Instruction for Use
OsteoCoil™ Nitinol Compression System – Sterile Implants

Rx Only

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INTENDED USE
The OsteoCoil™ Nitinol Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of the small bones for wrist, hand, and foot.

DESCRIPTION
The OsteoCoil™ Nitinol Compression System consists of multiple screw sizes, a 4.5mm, 6.5mm and 7.3mm screw are available in 30mm through 150mm in 5mm increment lengths., as well as various instruments to assist in implanting the system.

HOW SUPPLIED
All implants of the OsteoCoil™ Nitinol Compression System are provided individually sterile packaged and for single use only. Sterile components are provided in a convenient Flower Cube™. Instruments of the system are provided non-sterile in a tray which must be sterilized prior to use and reprocessed according to The OsteoCoil™ Nitinol Compression System. Reprocessing Instructions (FOCIFU-15). Please refer to the Surgical Technique Guide for a full listing of implants and instruments (FOC 1095).

MATERIAL
The implants are made from nickel titanium alloy (Nitinol, NiTi ASTM F2063) The instruments are made from medical grade stainless steel & aluminum.

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

CONTRAINDICATIONS
Do not use The OsteoCoil™ Nitinol Compression System in cases of:
- Inadequate bone quantity or bone quality, including osteoporotic or osteopenic bone
- Foreign body sensitivity to implant material
- Acute localized infections
- Patients with limited blood supply
- Patients who are unwilling or incapable of complying with post-operative care instructions
- Patients with closed or inadequate medullary canals

ADVERSE REACTIONS
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.

STORAGE:
- Always store the implants and instruments in the original protective packaging.
- Store the implants and instruments in a dry and dust-free place (standard hospital environment).

INSPECTION:
Before use, inspect the box carefully. Do not use when sterile barrier is visually damaged.

OPERATING INSTRUCTIONS
The OsteoCoil™ Nitinol Compression System should be implanted only with The OsteoCoil™ Nitinol Compression System instruments.

PRE-OPERATIVE
- Prior to use, thoroughly read the provided Surgical Technique Guide.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough understanding of both, the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon. The operating surgeon draws up an operation plan specifying and documenting the following:
  - Implant component(s) and their dimensions.
  - Determination of intra-operative orientation points.

The following conditions must be fulfilled prior to application:
- All required implant components are sterilized and readily available.
- All requisite implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

WARNING:
The use of implants for tasks other than those for which they are intended may result in damaged/ broken implants or patient injury.
- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects must be readily available at the workplace.
- The operating surgeon must be specially trained in orthopedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
  - The patient is aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.
  - The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
  - The implant can fail due to excessive load, wear and tear or infection.
  - The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload too early through extreme strain, work-related or athletic activities.
  - Corrective surgery may be necessary if the implant fails.
  - The patient must have his/her physician carry out follow-up examinations of the implants at regular intervals.

SAFETY PRECAUTIONS
- Each patient's record shall document the implant used (name, item number, lot number (if available)).

Never re-use an implant. Although the implant may appear undamaged, previous stresses may have created non-visible damage that could result in implant failure. The manufacturer accepts no responsibility for a re-used implant.

INTRA-OPERATIVE
- Prior to use, verify the integrity of the implant.
- Do not modify any components of the OsteoCoil™ Nitinol Compression System
- Use the appropriate OsteoCoil™ Nitinol Compression System instruments (as necessary) in the appropriate length to prepare the path for the implants.

POST-OPERATIVE
- Reiterate preoperative instructions to the patient.
- During the post-operative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

REVISION SURGERY / IMPLANT REMOVAL
Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed, particularly in young, active patients. The surgeon must make the final decision on implant removal if either of these occurs. If there are not any of these complications, we recommend the permanent implantation of this titanium implants because of the risk of refracture and the possible complications of an additional operation.

USE OF ORGINAL PRODUCTS
Implants and instruments of the OsteoCoil™ Nitinol Compression System are produced and designed to be used together.

WARNING
Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes reprocessing & that reprocessing can only be performed by an authorized third-party re-processor who has received 510(k) clearance for such.

WARRANTY
The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, and limitations of treatment methods or inadequate asepsis.
The manufacturer does not take responsibility for any effects on safety, reliability, or performance of the product if the product is not used in conformity with the instructions for use.
Technical alterations reserved.

FOR FURTHER INFORMATION
Please contact Flower Orthopedic Corporation if further information on this product is needed at 1-877-778-8587.

	Single use
REF	**Catalog number**
LOT	**Lot number**
	See instructions for use
STERILE R	**Sterile – gamma irradiation**
	Use until

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