OsteoCentric Cannulated Screw Fastener Set Instructions for Use

Non-Sterile
Prescription Use Only
Do Not Reuse

The OsteoCentric Trauma Cannulated Screw Fastener set consist of cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The screws are provided non-sterile. Screws are manufactured from Stainless Steel per ASTM F138.

Indications for use:
The OsteoCentric Trauma 7.0mm and 8.0mm Cannulated Screws are intended for fracture fixation of large bones and large bone fragments, femoral neck fractures, slipped capital femoral epiphyses, as an adjunct to DHS in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, and subtalar arthrodesis.

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

Magnetic Resonance environment:
Devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards including heating or migration of the device and artifacts on MR images.

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 applicable, prior to reprocessing. Disassemble parallel wire guides by unthreading knurled head from floating stem. Remove floating stem and head from base assembly.
2. Open devices with ratchets, box locks or hinges.
3. Ensure all devices have been completely removed from original packaging, including tip protectors.
4. 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.
    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.

5. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.
6. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.
7. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.
8. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.

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.

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 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
Preconditioning Pulses	4
Minimum 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.

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:
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