



OsteoCentric

## OsteoCentric Bone Plate and Screw System Instructions for Use

Non-Sterile

Prescription Use Only

Do Not Reuse

### Description:

The OsteoCentric Bone Plate and Screw System consists of implants and instruments designed for fixation to treat fractures, deformations, and revisions of bones and bone fragments.

The system features the following:

Nine (9) types of plates;

- one-third tubular plate without collar
- one-third tubular plate with collar
- straight compression plate
- straight reconstruction plate
- 2.7/3.5mm non-locking lateral distal fibula plate
- 2.7/3.5mm non-locking posterolateral distal fibula plate
- 2.7/3.5mm locking lateral distal fibula plate
- 2.7/3.5mm locking posterolateral distal fibula plate
- Proximal Humerus Plate

Bone fasteners for fixation included in the system are 2.7mm, 3.3mm, 3.5mm, and 4.0mm diameter fasteners provided in various lengths. Instruments are included to facilitate installation and removal of the bone fastener implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F138), and offered in various widths and lengths. Plates and screws are provided non-sterile.

The 3.3mm bone fasteners have the same core diameter as the 2.7mm fasteners with a 3.3mm outer diameter, resulting in a larger, more aggressive tooth height for use in applications such as the distal fibula where surgeons can dictate a preference for the 2.7mm or a 3.3mm fastener.

The OsteoCentric Bone Plate and Screw System also includes distal fibula plates with both non-locking or locking options. The system includes non-locking plates that accept the 2.7mm, 3.3mm, or 3.5mm non-locking bone fasteners- based on surgeon preference. Locking distal fibula plates are also provided that include distal locking features that accept 3.3mm locking fasteners or 2.7mm non-locking or 3.3mm non-locking fasteners, while 2.7mm/3.3mm/3.5mm non-locking bone fasteners can be used in the shaft.

Note: When using locking 3.3mm fasteners in the locking distal fibula plates, care should be taken to not apply finishing or tightening torque to the 3.3mm locking screws under power. All final torque should be applied using one of the supplied hand actuated hex drivers to prevent over-torquing the 3.3mm locking fastener to the plate.

The OsteoCentric Trauma Bone Plate and Screw System includes proximal humerus plates. The plates accept either the 3.5mm non-locking bone fastener or the 4.0mm locking bone fastener, based on surgeon preference. When using the 4.0mm locking bone fasteners in the proximal humerus plate, care should be taken to not apply finishing or tightening torque to the 4.0mm locking fasteners under power. All final torque should be applied using one of the supplied hand actuated hex drivers to prevent over-torquing the 4.0mm locking fastener to the plate.

Drill bits are also included in the OsteoCentric Bone Plate and Screw System. The single use drill bits are offered in the following sizes; 2.0mm x 100mm, 2.0mm x 110mm (calibrated) 2.5mm x 110mm, 2.5mm x 145mm, 2.7mm x 100mm, 2.8mm x 165mm, 2.8mm x 165mm (calibrated), 3.2mm x 145mm, 3.5mm x 110mm, and 4.5mm x 145mm. All drill bits are manufactured from medical grade stainless steel and are designed specifically to prepare bone to receive a tap, screw, or other implant. The drill bit is to be used in trauma and orthopedic cases involving bone screw, pins, or other implants that require pre-drilling of bone.

**Indications for Use:**

The OsteoCentric Bone Plate and Screw 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 has not tested compatibility between the OsteoCentric Bone Plate and Screw System and other devices provided by other manufacturers and assumes no liability in such instances.

**Magnetic Resonance environment:**

The OsteoCentric Bone Plate and 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 OsteoCentric Bone Plate and Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**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 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. Remove sharp devices for manual cleaning or place into a separate tray.
  5. 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. Reassembly of instruments can be accomplished by following step 1 in reverse.
  13. 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.
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Cleaning instructions have been validated.

It is recommended that devices should 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.

**Instruments and Implants Provided Non-Sterile:**

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. 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  $\leq 10^{-6}$ :

<b>Method</b>	Steam
<b>Cycle Type</b>	Pre-Vacuum
<b>Minimum Temperature</b>	132°C
<b>Full Cycle Time</b>	4 minutes
<b>Minimum Dry Time</b>	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.










**Storage:**

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

**Disposal:**

Dispose of implants according to facility protocol.

**Symbols and Definitions:**

Symbol	Definition
	Catalogue number
	Lot Number
	Serial 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



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