READY-FOR-SURGERY™

SnapFix Screw System

Surgical Technique Guide

conventus FLOWER

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BUILDING A MORE EFFICIENT CASE

Conventus Flower Orthopedics is the leader in Ready-For-Surgery™ bone fixation. The FlowerCube™ produces clinically equivalent outcomes while generating cost savings and surgical efficiencies when compared to traditional orthopedic implant and instrument sets.

- Innovative system that is pre-packaged and ready for use
- Contains single-use, sterile packaged implants & instruments required for specific surgical indications
- Eliminates pre-op handling and post-op reprocessing

FlowerCube™ Surgical Efficiency Study Results[1]:

Faster Case Time

Time saving of nearly 20 minutes per case with the FlowerCube compared to procedures using traditional implants

3rd Party Reimbursement Savings

Over $1,300 savings in third party reimbursement costs for procedures performed at an ASC compared to those done in an outpatient hospital setting

Joint Union

84.51% of study patients experienced union of the joints by 8 weeks post-surgery and 98.59% by 12 weeks post-surgery

Opportunity Savings

Sterilization, reprocessing and packaging of surgical trays would add $45 per instrument tray

1: Data on file at Flower Orthopedics

- IRB approved, prospective, multi-center clinical trial • Evaluating arthodesis of first MPJ • 71 patients at both hospital and ASC locations
- Primary Outcome Measure - Fusion rate 12 weeks post surgery • Secondary Outcome Measure - Cost & Time Efficiency

SYSTEM OVERVIEW

1.1 Indications for Use

The Conventus Flower SnapFix Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

1.2 Contraindications

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

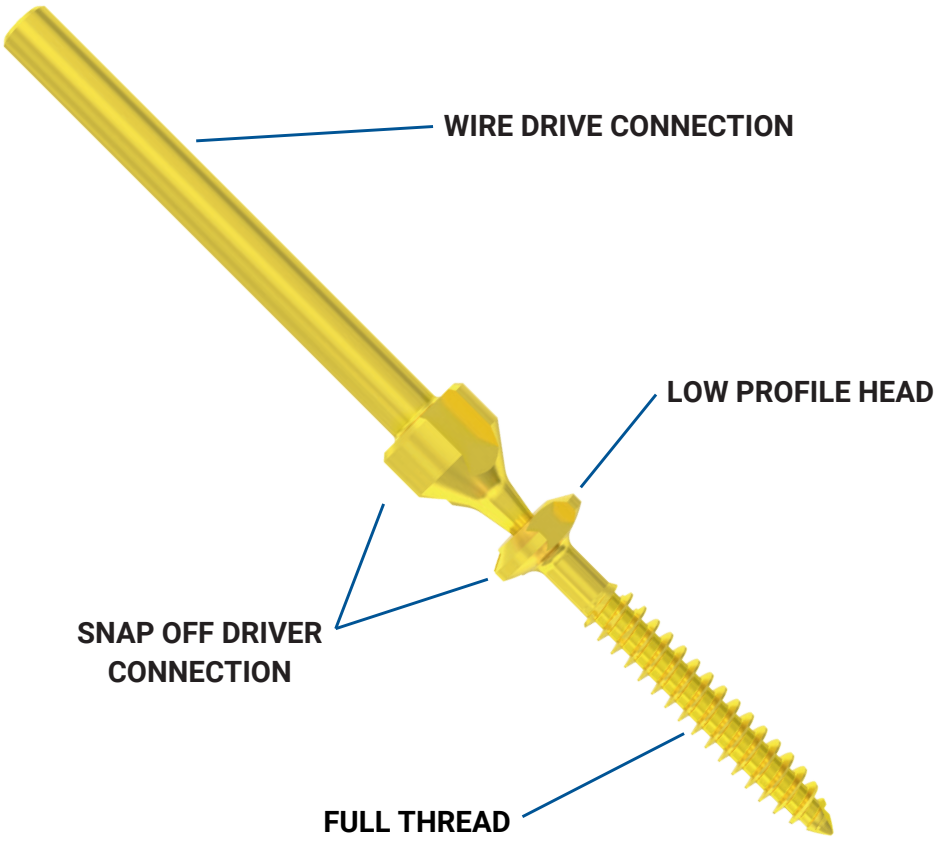
- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

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

2 System Features

The comprehensive Conventus Flower SnapFix Screw was designed to provide a superior level of stable compression. The headed screw exhibits the following advantages:

- Fully Threaded
- Self-Drilling & Self-Tapping
- Hybrid Cortical & Cancellous Thread
- Low Profile Head to Deliver Maximum Compresssion
- Optimized Snap-Off Feature



3 Preparation

Dissect a clean approach to the desired region of the bone where the screw will be inserted.

4 Implant Attachment

Optional Instruments:

FSS 200	SnapFix Driver for 2.0mm/3.0mm Screws
FHT 511	Mini Fixed AO Handle w/ 1.1mm Wires

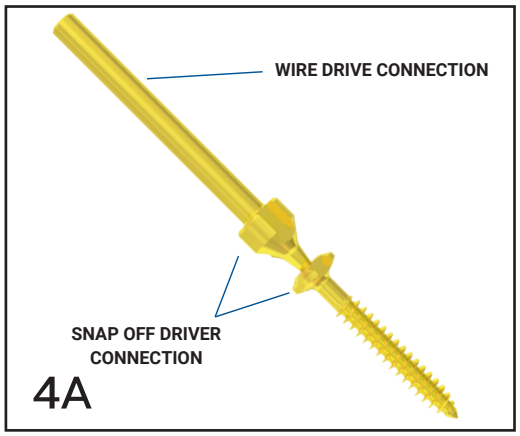
There are two techniques for the implant attachment.

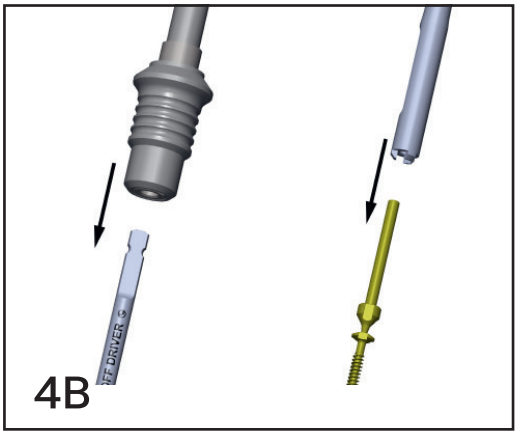
Option 1:
Attach the implant using a 2.0mm wire driver. The location of the wire drive connection is shown in 4A.

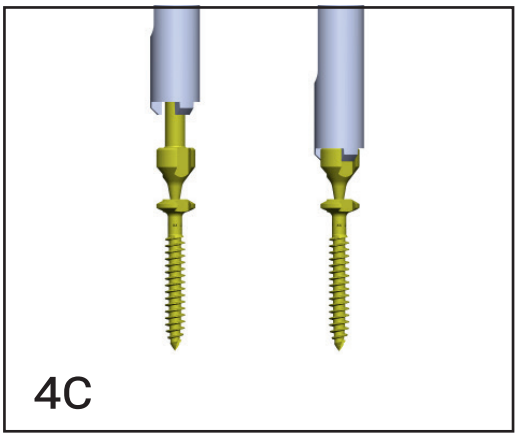
Option 2:
Insert the implant using the SnapFix Driver and Mini Fixed AO Handle. This method is recommended for applications that require a longer driver connection that could not be achieved with a wire driver.

First, attach the AO Handle to the SnapFix Driver. Once secured, slide the Driver over the 2.0mm wire drive shaft (4B).

Engage the implant at the SnapFix driver connection interface (4C).







5 Implant Insertion

Optional Instruments:

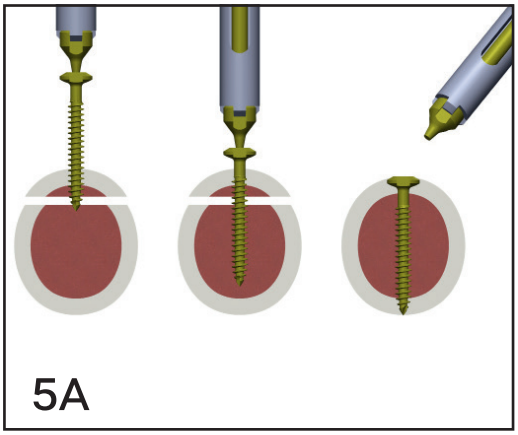
FSS 200	SnapFix Driver for 2.0mm/3.0mm Screws
FHT 511	Mini Fixed AO Handle w/ 1.1mm Wires

There are two techniques for implant insertion.

Option 1:
Insert the SnapFix Screw using the wire driver. Once the desired depth has been achieved, bend the wire driver to break off the SnapFix Screw.

Option 2:
Insert the SnapFix Screw by engaging the SnapFix Driver connection and apply a clockwise torque. Once the desired depth has been achieved, bend the driver to break off the SnapFix Screw (5A).

Precaution:
If further compression is desired after the driver connection has been snapped off, engage the driver with the screw head and apply further compression.


5A

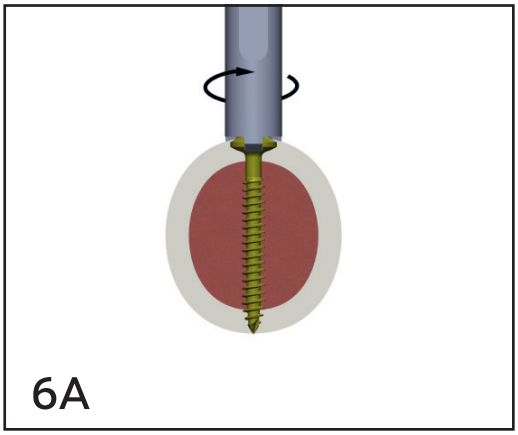
6 Implant Removal

Instruments:

FSS 200	SnapFix Driver for 2.0mm/3.0mm Screws
FHT 511	Mini Fixed AO Handle w/ 1.1mm Wires

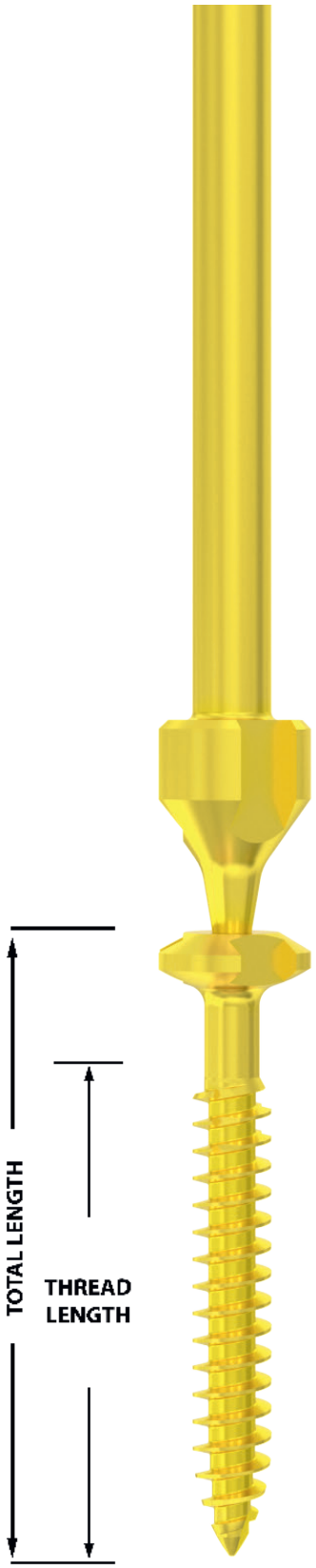
To remove the implant, first attach the AO Handle to the SnapFix Driver.

Once secured, engage the SnapFix Driver to the SnapFix screw head and rotate the implant counter-clockwise (6A).



6A

7 Implants



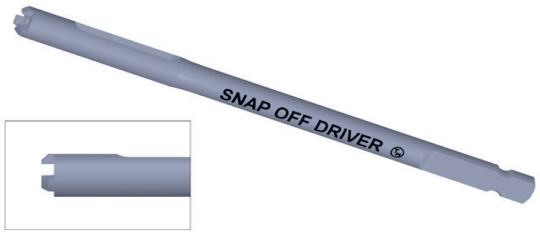
2.0mm SnapFix Screws	
FSS 210	2.0mm x 10mm
FSS 212	2.0mm x 12mm
FSS 214	2.0mm x 14mm
FSS 216	2.0mm x 16mm
FSS 218	2.0mm x 18mm

3.0mm SnapFix Screws	
FSS 310	3.0mm x 10mm
FSS 312	3.0mm x 12mm
FSS 314	3.0mm x 14mm
FSS 316	3.0mm x 16mm
FSS 318	3.0mm x 18mm
FSS 320	3.0mm x 20mm
FSS 322	3.0mm x 22mm

NOTES:

Full Thread:
Thread Length = Total Length - 4mm

8 Instruments



FSS 200	SnapFix Driver for 2.0mm/3.0mm Screws

FHT 511	Mini Fixed AO Handle with 1.1mm Wires

ADDITIONAL INFORMATION

9 WARNINGS AND POTENTIAL RISKS

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

The Conventus Flower 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 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 section for additional warnings.

10 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 Conventus Flower SnapFix Screw Systems should never be used with dissimilar materials. Preoperative 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. 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.

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

SnapFix Screw System manufactured by Tyber Medical and distributed by Conventus Flower Orthopedics.

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