

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:

- Guidewires, 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 (guidewires) and Radel (handle) per ASTM D6394.

HOW SUPPLIED

General instruments are provided sterile.


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,

PRECAUTIONS

 Federal law restricts this device to sale by or on the order of a physician.

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.

POSSIBLE ADVERSE EFFECTS

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.

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
	Expiration date
	Quantity
	Sterilized using ethylene oxide
	Single use
	Do not use if package is damaged
	Refer to instructions for use
	Distributed by
	Manufacturer

CUSTOMER SERVICE

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

DIST. BY

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

LBL-FO201817 Rev A-01

2018-06-20