon to be familiar with the procedure before using 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 *REDUCT® Headless Compression Screw System Surgical Technique Guide*(MKT-00079-00*)* or *REDUCT® Arthrodesis Screw System Surgical Technique Guide*(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.

Cleaning, Sterilization, and Inspection

For instructions on cleaning, disinfection, sterilization and inspection of the REDUCT® Systems products please refer to cleaning and sterilization instructions for use (IFU-04056-00). Please refer to the 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.

© 2026 Skeletal Dynamics, Inc

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

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.

Skeletal Dynamics Inc
7300 N. Kendall Dr. / Suite 800
Miami, FL 33156
United States of America
1-877-753-5396



© 2026 Skeletal Dynamics, Inc

SYMBOLS GLOSSARY

Symbols that follow BS EN ISO 15223-1 / Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Symbol Reference Number and Title	Description
	5.2.7 Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.2.6 Do not resterilize	Indicates a medical device that is not to be resterilized
	5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.4.3 Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	5.1.5 Batch Code	Indicates the manufacturer's batch code or lot can be identified
	5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.2.8 Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	5.7.7 Medical device	Indicated the item is a medical device
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured

© 2026 Skeletal Dynamics, Inc

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

IFU-01271-00 V.2 – February 2026
© 2026 Skeletal Dynamics, Inc

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

© 2026 Skeletal Dynamics, Inc

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

© 2026 Skeletal Dynamics, Inc

REDUCT® Arthrodesis 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

© 2026 Skeletal Dynamics, Inc

REDUCT® Arthrodesis Screw System
Inventory Control Sheet

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
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

© 2026 Skeletal Dynamics, Inc