FLOWER™
ORTHOPEDICS
A MORE EFFICIENT CASE

FlowerToe™

PROCEDURE GUIDE

www.flowerortho.com

INDICATIONS

The Flower Orthopedics FlowerToe is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. The device is intended for single use only.

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

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

WARNINGS AND POTENTIAL RISKS

FlowerToe implants are designed for single patient use only and must never be reused. As with all orthopedic implants, Flower Orthopedics components should never be re-implanted under any circumstances.

FlowerToe implants 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 contribute to the loosening of 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, experiences sensitization or hypersensitivity to foreign materials, or has 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.

PRECAUTIONS

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

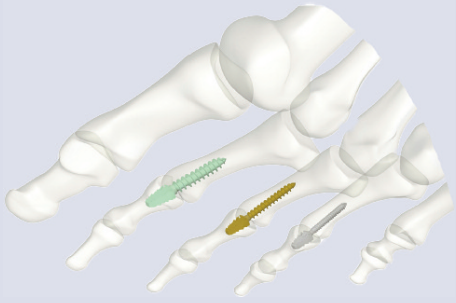
Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized. The FlowerToe System should never be used with dissimilar materials. Preoperative assessment of the suitability of the patient's anatomy for accepting implants should be made on the basis of X-rays, CT scans, and other radiological studies.

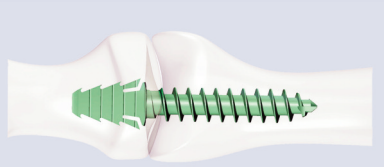
Only patients that meet the criteria described in the Indications for Use section should be selected. Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation, and/or degree of physical activity should be considered.

Proper implant handling before and during the procedure is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implant's surfaces to be damaged. Adequately instruct the patient. The physician should inform the patient about the advantages and disadvantages of the implant, post-operative limitations, weight/load bearing stresses which could affect bone healing, and implant limitations. The patient should be advised 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 guidewires included in the FlowerToe System are not intended for use as implants. The guidewires are only intended for use as instruments to facilitate screw insertion.

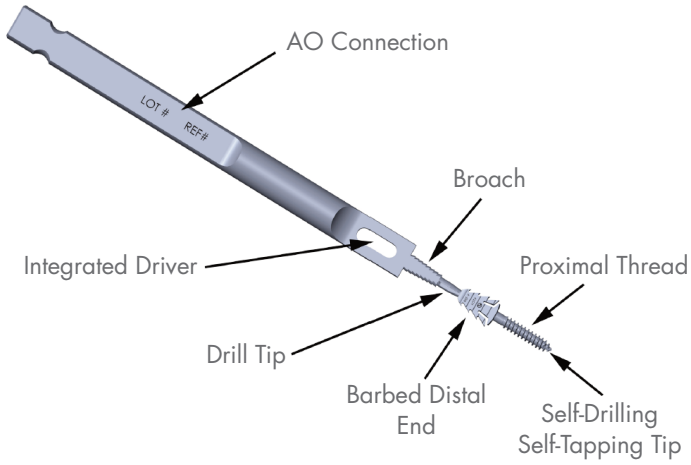
FlowerToe™ – Product Rationale





The comprehensive FlowerToe procedure guide was designed to provide the surgeon a detailed explanation of the procedure steps to aid in the accurate and efficient placement of the screw.

FlowerToe™ – Construct Features and Benefits



Integrated instruments including drill & broach for an efficient procedure

Built in AO Connection with minimal instrumentation for a faster procedure

Barbed distal end for enhanced bone purchase and fixation

Proximal thread contains self-drilling and tapping features

FlowerToe™ – Ordering Information

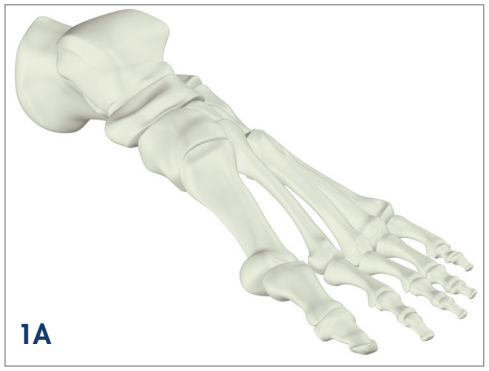
ITEM NO.	CONFIGURATION	SIZE
FHT 200	Cannulated Straight	Ø2.0mm x 13mm
FHT 202	Solid Angled 10°	Ø2.0mm x 13mm
FHT 509	Flower Mini Fixed AO Handle	Ø0.9mm Guidewire (6") Kit (Use with FHT 200 and FHT 202)
FHT 250	Cannulated Straight	Ø2.5mm x 15mm
FHT 252	Solid Angled 10°	Ø2.5mm x 15mm
FHT 511	Flower Mini Fixed AO Handle	Ø1.1mm Guidewire (6") Kit (Use with FHT 250 and FHT 252)

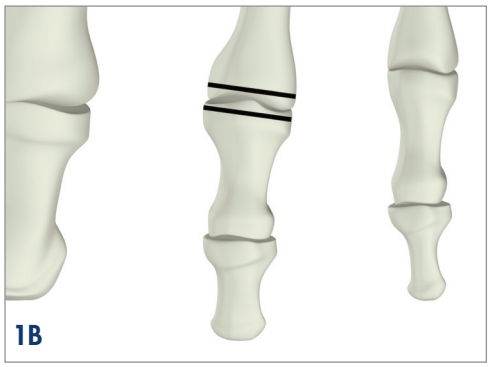
Step 1 – Joint Preparation and Guidewire Selection

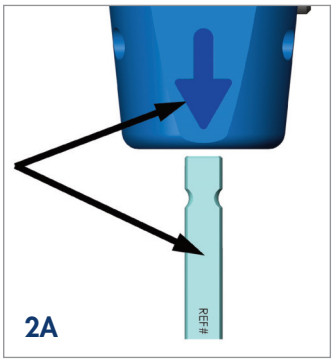
a. Dissect a clean approach to the joint and resect the joint surface. The use of an oscillating saw is preferred for the joint preparation over a rongeur. Figure 1A shows the foot prior to any bone preparation. Figure 1B shows the PIP joint and lines marking the location for the saw cuts.

b. The use of a double trocar guidewire is possible with the cannulated screw option. Select the correct guidewire for the chosen screw diameter (Table 1). The color code that appears on the sterile instrument package is shown in Table 1 and corresponds the 3 implant sizes to the 2 sterile instrument kits.

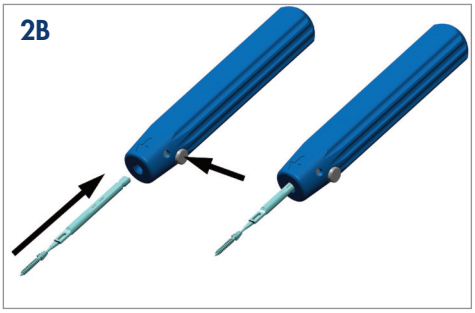
Screw Diameter (Screw Color)	Guidewire Diameter	Sterile Instrument Product Label Color Code
Ø2.0mm (●)	Ø0.9mm	Sterile Instrument System AO Handle and Ø 0.9 Guidewires
Ø2.5mm (●)	Ø1.1mm	Sterile Instrument System AO Handle and Ø 1.1 Guidewires


1A


1B



2A


2B

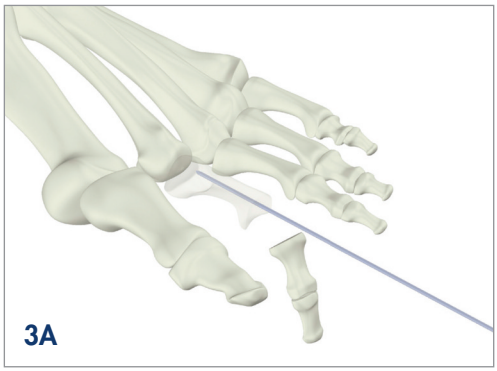
Step 2 – Handle to Implant Attachment

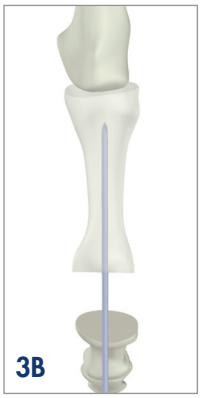
a. To attach the implant to the handle, align the AO connection flat of the implant to the arrow on the handle (Figure 2A). Press the button on the side of the handle and advance the implant into the handle (Figure 2B). To lock the implant into place, release the button. To remove the implant, press the button and pull the device from the handle.

Step 3 – Guidewire Insertion

a. Align the double trocar guidewire into the proximal medullary canal. Advance the guidewire until it reaches the distal pole of the desired proximal fixation region (Figures 3A & 3B). If using a solid implant, no guidewire is needed.

b. Fluoroscopy should be used to ensure correct guidewire position, alignment, and depth. Do not remove guidewire for fluoroscopy.

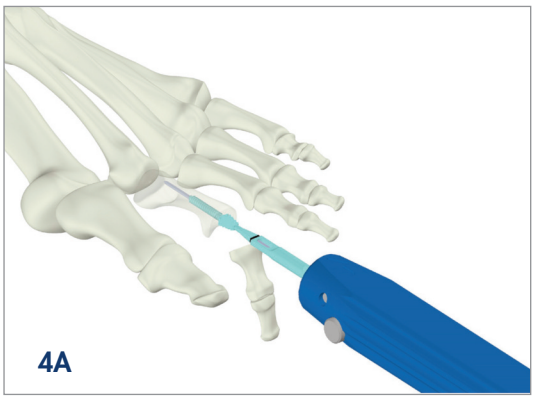

3A

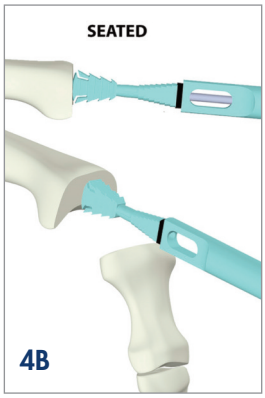

3B

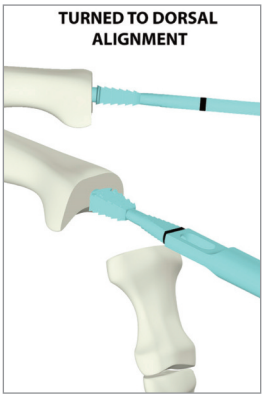
Step 4 – Proximal Screw Insertion

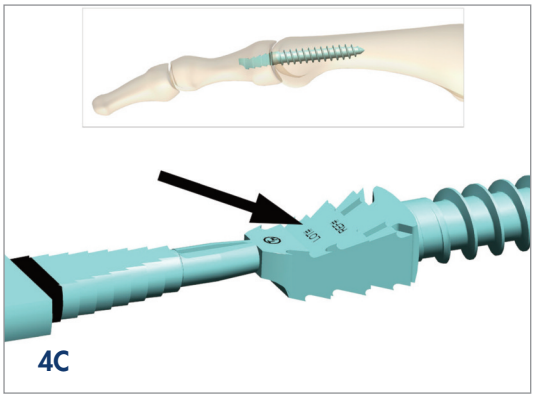
a. Align the implant in the proximal bone space (Figure 4A). Advance the implant until the beginning of the barbed head is seated against the bone as shown in Figure 4B. Once the barbed head is seated, turn counterclockwise to back out the implant until the barbed head is correctly aligned in the dorsal plane (Figure 4B). Correct alignment of the Solid 10° implant must have the lasermarking on the barbed head aligned with the dorsal side of the patient's foot (Figure 4C). Do not seat the implant past the proximal bone surface, as this will risk loss of bone engagement with the barbed head.

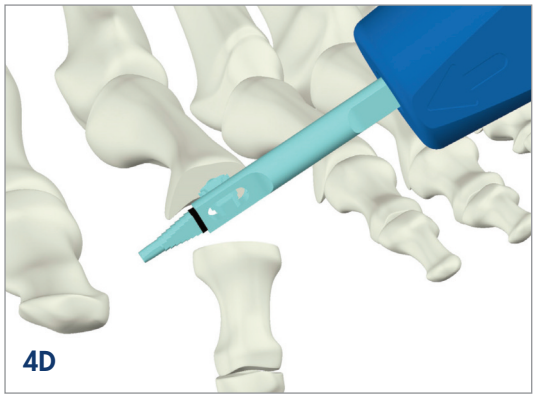
b. If the screw driver breaks off prior to the implant being advanced into the correct alignment, use the integrated driver to position the screw (Figure 4D).







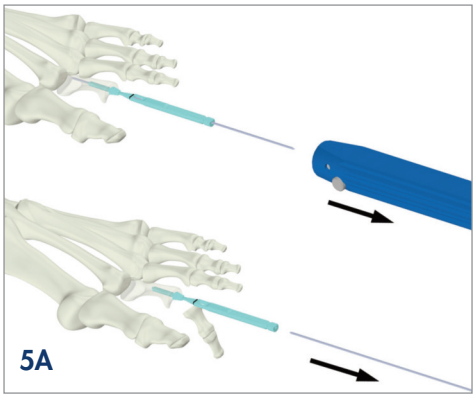


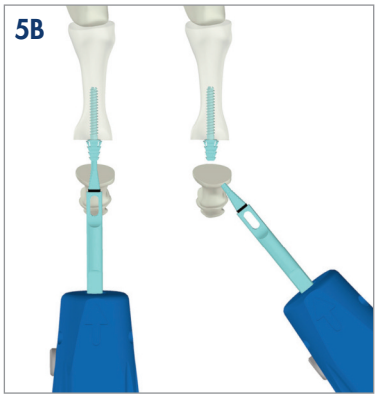


Step 5 – Breaking of the Snap Region

a. Remove the guidewire prior to breaking the snap region of the FlowerToe device. This two step process is shown in Figure 5A. The handle should be disengaged first, following the removal of the guidewire.

b. To break the snap region apply a bending force to angle the driver handle until the implant breaks away from the instrument portion (Figure 5B).





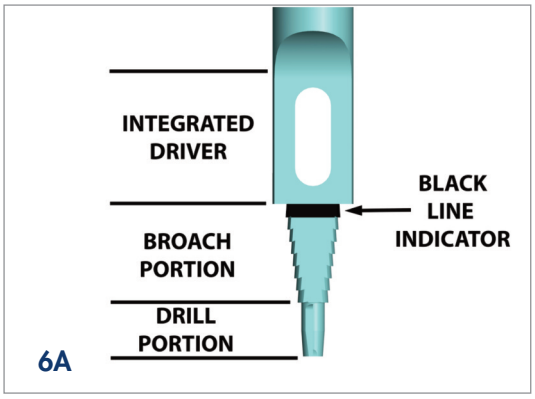
Note: Secure the toe when breaking the snap region. This can be done by hand or with surgical forceps.

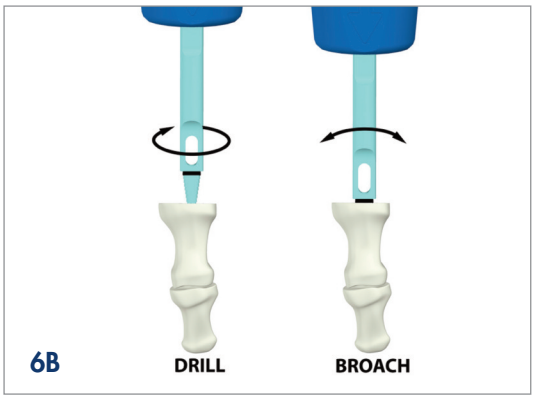
Step 6 – Distal Bone Preparation

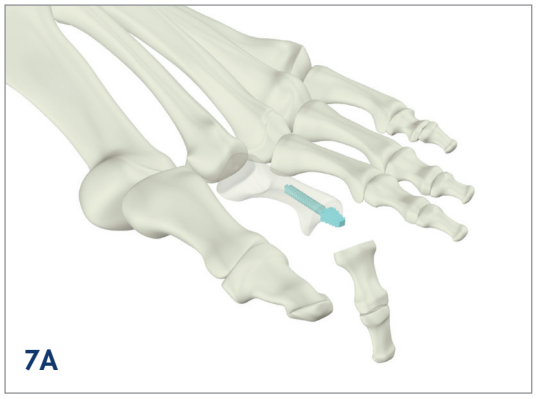
a. Figure 6A shows the integrated instrument portions following the breaking of the snap region. Using the integrated drill tip, prepare the distal bone space by hand. After drilling has occurred, broach the distal bone space using the integrated broach while keeping the black line visible (Figure 6B).

b. Drilling of the bone must be completed using a twisting motion, while broaching must occur in a side to side motion as to not over broach the distal bone space (Figure 6B).

Note: Do not use a guidewire for distal bone preparation. In addition, the bone preparation must be completed by hand and without the use of a mallet.







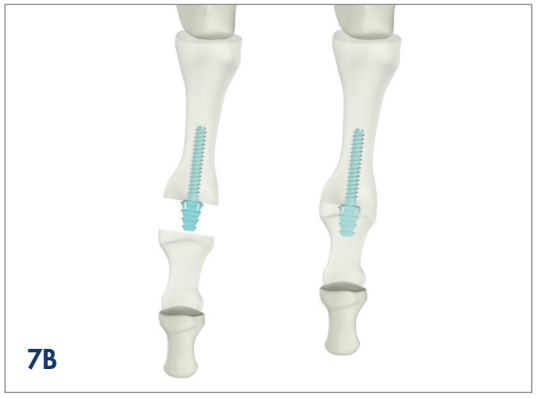
Step 7 – Barbed Head Insertion

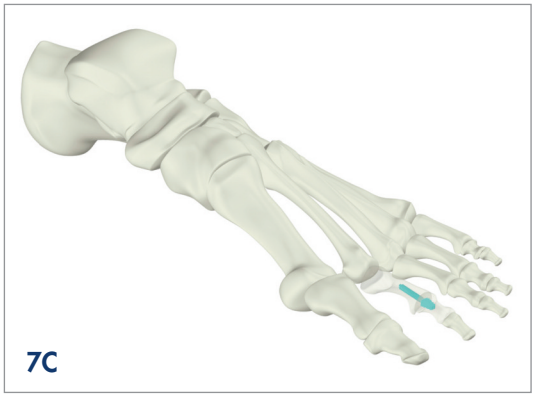
a. Align the barbed head into the distal bone space and advance the head until it is fully seated in the bone space (Figure 7A, 7B, 7C). Apply pressure on the distal phalanx to compress the construct.

Note: When using the Solid 10° implant the lasermarking should be aligned to be facing upward/dorsally.

Removal

To remove the implant, distract the bone space exposing the distal end of the implant. The implant can be backed out of the proximal bone space using the integrated driver. If an instrumentation kit is not available, surgical forceps may be used.





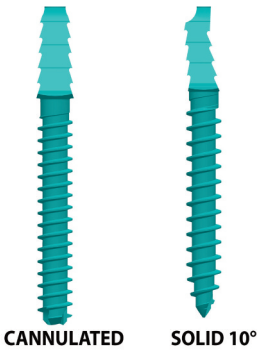
FlowerToe™ – Single-Use Implants

2.0 SCREWS

Part #	Product Description	Length
FHT 200	FlowerToe Cannulated	13mm
FHT 202	FlowerToe Solid	13mm

2.5 SCREWS

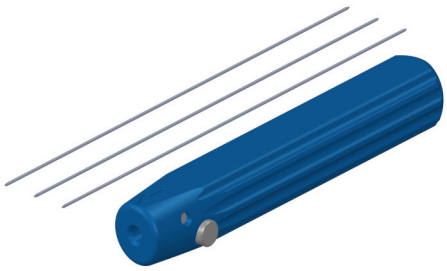
Part #	Product Description	Length
FHT 250	FlowerToe Cannulated	15mm
FHT 252	FlowerToe Solid	15mm



FlowerToe™ – Single-Use Instrument Kits

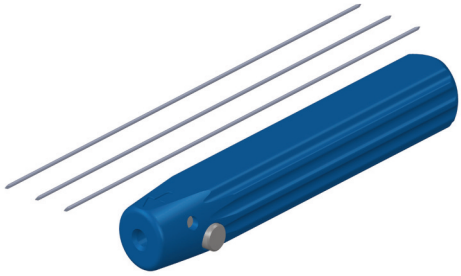
FOR USE WITH FHT 200 AND FHT 202

Part #	Contents of Kit
FHT 509	Flower Mini Fixed AO Handle 0.9mm Guidewire (6") Kit



FOR USE WITH FHT 250 AND FHT 252

Part #	Contents of Kit
FHT 511	Flower Mini Fixed AO Handle 1.1mm Guidewire (6") Kit



We Build a More Efficient Case

Flower Orthopedics is the leader in Ready-for-Surgery™ bone fixation. We deliver efficiencies throughout the supply chain that reduce the overall cost of care.

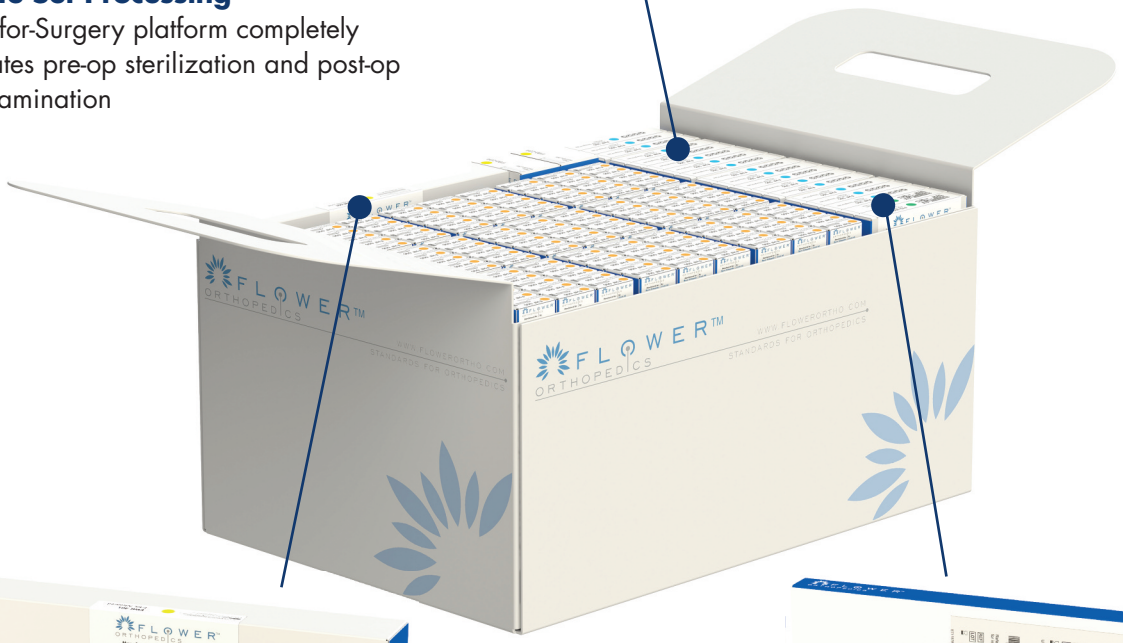
Designed for specific surgical indications, the FlowerCube™ contains all of the implants and instruments required for the case. All products are sterile packaged, single-use and always Ready-for-Surgery.

Complete Case Faster

- Single-use instruments are always sharp, pristine and specifically designed to reduce surgical steps

Eliminate Set Processing

- Ready-for-Surgery platform completely eliminates pre-op sterilization and post-op decontamination



Decrease Infection Risk

- Individually packaged instruments are always sterile, reducing infection potential

Reduce OR Turn Over Time

- Complete several back-to-back cases from one FlowerCube

The FlowerCube™

Flower Orthopedics Corporation
100 Witmer Road • Suite 280 • Horsham, PA 19044 • T: 877-778-8587 • F: 215-394-8904

www.flowerortho.com