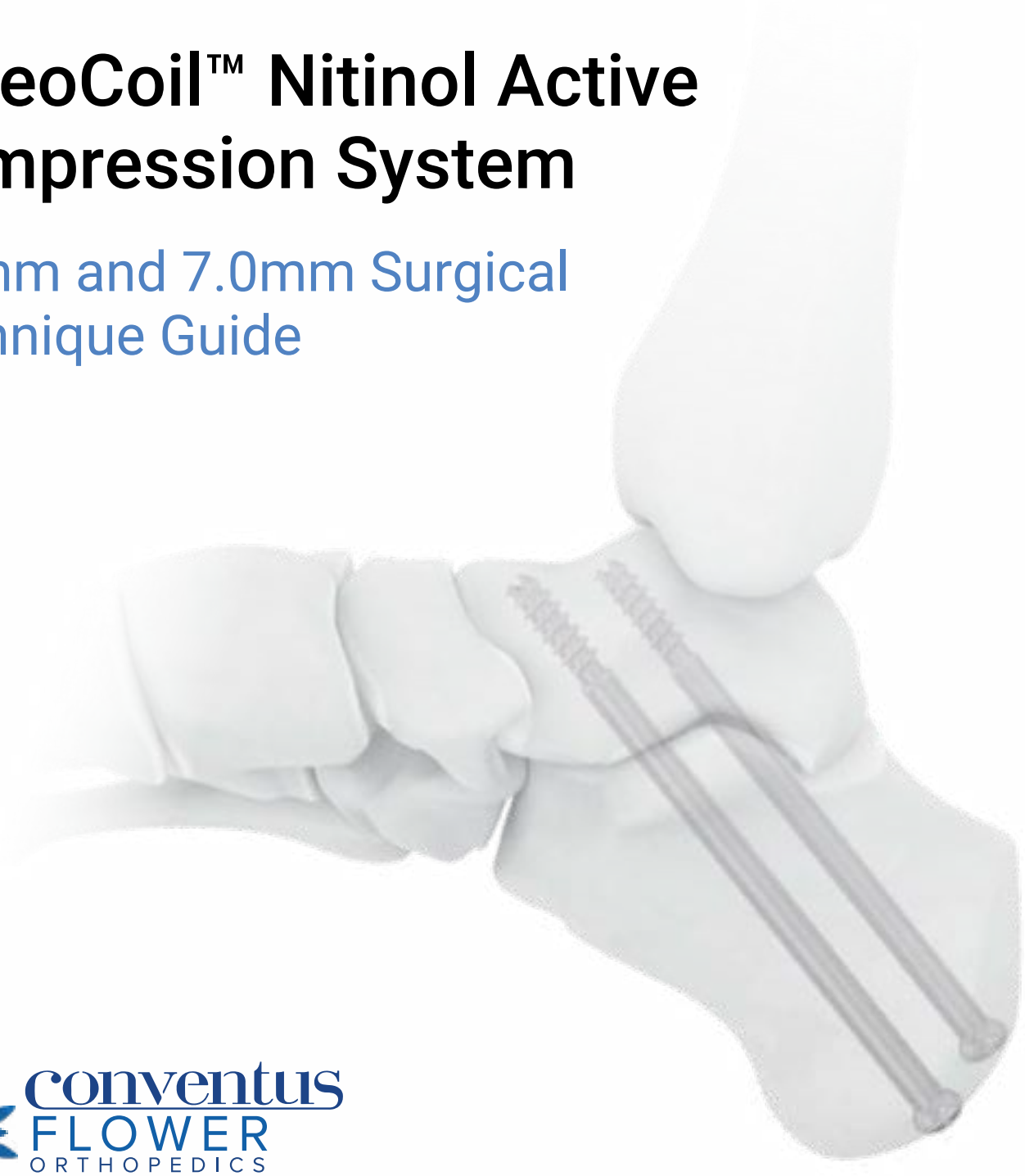
OSTEOCOIL

OSTEOCOIL
Nitinol Active Compression System

OsteoCoil™ Nitinol Active Compression System

5.5mm and 7.0mm Surgical Technique Guide



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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.

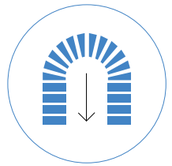
2 Contraindications

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

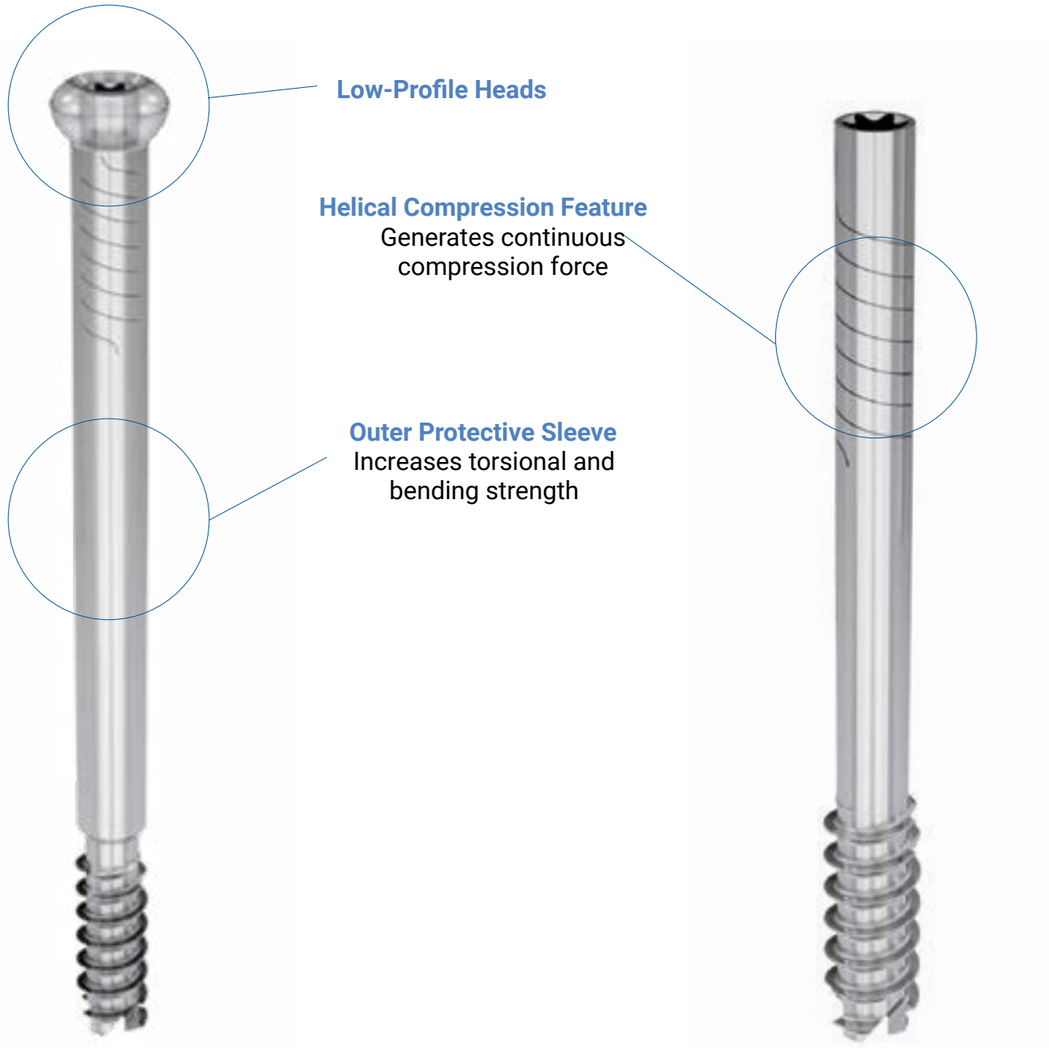
Early and safe mobilization

[1] MullerME, MAllgower, RSchneider, HWillenegger. ManualofInternalFixation. 3rded. BerlinHeidelbergNewYork:Springer. 1991
[2] RuediTP, REBuckley, CGMoran. AOPrinciplesofFractureManagement. 2nded. Stuttgart, NewYork:Thieme. 2007

IMPLANT FEATURES

4 Implant Design Ratio-

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.



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.

SURGICAL TECHNIQUE

5 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.

5.5mm OsteoCoil Implant

Item#	Length	Item#	Length
OC55040	40mm	OC55058	58mm
OC55042	42mm	OC55060	60mm
OC55044	44mm	OC55065	65mm
OC55046	46mm	OC55070	70mm
OC55048	48mm	OC55075	75mm
OC55050	50mm	OC55080	80mm
OC55052	52mm	OC55085	85mm

7.0mm OsteoCoil Implant

Item#	Length	Item#	Length
OC70040	40mm	OC70080	80mm
OC70045	45mm	OC70085	85mm
OC70050	50mm	OC70090	90mm
OC70055	55mm	OC70095	95mm
OC70060	60mm	OC70100	100mm
OC70065	65mm	OC70105	105mm
OC70070	70mm	OC70110	110mm
OC70075	75mm		

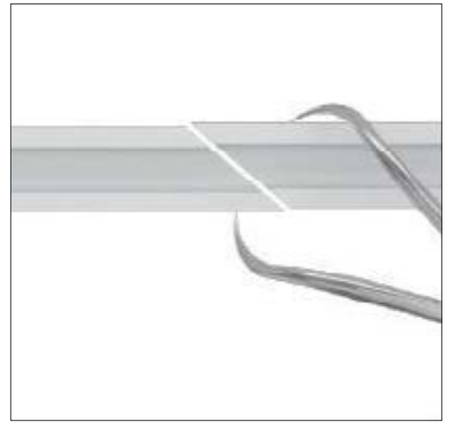
6 Bone Preparation

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.

7 Fracture Reduction

Reduce and clamp the fracture, fusion, or osteotomy with 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
For 7.0mm:		
OGW023	2.3mm	Blunt/Trocar
For 5.5mm:		
OGW016	1.6mm	Blunt/Trocar



8 Guide Wire Placement

Instruments:

For 7.0mm:

OGW023	SS Guide Wire 2.3mm Blunt/Trocar, Active Compression

For 5.5mm:

OGW016	SS Guide Wire 1.6mm Blunt/Trocar, Active Compression

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.

9 Parallel Guide (Optional)

Instruments:

For 5.5mm and 7.0mm:

OPG557	Parallel Guide, Active Compression 5.5mm & 7.0mm

If multiple guide wires are required or if the surgical plan intends to implant more than one OsteoCoil Nitinol Active Compression Implant, then the Parallel Guide may be used.

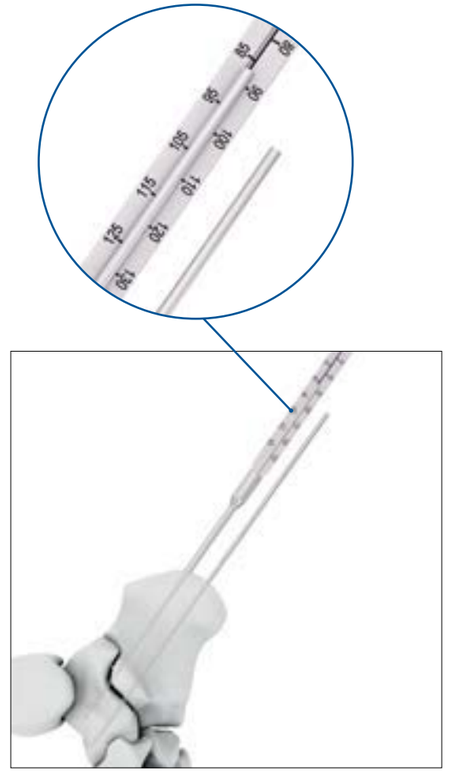
Place the Guide Wire Sleeve in the nominal position of the Parallel Guide and secure on bone in the area the wire is intended to be placed. Drive the wire into place such that it is firm.

You may place a second wire at 10, 15 or 20mm offset from the first. Place the second Guide Wire Sleeve into the appropriate offset hole, then drive the wire into the place.

10 Determine Implant Size

Instruments:

ODG001	Depth Gauge, Active Compression, 5.5mm & 7.0mm



Place the Universal Cannulated Depth Gauge onto the wire and rest firmly against the bone. Read the length from the end of 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. Similarly, when using the countersink, take into account the depth of countersinking in implant placement measurements.

Example: If the depth gauge reads 85mm, with 1mm planned countersink depth, given the 4mm extension of a 7.0mm diameter implant, an 80mm implant should be utilized.

Implant Diameter	Maximum Extension
7.0mm	4.0mm
5.5mm	3.5mm

11 Drill for Implant

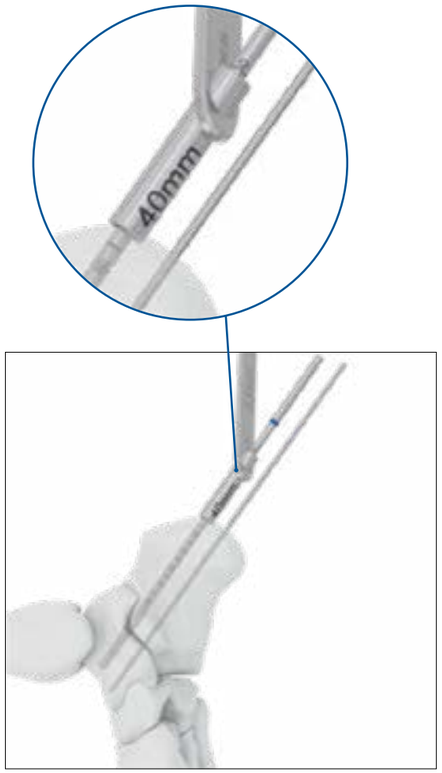
Instruments:

For 7.0mm:

OTP070	7.0mm Tissue Protector, Active Compression
ODB070	Cannulated Drill Bit for 7.0mm, Stepped, Active Compression

For 5.5mm:

OTP055	5.5mm Tissue Protector, Active Compression



To drill for the implant, advance the Drill Bit over the Guide Wire until the desired implant depth is achieved. The drill depth can be read from the calibrated lines on the Drill Bit, but implant length should still be determined using the Guide Wire and Depth Gauge.

The Tissue Protector may be used when drilling for the OsteoCoil implant. Ensure that the Tissue Protector is firmly against bone and place the Cannulated Drill Bit over the Guide Wire. Drill to desired length and read the Depth. If using the Tissue Protector while reading laser marks, 40mm of offset will be required.

Confirm appropriate depth under flouroscopy.

12 Tap for Implant

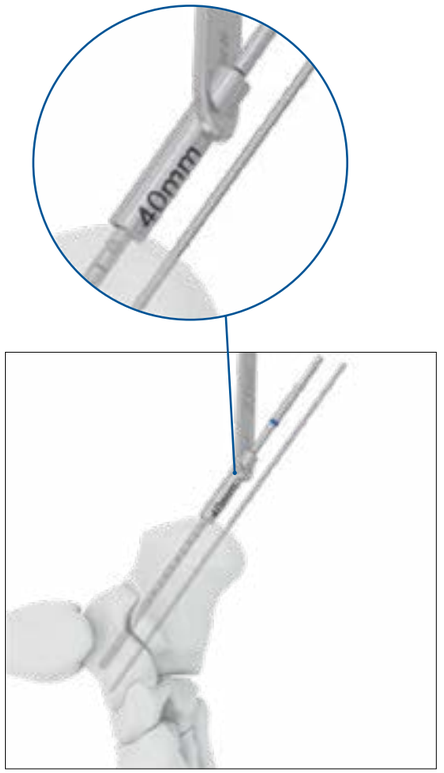
Instruments:

For 7.0mm:

OCT070	7.0 Tap, Active Compression
SHBLK	Ratchet Handle, Small Hudson

For 5.5mm:

OCT055	5.5 Tap, Active Compression
OOORG	Ratchet Handle, AO



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

Attach the Cannulated Tap to the 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 Tap.

The Tissue Protector may be used when tapping for the OsteoCoil implant. Tap fully to prepared depth and confirm the tapping depth using the calibrated lines marked on the Tap. If using the Tissue Protector while reading laser marks, 40mm of offset will be required.

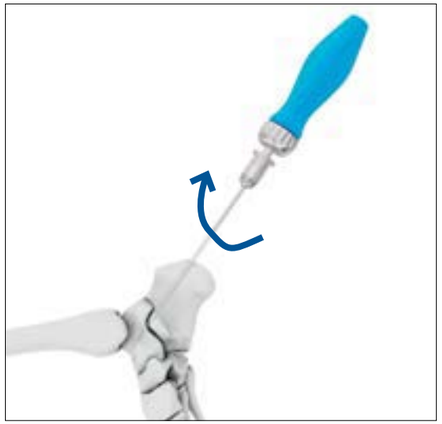
Confirm appropriate depth under flouroscopy.

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

13 Insert Implant

Instruments:

For 7.0mm:	
OCD070	T25 Cannulated Driver, Active Compression
SHBLK	Ratchet Handle, Small Hudson
For 5.5mm:	
OCD055	T15 Cannulated Driver, Active Compression
OSD055	T15 Solid Driver, Active Compression
OOORG	Ratchet Handle, AO



Attach the Driver Shaft to the 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 un-der fluoroscopy. Once flush contact is achieved, remove the Guide Wire before performing additional implant turns (1.5 turns for 7.0mm, 1.75 turns for 5.5mm) 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.

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

Please note: T25 is used for 7.0mm implant, T15 is used for 5.5mm implant.

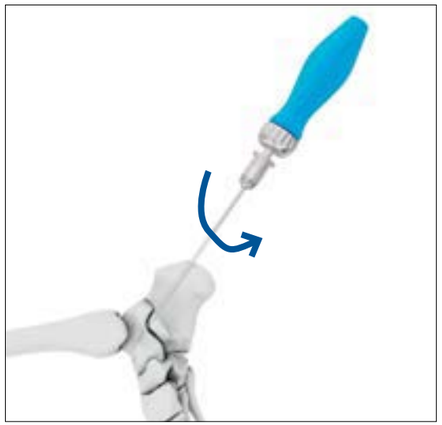
14 Final Placement

Confirm final implant placement under fluoroscopy.

15 Implant Removal (optional)

Instruments:

For 7.0mm:	
OCD070	T25 Cannulated Driver, Active Compression
SHBLK	Ratchet Handle, Small Hudson
For 5.5mm:	
OCD055	T15 Cannulated Driver, Active Compression
OSD055	T15 Solid Driver, Active Compression
OOORG	Ratchet Handle, AO



Attach the desired length Driver Shaft to the 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.

Please note: T25 is used for 7.0mm implant, T15 is used for 5.5mm implant.

PRODUCT INFORMATION

16 Instruments

5.5mm Instruments

T15 Cannulated Driver, Active Compression
OCD055

T15 Solid Driver, Active Compression
OSD055

SS Guide Wire 1.6mm Blunt/Trocar, Active Compression
OGW016

5.5mm Cannulated Countersink, Active Compression
OCC055

Ratchet Handle, AO
OOORG

Cannulated Drill Bit for 5.5mm, Stepped, Active Compression
ODB055

5.5 Tap, Active Compression
OCT055

5.5mm Tissue Protector, Active Compression
OTP055

7.0mm Instruments

T25 Cannulated Driver, Active Compression
OCD070

SS Guide Wire 2.3mm Blunt/Trocar,
Active Compression
OGW023

7.0mm Cannulated Countersink,
Active Compression
OCC070

Ratchet Handle, Small Hudson
SHBLK

Cannulated Drill Bit for 7.0mm, Stepped,
Active Compression
ODB070

7 Tap, Active Compression OCT070

7.0mm Tissue Protector, Active Compression
OTP070

Shared Instruments

Depth Gauge, Active Compression
ODG001

Wire Pusher, Active Compression
OWP557

Parallel Guide, Active Compression 5.5mm & 7.0mm
OPG557

Custom

Small Hudson Adaptor
SHADP

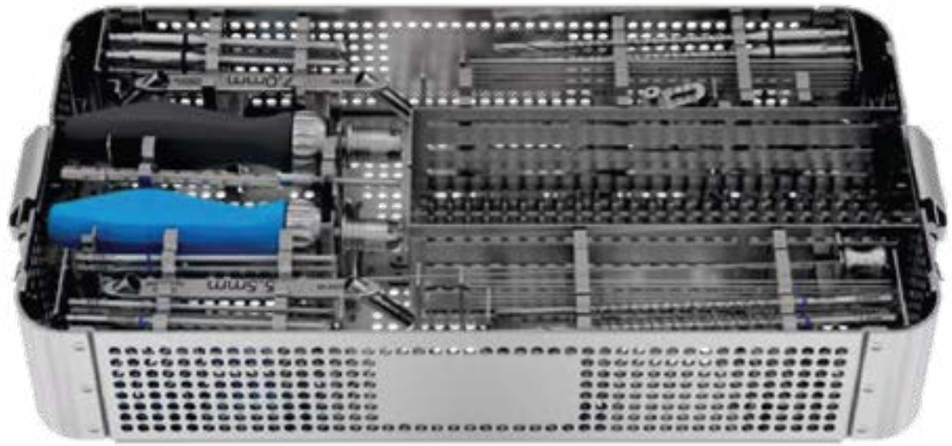
17 Sterile Implants

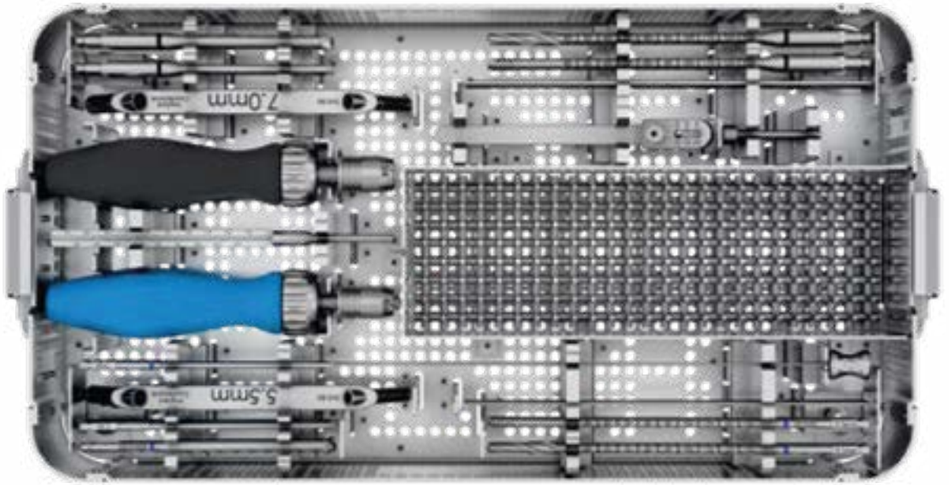
5.5mm OsteoCoil Implant	
Item #	**Length (mm)**
OC55040	40
OC55042	42
OC55044	44
OC55046	46
OC55048	48
OC55050	50
OC55052	52
OC55054	54
OC55056	56
OC55058	58
OC55060	60
OC55065	65
OC55070	70
OC55075	75
OC55080	80
OC55085	85

7.0mm OsteoCoil Implant	
Item #	**Length (mm)**
OC70040	40
OC70045	45
OC70050	50
OC70055	55
OC70060	60
OC70065	65
OC70070	70
OC70075	75
OC70080	80
OC70085	85
OC70090	90
OC70095	95
OC70100	100*
OC70105	105*

***Note:** Not part of core implant cube. Must be ordered separately.

18 Instrument Tray Layout





APPENDIX

19 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.

20 Notes

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

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