conventus FLOWER

FLOWERTOE™ IMPLANT & INSTRUMENT SYSTEM PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE:

FlowerToe™ System implants:

- The screws are offered in different diameters and lengths.
- The screws have a recess for engaging a driver.
- The screws are designed to be implanted into bone.
- The implants are offered in Titanium alloy within the frame of the standard ISO 5832-3 and ASTM F136.

The implants are shipped sterile.

INDICATIONS FOR USE

The FlowerToe™ System implant is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. Screws are intended for single use only.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

MATERIAL

FlowerToe™ System implants are manufactured from a Titanium alloy (ISO 5832-3 and ASTM F136). The specialized instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899) and Radel® polyphenylsulfone (ASTM D6394).

HOW SUPPLIED

The implants and instruments are shipped sterile as specified by the packaging.

All sterile implants are gamma radiation sterilized. All sterile instruments are sterilized using ethylene oxide. The packaging should be inspected prior to use to ensure the sterile barrier has not been compromised.

Do not reprocess.

CONTRAINDICATIONS

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

WARNINGS and POTENTIAL RISKS

The FlowerToe™ System is designed for **single patient use only and must never be reused** (for adverse effects related to the reuse of the device see POSSIBLE ADVERSE EFFECTS section). As with all other orthopedic implants, the Conventus Flower Orthopedics components should never be re-implanted under any circumstances.

The FlowerToe™ System can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of screw systems should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized.

The FlowerToe™ System implants should never be used with dissimilar materials. Specifically, the titanium and stainless steel components offered with this system should not be used together.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of X-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The guide wires included in the FlowerToe™ System is not intended as implants. The guide wires are only intended for use as instruments to facilitate screw insertion

POSSIBLE ADVERSE EFFECTS

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Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Non-clinical testing has demonstrated FlowerToe™ System implants are MR Conditional. A patient with these devices can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the FlowerToe™ System implants are expected to produce a maximum temperature rise of 8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the FlowerToe™ System implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

DIRECTIONS FOR USE

To implant the FlowerToe™ System implants, use only the specialized FlowerToe™ System instruments. Do not use implants or instruments from any other system or manufacturer.

The FlowerToe™ implants and instruments are provided sterile. Before using the FlowerToe™ System for the first time, the surgeon should be thoroughly familiar with the FlowerToe™ System Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all FlowerToe™ System implants and instruments, please refer to the FlowerToe™ System Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

FlowerToe™ System implants and instruments are provided sterile. Do not use if package is damaged.

POINT OF USE

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

STERILIZATION

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Conventus Flower.

STORAGE

FlowerToe™ instruments must be completely dry before storing and must be handled with care to prevent damage. Store in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Conventus Flower Orthopedics Customer Service for return of removed implants.

CUSTOMER SERVICE

For further information regarding the Conventus Flower Orthopedics FlowerToe™ System or a copy of the Conventus Flower Orthopedics FlowerToe™ System Surgical Technique Manual, please contact Conventus Flower Orthopedics or your local Conventus Flower Orthopedics Distributor.

DIST. BY

Conventus Flower Orthopedics
100 Witmer Road, Suite 280
Horsham, PA 19044
Phone: +1 (215) 394-8903
Fax: +1 (215) 394-8904

Tyber Medical, LLC
83 South Commerce Way, Suite 310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933
Fax: +1 (866) 889-9914

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

LABEL SYMBOLS

SYMBOL	MEANING
	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
	Reference Number
	Lot Number
	Material
	Date of Manufacture
	Expiration Date
	Quantity
	Sterilized Using Irradiation
	Sterilized Using Ethylene Oxide
	Single Use (Do Not Re-Use)
	Do Not Use If Package Is Damaged
	Refer to Instructions for Use
	Caution
	Non-Sterile
	Distributed by
	Manufacturer
	CE Mark
	EU Authorized Representative
	Unique Device Identifier (UDI)
	MR Conditional
	Medical Device
	Hazardous Substance
	Double Sterile Barrier