OsteoCentric TECHNOLOGIES

OsteoCentric Cannulated Fastener & Nut Sets
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

Description:

The OsteoCentric Cannulated Fastener set, and optional Cannulated Nut Set, consists of cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. Cannulated Nuts matching the threaded 7.0 and 8.0mm fasteners are also available. The screws and nuts are provided non-sterile. Screws and nuts are manufactured from Stainless Steel per ASTM.

Indications For Use 7.0mm to 8.0mm Cannulated Screw Fastener:

The OsteoCentric 7.0mm to 8.0mm Cannulated Screws are intended for fracture fixation of long bones and long bone fragments, long bone osteotomies, femoral neck fractures, slipped capital femoral epiphyses as an adjunct to treatment with a dynamic hip screw (DHS) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, SI joint disruptions, fixation of pelvis and iliosacral joints, and subtalar arthrodesis.

Indications for Use: Cannulated Nut:

The OsteoCentric 7.0mm & 8.0mm Cannulated Nut is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (i.e.: the syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

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 these systems, 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 Trauma has not tested compatibility between the cannulated bone screws and other devices provided by other manufacturers and assumes no liability in such instances.

MRI Saftey Information:

The OsteoCentric Cannulated Screw Fasteners have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the OsteoCentric Cannulated Screw Fasteners in the MR environment is unknown. Performing an MR 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 Cannulated Screw Fastener and Auxiliary Systems 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. 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.

Reprocessing of Reusable 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 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.

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. 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.
	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

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

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