GLW Foot & Ankle

creed™

Ortholucent Implants

Operative Technique

2.5mm, 4.3mm Headless and Headed
Cannulated Compression Screws.

Sterile, Disposable Instrumentation.

www.glwmed.com

creed™
Ortholucent Implants

CONTENTS

Contributing Surgeons:

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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.

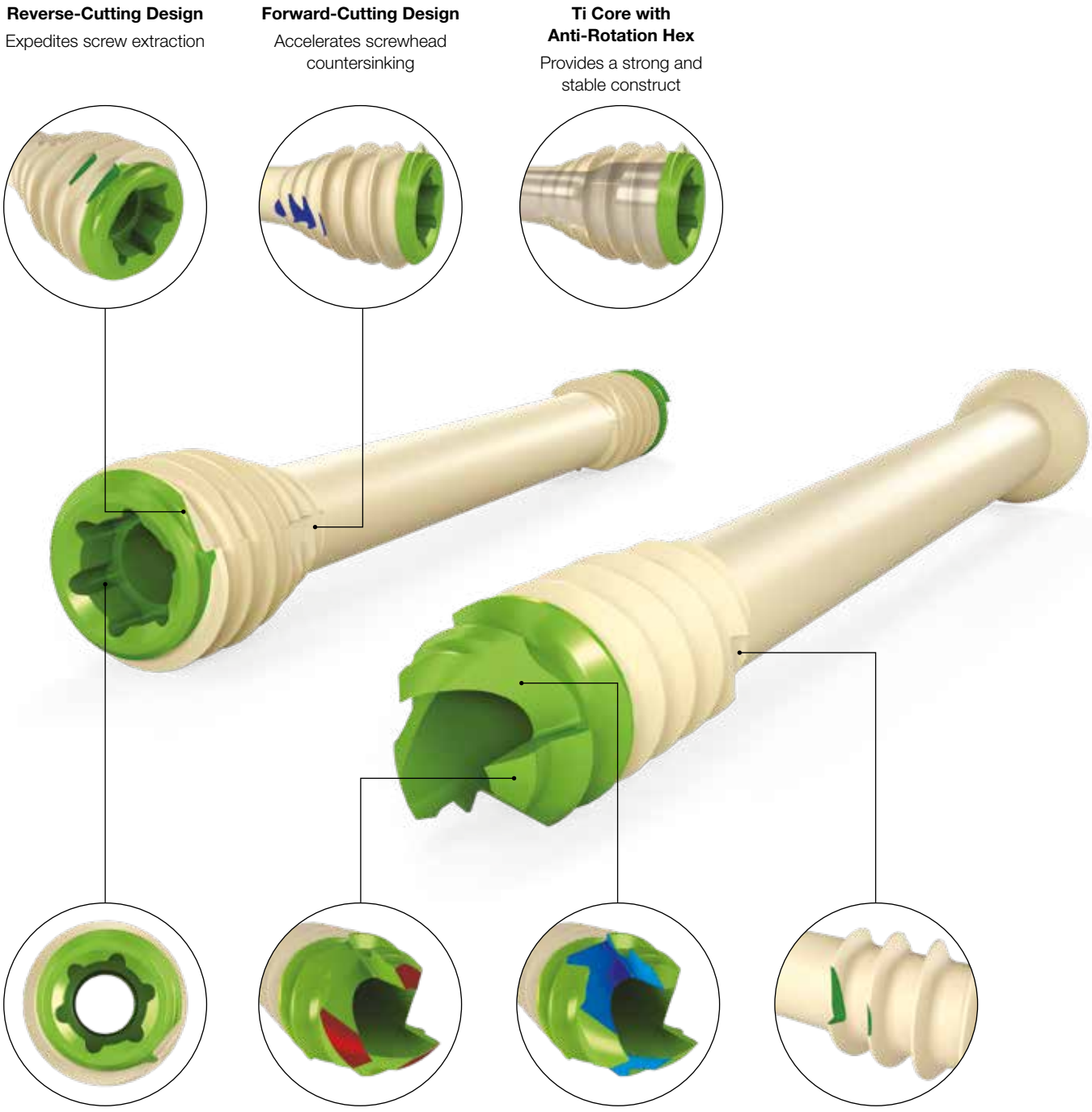
Precautions

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

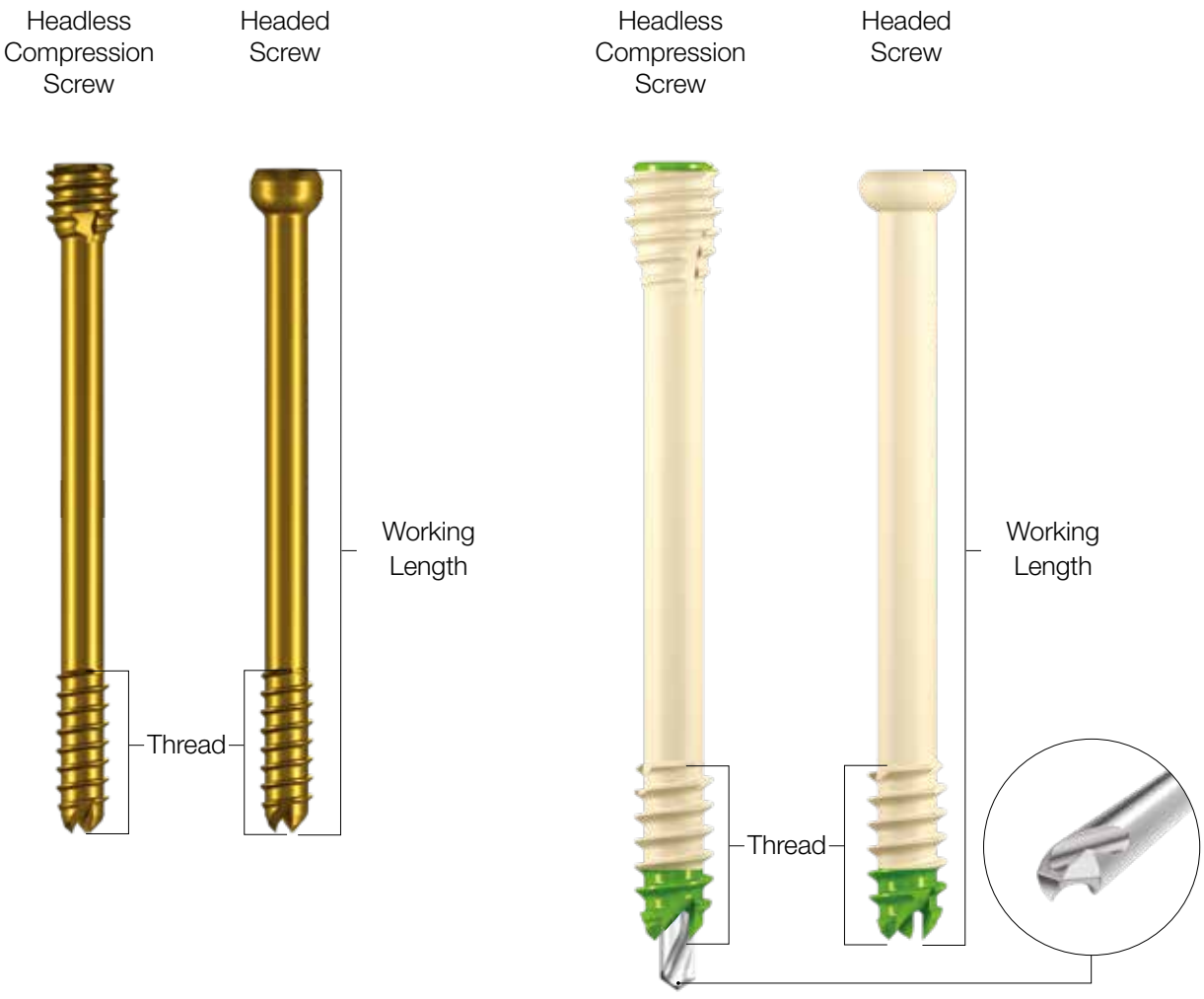
Created in conjunction with foot and ankle specialists, the Creed Ortholucent Implants are designed to deliver maximum compression with minimum torque to address a large variety of osteotomies, fusions and fractures.



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 *Headed ends at 75mm	From 42-50mm each 2mm From *50-75mm each 5mm	From 40-50mm each 2mm From *50-100mm each 5mm *Headed ends at 95mm	From *40-50mm each 2mm From *50-105mm each 5mm *Headless begin at 46mm *Headed ends at 95mm
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

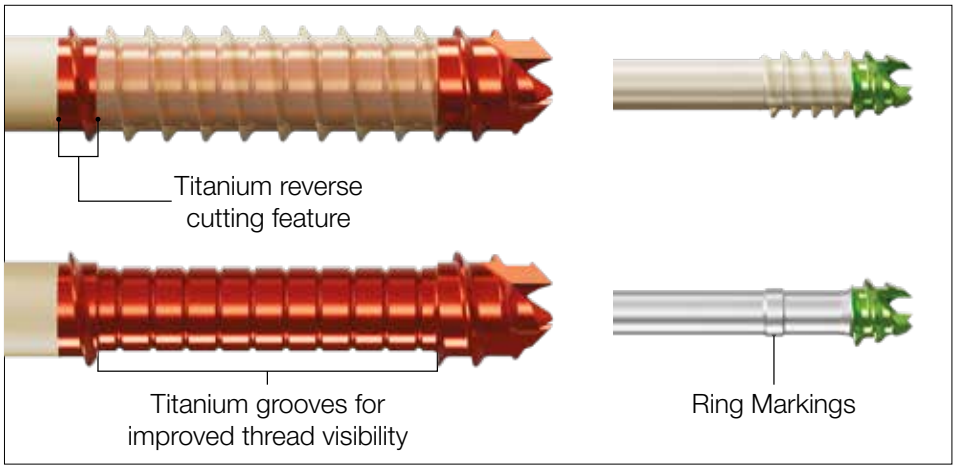


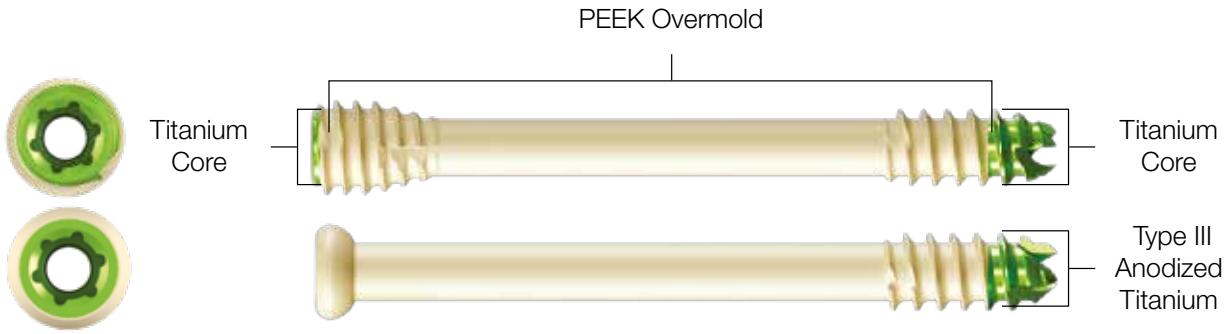
Design Features – Ortholucent Implants

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.

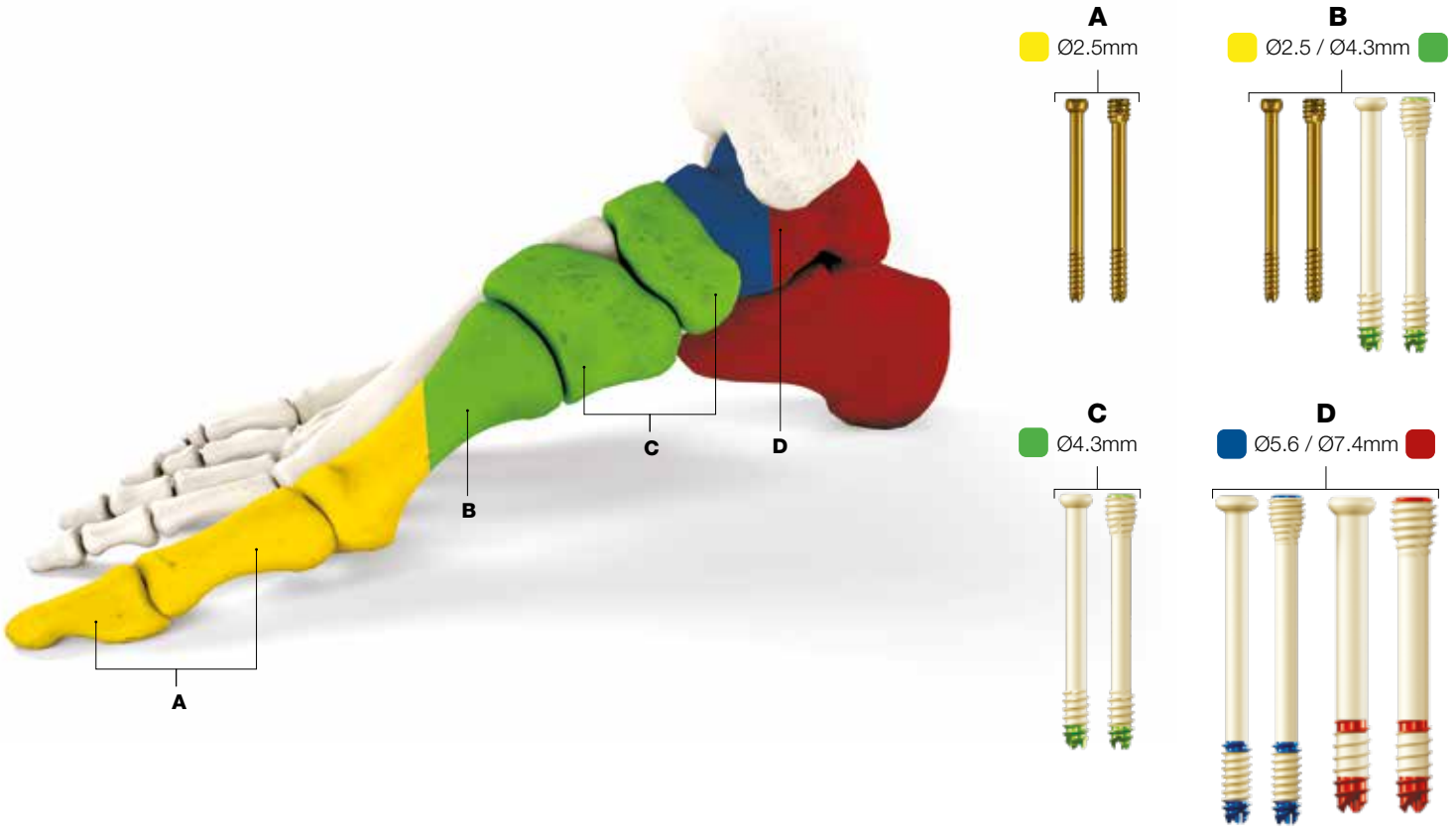
Due to the radiolucent properties of PEEK, the threads of the Creed Ortholucent Implants are invisible on radiographs. To identify where the screw threads end, the Creed Ø5.6mm and Ø7.4mm screws have a titanium reverse cutting geometry that performs as a marker on X-rays. The Ø4.3mm screws have titanium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





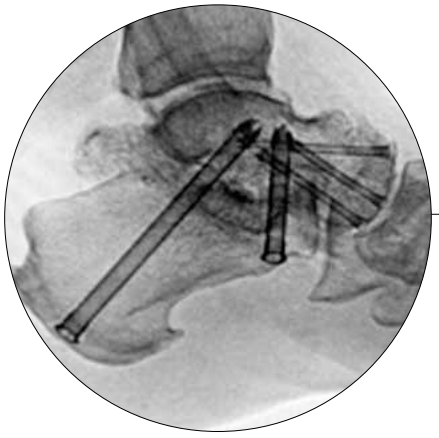
Applications

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				•



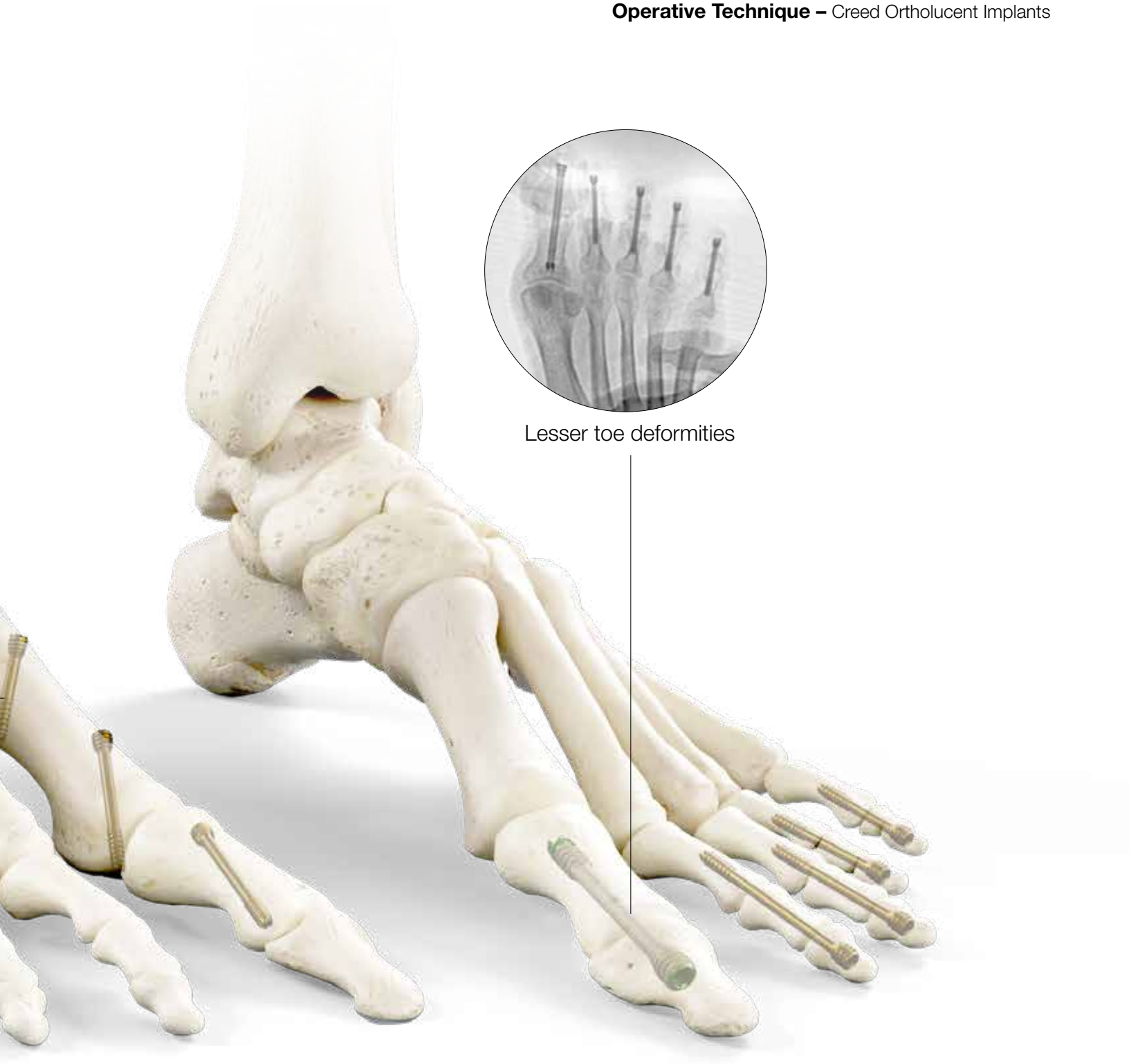
Applications – Ø2.5mm & Ø4.3mm Screws

Posterior malleolar fracture



Medial double arthrodesis
(TN and Subtalar fusion)

Scarf and Akin
bunionectomy


Lesser toe deformities

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.

Small Kit

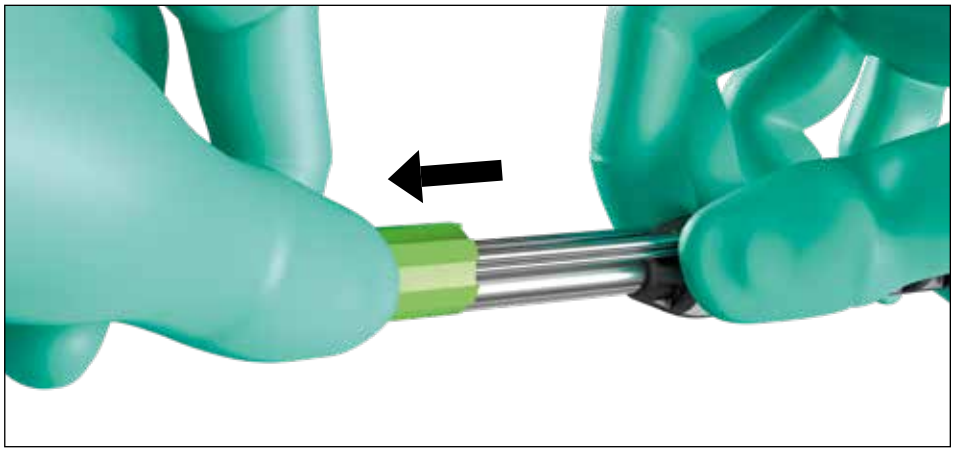
The small instrument kit contains a T8 and T15 cannulated screwdriver blade for Creed Ø2.5mm and Ø4.3mm screws, respectively, which is used in combination with the AO-handle. In addition, the small instrument kit includes a mini depth gauge, a countersink depth gauge with mounted Ø1.3mm and Ø2.0mm K-wires.

Small Instruments Blister Pack

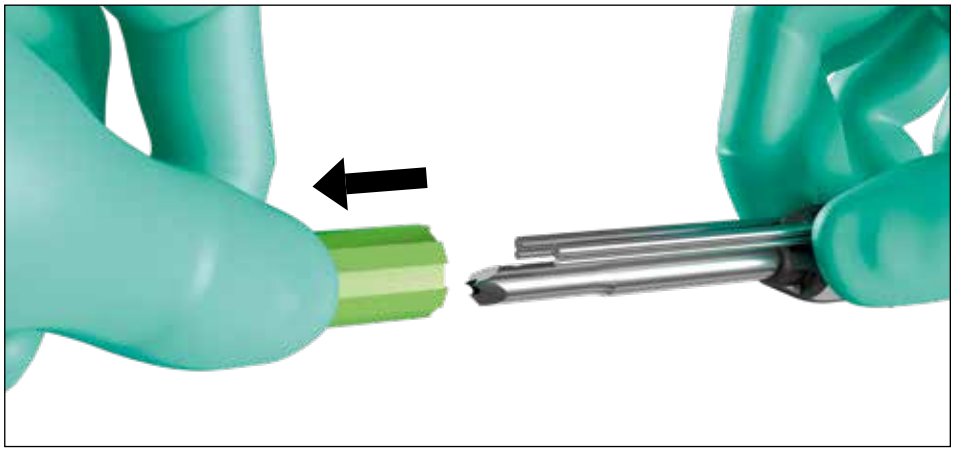
Protective cap removal

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 – Ø2.5mm & Ø4.3mm Screws

Small Screws
Sterile Packaging

Metatarsal Fracture

Step 1 – K-wire Selection

Choose the proper supplied K-wire for desired screw size. To confirm K-wire, utilize the Countersink / Depth Gauge instrument with provided holes on the reverse side of the instrument.

Step 2 – K-wire Insertion

Insert the supplied K-wire to the proper depth. If necessary, utilize fluoroscopy to maintain reduction and control K-wire position.

In hard or sclerotic bone, perforating the cortex with the Countersink / Depth Gauge (and driver handle) prior to K-wire insertion can reduce the risk of wire deviation and heat escalation.

Ø1.3mm for Ø2.5mm screws.
Ø2.0mm for Ø4.3mm screws.

Note:
Please ensure there is no visible bending of the K-wire before inserting the screw. Correct K-wire placement if required.

Step 3 – Screw Length Selection

Screw length can be read directly from the Countersink / Depth Gauge at the end of the K-wire. It is dependent upon proper positioning of K-wire and seating of the Countersink / Depth Gauge against the bone.

Note:
It is critical that the Countersink / Depth Gauge rests directly on bone and that proper K-wire placement has been achieved.

A second option is also provided if smaller measuring device preferred.

Operative Technique – Ø2.5mm & Ø4.3mm Screws

Step 4 – Screw Insertion

Attach the provided Cannulated Screwdriver Bit to the Universal Handle, AO small to insert the appropriate screw over the previously placed K-wire. If power insertion is preferred the drivers are compatible.

Note:
When necessary, fluoroscopy may be used to verify K-wire and screw placement.

Note:
Screwdriver shafts are color coded to match desired screw.

Drill bits are not required with Ø2.5mm & Ø4.3mm screws, as the screws are designed with forward cutting flutes, enabling the removal of less bone.

Step 5 – Final Reduction

Final position of the reduction and screw should be verified. The K-wire is removed and discarded. Repeat these steps as needed for additional screws.

Note:
K-wire removal can be assisted with the Countersink / Depth Gauge instruments.

Operative Technique
Percutaneous Interphalangeal Joint Fusion

Osteotomies and fusions 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.

Step 1 – Patient position

Patient is positioned supine. The operative leg is resting off the bed and on the mini c-arm. The non-operative leg can be placed in a frog leg position.

Step 2 – Incision

A 2mm incision is made medial to the Interphalangeal joint & a periosteal elevator is inserted into the portal dorsally to free up the surrounding soft tissue. Be mindful not to strip the periosteum and only free the extensor hallucis longus.

Step 3 – Osteotomy

Introduce the Creed cutting burr into the portal and begin taking down the joint through supination and pronation hand movement. The burr should not pull on the skin, instead rotating off a fulcrum.

Operative Technique
Percutaneous Interphalangeal Joint Fusion

Step 4 – Angiocath

Once the joint is fully prepared, a rasp may be introduced to the portal to remove excess debris and than irrigated using an 18 gauge angiocath.

Step 5 – K-wire insertion

Introduce the 2.0mm guidewire through the tip of the distal phalanx and cross the interphalangeal joint to the subchondral plate of the proximal phalanx.

Step 6 – Depth gauge

Utilize the depth gauge countersink instrument to countersink and than measure for appropriate screw length.

Step 7 – Screw insertion

Introduce the 4.3mm Creed screw and advance until fully seated using the T8 driver.

Operative Technique – Percutaneous MTP Fusion

Osteotomies & fusions 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.

Step 1 – Patient position

Patient is positioned supine. The operative leg is resting off the bed and on the mini c-arm. The non-operative leg can be placed in a frog leg position.

Step 2 – Incision

Using image intensification, identify the main portal to access the joint along the dorsal medial aspect.

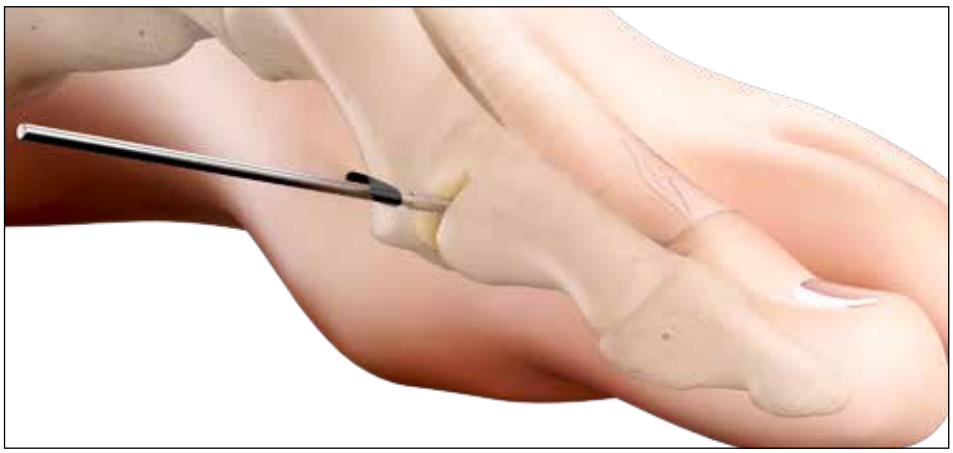
Make a 3mm incision giving access to the 1st mtp joint and introduce the Creed shaving burr into the joint.

Step 3 – Resurfacing the joint

Begin creating a series of flat cuts on the base of the proximal phalanx and head of the 1st metatarsal. Dorsiflexion can be controlled by making an oblique surface on either side of the joint.

The joint is prepped by removing bone in quadrants. Removing bone near dorsally and plantarly than moving laterally.

The distance of the cutting flutes of the burr is typically shorter than the medial and lateral distance of the joint.



Step 4 – Angiocath

A rasp can be introduced to the joint to remove excess bone debris and then thoroughly irrigated by introducing an 18 gauge angiocath.

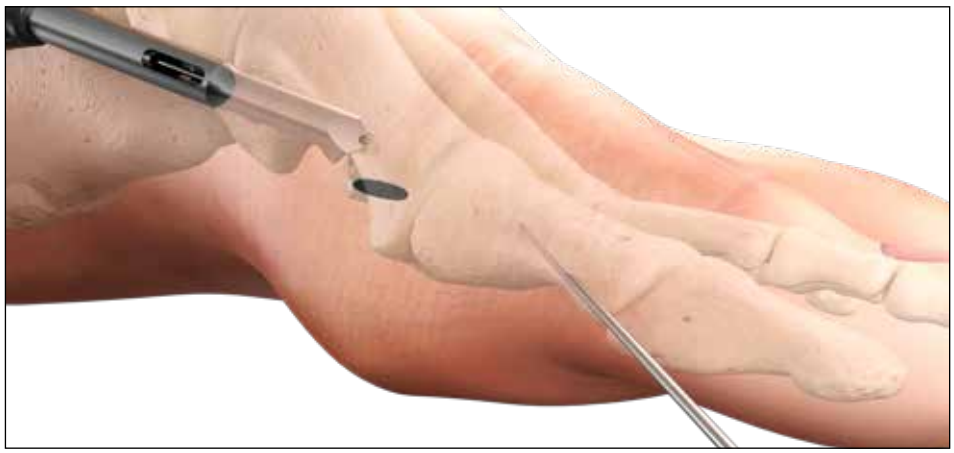
Step 5 – K-wire insertion

A cross-screw construct is recommended for fixation.

Introduce a 2.0mm kwire at the dorsal medial midpoint of the proximal phalanx crossing the MTP joint and exiting the lateral diaphyseal junction of 1st metatarsal. Introduce a second 2.0mm kwire medially at the diaphyseal junction of the 1st metatarsal, crossing the joint and exiting the lateral cortex of the proximal phalanx.

Step 6 – Measuring

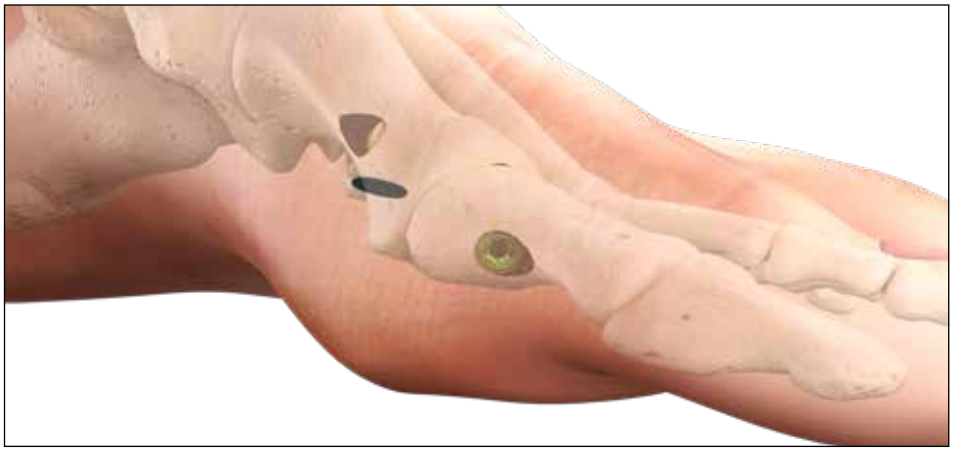
Using the depth gauge countersink combination instrument, countersink for the head of the Creed implant and measure.



Operative Technique – Percutaneous MTP Fusion

Step 7 – Screw insertion

Select the appropriate size implant and insert over the guidewire, advancing using the T15 driver.



Catalog Information – Implants

Ø2.5mm Headless Compression Screw / Headed Screw

Headless Ø2.5mm (REF)	Headed Ø2.5mm (REF)	Length (mm)	Thread (mm)
-	F2-0825-012S	12mm	8mm
F1-0825-014S	F2-0825-014S	14mm	8mm
F1-0825-016S	F2-0825-016S	16mm	8mm
F1-0825-018S	F2-0825-018S	18mm	8mm
F1-0825-020S	F2-0825-020S	20mm	8mm
F1-0825-022S	F2-0825-022S	22mm	8mm
F1-0825-024S	F2-0825-024S	24mm	8mm
F1-0825-026S	F2-0825-026S	26mm	8mm
F1-0825-028S	F2-0825-028S	28mm	8mm
F1-0825-030S	F2-0825-030S	30mm	8mm

Ø4.3mm Headless Compression Screw / Headed Screw

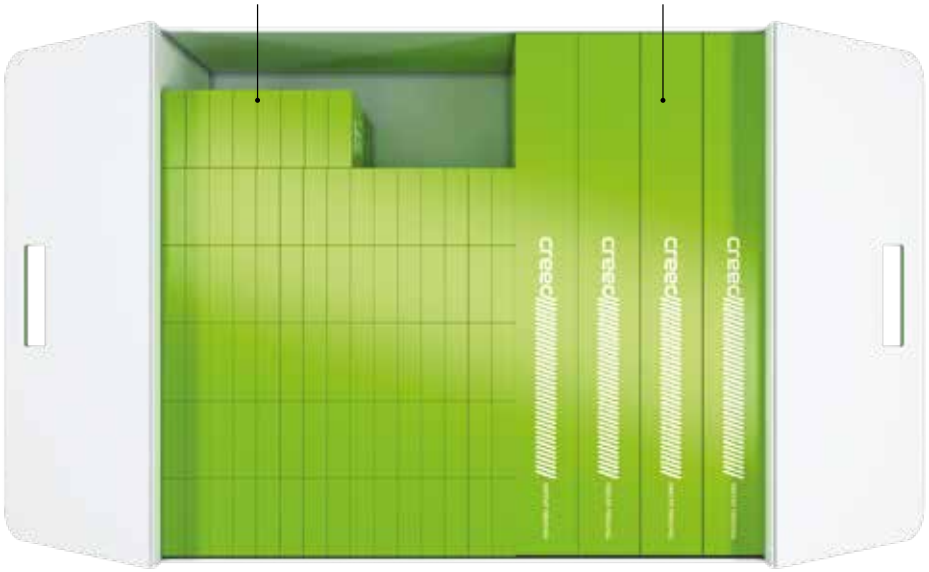
Headless Ø4.3mm (REF)	Headed Ø4.3mm (REF)	Length (mm)	Thread (mm)
F1-1040-018S	F2-1040-018S	18mm	10mm
F1-1040-020S	F2-1040-020S	20mm	10mm
F1-1040-022S	F2-1040-022S	22mm	10mm
F1-1040-024S	F2-1040-024S	24mm	10mm
F1-1040-026S	F2-1040-026S	26mm	10mm
F1-1040-028S	F2-1040-028S	28mm	10mm
F1-1040-030S	F2-1040-030S	30mm	10mm
F1-1040-032S	F2-1040-032S	32mm	10mm
F1-1040-034S	F2-1040-034S	34mm	10mm
F1-1040-036S	F2-1040-036S	36mm	10mm
F1-1040-038S	F2-1040-038S	38mm	10mm
F1-1040-040S	F2-1040-040S	40mm	10mm
F1-1040-042S	F2-1040-042S	42mm	10mm
F1-1040-044S	F2-1040-044S	44mm	10mm
F1-1040-046S	F2-1040-046S	46mm	10mm
F1-1040-048S	F2-1040-048S	48mm	10mm
F1-1040-050S	F2-1040-050S	50mm	10mm
F1-1040-055S	F2-1040-055S	55mm	10mm
F1-1040-060S	F2-1040-060S	60mm	10mm

Catalog Information – Implants

Screw Washer options

	REF	Description
	F2-0025-000S	Washer Ø2.5mm / OD 5mm
	F2-0043-000S	Washer Ø4.3mm / OD 7.5mm

Creed® – Small Screw System Dispenser Layout



Small Box
Cardboard Dispenser

Small Box
Shipping Container

Headless Compression Screws – Small

Part No	Description	Qty
F1-0825-014S	Thread 8mm / Ø2.5mm x 14mm	2
F1-0825-016S	Thread 8mm / Ø2.5mm x 16mm	3
F1-0825-018S	Thread 8mm / Ø2.5mm x 18mm	3
F1-0825-020S	Thread 8mm / Ø2.5mm x 20mm	3
F1-0825-022S	Thread 8mm / Ø2.5mm x 22mm	3
F1-0825-024S	Thread 8mm / Ø2.5mm x 24mm	3
F1-0825-026S	Thread 8mm / Ø2.5mm x 26mm	3
F1-0825-028S	Thread 8mm / Ø2.5mm x 28mm	3
F1-0825-030S	Thread 8mm / Ø2.5mm x 30mm	3
F1-1040-018S	Thread 10mm / Ø4.3mm x 18mm	3
F1-1040-020S	Thread 10mm / Ø4.3mm x 20mm	3
F1-1040-022S	Thread 10mm / Ø4.3mm x 22mm	3
F1-1040-024S	Thread 10mm / Ø4.3mm x 24mm	3
F1-1040-026S	Thread 10mm / Ø4.3mm x 26mm	3
F1-1040-028S	Thread 10mm / Ø4.3mm x 28mm	3
F1-1040-030S	Thread 10mm / Ø4.3mm x 30mm	3
F1-1040-032S	Thread 10mm / Ø4.3mm x 32mm	3
F1-1040-034S	Thread 10mm / Ø4.3mm x 34mm	3
F1-1040-036S	Thread 10mm / Ø4.3mm x 36mm	3
F1-1040-038S	Thread 10mm / Ø4.3mm x 38mm	3
F1-1040-040S	Thread 10mm / Ø4.3mm x 40mm	3
F1-1040-042S	Thread 10mm / Ø4.3mm x 42mm	3
F1-1040-044S	Thread 10mm / Ø4.3mm x 44mm	3
F1-1040-046S	Thread 10mm / Ø4.3mm x 46mm	3
F1-1040-048S	Thread 10mm / Ø4.3mm x 48mm	3
F1-1040-050S	Thread 10mm / Ø4.3mm x 50mm	3
F1-1040-055S	Thread 10mm / Ø4.3mm x 55mm	2
F1-1040-060S	Thread 10mm / Ø4.3mm x 60mm	2
F4-2540-000S	Instrument Kit Small for Ø2.5mm and Ø4.3mm screws	4
80-142	Small Box Shipping Container	1
40-225F	Small Box Inlay	1
40-296	Small Box Cardboard Dispenser	1
F4-0013-150S	Ø1.3 K-Wire Kit (2 K-Wires per Kit)	5
F4-0020-150S	Ø2.0 K-Wire Kit (2 K-Wires per Kit)	5

Small Box
Cardboard Dispenser

Small Box
Shipping Container

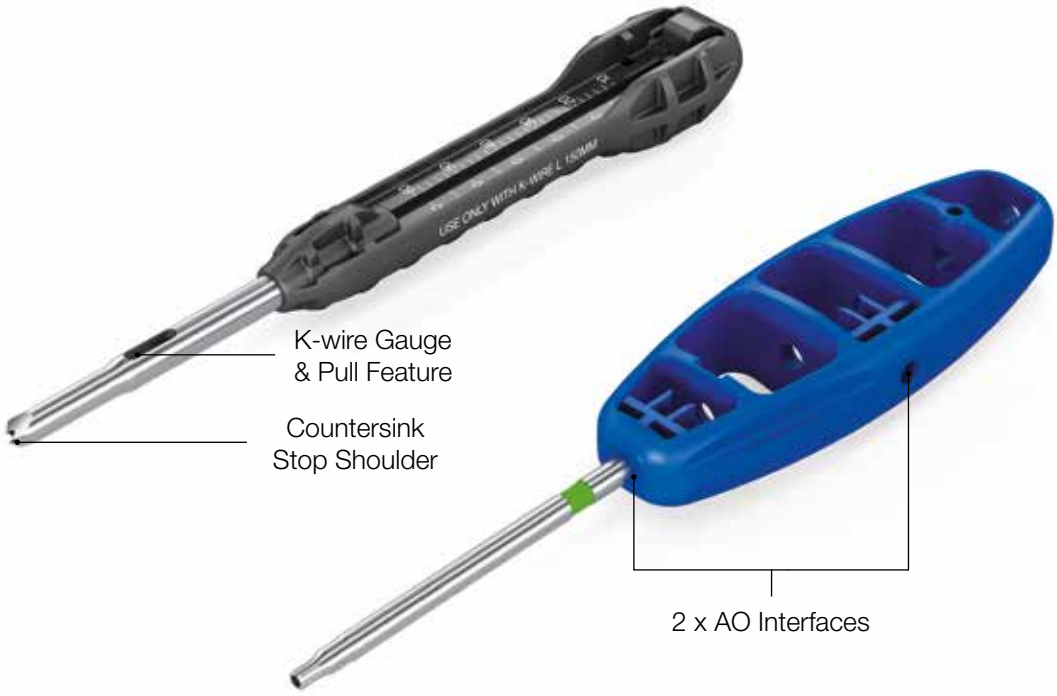
Headed Compression Screws – Small

Part No	Description	Qty
F2-0825-012S	Thread 8mm / Ø2.5mm x 12mm	3
F2-0825-014S	Thread 8mm / Ø2.5mm x 14mm	3
F2-0825-016S	Thread 8mm / Ø2.5mm x 16mm	3
F2-0825-018S	Thread 8mm / Ø2.5mm x 18mm	3
F2-0825-020S	Thread 8mm / Ø2.5mm x 20mm	3
F2-0825-022S	Thread 8mm / Ø2.5mm x 22mm	3
F2-0825-024S	Thread 8mm / Ø2.5mm x 24mm	3
F2-0825-026S	Thread 8mm / Ø2.5mm x 26mm	3
F2-0825-028S	Thread 8mm / Ø2.5mm x 28mm	3
F2-0825-030S	Thread 8mm / Ø2.5mm x 30mm	3
F2-1040-018S	Thread 10mm / Ø4.3mm x 18mm	2
F2-1040-020S	Thread 10mm / Ø4.3mm x 20mm	2
F2-1040-022S	Thread 10mm / Ø4.3mm x 22mm	3
F2-1040-024S	Thread 10mm / Ø4.3mm x 24mm	3
F2-1040-026S	Thread 10mm / Ø4.3mm x 26mm	3
F2-1040-028S	Thread 10mm / Ø4.3mm x 28mm	3
F2-1040-030S	Thread 10mm / Ø4.3mm x 30mm	3
F2-1040-032S	Thread 10mm / Ø4.3mm x 32mm	3
F2-1040-034S	Thread 10mm / Ø4.3mm x 34mm	3
F2-1040-036S	Thread 10mm / Ø4.3mm x 36mm	3
F2-1040-038S	Thread 10mm / Ø4.3mm x 38mm	3
F2-1040-040S	Thread 10mm / Ø4.3mm x 40mm	3
F2-1040-042S	Thread 10mm / Ø4.3mm x 42mm	3
F2-1040-044S	Thread 10mm / Ø4.3mm x 44mm	3
F2-1040-046S	Thread 10mm / Ø4.3mm x 46mm	3
F2-1040-048S	Thread 10mm / Ø4.3mm x 48mm	3
F2-1040-050S	Thread 10mm / Ø4.3mm x 50mm	3
F2-1040-055S	Thread 10mm / Ø4.3mm x 55mm	2
F2-1040-060S	Thread 10mm / Ø4.3mm x 60mm	2
F2-0025-000S	Washer Ø2.5mm / OD 5mm	4
F2-0042-000S	Washer Ø4.3mm / OD 7.5mm	4
F4-2540-000S	Instrument Kit Small for Ø2.5mm and Ø4.3mm screws*	4
80-142	Small Box Shipping Container	1
40-225F	Small Box Inlay	1
40-296	Small Box Cardboard Dispenser	1
F4-0013-150S	Ø1.3 K-Wire Kit (2 K-Wires per Kit)	5
F4-0020-150S	Ø2.0 K-Wire Kit (2 K-Wires per Kit)	5

Catalog Information – Instruments

REF	Description
F4-2540-000S	CREED Instrument Kit Small for Ø2.5mm and Ø4.3mm screws

S = items are sterile



		Qty.
	Countersink / Depth Gauge Small	1
	K-wire Ø1.3 x 150mm Stinger Trocar Tip	2
	K-wire Ø2.0 x 150mm Stinger Trocar Tip	2
	Universal Handle, AO Small	1
	Screwdriver Blade T8 x 85mm	1
	Screwdriver Blade T15 x 85mm	1
	Mini Depth Gauge for Ø1.3mm K-wire Length 150mm, Scale 10 - 60mm	1

REF	Description	
F4-0013-150S	CREED Ø1.3 K-Wire Kit	
		Qty.
	K-wire Ø1.3 x 150mm Drill Tip	2

REF	Description	
F4-0020-150S	CREED Ø2.0 K-Wire Kit	
		Qty.
	K-wire Ø2.0 x 150mm Drill Tip	2

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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