OsteoCentric® Small Frag Bone Plate and Screw System
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

Description:

The OsteoCentric Small Frag 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 locking lateral distal fibula plate
- Proximal Humerus Plate
- Posterolateral Distal Fibula 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 Small Frag 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-torqueing the 3.3mm locking fastener to the plate.

The OsteoCentric Small Frag 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-torqueing the 4.0mm locking fastener to the plate.

Drill bits are also included in the OsteoCentric Small Frag 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 Small Frag 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 intra-articular fractures.

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:

- 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.

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

- Contraindications
- Presence of bends, scratches, breaks, or other defects in the device
- Device damage due to excessive bending force during contouring
- Potential for corrosion due to mixing metals within the same construct
- 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

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 Small Frag Bone Plate and Screw System and other devices provided by other manufacturers and assumes no liability in such instances.

MRI Safety Information:

The OsteoCentric Small Frag Bone Plate and Screw System fasteners have not been evaluated for safety in the magnetic resonance environment. It has not been tested for heating or unwanted movement in the magnetic resonance environment. The safety of the OsteoCentric Small Frag Bone Plate and Screw System fasteners in the magnetic resonance environment is unknown. Performing an magnetic resonance exam on a person who has this medical device may result in injury or device malfunction.

Non-Sterile Products:

All implants, instruments, and containers in the OsteoCentric Small Frag Bone Plate and Screw System are supplied in a non-sterile condition and must be 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).

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.

Point of Use Care:

Wipe blood and/or debris from device immediately following the surgical procedure to prevent it from drying onto the surface. Flush cannulated devices with water to prevent the drying of soil and/or debris to the inside. Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with water to prevent blood and/or debris from drying.

These recommendations are for processing reusable devices. Reusable devices include certain surgical instruments, instrument trays and cases. The information provided does not apply to implants.

Preparation for Cleaning & Reprocessing:

1. It is recommended that devices be reprocessed as soon as is reasonably practical following use.
2. Disassemble device, if applicable, prior to reprocessing. Disassemble parallel wire guides by unthreading knurled head from floating stem. Remove floating stem and head from base assembly.
3. 3.5mm/2.5mm Universal Drill Sleeve needs to be disassembled prior to cleaning part #110522, please note: that the universal drill sleeve contains a small internal spring, and this spring can be easily misplaced. If a replacement is required, please request part #110522-01.
4. The Metaphyseal Drill guide part #120008 and the Metaphyseal drill guide, short, part #120011 both contain a set screw, if this set screw is lost or misplaced during disassembly and cleaning a replacement can be ordered using part #120012.
5. Open devices with ratchets, box locks or hinges.
6. Ensure all devices have been completely removed from original packaging, including tip protectors.
7. 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.

Reprocessing of Re-Usable Instruments:

Note: For manual cleaning, all devices should be positioned to allow cleaning solution to come in contact with all surfaces. Care should be taken to protect devices from mechanical damage.

1. 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.
2. Manual washing: Immerse the devices in room temperature neutral pH enzymatic cleaner (for example, Metrizyme). Scrub devices with appropriate soft bristle brush for a minimum of 30 seconds. (scrub the exterior for 15 seconds and then scrub the lumen for 15 seconds)
3. Re-immerse each device in the cleaning solution and brush for a total of 10 minutes (6 minutes on the exterior and 4 minutes in the lumen).
4. Rinsing: Thoroughly rinse the devices three times for a duration of two minutes each time with critical water, critical water is defined as water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization, reverse osmosis, distillation, or submicron filtration) to ensure that the microorganisms and the inorganic and organic material are removed from the water.
5. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeat steps 1-4 if not visibly clean.
6. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.
7. Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or burrs should be disposed of properly.
8. Reassembly of instruments can be accomplished by following the disassembly steps in reverse.

The manual cleaning instructions have been validated.

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.

Products are supplied non-sterile. 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 cleared wrap or container. The following parameters have been validated to a sterility assurance level (SAL) of ≤ 10^{-6}:

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132°C
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. FDA-cleared wraps should be utilized for steam sterilization. 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.

Torque Limiter Inspection, Maintenance, Test, and Lifespan:

No inspection, calibration, or test is necessary for the included torque limiter. The torque limiter is delivered with a torque value of 1.5Nm ± 0.15Nm. The usage is intended for a limited time only. The torque limiters are designed for usage of 3 years per indication of the expiration date on the label and pack slip associated with the shipment (if applicable).

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 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. 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.

Note

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

Symbols Glossary

Symbol	Symbol Title	Reference Number	Explanatory Text
	Catalogue number	5.1.6.(1)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch Code	5.1.5.(1)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Serial Number	5.1.7.(1)	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Prescription only	N/A	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Consult instructions for use	5.4.3(1)	Indicates the need for the user to consult the instructions for use.
	Do not reuse	5.4.2(1)	Indicates a medical device that is not to be re-sterilized.
	Manufacturer	5.1.1.(1)	Indicates the medical device manufacturer.
	Date of Manufacture	5.1.3.(1)	Indicates the date when the medical device was manufactured.
	Non-Sterile	5.2.7(1)	Indicates a medical device that has not been subjected to a sterilization process.

(1) ISO 15223-1:2021(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Manufacturer: **OsteoCentric Technologies, Inc.**
75 West 300 North | Suite #150 | Logan, UT 84321
Phone: 1-800-969-0639

OsteoCentric® TECHNOLOGIES

UnifiMI™ An OsteoCentric Technology

75 West 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639
info@osteocentric.com
osteocentric.com