Instruction for Use
Flower Ankle Plating Set
Implants

Manufacturer:

FLOWER ORTHOPEDICS CORPORATION (FOC)

100 Witmer Road
Horsham, PA 19044

US: 1-877-778-8587
Intern.: +1 267-437-3063

Caution: Federal law restricts this device to sale by or on the order of a physician.	
	• **Single use**
	• **Catalog number**
	• **Lot number**
	• **See instructions for use**
	• **Sterile**
	• **Use until**

FOCIFU03 Rev B

CONTENTS
The package contains one implant device of the Flower Ankle Plating Set.

DESCRIPTION
The devices are supplied **sterile.** The devices are available in several sizes.

MATERIAL
The plates are made from pure titanium (Ti Grade 2 ASTM F67)
The screws are made from titanium alloy (Ti6Al4V ASTM F136)

MRI SAFETY INFORMATION
The Flower Orthopedics Ankle Plating Set 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 of Flower Orthopedics Ankle Plating Set in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INTENDED USE
The Flower Ankle Plating Set is intended for use for fixation of the ankle in adults and adolescents (12-21) in whom the growth plates have fused, and particularly in osteopenic bone. Specifically,
- Distal Medial and Lateral Tibia plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- Distal Tibia A-Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia,
- Straight and Distal Lateral Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

CONTRAINDICATIONS
Do not use the Flower Orthopedics implants in cases of:
- Inadequate bone quantity and/or bone quality
- Foreign body sensitivity to implant material
- Acute localized infections
- Patients with limited blood supply
- Patients with unstable physical and / or mental health conditions

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.

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.

HOW SUPPLIED/STORAGE:
The implants are individually packed in protective packaging that is labeled to its contents. All implants are supplied **sterile**.
- Always store the implants in the original protective packaging.
- Store the implants 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 Flower Orthopedics implants should be implanted only with the Flower Orthopedics instruments applicable for the respective sizes.

PRE-OPERATIVE
- Prior to use, thoroughly read the provided operation manual and become familiar with the surgical technique.
- 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 sterile 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 especially 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.

INTRA-OPERATIVE
- Prior to use, verify the integrity of the implant.
- Modification of the Flower Ankle Plating Set is not allowed.
- Bending of the Flower Ankle Plating Set is possible. When contouring these plates, do not over bend and / or bend back in original shape.
- Use the appropriate Flower Drill Guide and Flower Drill to prepare the holes for the bone screws to avoid damaging the plate.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material
- Before locking the screw to the plate, the bone has to be correctly repositioned

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 original products
Implants and instruments of the Flower Ankle Plating Set 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 reprocessor 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.
All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. 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.

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LOT	• **Lot number**
	• **See instructions for use**
STERILE R	• **Sterile**
	• **Use until**

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CONTENTS
The package contains one or several surgical instrument(s) for use with the Flower Ankle Plating Set.

DESCRIPTION
General instruments such as Trials, Drills, Drill Guides, Depth Gauges, and Screwdrivers.

MATERIAL
The instruments are made from medical grade stainless steel (301, 304, 316L, 420 and/or 440) per ISO 7153-1 & plastic.

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ADVERSE REACTIONS
Possible reactions may include but are not limited to:
Clinical failure due to inappropriate usage.
Necrosis due to thermal load (power driven tools).

SAFETY PRECAUTIONS
Prior to use, thoroughly read this instruction for use.
Keep the instructions for use accessible to all staff.
The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.

HOW SUPPLIED/STORAGE/DISPOSAL:
The instruments are packed in protective packaging that is labeled to its contents. All instruments are supplied **sterile**.

- Always store the instruments in the original protective packaging.
- Store the instruments in a dry and dust-free place (standard hospital environment).
- Instruments are single use devices (SUD) only
- Dispose used single use devices and associated packaging in a safe and appropriate manner.

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

OPERATING INSTRUCTIONS
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WARNING
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FOR FURTHER INFORMATION
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