OSTEOCOIL

OSTEOCOIL
Nitinol Compression System

OsteoCoil™ Nitinol Compression System

Surgical Technique Guide

conventus
FLOWER
ORTHOPEDICS

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SYSTEM OVERVIEW

1 Indications for Use

The OsteoCoil™ Nitinol Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of the small bones for wrist, hand, and foot.

2 Contraindications

Do not use the OsteoCoil Nitinol Compression System in cases of:

- inadequate bone quantity or bone quality, including osteoporotic or osteopenic bone
- foreign body sensitivity to implant material
- acute localized infections
- patients with limited blood supply
- patients who are unwilling or incapable of complying with post-operative care instructions
- patients with closed or inadequate medullary canals

3 AO Principles [1, 2]

The OsteoCoil Nitinol Compression System adheres to the AO Principles of Fracture Management such as:

Fracture reduction to restore anatomical relationships

Fracture fixation providing absolute or relative stability

Preservation of blood supply

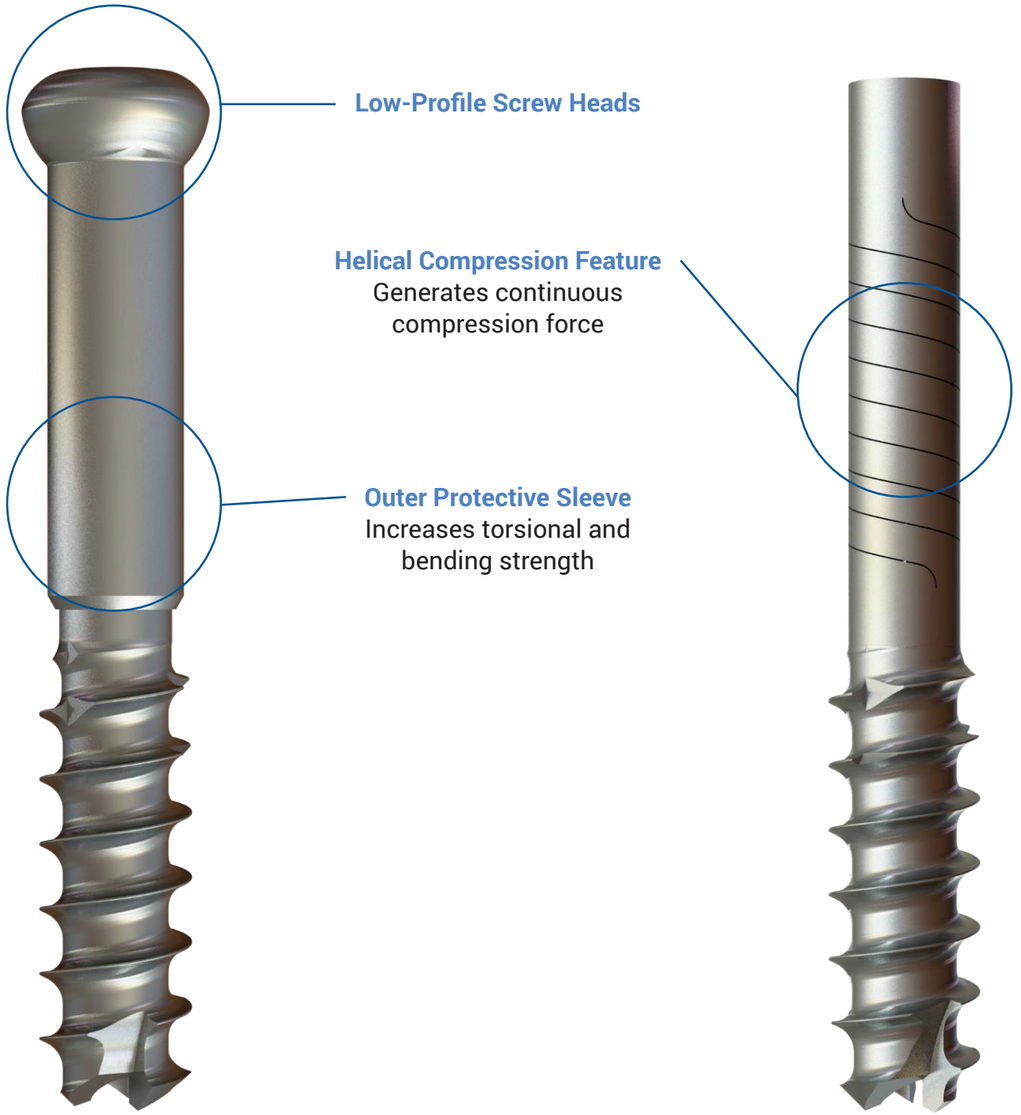
Early and safe mobilization

[1]Muller ME, M Allgower, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991
[2]Ruedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007

IMPLANT FEATURES

4 Implant Design Rationale

The proprietary compressive technology allows the implant to extend as it is implanted. As the implant is inserted, the helical shaft feature expands, causing an opposing compression force between the implant head and threads. Typically, a compression implant provides an initial compression force which is lost as soon as there is bone length loss due to bone remodeling. The unique OsteoCoil implant results in a compression force applied across a bony fusion site even with loss of length throughout bone resorption.

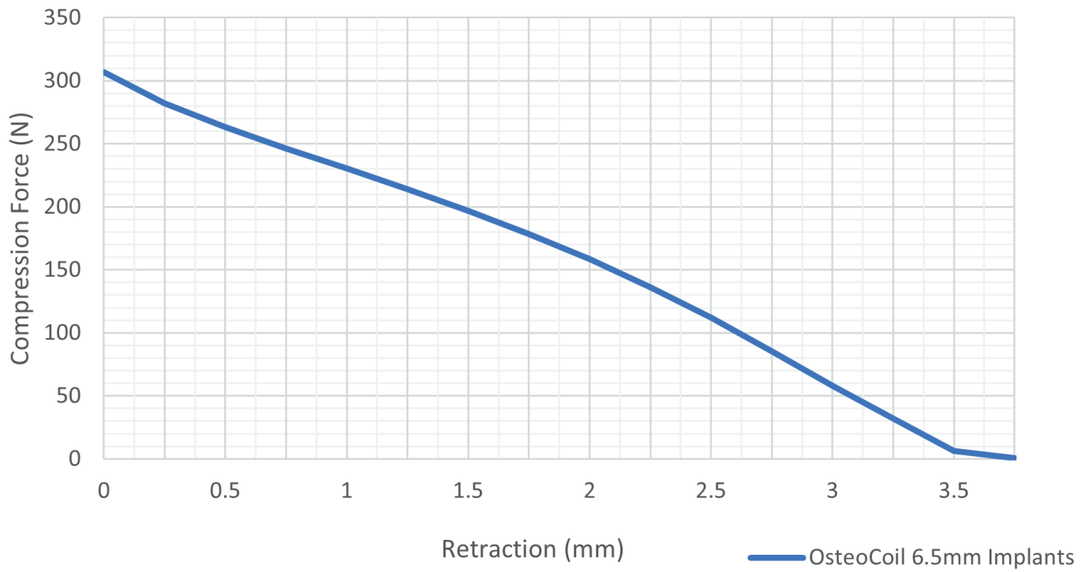


5 Active Compression

The OsteoCoil technology is designed to allow the implant to extend when inserted across a fracture, fusion, or osteotomy. This pre-load allows the implant to retract and maintain a continuous compression force across the fusion site*. The implant provides active compression across a length that is equal to the length extended*. The chart below shows the maximum extension length for the 6.5mm implant diameter and the expected compression force as the implant retracts.*

Implant Diameter	Maximum Extension Length	Force at Max Extension
6.5mm	4.0mm	306N

Compression Force vs. Retraction



	Compressive Force at Distance Retracted (mm) from Max. Extension								
Implant Diameter	0mm	0.5mm	1mm	1.5mm	2mm	2.5mm	3mm	3.5mm	4mm
6.5mm	306N	262N	230N	196N	158N	111N	57N	6N	<1N

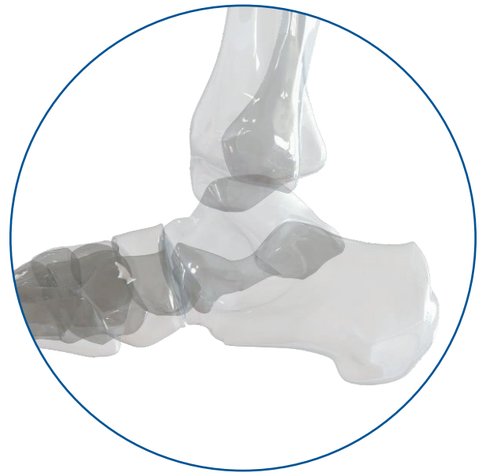
*Testing information on file at Conventus Flower Orthopedics

SURGICAL TECHNIQUE

Note: The OsteoCoil Nitinol Compression System can be used for a variety of indications. A subtalar arthrodesis is illustrated to demonstrate a universal operative technique.

6 Preoperative Planning

Use AP & Lateral radiographs to evaluate the geometry of the target indication.



Available Implant Sizes

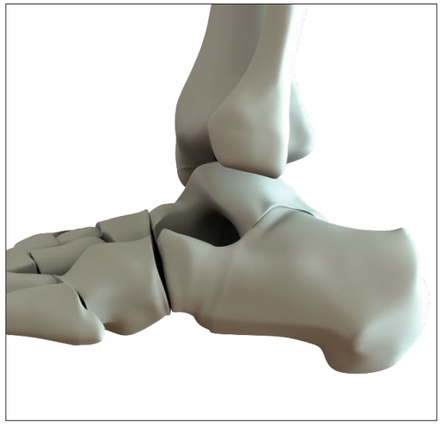
The following OsteoCoil implants are available sterile-packaged. Implants are universal and are not right and left specific.

6.5mm OsteoCoil Implant

Item#	Length (mm)
OC65050	50
OC65055	55
OC65060	60
OC65065	65
OC65070	70
OC65075	75
OC65080	80
OC65085	85
OC65090	90
OC65095	95
OC65100	100

7 Bone Preparation

Reduce the target operative site, exposing the bone if necessary. If needed, distract and prepare the area for fusion by removing cartilage until there is exposed subchondral bone. Leave the overall contours of the bones intact. Once all cartilage is removed, the subchondral bone may also be fenestrated to promote bone fusion. Place any graft material if desired.



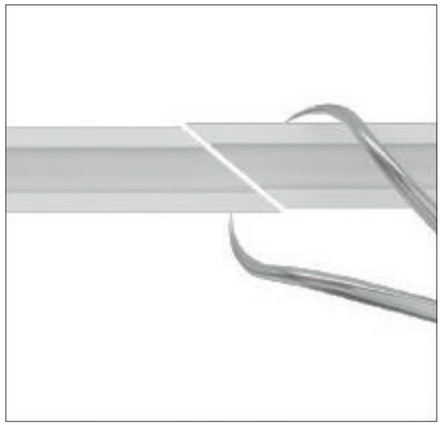
8 Fracture Reduction

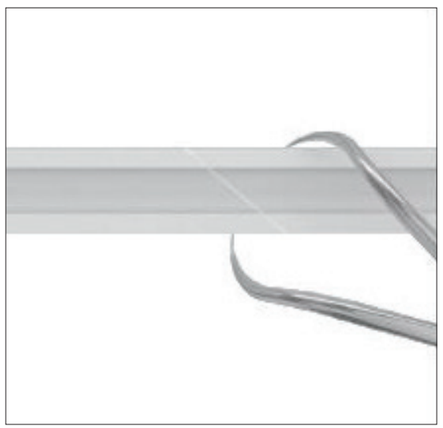
Instruments:

BRCLGP	Bone Reduction Clamps, Large, Pointed

Reduce and clamp the fracture, fusion, or osteotomy with the Large Pointed Bone Reduction Clamps. Consider reduction clamp placement so that it does not interfere with future implant insertion. Alternatively, temporary wires may be used to facilitate fracture reduction. The following wires are available in the instrument tray:

Item#	Size	Tip
OGW212	2.0mm x 12"	Trocar
ODW212	2.0mm x 12"	Drill





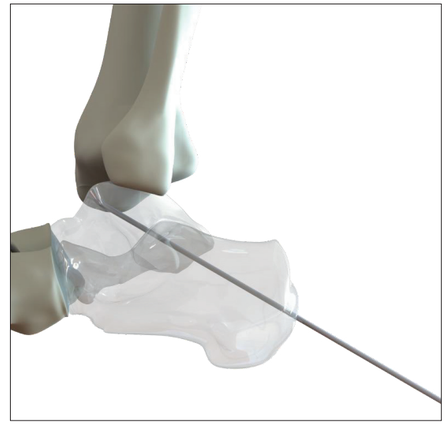
9 Guide Wire Placement

Instruments:

OGW 212	2.0mm x 12" Trocar Tip Wire
ODW 212	2.0mm x 12" Drill Tip Wire

Manually compress the joint or fracture before placing a wire. Keep bones in proper orientation and under compression throughout procedure. Additional Guide Wires may be used to fixate the fusion site.

TIP: Verify wire placement under fluoroscopy in at least two planes. Additional oblique views may be helpful to visualize the wire trajectory. Ensure there is sufficient Guide Wire length to allow for the threaded tip of the implant to cross the fusion site entirely.



10 Determine Implant Size

Instruments:

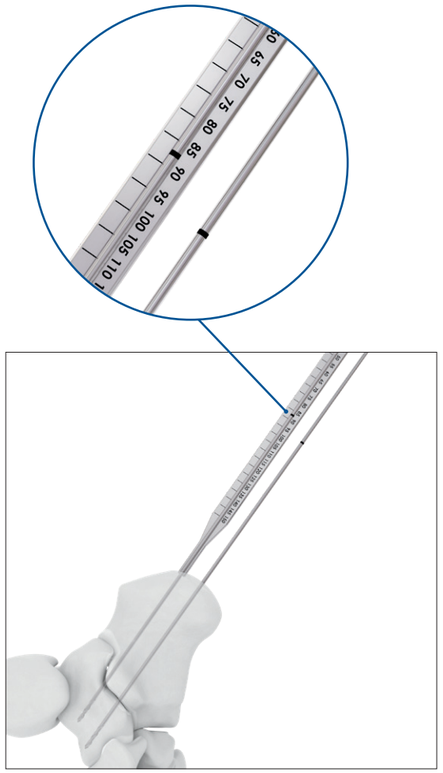
ODG LG	Universal Canulated Depth Gauge

Place the Universal Cannulated Depth Gauge onto the wire and rest firmly against the bone. Read the length from the calibrated laser mark on the wire.

Note: Implant length will extend during insertion. The table below indicates the maximum extension for each implant diameter. Extension should be accounted for when selecting an implant.

Example: When using a 6.5mm diameter implant, expect up to 4mm of extension. As the implants come in 5mm length increments, consider using the next lower length implant than what is measured.

Implant Diameter	Maximum Extension
6.5mm	4mm



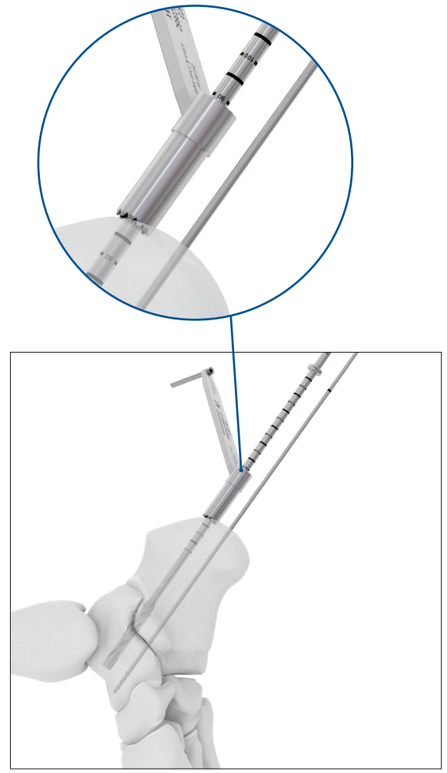
11 Drill for Implant

Instruments:

OST 6573	2.0/6.5mm Tissue Protector
ODB 6573	6.5mm Cannulated Drill Bit, Stepped & Calibrated

The Tissue Protector should be used when drilling for the OsteoCoil implant. Ensure that the Tissue Protector is firmly against bone and place the desired 6.5mm Cannulated Drill Bit over the Guide Wire.

Slowly advance the Drill Bit until the desired depth is achieved. Drill depth can be read from the Drill Bit calibration lines on the back of the Tissue Protector. Confirm appropriate depth under flouroscopy.



12 Tap for Implant

Instruments:

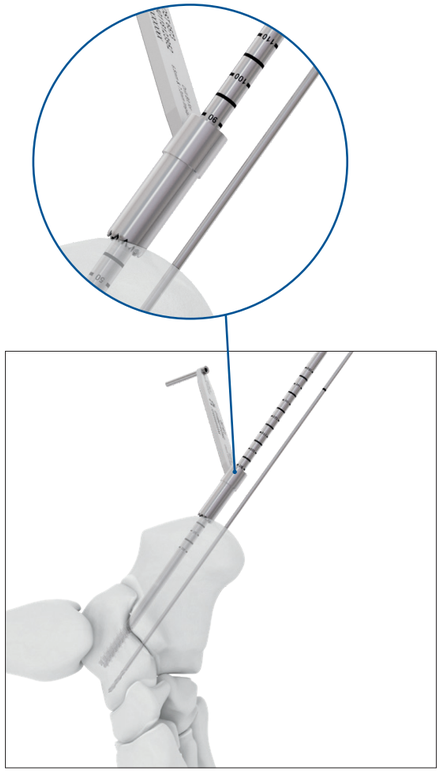
8548-1	Screwdriver Handle, Black
OTP 065	6.5mm Cannulated Tap, Calibrated

Tapping should be performed prior to implant insertion to ensure proper implant extension.

Attach the 6.5mm Cannulated Tap to the Black Screwdriver Handle. Place the Cannulated Tap over the Guide Wire and slowly advance to the desired depth. Tapping depth can be monitored using the calibrated lines marked on the Cannulated Tap.

Note: Tapping should be performed by hand only, not under power.

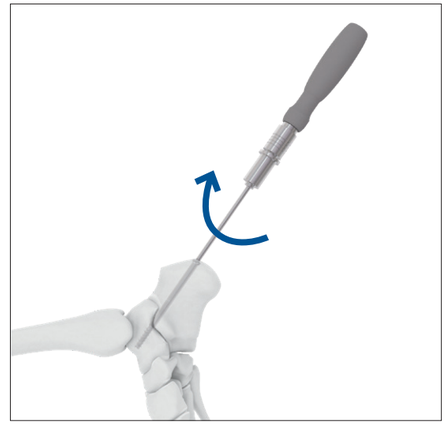
Tip: For soft or osteopenic bone, consider partially tapping, saving the last 1-2cm of native bone for thread purchase.



13 Insert Implant

Implants:

HAN RAT	Ratchet Driver Handle, Gray
OSS S25	T25 Driver Shaft, Short
OSS L25	T25 Driver Shaft, Long



Attach the T25 Driver Shaft to the Gray Ratchet Handle. Slowly advance the OsteoCoil implant into bone by turning in a clockwise direction until the implant head is fully seated against the exterior bone surface. Monitor progress under fluoroscopy. Once flush contact is achieved, perform 1.5 additional implant turns to activate the compression feature. Activation of the compression feature can be confirmed by observing an increase in distance between the implant sleeve and implant threads from before to after activation.

Precautions:

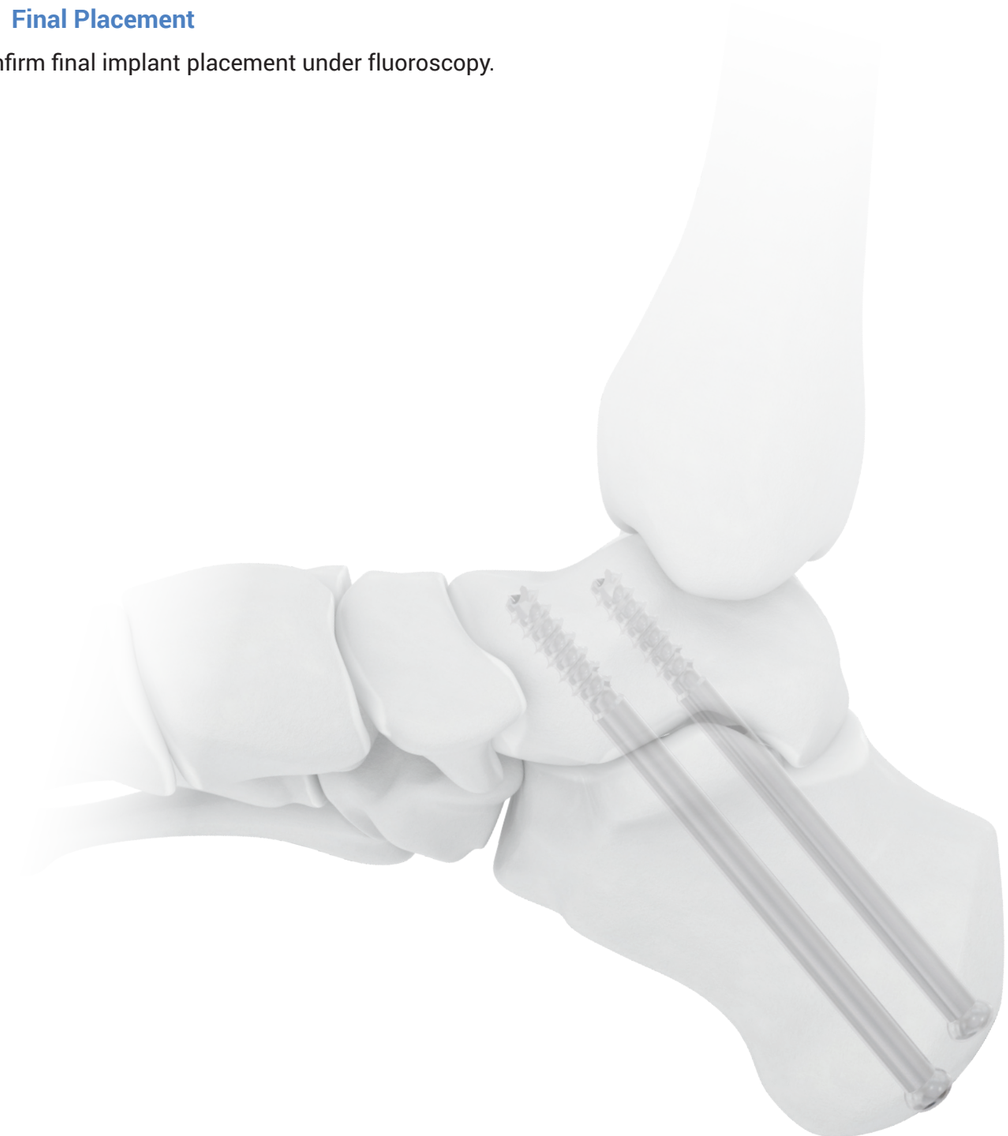
If the implant does not advance under torsion, immediately stop and remove the implant.

Make sure the implant is advancing during insertion by periodically monitoring under fluoroscopy. Twisting without advancing can cause implant failure.

Do not insert the OsteoCoil implant using power. Only insert using the Gray Ratchet Driver Handle by hand.

14 Final Placement

Confirm final implant placement under fluoroscopy.



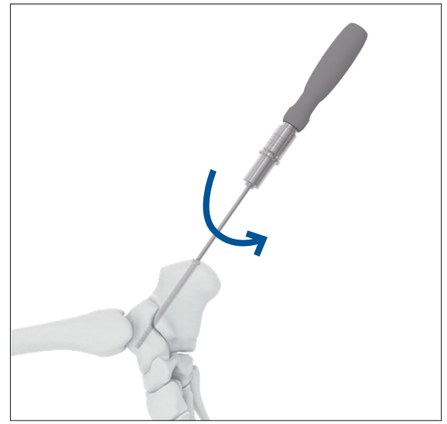
15 Implant Removal (optional)

Implants:

HAN RAT	Ratchet Driver Handle, Gray
OSS S25	T25 Driver Shaft, Short
OSS L25	T25 Driver Shaft, Long

Attach the desired length T25 Driver Shaft to the Gray Ratchet Handle. Slowly rotate the OsteoCoil implant in a counterclockwise direction until the implant is fully removed.

Confirm all implants have been successfully removed using fluoroscopy.



PRODUCT INFORMATION

16 Instruments

2.0mm x 12" Trocar Tip Wire
OGW 212

2.0mm x 12" Drill Tip Wire
ODW 212

Universal Cannulated Depth Gauge
ODG LG

6.5mm Cannulated Drill Bit, Stepped, Calibrated
ODB 06573

2.0mm/6.5mm Soft Tissue Protector
OST 6573

6.5mm Cannulated Tap, Calibrated
OTP 065

Ratchet Driver Handle, Gray
HAN RAT

Screwdriver Handle, Black
8548-1

T25 Screwdriver Handle, Short
OSS S25

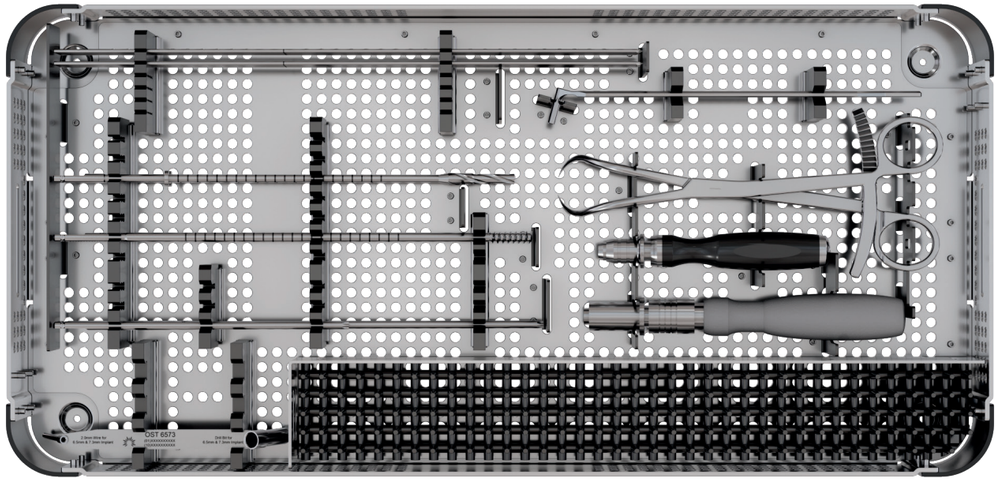
T25 Screwdriver Handle, Long
OSS L25

Bone Reduction Clamps, Large
BRCLGP

17 Sterile Implants

6.5mm OsteoCoil Implant	
Item #	**Length (mm)**
OC65050	50
OC65055	55
OC65060	60
OC65065	65
OC65070	70
OC65075	75
OC65080	80
OC65085	85
OC65090	90
OC65095	95
OC65100	100

18 Instrument Tray Layout



APPENDIX

20 References/Disclaimers

Testing data on file at Conventus Flower Orthopedics.

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Conventus Flower Orthopedics products.

The medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product instructions for use.

Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

Please also refer to the OsteoCoil Nitinol Compression System reprocessing instructions for cleaning and sterilization information.

15 Notes

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

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