Instruction for Use
NiTE Force™ Continuous Compression System – Instruments and non-sterile implants

Rx Only

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DESCRIPTION
The Conventus Flower NiTE ForceContinuous Compression Screw System consists of 4.0mm cannulated nickel titanium (NiTi) screws and instrumentation for implantation. The compression screw is available in length configurations between 28mm - 60mm, with increments of 2mm. The system is provided non- sterile.

MATERIAL
Conventus Flower Orthopedics' surgical instruments are manufactured from medical grade stainless steels and plastics. All instruments are user sterilized and are re-usable unless specified otherwise. The Nitinol Compression implants are made from Nitinol (ASTM F2063).

INDICATIONS FOR USE
The Conventus Flower NiTE Force Continuous Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, of small bones and small bone fragments.

CLEANING AND STERILIZATION
Surgical instruments and implants are supplied non-sterile. Remove instruments and implant5s 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 20 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.
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: 20 minutes
Storage	Store wrapped or in Sterile Container prior to immediate use.

MRI SAFETY INFORMATION
The Conventus Flower Nitinol Compression Screw System has not been evaluated for safety and compatibility in the MRI environment. The Conventus Flower Nitinol Compression Screw System has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the Conventus Flower Continuous Compression Screw System in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS
Prior to using the Conventus Flower Screw System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions.

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.

	Single use
REF	**Catalog number**
LOT	**Lot number**
	See instructions for use
STERILE R	**Sterile**

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