GENERAL INSTRUMENTS
PACKAGE INSERT

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

DESCRIPTION OF THE MEDICAL DEVICE

The instruments, delivered sterile - are:

- Guide wires, handle;
- Surgical instruments used to assist in installation of devices;

INDICATIONS FOR USE

The Flower Orthopedics General Instruments are used in conjunction with Flower Orthopedics Implant Systems. Specific indications are provided in the appropriate Flower Orthopedics Implant System.

MATERIAL

The general instruments are made of surgical grade stainless steel per ASTM F899 (guide wires) and Radel (handle) per ASTM D6394.

HOW SUPPLIED

General instruments are provided **sterile**. All sterile instruments are sterilized using gamma radiation.. The packaging should be inspected prior to use to ensure the sterilebarrier has not been compromised.

Do not reprocess.

CONTRAINDICATIONS

- Specific contraindications are provided in the appropriate Flower Orthopedics Implant System.

WARNINGS AND POTENTIAL RISKS

- The general instruments are 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).

PRECAUTIONS

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Preoperative:

1. Care should be used in the handling and storage of the instrument components. The instruments should not be scratched or otherwise damaged. Instruments should be protected during storage especially from corrosive environments.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. The use of general instruments should be performed only by experienced surgeons with specific training in the use of these general instruments because this is a technically demanding procedure presenting a risk of serious injury to the patient.
3. The Conventus Flower general instruments should never be used with dissimilar materials.

POSSIBLE ADVERSE EFFECTS

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:

1. Sensitivity to a metallic foreign body, including possible tumor formation;
2. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
3. Infection;
4. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
5. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
6. Pain or discomfort;
7. Hemorrhage of blood vessels and/or hematomas;
8. Death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The general instruments have not been evaluated for safety and compatibility in the MR environment. The general instruments have not been tested for heating or migration in the MR environment. The safety of general instruments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the instrument components and their dimensions
- Positioning of the instrument components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite instrument components are ready to hand.
- Operating conditions are highly aseptic.
- The implantation instruments, including the special general instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

For complete instructions regarding the proper use and application of all Flower Orthopedics System Implants and Instruments, please refer to the Flower Orthopedics Implant System Surgical Technique Manual (provided with the system).

CARE AND HANDLING

General 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. Follow internal hospital procedures for the disposal of instruments used during surgery.

STERILIZATION

For components provided Sterile, the sterilization method is noted on label. Sterile instrument 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 the component to Conventus Flower.

STORAGE

Conventus Flower General 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 intemperature and humidity.

CUSTOMER SERVICE

For further information regarding the Flower Orthopedics General Instruments, please contact Flower Orthopedics or your local Flower Orthopedics Distributor.

DIST. BY

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LABEL SYMBOLS

SYMBOL	MEANING
℞ only	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference Number
LOT	Lot Number
	Expiration Date
QTY	Quantity
STERILE R	Sterilized using irradiation
	Single Use (Do Not Re-Use)
	Do Not Use If Package Is Damaged
	Refer to Instructions for Use
	Manufacturer
UDI	Unique Device Identifier (UDI)