OsteoCentric
Headless Compression Screw System
Instructions for Use

Non-Sterile
Prescription Use Only

The OsteoCentric Extremities Headless Compression System Micro-2.8 Mini-3.9, consists of headless compression screw fasteners and select instrumentation to facilitate implantation. The Headless Compression Screw Fasteners are threaded, cannulated implants designed to provide fixation of various fractures and osteotomies while they heal. The implants and instruments are provided non-sterile.

The OsteoCentric Extremities Headless Compression System Micro-2.8 Mini-3.9 includes the following implants:

- 2.8mm diameter screw fastener (Micro)
- 3.9mm diameter screw fastener (Mini)

The screw fasteners are available in a variety of lengths to accommodate different anatomic sizes of patients.

Indications for use:

The Headless Compression Screw System Micro-2.8 screw fasteners are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The Headless Compression Screw System Mini-3.9 screw fasteners are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodeses of the carpals and phalanges, steochondritis dissecans, and ligament fixation.

The screw fasteners are intended for single use only and may not be reused under any circumstances.

The system drills and guide wires are single use instruments.

Material Specifications:
All implants are made of FDA approved Titanium per ASTM F136.
All k-wires are made of stainless steel per ASTM F138.
All instruments are made of various grades of stainless steel, aluminum, and polymer materials that are FDA approved.

Contraindications:
The physician's education, training, and professional judgment are necessary to determine the appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment protocol. Specific contraindications include:

- Allergies and sensitivities to materials in the device
- Active or latent infection
- Obesity
- Pathologic fractures
- Skeletal immaturity
- Osteoporosis or other disease resulting in osteopathology
- Previous implantation
- Tissue viability at or near the operative site
- Compromised blood flow at or near the operative site
- Mental or neuromuscular disorders
- Patient compliance
- Spinal fixation – this device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Potential Adverse Events:
Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture of implant, loss of fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to implant material
- Limb shortening due to compression of the fracture or bone resorption
- Necrosis of bone or decrease of bone density
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage

Warnings and Precautions:
For safe effective use of this system the surgeon must be thoroughly familiar with these types of implants, the methods of application, instruments, and the recommended surgical technique for this type of device. Implants should not be used to permanently replace normal body structure. To reduce the risks associated with the use of implants, surgical staff should follow the warnings and precautions contained in this document. Weight bearing with these devices is at the risk of the surgeon's understanding that device breakage or damage can occur when the implants are subjected to increased loading associated with delayed union, nonunion, or incomplete healing.

Additionally, the following risk factors should be considered when using the implants:

- Contraindications
- Presence of bends, scratches, breaks, or other defects in the device
- Patient sensitivity to materials used in manufacture of implants
- Improper sterilization of implants
- Improper storage of implants
- Proximity to vascular structures and joint surfaces
- Screw damage due to excessive torque application during insertion/removal
- Risk factors of patients including: smoking, obesity, and compliance in following post-operative care instructions

Improper insertion of the devices during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant.

Instrument breakage or damage, as well as tissue damage, can occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use. The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.

Single-use device:
Products intended for single-use must not be re-used. Contaminated implants must not be reprocessed. Any implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Combination of Medical Devices:
OsteoCentric Extremities has not tested compatibility between the Headless Compression Screw Fasteners and other devices provided by other manufacturers and assumes no liability in such instances.

MR Safety Information:
The OsteoCentric Extremities Headless Compression Screw Fasteners have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of the OsteoCentric Headless Compression Screw Fasteners in the MR environment is unknown. Scanning a patient who has one of these devices may result in patient injury.

Non-Sterile Products
All implants, instruments, and containers in the OsteoCentric Extremities Headless Compression System are supplied in a non-sterile condition must be cleaned and steam sterilized prior to first and every surgical use, and before returning for maintenance and repair. This also applies to first use after delivery (remove and dispose all original disposable packaging).

Thorough cleaning and disinfection as essential for effective sterilization.

All implants are intended for one single application in a single patient. Implants that were used in a patient and removed must be discarded. Implants that have not come into direct contact with a patient may be reprocessed.

After cleaning and prior to steam sterilization, place the product in an approved wrap or container.

Implant Cleaning:
Single-use devices must be cleaned separately from soiled devices.

Instrument Cleaning:
The first and most important step in decontaminating all re-usable devices is thorough (manual and/or mechanical) cleaning and rinsing. Thorough cleaning is a complex process whose success depends on various interrelated factors: Water quality, quantity and type of cleaning agent, cleaning method (manual, ultrasonic bath, washer/disinfector), thorough rinsing and drying, proper product preparation, time, temperature, and thoroughness of the individual responsible for cleaning.

Residual organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilization process.

Cleaning & Reprocessing:
All devices should be positioned to allow sterilant to come in contact with all surfaces. Care should be taken to protect devices from mechanical damage.

1. Disassemble devices, if devices are able to be disassembled, prior to reprocessing.
2. Ensure all devices have been completely removed from original packaging, including tip protectors.
3. Remove sharp devices for manual cleaning or place into a separate tray.
4. Open devices with ratchets, box locks or hinges.
5. Special attention should be given to devices with Lumens/cannula and may require extra time as deemed necessary by trained personnel. Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation.
6. Pre-Cleaning: Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner (i.e., Metrizyme). Scrub with appropriate soft bristle brush until visibly and thoroughly clean.
7. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.
8. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.
9. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.
10. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.
11. Preparation: After cleaning/disinfection, visually inspect the devices. Check for burrs or scraps.
12. Sterilization: It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specified in this package insert.

Cleaning instructions have been validated.

Reassembly of instruments can be accomplished by following the disassembly steps in reverse.

It is recommended that devices be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be disposed of properly.

Sterilization:
Products are supplied non-sterile must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an FDA approved wrap or container. The following parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$:

Method	Steam
Cycle Type	Pre-Vacuum
Minimum Temperature	132ºC
Full Cycle Time	4 minutes
Minimum Dry Time	30 minutes

Other sterilization methods have not been validated and may damage the product resulting in a device malfunction, injury to the patient, or both.

Only use FDA-cleared sterilization wraps or another appropriate FDA-cleared accessory that has been validated to allow sterilant penetration and to subsequently maintain sterility.

The manufacturer and distributor assume no responsibility for cleaning and re-sterilization of reusable instruments performed by the individual or hospital.

Storage:
Do not store in a damp environment. Keep devices covered until needed. Prior to use, inspect product for signs of damage or contamination. In the operating room and during transport, keep devices separate from contaminated instruments or implants.

Disposal:
Dispose of implants according to facility protocol.

Symbols and Definitions:

Symbol	Definition
	**Catalogue number**
	**Lot number**
	**Prescription only**
	**Consult instructions for use**
	**Do not reuse**
	**Manufacturer**
	**Date of Manufacture**
	**Non-Sterile**

MANUFACTURER:
OsteoCentric Technologies, Inc
75 W 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639

OsteoCentric Trauma, OsteoCentric Extremities, OsteoCentric Sports, OsteoCentric Recon, OsteoCentric Spine, OsteoCentric Dental and OsteoCentric Vet are a family of the companies under the OsteoCentric brand and are under common ownership and control within OsteoCentric Technologies.