OsteoCentric Trauma Schanz Pin Fastener System
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

The OsteoCentric Trauma Schanz Pin Fastener System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions, and replantations of bones and bone fragments. The system features Schanz Pin Fasteners in a variety of lengths and diameters to accommodate different anatomic sizes of patients. All implantable devices are manufactured from medical grade stainless steel per ASTM F138, and are provided non-sterile.

Indications for Use:

The OsteoCentric Trauma Schanz Pin Fastener System is intended for use in external fixation for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Contraindications:

- Active or latent infection
- Material Sensitivity – If suspected, tests should be performed prior to implantation
- Insufficient quantity or quality of bone/soft tissue
- 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:

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
- 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 (from contact with patient materials, physiological fluids, or tissues) or damaged should never be used again and must be properly discarded 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 Trauma Schanz Pin Fastener System and other devices provided by other manufacturers and assumes no liability in such instances.

MRI Safety Information:

The OsteoCentric Trauma Schanz Pin Fastener System 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 Trauma Schanz Pin Fastener System 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.

OsteoCentric Schanz Pin Fasteners are composed of similar materials and offered in similar diameters/lengths as pins found in many common external fixation systems. (see chart next page).

Manufacturer – Device (Pin)	Material(s)	Diameter (mm)	Length (mm)
OsteoCentric – Schanz Pin Fastener	Stainless Steel	4 / 5 / 5.5 / 6	95 - 275
Synthes – Schanz Screw	Stainless Steel/Titanium	4 / 4.5 / 5 / 6	60 - 300
Smith & Nephew – JET-X Half Pin	Stainless Steel	4 / 5 / 6	135 - 375
Stryker – Apex Pin	Stainless Steel/Titanium	4 / 5 / 6	90 - 300
Zimmer – XtraFix Large Half Pin	Stainless Steel	4 / 5 / 6	100 - 275
Globus – Schanz Pin	Cobalt Chrome / Stainless Steel / Titanium	4 / 5 / 6	150 - 400

Non-Sterile Products:

All implants, instruments, and containers in the OsteoCentric Distal Femur Plating 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 throughout surgical procedure to prevent it from drying onto the surface. Flush cannulated devices with sterile or purified 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 sterile or purified 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. Remove sharp devices for manual cleaning or place into a separate tray.
3. Open devices with ratchets, box locks or hinges.
4. Special attention should be given to devices with lumens/cannulae and may require extra time as deemed necessary by trained personnel. Lumens/cannulae of devices should be manually processed prior to cleaning. Lumens/cannulae should first be cleared of debris. Lumens/cannulae 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/cannula may not effectively clean the surface of a lumen/cannula.

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: Rinse each device with tap water for a minimum of 1 minute to remove any visual debris.
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, and RO or distillation) 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:

1. Products are supplied non-sterile. Non-sterile devices must be cleaned and steam-sterilized prior to surgical use. Prior to steam-sterilization, place the product in an FDA cleared wrap or container. Do not stack trays during sterilization.

2. The following parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$.

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132ºC
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. 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:

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

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.
	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 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Manufacturer

OsteoCentric Sports Medicine
A Subsidiary of OsteoCentric Technologies Inc.
75 W 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639

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.

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