



## OsteoCentric Long Screw Fastener Set Instructions for Use

Non-Sterile  
Prescription Use  
Only Do Not Reuse

### Description:

The OsteoCentric Trauma Long Screw Fastener Set consists of cortical fasteners in a variety of lengths and diameters to accommodate different anatomic sizes of patients. This set offers a larger range of implants which better equips physicians to choose the best implant for the anatomy. This set also includes washers and select instrumentation, which has been lengthened to facilitate implantation in anatomies which are located deep within the soft tissue.

All implants are made of FDA approved stainless steel per ASTM F138, and all instrumentation materials are FDA approved.

### Indications for use:

The OsteoCentric Trauma Long Screw Fastener System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including periarticular and intraarticular fractures.

### Contraindications:

- Active or latent infection
- Insufficient quantity or quality of bone/soft tissue
- Material sensitivity - If suspected, tests should be performed prior to implantation.
- Sepsis
- Patients who are unwilling or incapable of following postoperative care instructions.
- 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. 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.



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.

### **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 Trauma has not tested compatibility between the cortical bone screw fasteners and other devices provided by other manufacturers and assumes no liability in such instances. Titanium and stainless steel components should not be used together.

### **Magnetic Resonance environment:**

The OsteoCentric Trauma Bone Screws have not been evaluated for safety and compatibility in the MR environment. The OsteoCentric Trauma Bone Screws have not been tested for heating or migration in the MR environment.

### **Cleaning:**

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 device, if device is able to be disassembled, prior to reprocessing. Unthread end caps of depth gauge and handles to remove the inner shaft prior to reprocessing. Remove the inner shaft from outer sleeve.
2. Further detailed instrument dismantling instructions are available from your local sales representative.
3. Open devices with ratchets, box locks or hinges.
4. Ensure all devices have been completely removed from original packaging, including tip protectors.
5. Pre-Cleaning:
  - a. Rinse each device with cold running tap water to loosen any dried soil and to remove any visible debris for one (1) minute per test sample.
    - i. Special attention should be given to devices with Lumens/cannula and may require extra time as deemed necessary by trained personnel. 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.
  - b. Immerse each device in room temperature neutral pH enzymatic cleaner (i.e. Metrizyme). Scrub each device with an appropriate soft bristle brush for thirty (30) seconds.
6. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.
7. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.



8. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.
9. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.
10. Preparation: After cleaning/disinfection, visually inspect the devices. Check for burrs or other potential deformities.

**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.

Non-sterile devices 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. Due to the variations in steam sterilization systems, sterilization parameters should be determined and validated by reference to current ANSI/AAMI standards in addition to your facility's own procedures. The following parameters have been validated to a sterility assurance level (SAL) of  $\leq 10^{-6}$ .

Method	Steam
Cycle Type	Pre-Vacuum
Minimum Temperature	132°C
Full Cycle Time	$\geq 4$ 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. FDA-cleared wraps should be utilized for steam sterilization.

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

**Storage:**

Products that 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.









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.