Instruction for Use
Flex-Thread™ Plating System – Instruments

Rx Only

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INTENDED USE
The Flex-Thread™ Plating System is intended for use in the fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for long bone in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. This system can be used for palmar, ventral, dorsal or orthogonal application.

DESCRIPTION
The Flex-Thread™ Plating System consists of multiple plate families of various anatomical sizes and shapes, 2.7mm, 3.5mm, 4.0mm, and locking and nonlocking screws which mate into the plates, as well as various instruments to assist in implanting the system

MATERIAL
The implants are made from titanium alloy (Ti6Al4V ELI ASTM F136). The instruments are made from medical grade stainless steel & aluminum.

CLEANING AND STERILIZATION
Surgical instruments as well as implantable washers and screws are supplied non-sterile. Remove instruments from all individual sales packaging, clean and place in the appropriate location in the instrument pan provided by Flower Orthopedics prior to sterilization.

Autoclave sterilization is recommended. The autoclave must be properly maintained by the hospital and regularly checked to assure the recommended sterilization temperatures are reached for the entire exposure time. Other sterilization methods are possible but must be maintained by the user. The following Cleaning and Sterilization parameters have been validated and are recommended:

Point-of-Use	Prompt, initial treatment to remove and/or prevent drying of soil and contaminants is recommended to facilitate subsequent cleaning steps after each use.
Pre-Clean	-Disassemble any instrumentation that requires disassembly per manufacturer's instructions provided before cleaning. -Thoroughly Clean all instruments before sterilization, including the instrument tray. -Submerge instruments in enzymatic detergent & soak for 10 minutes per manufacturer's instructions. -Scrub submerged articles with a soft sponge & agitate. -Use a pipe cleaner or brush in any lumens and crevices. -Actuate any moving parts to loosen trapped contaminants. -Rinse in warm (38-49°C) water for 2 minutes. Thoroughly flush all lumens & other difficult to reach areas. Actuate while rinsing.
Cleaning (manual)	-Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent per manufacturer's instructions. -Rinse with final rinse water quality of reverse osmosis or distilled water, actuating any moving parts while rinsing for 2 minutes. Repeat rinse twice. -Dry instruments thoroughly with a clean, lint free cloth.
Cleaning (automated)	Execute the cycle using a pH neutral enzymatic detergent according to the following parameters: Step 1: Pre-Wash: Minimum Temperature: Cold Tap Water Minimum cycle time: 2 minutes Step 2: Enzyme Wash: Minimum Temperature: Hot Tap Water Minimum cycle time: 4 minutes Step 3: Wash (Detergent % according to manufacturer specification): Minimum Temperature: 65.5 °C (149.9°F) Minimum cycle time: 2 minutes Step 4: Neutralization: Minimum Temperature: Hot Tap Water Minimum cycle time: 2 minutes Step 5: Rinse: Minimum Temperature: Hot Tap Water Minimum cycle time: 15 seconds Step 6: Thermal Rinse (A0 = 3000): Minimum Temperature: 82.2 °C (180.0°F) with Lubricant (% Lubricant according to manufacturer specification) Minimum cycle time: 1 minute Step 7: Hot Air Dry: Minimum Temperature: HIGH Minimum cycle time: 6 minutes
Visual Inspection	-Inspect instruments for any damage or remaining contaminants, devices must be visually clean and without visual contaminants. -Repeat cleaning if contamination remains. -Contact **Conventus Flower Orthopedics** if instruments are damaged.
Sterilization Preparation	-Place instruments in the correct location in the instrument pan. -Do not stack pans for sterilization -Wrap the pan in a double layer of FDA cleared CSR wrap. OR -Place instruments into a Sterile Container
Sterilization	-Pre-vacuum cycle -Temperature: 132°C or 270°F -Exposure time: 4 minutes -Dry time: 40 minutes
Storage	Store wrapped or in Sterile Container prior to immediate use.

STORAGE
Store instruments in the corresponding instrument system pans. After use and cleaning, instruments must be stored in a clean, dry and temperate place.

EXAMINATION PRIOR TO USE
All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.

Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of **Conventus Flower Orthopedics**.

WARNING AND PRECAUTIONS
- Conventus Flower Orthopedics devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- The surgeon must take care not to exert inappropriate stress on the device and must comply with the operating procedure described in the surgical technique.
- Prior to using the instrument system, the surgeon should give careful consideration to all aspects of the surgical intervention as well as the limitations of the implant and instruments.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

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Approved By:

(CO-340) Plate IFUs

Description

Initial Release of Flex Thread Plating System IFUs FOCIFU12 and 13

Justification

Initial Release of Flex Thread Plating System IFUs FOCIFU12 and 13

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