# OsteoCentric® Femoral Neck Fracture System

## Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

### Device Description

The OsteoCentric Femoral Neck Fracture System is intended for use in internal fixation of femoral neck fractures of the proximal femur. The OsteoCentric Femoral Neck Fracture System consists of plates and fasteners in a variety of lengths and diameters to accommodate different anatomic sizes of patients. Lag Fasteners are offered in Ø11mm, Ø13mm, & Ø15mm sizes with lengths ranging from 75 – 120mm in 5mm increments. Femoral Neck Fixation Plates are offered in 1-hole to 4-hole configurations (45 – 110mm). 6.0mm support fasteners are offered in 55 – 125mm lengths. 5.2mm shaft fasteners are offered in 28 – 46mm lengths. Compression screws are also available. The Femoral Neck Fracture System is provided non-sterile. All implantable devices are manufactured from stainless steel per ASTM F138.

### Indications For Use

The OsteoCentric Femoral Neck Fracture System is indicated for stable and unstable intertrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

The OsteoCentric Femoral Neck Fracture System is indicated for femoral neck fractures including intracapsular, transcervical, and subcapital 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:

- 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.
- Sepsis
- Malignant primary or metastatic tumors

## 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

Implants should not be used to permanently replace normal body structure. To reduce risks associated with the use of implants, surgical staff should follow the warnings and precautions contained in this document. While many possible reactions and adverse events may occur, some of the most common include: problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues including swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy / hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

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 Femoral Neck Fracture System and other devices provided by other manufacturers and assumes no liability in such instances.

## Magnetic Resonance Environment

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## Non-Sterile Products

All implants, instruments, and containers in the OsteoCentric Femoral Neck Fracture 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 the depth gauge prior to reprocessing by unthreading the end cap and then removing the inner shaft from the outer sleeve.
3. Remove sharp devices for manual cleaning or place into a separate tray.
4. Open devices with ratchets, box locks or hinges.
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.

## 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, DI, RO, 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 & accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, & 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** | 132ºC (270ºF) |
| **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.

## 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 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. |
|  | 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. (Implants, single-use instruments) |
|  | 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, labelling and information to be supplied – Part 1: General requirements

## Manufacturer

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To request a surgical technique guide, additional product information, or to report any adverse experience, please contact customer service at **1-800-969-0639**.

## 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.



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