GLWmedical

creed™

Orthholucent Implants

Operative Technique

5.6mm, 7.4mm Headless and Headed Cannulated Compression Screws.

Sterile, Case Ready™ instrument kits.

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creed™
Ortholucent Implants

CONTENTS

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This document offers technical guidance pertaining to the Creed Ortholucent Implants. As with any medical device, surgeons should rely on their training, making any necessary adjustments based on the needs of the patient.

Indications

Indications for Use and Intended Use:

CREED™ Ortholucent Implants are intended to maintain alignment and fixation of bone fractures, comminuted fractures in the presence of appropriate additional immobilization such as rigid fixation implants, cast or brace, non-unions, osteotomies, arthrodesis or bone grafts in the hand, foot, and ankle including distal tibia and fibula. These implants are not intended for spinal use.

Contraindications

Severe muscular, neurological or vascular deficiency in the extremity concerned.

Bone destruction or poor bone quality, likely to impair implant stability.

Surgical procedures other than those listed in the Indications section.

Known or suspected allergy to any of the device components.

Use of this implant together with implants of another origin not recommended by GLW, Inc.

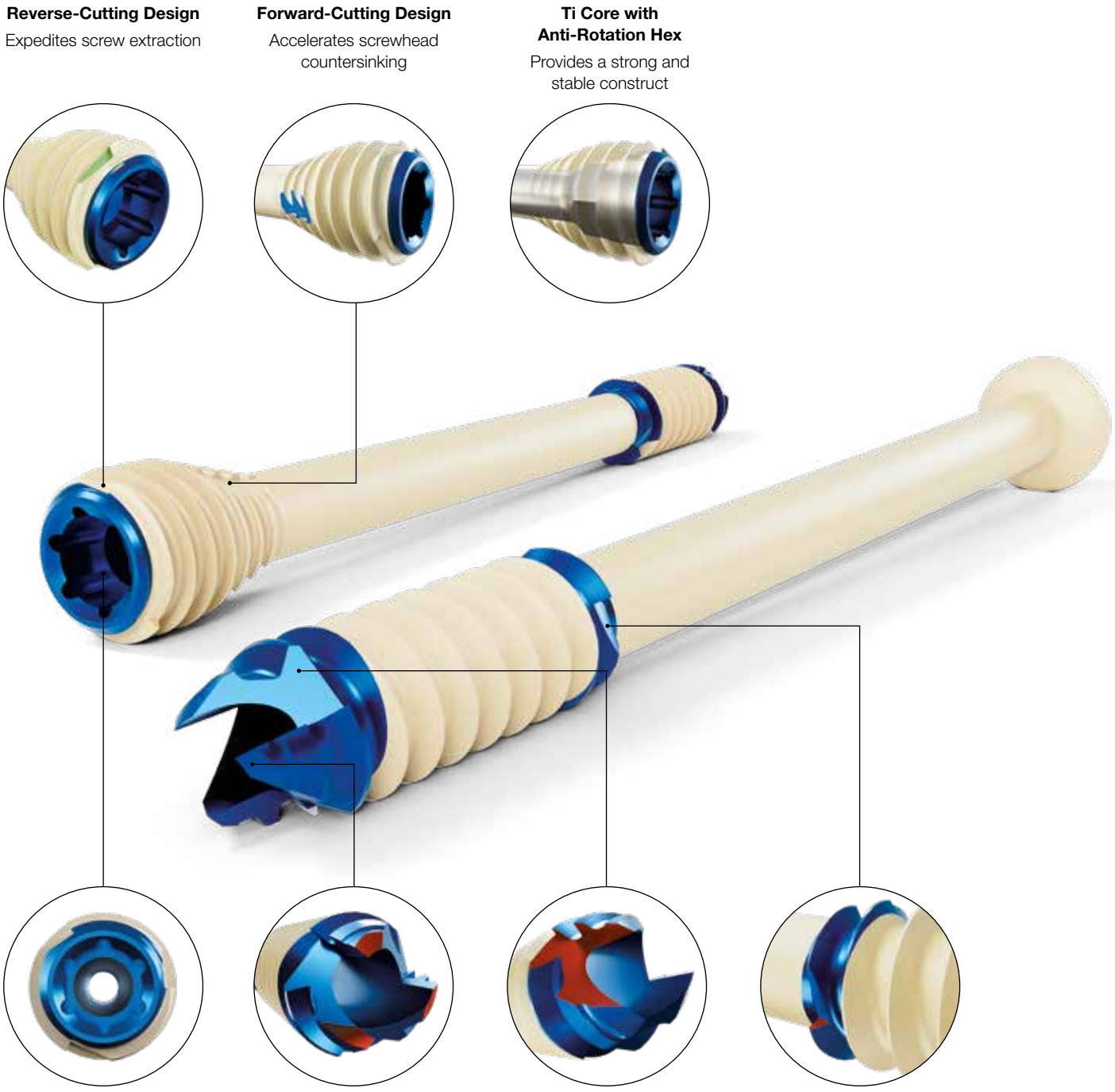
Precautions

If either the implant or the package appears damaged the implant should not be used.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.

Design Features

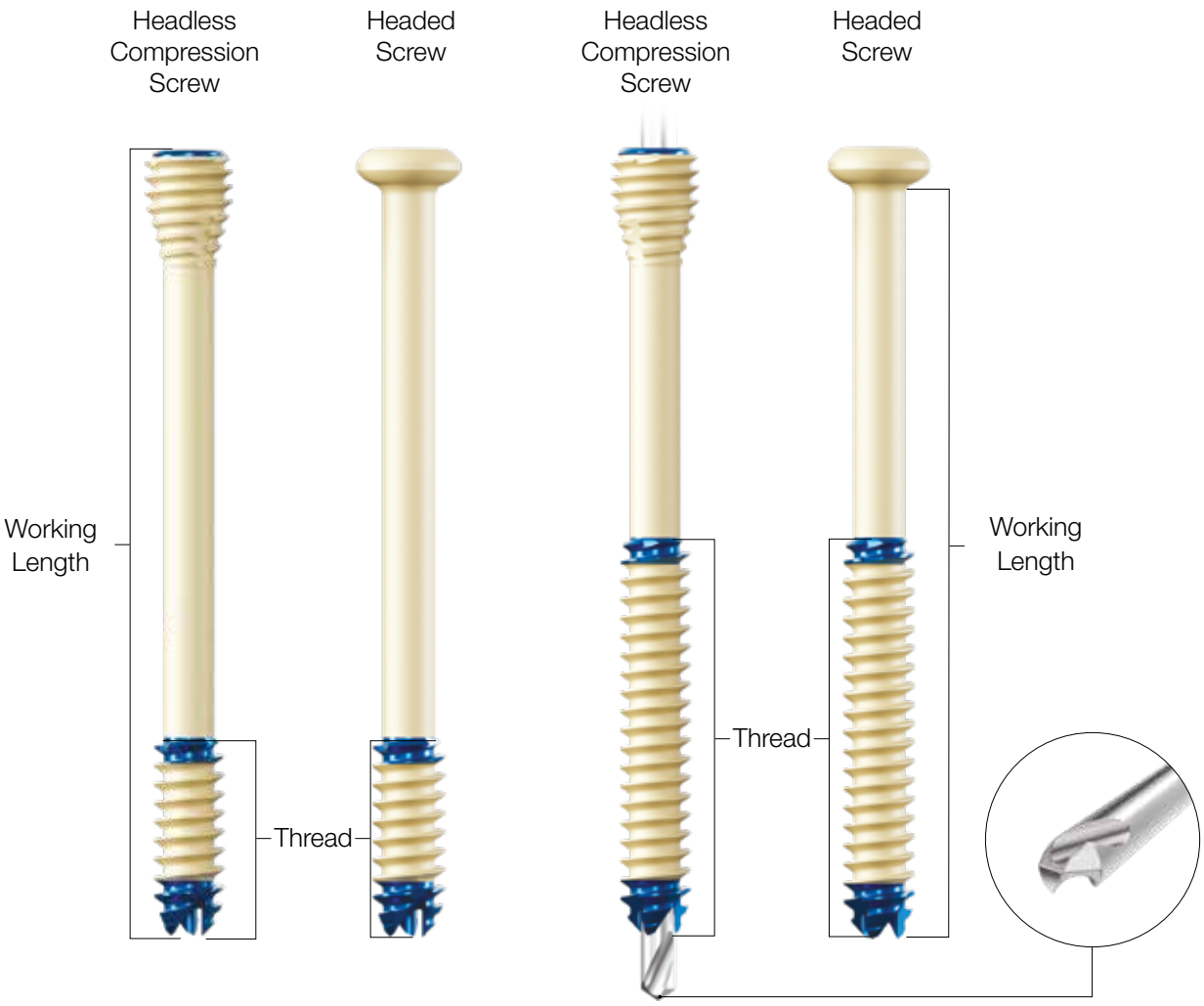
Created in conjunction with foot and ankle specialists, the Creed Ortholucent Implants are designed to deliver maximum compression with minimum torque to address a large variety of osteotomies, fusions and fractures.



Design Features – Technical Specifications

Creed Ortholucent Implants are available in four diameters and offer a wide range of lengths with 2mm and 5mm increments:

Ø Size Range	2.5mm	4.3mm	5.6mm	5.6mm	7.4mm	7.4mm
Material	Ti6Al4V	Ti6Al4V / PEEK				
Type	Headless Compression Screw / Headed Screw	Headless Compression Screw / Headed Screw	Headless Compression Screw / Headed Screw	Headless Compression Screw / Headed Screw	Headless Compression Screw / Headed Screw	Headless Compression Screw / Headed Screw
Thread	8mm	10mm	16mm	32mm	19mm	32mm
Length	Headed: 12-30mm Headless: 14-30mm each 2mm	From 18-50mm each 2mm From 50-60mm each 5mm	From 30-50mm each 2mm From 50-80mm each 5mm	From 42-50mm each 2mm From 50-80mm each 5mm	From 40-50mm each 2mm From 50-120mm each 5mm	From *40-50mm each 2mm From 50-120mm each 5mm *Headless begin at 46mm
K-wire	Ø1.3mm x 150mm	Ø2.0mm x 150mm	Ø2.8mm x 230mm	Ø2.8mm x 230mm	Ø3.2mm x 230mm	Ø3.2mm x 230mm
Torx Tip	T8	T15	T25	T25	T30	T30

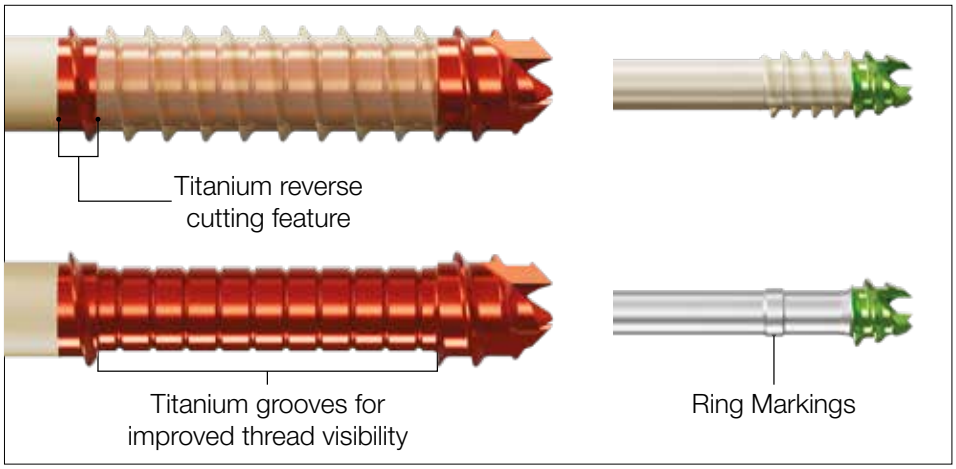


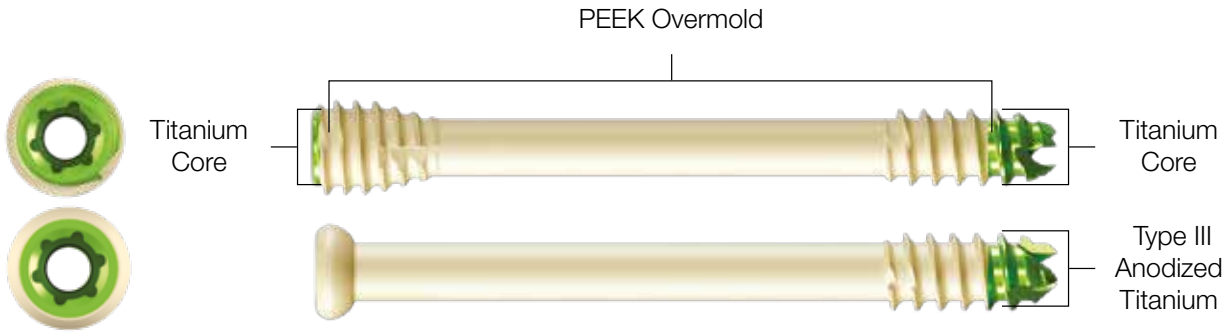
Design Features – Ortholucent Implants

The radiotranslucent properties of the Creed Ortholucent Implants provide a significant clinical advantage over traditional metal implants by drastically improving the visualization of bones and joint spaces. Surgeons can better assess post-operative healing by "seeing through" the implant and down to the bony structures on radiographs.

The lower titanium load, which is reinforced by a polyetheretherketone (PEEK) overmold, provides clear bone visibility during plain radiography as well as less scatter with advanced imaging techniques. Improved visualization enables the clinician to interpret bone healing with greater confidence leading to faster advancement of recovery protocols.

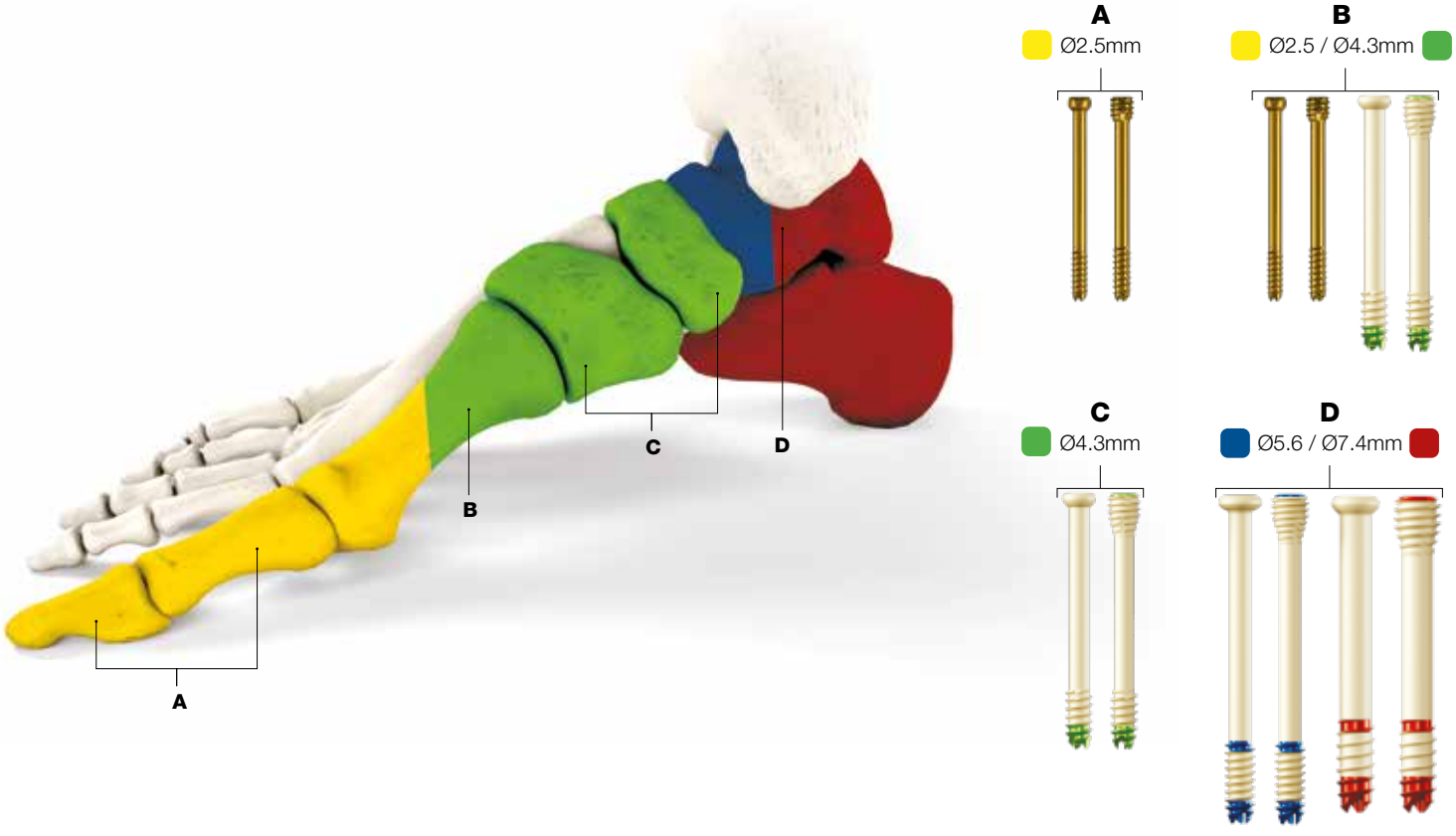
Due to the radiolucent properties of PEEK, the threads of the Creed Ortholucent Implants are invisible on radiographs. To identify where the screw threads end, the Creed Ø5.6mm and Ø7.4mm screws have a titanium reverse cutting geometry that performs as a marker on X-rays. The Ø4.3mm screws have titanium ring markings located underneath the PEEK reverse cutting geometry while the Ø2.5mm screws have titanium threads and do not require this feature.



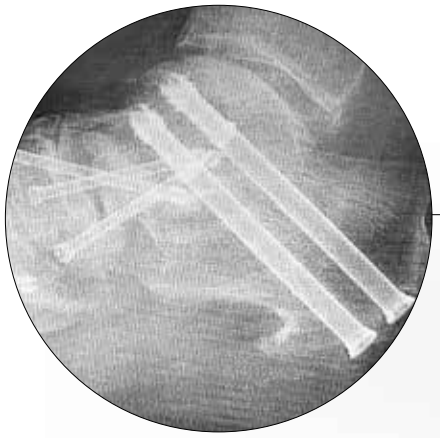


Applications

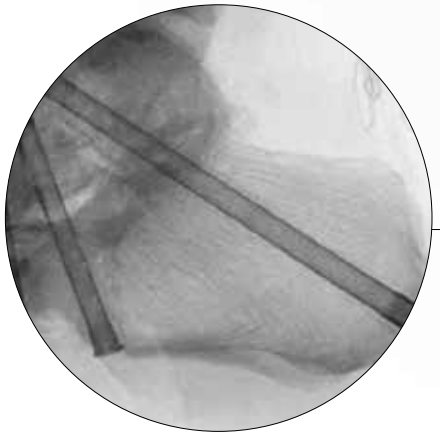
Ø Screw Size	Ø2.5mm	Ø2.5 / Ø4.3mm	Ø4.3mm	Ø5.6 / Ø7.4mm
Procedure/Anatomy	A. Forefoot	B. Forefoot / Midfoot	C. Midfoot / Hindfoot	D. Hindfoot / Ankle
Akin Osteotomy (Bunion)	•			
Weil Osteotomy (Metatarsal Shortening)	•			
Austin / Chevron Osteotomy (Bunion)	•	•		
Scarf Osteotomy (Bunion)	•	•		
MTP Fusion		•	•	
Lapidus Procedures (Bunion)		•	•	
TMT Fusion		•	•	
Intercuneiform Fusion		•	•	
Talo-Navicular (TN) Fusion		•	•	
Calcaneo-Cuboid (CC) Fusion		•	•	
Navicular Cuneiform (NC) Fusion		•	•	
Lisfranc Injury		•	•	
Tarsal / Metatarsal Fracture		•	•	
Syndesmosis Repair			•	
Ankle Fracture			•	
Jones Fracture			•	•
Triple Arthrodesis			•	•
Calcaneal Osteotomy / Calc Slide (MDCO)			•	•
Ankle Arthrodesis				•
Subtalar Fusion				•



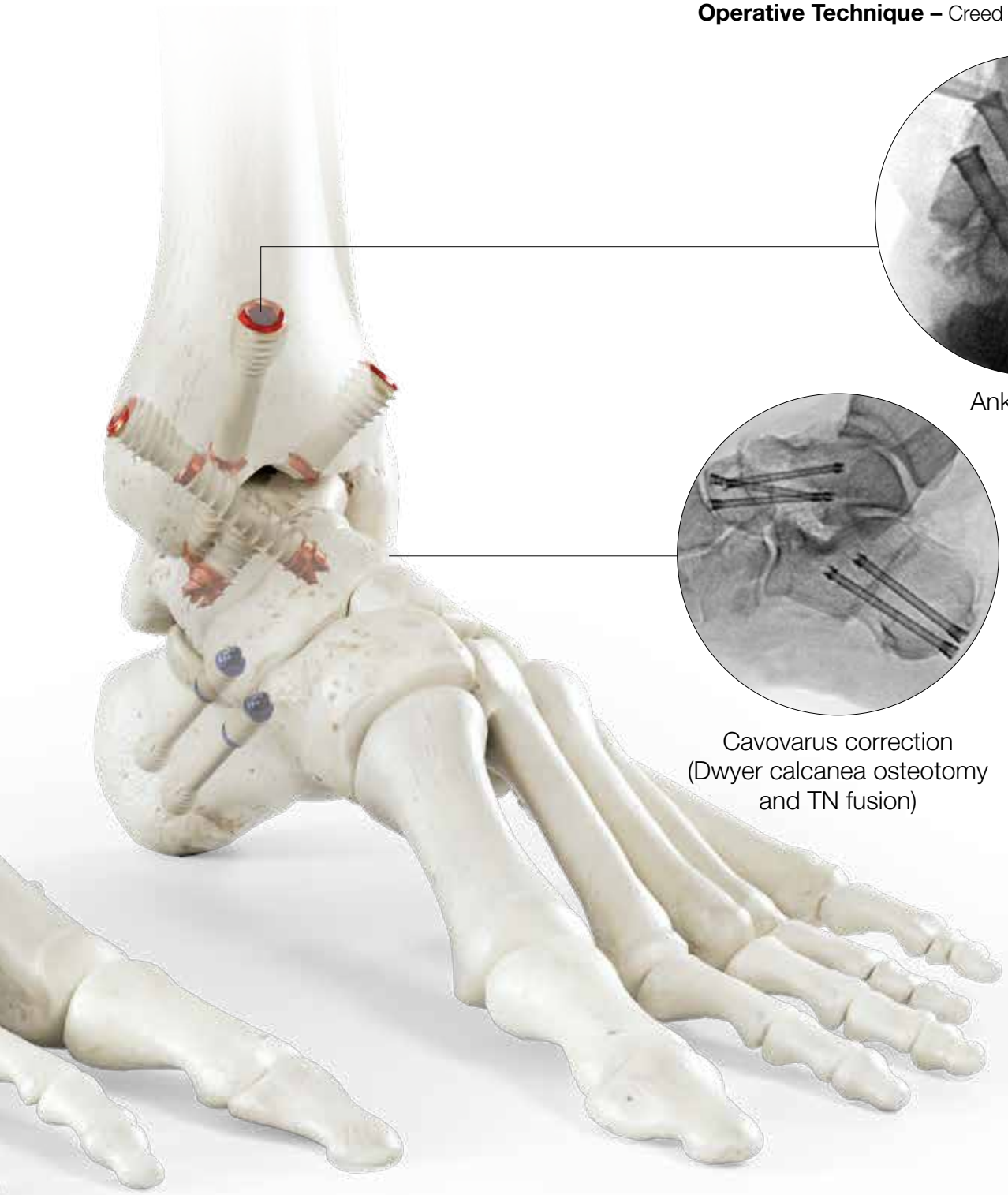
Applications – Ø5.6mm & Ø7.4mm Screws

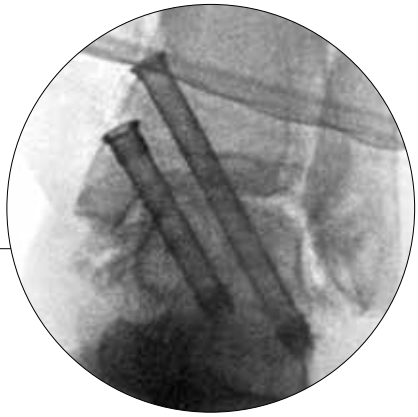


Medial double arthrodesis
(TN and Subtalar fusion)



Subtalar fusion





Ankle fusion

Cavovarus correction
(Dwyer calcanea osteotomy
and TN fusion)

Design Features – Surgery-ready Instrument Kits

CREED Single Use Kits

Creed Ortholucent Implants and instrument kits are sterile packaged, enabling a surgery-ready solution for the hospital and ambulatory surgical centers.

Large Kit

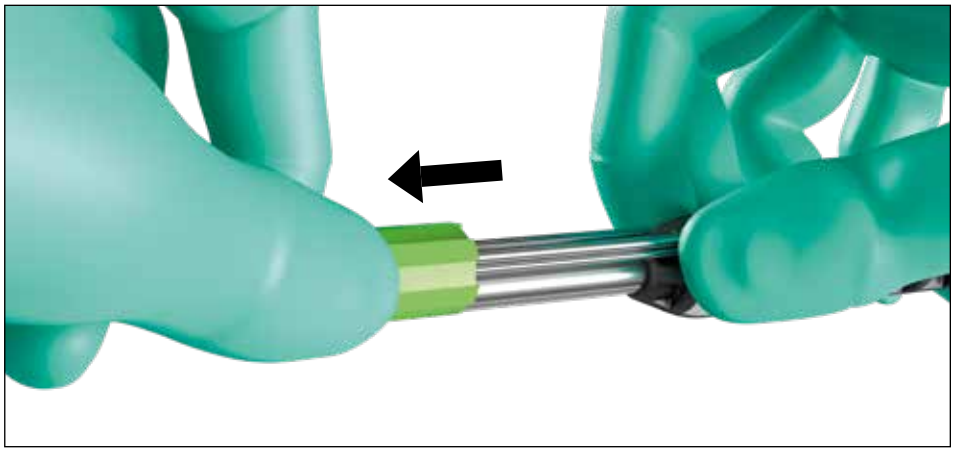
The large instrument kit contains a T25 and T30 cannulated screwdriver blade for Creed Ø5.6mm and Ø7.4mm screws, respectively, which is used in combination with the Zimmer-Hall-handle. In addition, the large kit includes a Ø6.1mm cannulated drill for Creed Ø7.4mm screws, and a countersink depth gauge with mounted Ø2.8mm and Ø3.2mm K-wires.

Large Instruments Blister Pack

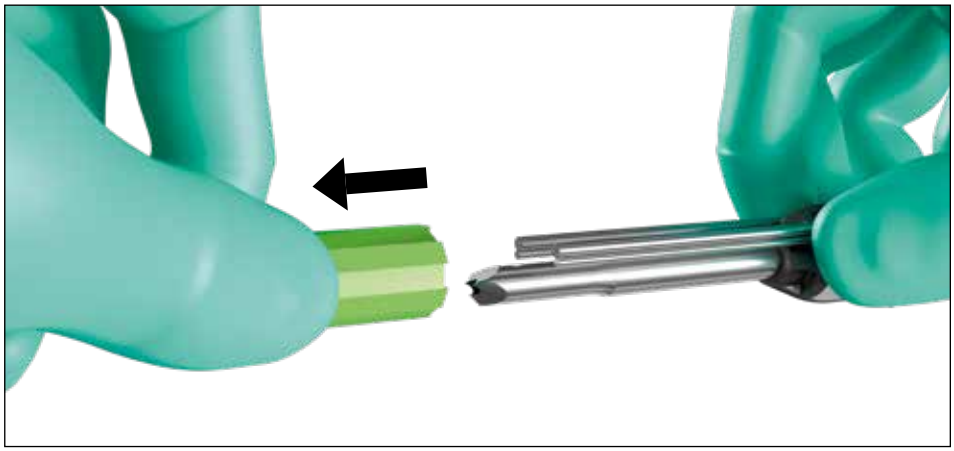
Protective cap removal

Each countersink depth gauge is pre-assembled with a protective cap designed to prevent puncturing of the blister. Follow the steps below on how to remove the protective cap correctly.

Extract the countersink depth gauge from the blister. With one hand hold the countersink depth gauge and K-wires in place.



Remove the green cap from the tip of the countersink depth gauge while keeping the wires fixated. Extract the K-wires from the countersink once the cap is fully removed.



Operative Technique – Zadek Osteotomy

Large Screws
Sterile Packaging

Step 1 – Patient Positioning

Patient is positioned in a lateral position with the operative foot at the edge of the bed.

Position the mini c-arm at the contralateral side of the surgical extremity & power equipment at the ipsilateral side of the surgical extremity.

Positioning of OR equipment is a recommendation until a surgeon's preference is identified.

Step 2 – Mark the Osteotomy

Using fluoroscopy mark the osteotomy site on the lateral aspect of the heel. A visual drawing of the dorsal closing wedge is recommended. The surgeon should plan to remove 8-10mm of the dorsal closing wedge.

The apex (hinge) of the osteotomy should be 5-10mm proximal to the plantar cortex of the calcaneus.

The osteotomy should be halfway between the insertion of the achilles and the posterior subtalar joint.

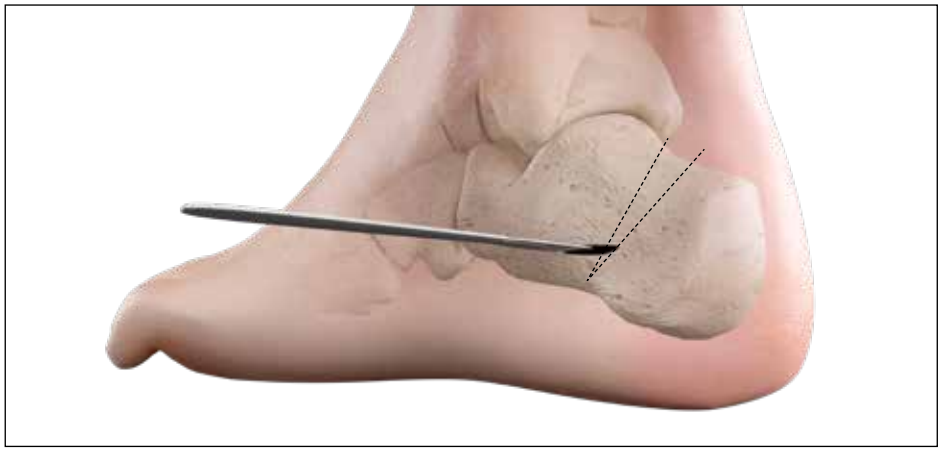
in patients with a flatfoot the osteotomy should be more obliquely oriented (from dorsal-posterior to plantar-anterior to prevent further reduction of the calcaneal pitch, whereas patients with cavus allignment would benefit from a more vertically oriented osteotomy to reduce the pitch).

The surgeon may also place two K-wires through the plantar aspect of the calcaneus to create a visual guideline to be seen under fluoroscopy.

Step 3 – Incision

A 3mm incision is made corresponding to the apex of the osteotomy. Bluntly dissect the soft tissues with a hemostat, creating a safe pathway to insert the burr.

Osteotomies performed with a burr, should be powered with a high torque & low rpm motor to avoid complications.



Step 4 – Osteotomy

The osteotomy should be performed in quadrants. Insert the burr and punch through the medial cortex and complete each quadrant before moving on to the next:

Near cancellous bone, far cancellous bone, poke holes in the far cortex, then “connect the dots” along the far cortex to complete the osteotomy.

Once the osteotomy is complete use a 3 or 4 mm wedge bur or a 3x30mm cutting burr to start removing the bone wedge from the dorsal aspect of the osteotomy. Remove 8-10mm.

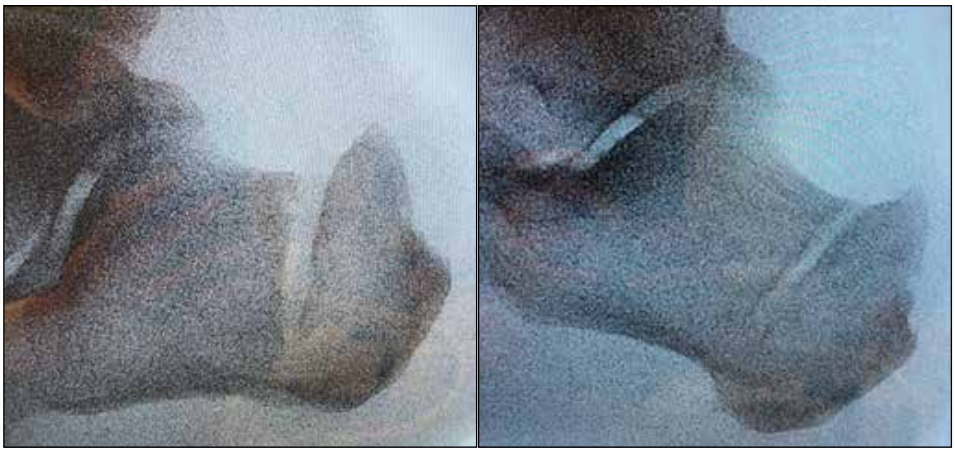
Once the near cortices are complete, make a series of poke holes along the far cortex to feel the cortex break as the burr passes through.

Operative Technique – Zadek Osteotomy

Step 5 – Closing the Osteotomy

To reduce the wedge, maximally dorsiflex the ankle. Insert the guidewire for two Creed Screws for the 7.4mm.

Make an incision over the guidewire, measure, drill, countersink and advance selected screw(s).



Make an incision over the guidewire, measure, drill, countersink and advance selected screw(s).

Operative Technique – Medial Displaced Calcaneal Osteotomy

Step 1 – Patient Positioning

Patient is positioned supine with the operative foot at the edge of the bed. To internally rotate the operative leg, place a bump under the hip.

Position the mini c-arm at the contralateral side of the surgical extremity & power equipment at the ipsilateral side of the surgical extremity.

Positioning of OR equipment is a recommendation until a surgeon's preference is identified.

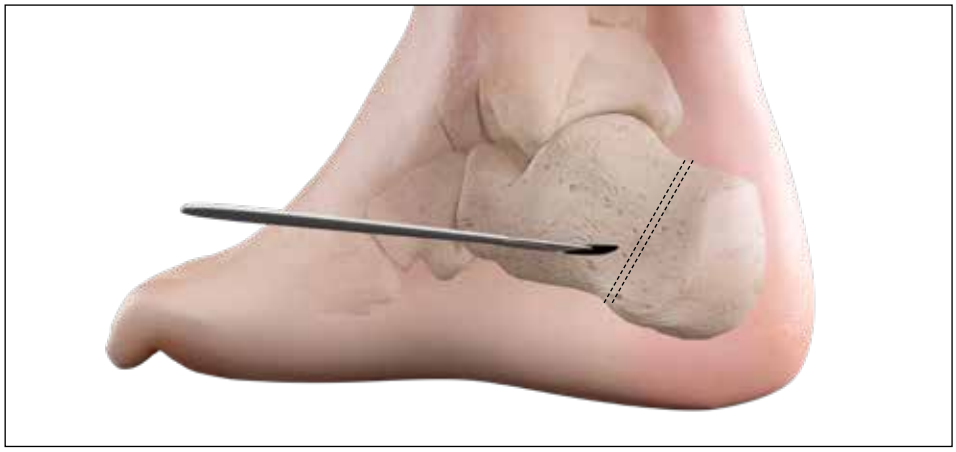
Step 2 – Mark the osteotomy

Under fluoroscopic guidance take a lateral image of the calcaneus. The desired trajectory of the osteotomy can be outlined with the use of a k-wire and a marking pen. The path of the osteotomy should be a safe distance from the posterior facet of the subtalar joint.

A 3mm incision is made at the center of the osteotomy and using a hemostat to create a pathway to introduce the burr.

Step 3 – Incision

A 3mm incision is made at the center of the osteotomy and using a hemostat to create a pathway to introduce the burr.



Step 4 – Osteotomy

Osteotomies performed with a burr should always be powered with high torque, low rpm motor, and kept at safe speeds. Be mindful to avoid pulling on the skin by rotating around the fulcrum by supinating and pronating to perform osteotomies.

The calcaneal osteotomy is performed in quadrants, completing each section before moving on to the next.

Introduce the burr into the calcaneus and punch through the medial cortex. The osteotomy is then completed in the following steps:

Near cancellous, far cancellous, poke holes, connect the dots.

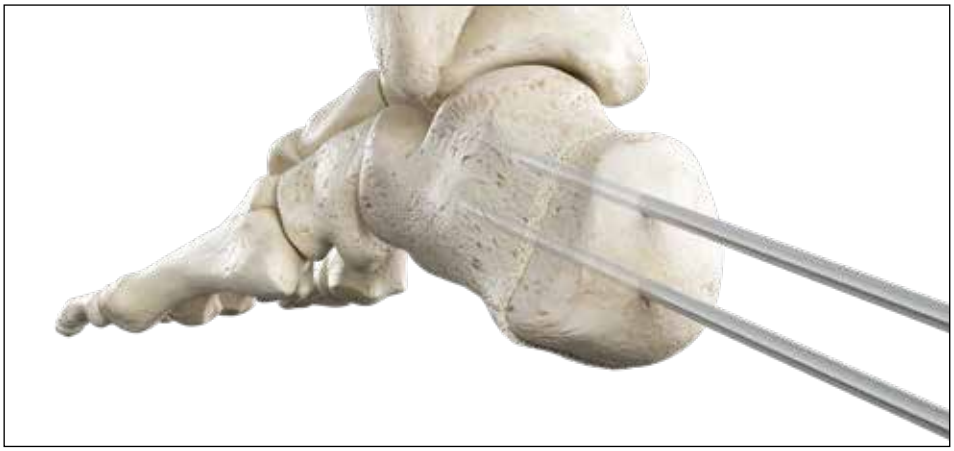
Once the near cortices are complete, make a series of poke holes along the far cortex to feel the cortex break as the burr passes through. Bone paste and fluid will begin exiting the incision as evidence the osteotomy has been completed.

Step 5 – Translation

Once the osteotomy is mobile, introduce a periosteal elevator or instrument of choice into the anterior aspect of the calcaneus. Acting as a lever apply pressure to displace into the desired position.

Step 6 – Fixation

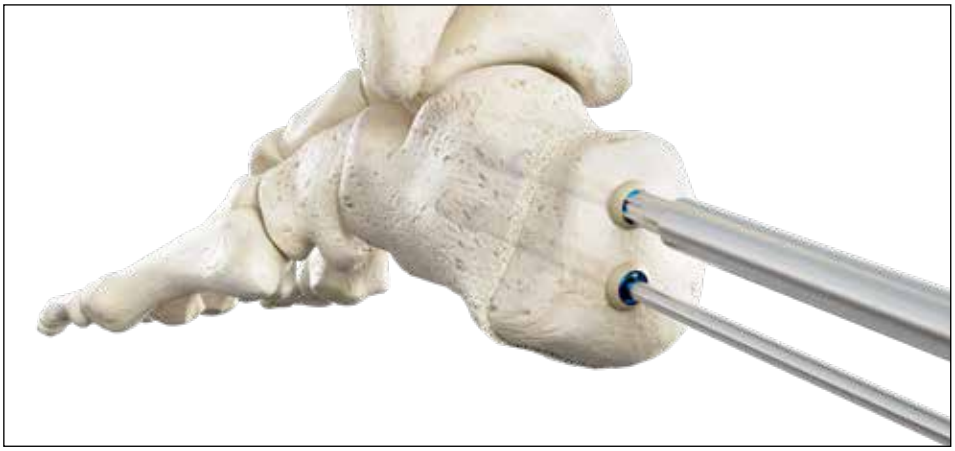
Introduce two guidewires corresponding to either the 5.6mm or 7.4mm Creed screw to provisionally fixation. Once in the desired position, measure, drill, countersink, and fixate.



Operative Technique – Medial Displaced Calcaneal Osteotomy

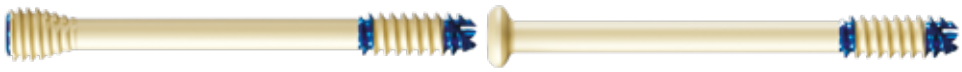
Step 7 – Screw insertion

Once in the desired position, measure, drill, countersink, and fixate.



Catalog Information – Implants

Ø5.6mm Headless Compression Screw / Headed Screw



Headless Ø5.6mm (REF)	Headed Ø5.6mm (REF)	Length (mm)	Thread (mm)
F1-1656-030S	F2-1656-030S	30mm	16mm
F1-1656-032S	F2-1656-032S	32mm	16mm
F1-1656-034S	F2-1656-034S	34mm	16mm
F1-1656-036S	F2-1656-036S	36mm	16mm
F1-1656-038S	F2-1656-038S	38mm	16mm
F1-1656-040S	F2-1656-040S	40mm	16mm
F1-1656-042S	F2-1656-042S	42mm	16mm
F1-1656-044S	F2-1656-044S	44mm	16mm
F1-1656-046S	F2-1656-046S	46mm	16mm
F1-1656-048S	F2-1656-048S	48mm	16mm
F1-1656-050S	F2-1656-050S	50mm	16mm
F1-1656-055S	F2-1656-055S	55mm	16mm
F1-1656-060S	F2-1656-060S	60mm	16mm
F1-1656-065S	F2-1656-065S	65mm	16mm
F1-1656-070S	F2-1656-070S	70mm	16mm
F1-1656-075S	F2-1656-075S	75mm	16mm
F1-1656-080S	-	80mm	16mm
F1-3256-042S	F2-3256-042S	42mm	32mm*
F1-3256-044S	F2-3256-044S	44mm	32mm*
F1-3256-046S	F2-3256-046S	46mm	32mm*
F1-3256-048S	F2-3256-048S	48mm	32mm*
F1-3256-050S	F2-3256-050S	50mm	32mm*
F1-3256-055S	F2-3256-055S	55mm	32mm*
F1-3256-060S	F2-3256-060S	60mm	32mm*
F1-3256-065S	F2-3256-065S	65mm	32mm*
F1-3256-070S	F2-3256-070S	70mm	32mm*
F1-3256-075S	F2-3256-075S	75mm	32mm*

***Note: Special Order**

Catalog Information – Implants

Ø7.4mm Headless Compression Screw / Headed Screw

Headless Ø7.4mm (REF)	Headed Ø7.4mm (REF)	Length (mm)	Thread (mm)
F1-1974-040S	F2-1974-040S	40mm	19mm
F1-1974-042S	F2-1974-042S	42mm	19mm
F1-1974-044S	F2-1974-044S	44mm	19mm
F1-1974-046S	F2-1974-046S	46mm	19mm
F1-1974-048S	F2-1974-048S	48mm	19mm
F1-1974-050S	F2-1974-050S	50mm	19mm
F1-1974-055S	F2-1974-055S	55mm	19mm
F1-1974-060S	F2-1974-060S	60mm	19mm
F1-1674-065S	F2-1674-065S	65mm	19mm
F1-1974-070S	F2-1974-070S	70mm	19mm
F1-1974-075S	F2-1974-075S	75mm	19mm
F1-1974-080S	F2-1974-080S	80mm	19mm
F1-1974-085S	F2-1974-085S	85mm	19mm
F1-1974-090S	F2-1974-090S	90mm	19mm
F1-1974-095S	F2-1974-095S	95mm	19mm
F1-1974-100S	-	100mm	19mm

Screw Washer options

	REF	Description
	F2-0025-000S	Washer Ø2.5mm / OD 5mm
	F2-0043-000S	Washer Ø4.3mm / OD 7.5mm
	F2-0056-000S	Washer Ø5.6mm / OD 11mm
	F2-0074-000S	Washer Ø7.4mm / OD 13mm

Ø7.4mm Headless Compression Screw / Headed Screw

Headless Ø7.4mm (REF)	Headed Ø7.4mm (REF)	Length (mm)	Thread (mm)
-	F2-3274-040S	40mm	32mm*
-	F2-3274-042S	42mm	32mm*
-	F2-3274-044S	44mm	32mm*
F1-3274-046S	F2-3274-046S	46mm	32mm*
F1-3274-048S	F2-3274-048S	48mm	32mm*
F1-3274-050S	F2-3274-050S	50mm	32mm*
F1-3274-055S	F2-3274-055S	55mm	32mm*
F1-3274-060S	F2-3274-060S	60mm	32mm*
F1-3274-065S	F2-3274-065S	65mm	32mm*
F1-3274-070S	F2-3274-070S	70mm	32mm*
F1-3274-075S	F2-3274-075S	75mm	32mm*
F1-3274-080S	F2-3274-080S	80mm	32mm*
F1-3274-085S	F2-3274-085S	85mm	32mm*
F1-3274-090S	F2-3274-090S	90mm	32mm*
F1-3274-095S	F2-3274-095S	95mm	32mm*
F1-3274-100S	-	100mm	32mm*
F1-3274-105S	-	105mm	32mm*

***Note: Special Order**

Catalog Information – Instruments

REF	Description
F4-5674-000S	CREED Instrument Kit Large for Ø5.6mm and Ø7.4mm screws

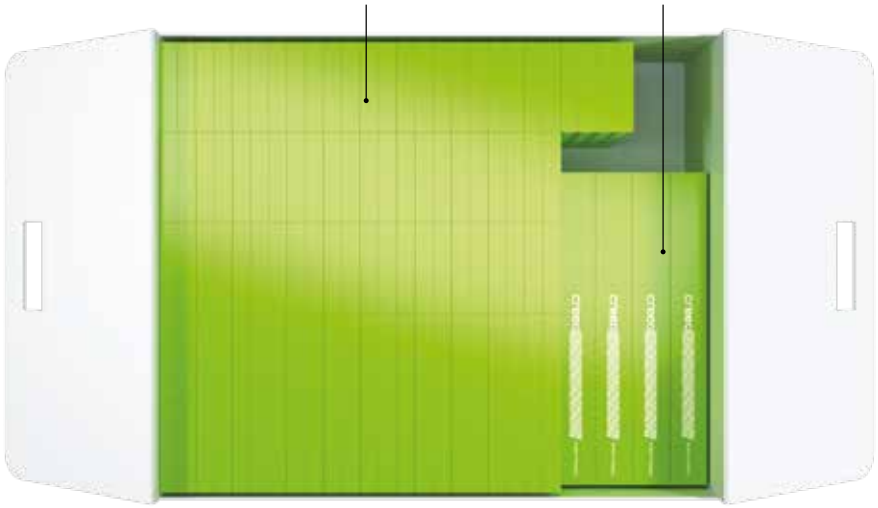
S = items are sterile

		Qty.
	Countersink / Depth Gauge Large	1
	K-wire Ø2.8 x 230mm Drill Tip	2
	K-wire Ø3.2 x 230mm Drill Tip	2
	Universal Handle, Zimm / Hall Interface	1
	Screwdriver Blade T25 x 140mm	1
	Screwdriver Blade T30 x 140mm	1
	Cannulated Drill Ø6.1mm x 200mm	1

REF	Description	
F4-0028-230S	CREED Ø2.8 K-Wire Kit	
		Qty.
	K-wire Ø2.8 x 230mm Drill Tip	2

REF	Description	
F4-0032-230S	CREED Ø3.2 K-Wire Kit	
		Qty.
	K-wire Ø3.2 x 230mm Drill Tip	2

Creed® – Large Headless Screw System Dispenser Layout



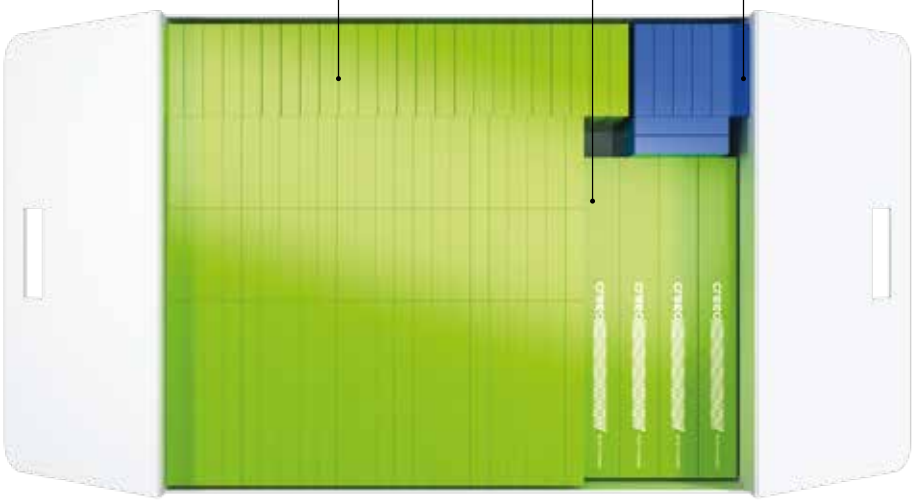
Large Box
Cardboard Dispenser

Large Box
Shipping Container

Headless Compression Screws – Large

Part No	Description	Qty
F1-1656-030S	Thread 16mm / Ø5.6mm x 30mm	2
F1-1656-032S	Thread 16mm / Ø5.6mm x 32mm	2
F1-1656-034S	Thread 16mm / Ø5.6mm x 34mm	2
F1-1656-036S	Thread 16mm / Ø5.6mm x 36mm	2
F1-1656-038S	Thread 16mm / Ø5.6mm x 38mm	2
F1-1656-040S	Thread 16mm / Ø5.6mm x 40mm	2
F1-1656-042S	Thread 16mm / Ø5.6mm x 42mm	2
F1-1656-044S	Thread 16mm / Ø5.6mm x 44mm	2
F1-1656-046S	Thread 16mm / Ø5.6mm x 46mm	2
F1-1656-048S	Thread 16mm / Ø5.6mm x 48mm	2
F1-1656-050S	Thread 16mm / Ø5.6mm x 50mm	2
F1-1656-055S	Thread 16mm / Ø5.6mm x 55mm	2
F1-1656-060S	Thread 16mm / Ø5.6mm x 60mm	2
F1-1656-065S	Thread 16mm / Ø5.6mm x 65mm	2
F1-1656-070S	Thread 16mm / Ø5.6mm x 70mm	2
F1-1656-075S	Thread 16mm / Ø5.6mm x 75mm	2
F1-1656-080S	Thread 16mm / Ø5.6mm x 80mm	2
F1-1974-040S	Thread 16mm / Ø7.4mm x 40mm	2
F1-1974-042S	Thread 16mm / Ø7.4mm x 42mm	2
F1-1974-044S	Thread 16mm / Ø7.4mm x 44mm	2
F1-1974-046S	Thread 16mm / Ø7.4mm x 46mm	2
F1-1974-048S	Thread 16mm / Ø7.4mm x 48mm	2
F1-1974-050S	Thread 16mm / Ø7.4mm x 50mm	2
F1-1974-055S	Thread 16mm / Ø7.4mm x 55mm	2
F1-1974-060S	Thread 16mm / Ø7.4mm x 60mm	2
F1-1674-065S	Thread 16mm / Ø7.4mm x 65mm	2
F1-1974-070S	Thread 16mm / Ø7.4mm x 70mm	2
F1-1974-075S	Thread 16mm / Ø7.4mm x 75mm	2
F1-1974-080S	Thread 16mm / Ø7.4mm x 80mm	2
F1-1974-085S	Thread 16mm / Ø7.4mm x 85mm	2
F1-1974-090S	Thread 16mm / Ø7.4mm x 90mm	2
F1-1974-095S	Thread 16mm / Ø7.4mm x 95mm	2
F1-1974-100S	Thread 16mm / Ø7.4mm x 100mm	2
F4-5674-000S	Instrument Kit Large for Ø5.6mm and Ø7.4mm screws*	4
80-143	Large Box Shipping Container	1
40-226F	Large Box Inlay	1
40-224F	Large Box Cardboard Dispenser	1
F4-0028-230S	Ø2.8 K-Wire Kit (2 K-Wires per Kit)	5
F4-0032-230S	Ø3.2 K-Wire Kit (2 K-Wires per Kit)	5

Creed® – Large Headed Screw System Dispenser Layout



Large Box
Cardboard Dispenser

Large Box
Shipping Container

Headed Compression Screws – Large

Part No	Description	Qty
F2-1656-030S	Thread 16mm / Ø5.6mm x 30mm	2
F2-1656-032S	Thread 16mm / Ø5.6mm x 32mm	2
F2-1656-034S	Thread 16mm / Ø5.6mm x 34mm	2
F2-1656-036S	Thread 16mm / Ø5.6mm x 36mm	2
F2-1656-038S	Thread 16mm / Ø5.6mm x 38mm	2
F2-1656-040S	Thread 16mm / Ø5.6mm x 40mm	2
F2-1656-042S	Thread 16mm / Ø5.6mm x 42mm	2
F2-1656-044S	Thread 16mm / Ø5.6mm x 44mm	2
F2-1656-046S	Thread 16mm / Ø5.6mm x 46mm	2
F2-1656-048S	Thread 16mm / Ø5.6mm x 48mm	2
F2-1656-050S	Thread 16mm / Ø5.6mm x 50mm	2
F2-1656-055S	Thread 16mm / Ø5.6mm x 55mm	2
F2-1656-060S	Thread 16mm / Ø5.6mm x 60mm	2
F2-1656-065S	Thread 16mm / Ø5.6mm x 65mm	2
F2-1656-070S	Thread 16mm / Ø5.6mm x 70mm	2
F2-1656-075S	Thread 16mm / Ø5.6mm x 75mm	2
F2-1974-040S	Thread 16mm / Ø7.4mm x 40mm	2
F2-1974-042S	Thread 16mm / Ø7.4mm x 42mm	2
F2-1974-044S	Thread 16mm / Ø7.4mm x 44mm	2
F2-1974-046S	Thread 16mm / Ø7.4mm x 46mm	2
F2-1974-048S	Thread 16mm / Ø7.4mm x 48mm	2
F2-1974-050S	Thread 16mm / Ø7.4mm x 50mm	2
F2-1974-055S	Thread 16mm / Ø7.4mm x 55mm	2
F2-1974-060S	Thread 16mm / Ø7.4mm x 60mm	2
F2-1974-065S	Thread 16mm / Ø7.4mm x 65mm	2
F2-1974-070S	Thread 16mm / Ø7.4mm x 70mm	2
F2-1974-075S	Thread 16mm / Ø7.4mm x 75mm	2
F2-1974-080S	Thread 16mm / Ø7.4mm x 80mm	2
F2-1974-085S	Thread 16mm / Ø7.4mm x 85mm	2
F2-1974-090S	Thread 16mm / Ø7.4mm x 90mm	2
F2-1974-095S	Thread 16mm / Ø7.4mm x 95mm	2
F2-0056-000S	Washer Ø5.6mm / OD 11mm	4
F2-0074-000S	Washer Ø7.4mm / OD 13mm	4
F4-5674-000S	Instrument Kit Large for Ø5.6mm and Ø7.4mm screws	4
80-143	Large Box Shipping Container	1
40-226F	Large Box Inlay	1
40-224F	Large Box Cardboard Dispenser	1
F4-0028-230S	Ø2.8 K-Wire Kit (2 K-Wires per Kit)	5
F4-0032-230S	Ø3.2 K-Wire Kit (2 K-Wires per Kit)	5

Notes

Notes

creed™
Ortholucent Implants

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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