

REDUCT™ Headless Compression Screw System
















INSTRUCTIONS FOR USE

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 Compression Screw 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
	BATCH CODE		MANUFACTURER
	STERILIZED USING ETHYLENE OXIDE		TEMPERATURE LIMITATION
	STERILIZED USING IRRADIATION		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	NON STERILE PRODUCT		DO NOT USE IF PACKAGE IS DAMAGED
	CATALOG NUMBER		

Description:

The Skeletal Dynamics Headless Compression Screw (HCS) System consists of 2.5mm and 3.5mm cannulated titanium screws and specialized instrumentation. The 2.5mm screw is available in 11 length configurations between 10mm - 30mm, with increments of 2mm. The 3.5mm screw is available in 11 length configurations between 10mm - 30mm, with increments of 2mm.

The system is provided non-sterile and is sterilized in the user facility.

Indications:

The Skeletal Dynamics HCS System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw. Examples include:

Scaphoid fractures, lunate fractures, capitate fractures, trapezial fractures, metacarpal and metatarsal fractures, phalangeal fractures, radial head fractures, ulnar styloid fractures, osteo-chondral fractures, small joint fusions, carpal fractures and non-unions, capitellum fractures, distal radius fractures, humeral head fractures, glenoid fractures, intercarpal fusions, interphalangeal fractures, metatarsal osteotomies, tarsal fusions, malleolar fractures, patellar fractures, odontoid fractures, and mandibular fractures.

Contraindications:

Prior to using the HCS 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:

- The patient must be cautioned, preferably in writing, 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 loose fixation and/or 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 prescribed post-operative rehabilitation protocol and to 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.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the Headless Compression Screw System may include delayed union, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or non compliance to post operative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- The components of these systems have not been evaluated for safety and compatibility in the MR environment; nor have they been tested for heating or migration in the MR environment.
- DO NOT reuse any of the HCS System implantable components. Reuse may compromise the structural integrity of the screw and/or lead to failure, which may result in patient injury.

⚠ Precautions:

- Protect the HCS System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the HCS 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.
- Do not mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons.
- DO NOT use screw 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 HCS System implantable components, record each of the respective components LOT numbers in the patient records post implantation.

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 HCS 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 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 Headless Compression Screw 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:

The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Implant Cleaning:

The HCS System implants must be cleaned thoroughly to achieve sterilization. Implanted screws or associated components should never be re-used. Any implant that has not been used, but has become soiled, must be cleaned.

Warnings & Precautions

- Any implant contaminated with blood, tissue, and/or bodily fluids/matter should be processed according to healthcare facility protocol.
- Do not use an implant if the surface has been damaged. Damaged implants should be discarded
- Users should wear appropriate personal protective equipment (PPE).
- Users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.

Instrument Cleaning:

The HCS System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- HCS reusable instruments and accessories should be decontaminated immediately after completion of the surgical procedure. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying
- Only qualified personnel with documented evidence of training and competency should clean the instruments. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.
- Avoid the use of metal brushes or scouring pads during the cleaning process.
- Instruments should be rinsed of cleaning agents to prevent residue.
- Do not use mineral oil or silicone lubricants on instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear
- The tray lid may be made of anodized aluminum and should not come in contact with certain cleaning or disinfectant solutions, strong alkaline cleaners or solutions containing iodine, chlorine or certain metal salts. In solutions with pH values greater than 11, the anodization layer may dissolve and/or discolor the lid.

Cleaning Instructions:

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.
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.

Sterilization:

The HCS 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.

Storage:

When not in use, store the clean and disinfected HCS System within the Sterilization Tray. Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect the instrumentation for serviceability.

Disclaimer of Warranty and Limited Remedies:




































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REDUCT™ Headless Compression Screw System - Cat.# HCS-SYS	
Catalog #	Nomenclature
Implants	
HCS-35010	Screw, Headless Compression, 3.5mm x 10mm, Ti
HCS-35012	Screw, Headless Compression, 3.5mm x 12mm, Ti
HCS-35014	Screw, Headless Compression, 3.5mm x 14mm, Ti
HCS-35016	Screw, Headless Compression, 3.5mm x 16mm, Ti
HCS-35018	Screw, Headless Compression, 3.5mm x 18mm, Ti
HCS-35020	Screw, Headless Compression, 3.5mm x 20mm, Ti
HCS-35022	Screw, Headless Compression, 3.5mm x 22mm, Ti
HCS-35024	Screw, Headless Compression, 3.5mm x 24mm, Ti
HCS-35026	Screw, Headless Compression, 3.5mm x 26mm, Ti
HCS-35028	Screw, Headless Compression, 3.5mm x 28mm, Ti
HCS-35030	Screw, Headless Compression, 3.5mm x 30mm, Ti
HCS-25010	Screw, Headless Compression, 2.5mm x 10mm, Ti
HCS-25012	Screw, Headless Compression, 2.5mm x 12mm, Ti
HCS-25014	Screw, Headless Compression, 2.5mm x 14mm, Ti
HCS-25016	Screw, Headless Compression, 2.5mm x 16mm, Ti
HCS-25018	Screw, Headless Compression, 2.5mm x 18mm, Ti
HCS-25020	Screw, Headless Compression, 2.5mm x 20mm, Ti
HCS-25022	Screw, Headless Compression, 2.5mm x 22mm, Ti
HCS-25024	Screw, Headless Compression, 2.5mm x 24mm, Ti
HCS-25026	Screw, Headless Compression, 2.5mm x 26mm, Ti
HCS-25028	Screw, Headless Compression, 2.5mm x 28mm, Ti
HCS-25030	Screw, Headless Compression, 2.5mm x 30mm, Ti
System Instrumentation	
KWIR-HCS-14165	K-Wire, HCS, 1.4mm x 165mm
VHCS-DGA-35	HCS Depth Gage, 3.5mm
DRLL-CDC-27	Drill, Quick Connect, 2.7mm Cannulated
DRLL-CSK-35	Drill, Countersink, 3.5mm, Cannulated
DRVR-HCS-1420	HCS Driver, 3.5mm
KWIR-STD-09152	K-Wire, Standard Tip, 0.9mm x 152mm
VHCS-DGA-25	HCS Depth Gage, 2.5mm
DRLL-CDC-19	Drill, Quick Connect, 1.9mm Cannulated
DRLL-CSK-27	Drill, Countersink, 2.7mm, Cannulated
DPGA-UNV-030	Depth Gauge, Universal, 30mm
HNDL-SQC-FXD	Handle, Small QC, Fixed
Sterilization Trays	
HCS-MOD	REDUCT Headless Compression Screw Module

Further information:

To request further material, please use the following contact information:

Skeletal Dynamics, LLC
8905 SW 87th Avenue
Suite 201
Miami, FL 33176
orders@skeletaldynamics.com
1-877-753-5396

Quantity	Instruments, 2.5 mm		Instruments, 3.5 mm		
	K-Wire, Standard Tip, 0.9mm x 152mm KWIR-STD-09152 (01)00841506102498	 (01) 00841506102498		K-Wire, HCS, 1.4mm x 165mm KWIR-HCS-14165 (01)00841506102481	 (01) 00841506102481
	Drill, Quick Connect, 1.9mm, Cannulated DRLL-CDC-19 (01)00841506101200	 (01) 00841506101200		Drill, Quick Connect, 2.7mm, Cannulated DRLL-CDC-27 (01)00841506101217	 (01) 00841506101217
	Drill, Countersink, 2.7mm, Cannulated DRLL-CSK-27 (01)00841506103846	 (01) 00841506103846		Drill, Countersink, 3.5mm, Cannulated DRLL-CSK-35 (01)00841506103853	 (01) 00841506103853
	HCS Driver, 2.5mm DRVR-HCS-0915 (01)00841506101309	 (01) 00841506101309		HCS Driver, 3.5mm DRVR-HCS-1420 (01)00841506101316	 (01) 00841506101316
	Headless Compression Screw, 2.5 mm		Headless Compression Screw, 3.5 mm		
	Screw, Headless Compression, 2.5mm x 10mm, Ti HCS-25010 (01)00841506101835	 (01) 00841506101835		Screw, Headless Compression, 3.5mm x 10mm, Ti HCS-35010 (01)00841506101941	 (01) 00841506101941
	Screw, Headless Compression, 2.5mm x 12mm, Ti HCS-25012 (01)00841506101842	 (01) 00841506101842		Screw, Headless Compression, 3.5mm x 12mm, Ti HCS-35012 (01)00841506101958	 (01) 00841506101958
	Screw, Headless Compression, 2.5mm x 14mm, Ti HCS-25014 (01)00841506101859	 (01) 00841506101859		Screw, Headless Compression, 3.5mm x 14mm, Ti HCS-35014 (01)00841506101965	 (01) 00841506101965
	Screw, Headless Compression, 2.5mm x 16mm, Ti HCS-25016 (01)00841506101866	 (01) 00841506101866		Screw, Headless Compression, 3.5mm x 16mm, Ti HCS-35016 (01)00841506101972	 (01) 00841506101972
	Screw, Headless Compression, 2.5mm x 18mm, Ti HCS-25018 (01)00841506101873	 (01) 00841506101873		Screw, Headless Compression, 3.5mm x 18mm, Ti HCS-35018 (01)00841506101989	 (01) 00841506101989
	Screw, Headless Compression, 2.5mm x 20mm, Ti HCS-25020 (01)00841506101880	 (01) 00841506101880		Screw, Headless Compression, 3.5mm x 20mm, Ti HCS-35020 (01)00841506101996	 (01) 00841506101996
	Screw, Headless Compression, 2.5mm x 22mm, Ti HCS-25022 (01)00841506101897	 (01) 00841506101897		Screw, Headless Compression, 3.5mm x 22mm, Ti HCS-35022 (01)00841506102009	 (01) 00841506102009
	Screw, Headless Compression, 2.5mm x 24mm, Ti HCS-25024 (01)00841506101903	 (01) 00841506101903		Screw, Headless Compression, 3.5mm x 24mm, Ti HCS-35024 (01)00841506102016	 (01) 00841506102016
	Screw, Headless Compression, 2.5mm x 26mm, Ti HCS-25026 (01)00841506101910	 (01) 00841506101910		Screw, Headless Compression, 3.5mm x 26mm, Ti HCS-35026 (01)00841506102023	 (01) 00841506102023
	Screw, Headless Compression, 2.5mm x 28mm, Ti HCS-25028 (01)00841506101927	 (01) 00841506101927		Screw, Headless Compression, 3.5mm x 28mm, Ti HCS-35028 (01)00841506102030	 (01) 00841506102030
	Screw, Headless Compression, 2.5mm x 30mm, Ti HCS-25030 (01)00841506101934	 (01) 00841506101934		Screw, Headless Compression, 3.5mm x 30mm, Ti HCS-35030 (01)00841506102047	 (01) 00841506102047
	Reusable Instruments				
	HCS Depth Gage, 3.5mm VHCS-DGA-35 (01)00841506103723	 (01) 00841506103723		Handle, Small QC, Fixed HNDL-SQC-FXD (01)00841506102078	 (01) 00841506102078
	Drill, Quick Connect, 1.9mm, Cannulated DRLL-CDC-19 (01)00841506103716	 (01) 00841506103716		Headless Compression Screw Module HCS-MOD (01)00841506100630	 (01) 00841506100630
	Drill, Countersink, 2.7mm, Cannulated DRLL-CSK-27 (01)00841506101194	 (01) 00841506101194			