innov8ortho

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Value Analysis Guide

creed™

Ortholucent Implants

creed™
Ortholucent Implants

Value Analysis Guide

This publication sets forth detailed recommended procedures for using Creed Implants.
It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

Creed Contents

Seeing is Believing

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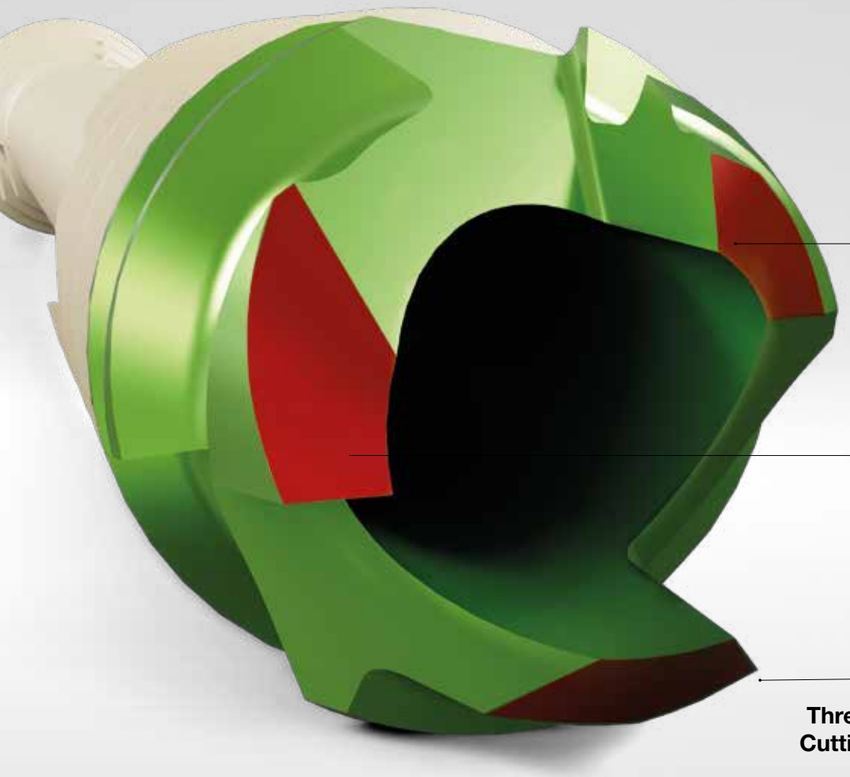


Three Unique Cutting Flutes

Precision Cutting

The three aggressive cutting flutes of the screw tip are designed to deliver maximum compression[1] with minimum torque. Superior cutting geometry delivers optimal bone chip displacement, reduces insertion force, and requires no predrilling.[2]

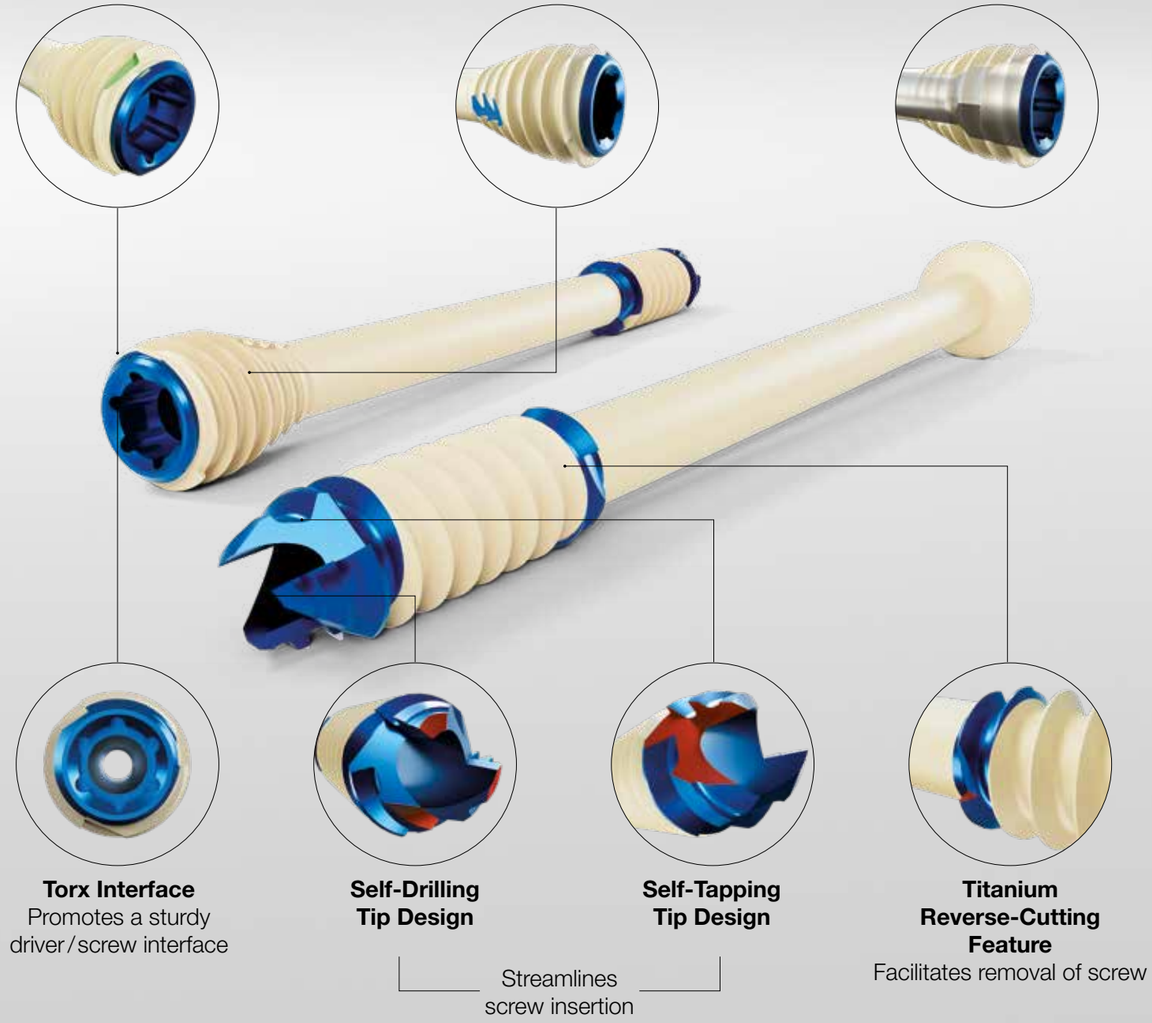
[1] Data on file.

[2] For Ø7.4mm screw minimized predrilling recommended.

Reverse-Cutting Design
Expedites screw extraction

Forward-Cutting Design
Accelerates screw head countersinking

Ti Core with
Anti-rotation hex provides a strong and stable construct



Torx Interface
Promotes a sturdy driver/screw interface

Self-Drilling Tip Design

Self-Tapping Tip Design

Streamlines screw insertion

Titanium Reverse-Cutting Feature
Facilitates removal of screw

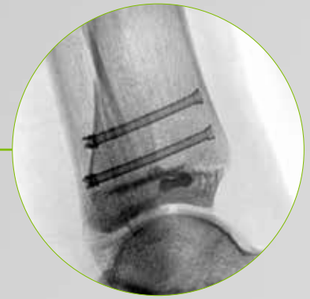
Largest Screw Cannulation

With the largest cannulation and k-wire diameter per screw size on the market, Creed screws are easily inserted using low torque. The larger k-wire, combined with “Stinger Tip” technology, results in a more precise screw insertion trajectory.

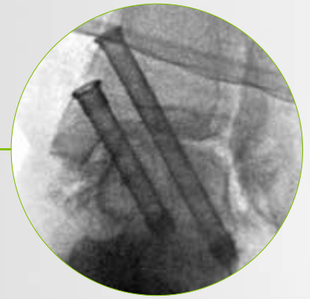
Headed	Headless	Ø Screw Size	Ø Screw Cannulation	Ø K-wire Size
		Ø2.5mm	Ø1.4mm	Ø1.3mm
		Ø4.3mm	Ø2.15mm	Ø2.0mm
		Ø5.6mm	Ø2.9mm	Ø2.8mm
		Ø7.4mm	Ø3.3mm	Ø3.2mm

Orthoucent Technology

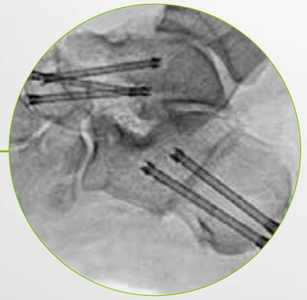
The patented[3] combination of thin-walled titanium, reinforced with a PEEK overmold, provides significant clinical benefits over traditional metal implants by drastically improving the visualization of bones and joint spaces. This novel hybrid material combination provides clear bone visibility during plain radiography as well as less scatter with advanced imaging techniques.



Posterior malleolar fracture

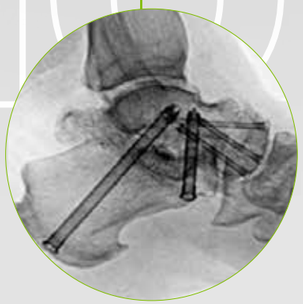


Ankle fusion

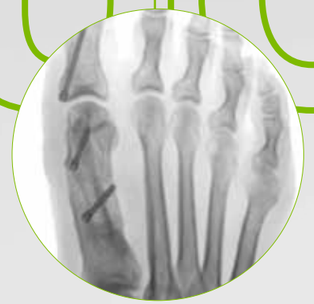


Cavovarus correction (Dwyer calcaneal osteotomy and TN fusion)

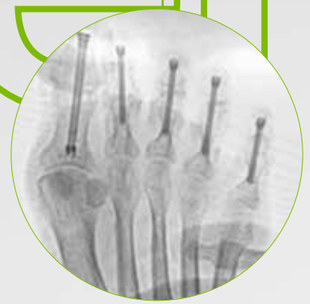
Subtalar fusion



Medial double arthrodesis (TN and Subtalar fusion)



Scarf bunionectomy with Akin osteotomy

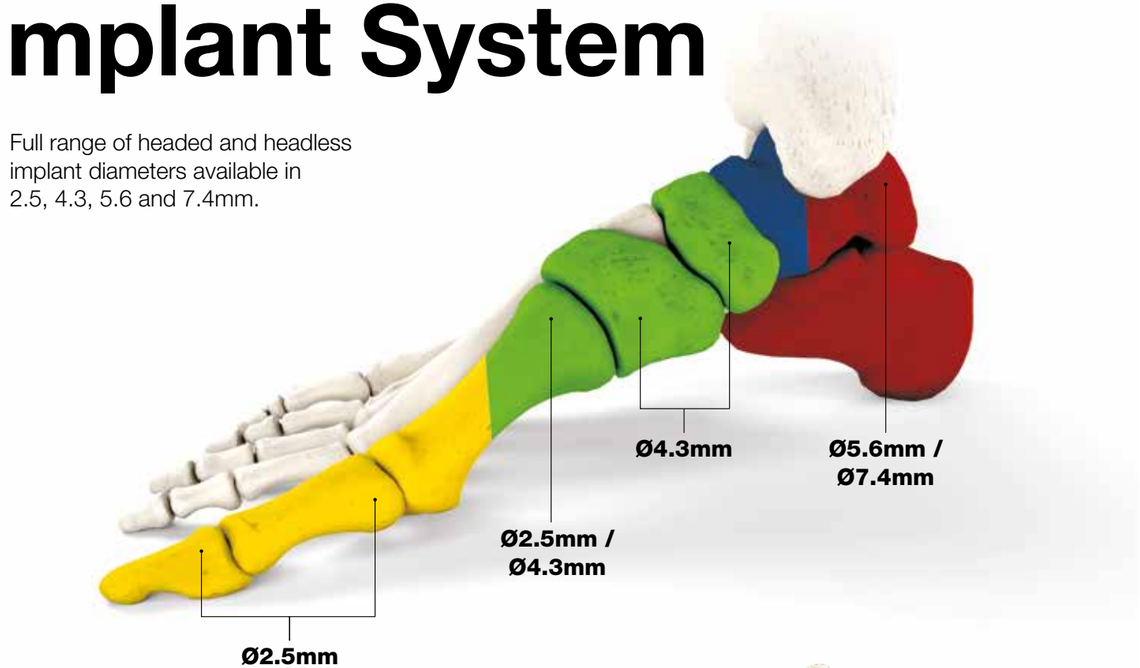


Lesser toe deformities

[3]Patent US11253304B2.

Versatile Cannulated Implant System

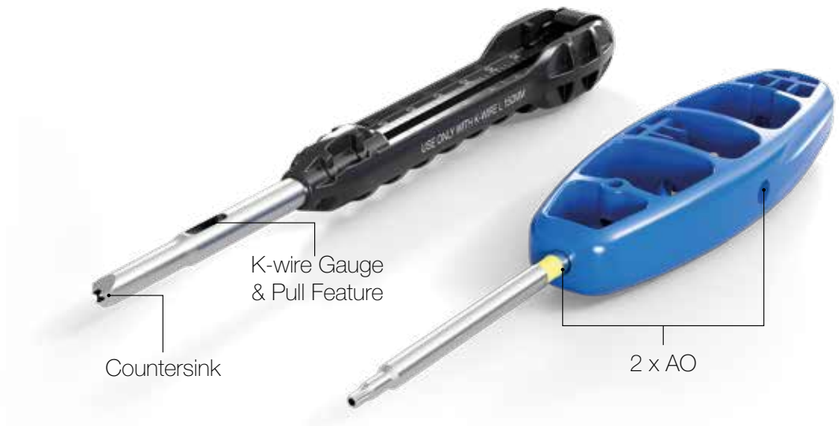
Full range of headed and headless implant diameters available in 2.5, 4.3, 5.6 and 7.4mm.

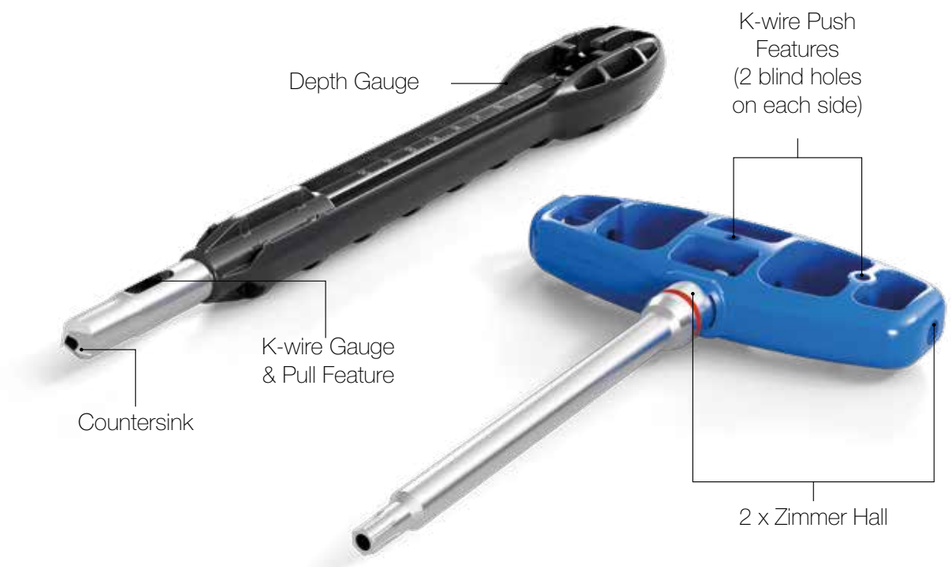


170	85	85	4x	5x
Screw Variations	Headless Screws	Headed Screws	Various Diameters	Thread Lengths

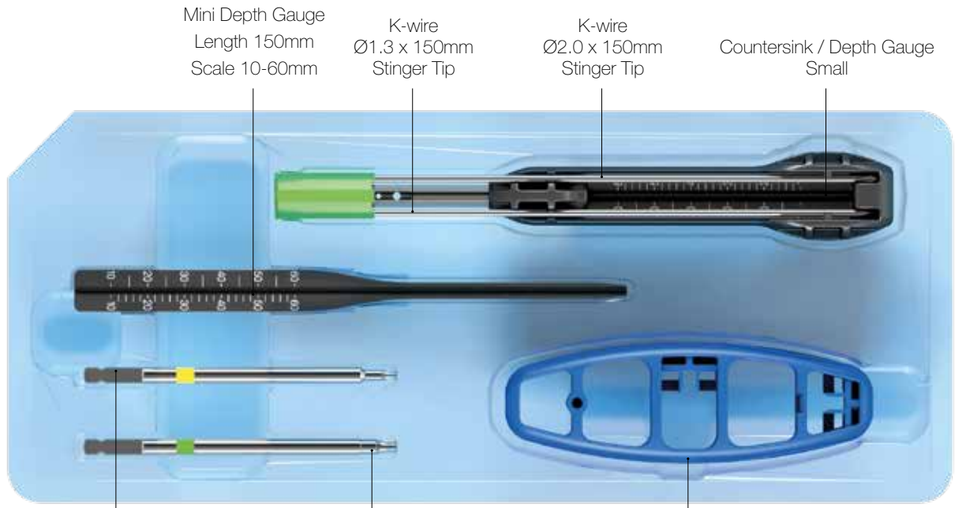
Sterile, Disposable Instrument Kits

Single-use

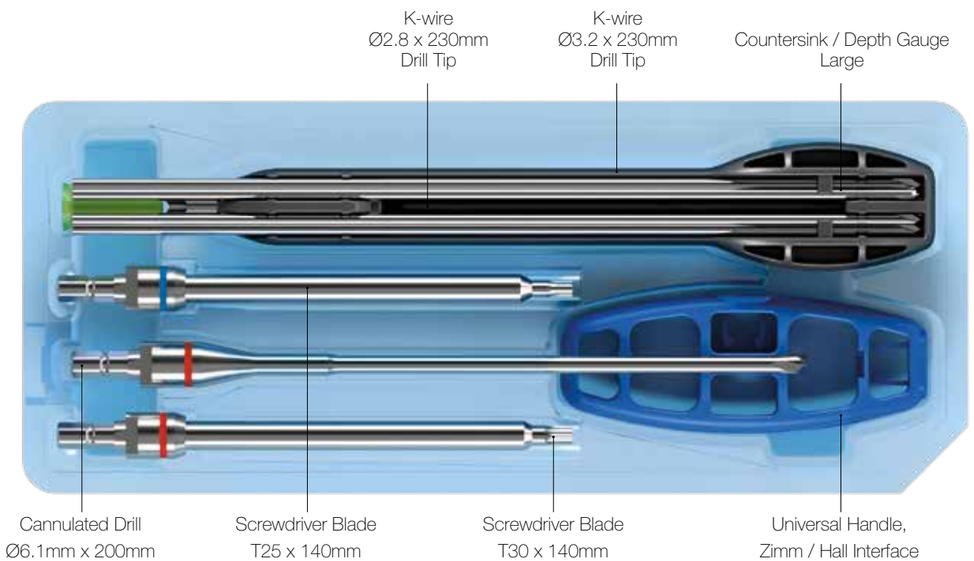




Small Instrument Kit



Large Instrument Kit



*For headed screw configurations only.

December 16, 2020

GLW Medical Innovation
% Cheryl Wagoner
Consultant
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K200291
Trade/Device Name: CREED™ Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 14, 2020
Received: December 16, 2020

Dear Cheryl Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary for K200291
(as required by 21 CFR 807.92)

Date Prepared	November 30, 2020
Manufacturer	GLW, Inc.
Address	300 Sylvan Ave Englewood Cliffs, NJ 07632
Telephone	917-794-2583
Contact Person	Arundhati Radhakrishnan
Address	300 Sylvan Ave Englewood Cliffs, NJ 07632
Telephone	201-268-3281
Email	arundhati.radhakrishnan@glwmed.com

Trade Name	CREED™ Cannulated Screws
Common Name	Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Smooth Or Threaded Metallic Bone Fixation Fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	HWC

Name of Primary Predicate Device	**510(k) #**	**Manufacturer**
OsteoBullet Compression Screw	K160304	Phalanx Innovations
Name of Additional Predicate Devices		
DARCO Headless Compression Screw	K080850	Wright Medical Technology Inc.
Biomet BioDrive Cannulated Screw System	K082874	Biomet
Inion Freedomscrew	K123672	Inion OY

Description	CREED™ Cannulated Screws consists of subject components that will be available in thread diameters ranging from Ø2.5mm to Ø7.4 mm and lengths ranging from 14-120mm. They are either headed or headless compression. All screws are self-drilling and self-tapping. The screws are offered in configurations that include a Titanium alloy Ti-6AL-4V ELI (ASTM F136) screw and a Titanium alloy Ti-6AL-4V ELI (ASTM F136) screw with an outer layer of Zeniva ZA-600 PEEK (ASTM F2026). A variety of instrumentation is offered as part of the kit to facilitate delivery of the screws. The screws are provided sterile via Gamma irradiation. -

Traditional 510(k) Premarket Notification
CREED™ Cannulated Screws

Indications and Intended Use	*CREED™ Cannulated Screws 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.*

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the predicate devices. The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labeling. The Subject device is similar in size and thread form as the predicate(s). The Subject and predicate both contain Ti-alloy screws. The subject device differs from the predicate because it contains PEEK screws with a titanium alloy core, whereas the predicate system offers all PEEK screws or all titanium alloy screws (no mixing of materials in a single screw).

Performance Data	Performance data presented in the application included: Axial pullout strength testing, torque to failure testing and insertion torque testing (ASTM F543). Static and dynamic 3-point bending (ASTM F1264) were also presented in addition to interface bond testing/delamination testing. Torsional resistance testing was performed for characterization. Biocompatibility per ISO 10993 and FDA guidance including cytotoxicity, irritation, sensitization, and chemical characterization were also evaluated.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and performance comparison to predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.

creed™
Ortholuced Implants

℞ Only
Last revision 06/2022

INSTRUCTIONS FOR USE CREED IMPLANTS

Legal Manufacturer:
GLW, Inc.
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

Distributed by:
Innov8ortho, LLC
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

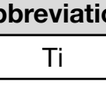
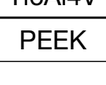
Important information – please read prior to use

Outline:

Definitions:

Symbols and abbreviations may be used on the package label.
The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
REF	Catalog number.
LOT	Batch number.
	Date of manufacture.
	Manufacturer.
	Use by.
STERILE R	Sterilized using irradiation.
	Caution, consult accompanying documents.
	Do not re-use.
	Do not use if package is damaged.
℞ Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Abbreviation	Material
Ti	Titanium Alloy
Ti6Al4V	Titanium alloy Ti-6AL-4V ELI
PEEK	Zeniva ZA-600 Polyetheretherketone

Description:

Each (double-wrapped) pack contains a ready-to-use implant.

STERILE SINGLE USE IMPLANT – DO NOT REUSE OR RESTERILISE.

A. Indications

CREED™ Cannulated Screws 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, nonunions, osteotomies, arthrodesis or bone grafts in the hand, foot, and ankle including distal tibia and fibula. These implants are not intended for spinal use.

B. 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 section << Indications >>.
- Known or suspected allergy to any of the device components.
- Use of this implant together with implants of another origin not recommended.

C. 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.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- This implantable product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

D. Potential Adverse Effects

General Surgery Related Risks:

- bleeding
- infection
- pain, discomfort, or abnormal sensation due to the presence of the implant
- metal sensitivity or allergic reaction to a foreign body
- delayed correction in alignment
- decrease in bone density due to stress shielding
- bursitis
- loss of use of the foot
- permanent disability
- death

E. WARNINGS (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- If excessive loading cannot be prevented, an implant should not be used.
- Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.

F. IMPLANT MATERIALS

The Creed Cannulated Headed and Headless Compression Screw System implants are manufactured from Ti6Al4V / PEEK.

G. STERILIZATION

- The implants covered by this ASD with it have been sterilized by gamma irradiation.
- Do not resterilize if the implant comes in direct contact with human tissue. Dispose of implants that come in contact with human tissue and are not used in the surgery.
  If either the implant or the package appears damaged the implant should not be used.

H. SURGICAL PROCEDURES

An operating technique manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

I. POST-OPERATIVE PROTOCOL

Protected weight bearing with below the knee walking cast or walking boot is recommended. A gradual return to limited activity in 4 to 6 weeks is allowed as tolerated. Patient specific post-operative care is the responsibility of the surgeon.

J. PATIENT COUNSELING INFORMATION (See also Warnings)

In addition to the patient related information contained in the Warnings, Adverse Events and Post- Operative Protocol sections, the following information should be conveyed to the patient:

While the expected life of an implant is difficult to estimate it is finite.
These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved bone or joint.

K. CAUTION

Federal Law (United States) restricts this device to sale, distribution, and use by or on the order of a physician.

L. LIABILITY

GLW has taken reasonable precautions in the selection of materials and in the manufacture of these products. However, GLW excludes any legal guarantee, whether express or implicit, including but not limited to, any implicit guarantee of the marketable quality or suitability for a specific use. GLW cannot under any circumstances be held responsible for any loss, damage or related costs or incidents, directly or indirectly linked to the use of this product.

GLW does not assume and does not authorize any third party to assume on its behalf, any other responsibilities relating to these products. The intention of GLW is that this device should be used only by doctors having received appropriate training in techniques of orthopaedic surgery for its use.

Ortholucent Implants

Rx Only

Last revision 06/2022

INSTRUCTIONS FOR USE CREED STERILE SINGLE USE INSTRUMENTS

Legal Manufacturer:

GLW, Inc.
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

Distributed by:

Innov8ortho, LLC
300 Sylvan Ave, 2nd Floor
Englewood Cliffs, NJ 07632

Important information – please read prior to use

Outline:

Definitions / Description

A. Indications
B. Precautions
C. Potential Adverse Effects
D. Warnings
E. Instrument Materials
F. Sterilization
G. Surgical Procedures
H. Storage Conditions
I. Caution
J. Liability

Definitions:

Symbols and abbreviations may be used on the package label.
The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Catalog number.
	Batch number.
	Date of manufacture.
	Manufacturer.
	Use by.
	Sterilized using irradiation.
	Caution, consult accompanying documents.
	Do not re-use.
	Do not use if package is damaged.
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Abbreviation	Material
IXEF HC-1022 BK 001	50% glas-fiber reinforced Polyarymide - Black
IXEF GS-1022 BU01	50% glas-fiber reinforced Polyarymide - Blue
SST	Stainless Steel

Description:

Each (double-wrapped) pack contains ready-to-use surgical instruments.

STERILE SINGLE USE INSTRUMENTS – DO NOT REUSE OR RESTERILISE.

A. Indications

These instruments are intended for use in surgery and should be used only for the introduction of associated GLW products. None of the instruments shall be implanted.

B. Precautions

- If either the instrument or the package appears damaged the instrument should not be used.
- The instruments are supplied sterile. They must be used by qualified surgeons, in the operating.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- This product is for single use only. An instrument should never be re-sterilized after contact with body tissues or fluids.

C. Potential Adverse Effects

General Surgery Related Risks:

- bleeding
- infection
- pain, discomfort, or abnormal sensation due to the presence of the implant
- metal sensitivity or allergic reaction to a foreign body
- delayed correction in alignment
- decrease in bone density due to stress shielding
- bursitis
- loss of use of the foot
- permanent disability
- death

D. WARNINGS (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- If excessive loading cannot be prevented, an implant should not be used.
- Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.

E. INSTRUMENT MATERIALS

Stainless Steel complying with ASTM-F899 and 50% glass-fiber reinforced polyarymide compounds.

F. STERILIZATION

- The sterilization method is specified on the packaging. Components are sterilized by gamma irradiation. The expiry date of a sterile device is indicated on the label.
- Do not resterilize if the device comes in direct contact with human tissue. Dispose of device that comes in contact with human tissue and is not used in the surgery.
- If either the device or the package appears damaged, the device should not be re-used and should be returned to the manufacturer or properly disposed. The company declines all responsibility in the event of such re-use.

G. SURGICAL PROCEDURES

- GLW does not practice medicine and does not recommend any specific operating technique.
- It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature. GLW is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
- Criteria for patient selection are the responsibility of the surgeon. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device. Information contained within this document should be taken into consideration during the selection process.
- Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon.
- Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.

H. STORAGE CONDITIONS

Store in a dry place, at ambient temperature, protected from light.

I. CAUTION

Federal Law (United States) restricts this device to sale, distribution, and use by or on the order of a physician.

J. LIABILITY

GLW has taken reasonable precautions in the selection of materials and in the manufacture of these products. However, GLW excludes any legal guarantee, whether express or implicit, including but not limited to, any implicit guarantee of the marketable quality or suitability for a specific use. GLW cannot under any circumstances be held responsible for any loss, damage or related costs or incidents, directly or indirectly linked to the use of this product.

GLW does not assume and does not authorize any third party to assume on its behalf, any other responsibilities relating to these products. The intention of GLW is that this device should be used only by doctors having received appropriate training in techniques of orthopaedic surgery for its use.

Orders – Customer Service

Phone: 917.765.7847

Email: custsvc@innov8ortho.com

Shipping FOB Origin, Freight Prepay & Add
*Expedited shipments will be invoiced for the change associated with the expedited delivery

510 K Clearance #'s

Creed Screws K200291

Apollo AFX Plating K213005

FusionFrame K200343

Artemis PFN Nail K221489

Remit to Address

Innov8ortho, LLC

P.O. Box 154

Edgewater, NJ 07020

CORPORATE OFFICE

Innov8ortho, LLC

300 Sylvan Ave, 2nd Floor

Englewood Cliffs, NJ 07632

Email: enquiries@innov8ortho.com

Website

www.innov8ortho.com

Terms and Conditions of Sale

The following terms and conditions of sale constitute an integral part of this Innov8ortho, LLC. ("Innov8ortho") product list and are applicable to all purchase orders. All prices and terms are subject to change.

I. Acceptance of Purchase Orders
All purchase orders are subject to acceptance at Innov8ortho's customer service department located in Englewood Cliffs, NJ and will be deemed accepted only when confirmed in writing or upon Innov8ortho's commencement of performance. For convenience, customers may place purchase orders or make inquiries (between the hours of 8:30 a.m. – 5:30 p.m. EST, Monday – Friday, exclusive of all federal and state holidays) by calling 917.765.7847 or email custsvc@innov8ortho.com.

II. Payment Terms
Payment is due no later than 30 days from the date of the invoice.

Mail purchase order to:
Innov8ortho, LLC.
300 Sylvan Ave, 2nd Flr
Englewood Cliffs, NJ 07632

Mail payments to:
Innov8ortho, LLC.
P.O. Box 154
Edgewater, NJ 07020

III. Additional Charges
All applicable excise, sales, or other taxes will be invoiced to customer and are not included in product prices.

IV. Shipping and Related Charges
Terms of sale on all purchase orders are F.O.B. shipping point. Each purchase order will incur a shipping and handling charge of $75.00. All shipments of product will be placed with the carrier for requested 2-day delivery.

Expedited Shipments: Customers requiring expedited delivery will be invoiced for the change associated with the expedited delivery.

Shipping Damage: Although Innov8ortho takes special care in the packaging of its products, damage may occur in transit. All products must, therefore, be inspected and any damage noted on the freight bill and reported to the carrier, upon receipt of product. Although Novastep's responsibility for damage ceases upon deposit with carrier, Innov8ortho may extend assistance in helping customer settle damage claims.

V. Return Goods and Related Charges
Return Authorization/Repairs: Customer must obtain a return authorization number from Innov8ortho or Innov8ortho account representative before any Innov8ortho product can be returned for repair, replacement, refund, or credit. To obtain a return authorization number, customer must provide Innov8ortho with (1) the Innov8ortho catalog number and quantity of Innov8ortho product to be returned; (2) the reason for the return/repair; (3) a description of the Innov8ortho product being returned for repair; (4) the name and telephone number of a customer contact who may be called if Innov8ortho requires further information; and (5) at least one of the following: (i) the applicable customer purchase number, (ii) the applicable Innov8ortho invoice number, and (iii) the applicable Innov8ortho product lot or serial number. A purchase order is required for all repairs even in situations where there is no charge. If the Innov8ortho product to be repaired is covered by a written limited product warranty, a copy of the original invoice must be sent with the Innov8ortho product. The cost of repair not covered by a written limited product warranty must be paid by the customer.

Non-Returnable Products: Customer is not entitled to return nor eligible to receive repair, replacement, refund , or credit for any Innov8ortho product described below (collectively, "Non-Refundable Products"):

- Product damaged in transit;
- Product shipped in error and returned more than 30 days after the date of the applicable Innov8ortho invoice (unless such product is subject to a recall arising out of the negligent acts or omissions of Innov8ortho (a "Quality Recall);
- Non-defective product return in quantity less than Innov8ortho's original unit of sale;
- Non-defective product returned more than 90 days after date of applicable Innov8ortho invoice (unless part of a Qualified Recall);
- Defective product returned after expiration of applicable warranty period (unless part of a Qualified Recall);
- Product sold non-sterile that has been subjected to sterilization processing;
- Product sold for single use that has been re-used or re-processed;
- Product that has been altered, further manufactured, packaged, processed, abused, or misused;
- Product that has been adjusted or repaired by anyone other than by Innov8ortho or a person or entity authorized in writing by Innov8ortho; and
- Product that is a "custom" device unless such product is defective for a reason other than manufacture to customer's specifications.

Authorized Return Products and Freight Charges: With regard to those Innov8ortho products (other than Non-Returnable Products) for which customer has obtained a return authorization number. Innov8ortho will accept returns for such products if they are: (1) determined by Innov8ortho to be defective and returned within applicable warranty period; (2) no defective, in saleable condition and returned within 90 days of the corresponding Innov8ortho invoice date and represent product shipped in error by Innov8ortho (such products, collectively, "Authorized Return Products"). All Authorized Return Products must be returned freight prepaid by customer. All Authorized Return Product returned freight collect will be refused by Innov8ortho and returned to customer at its expense. Innov8ortho will, at its option, refund or credit customer for all freight charges incurred in connection with returning to Innov8ortho any Authorized Return Product.
Allowance Schedule for Authorized Return Products: For those Authorized Return Products that Innov8ortho has elected to provide a refund or credit, Innov8ortho will pay a refund or issue a credit to customer within 30 business days of Innov8ortho's receipt of the Authorized Return Product, based on the original purchase price, in accordance with following:

CONDITION	CREDIT
Defective product returned within applicable product warranty period	Full Credit*
Non-defective product returned in a saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Non- defective product returned is saleable condition within 46-90 days of corresponding Innov8ortho invoice date	Full Credit* minus 20% reprocessing charge min. $10.00 charge
Product shipped in error by Innov8ortho and returned is saleable condition within 45 days of corresponding Innov8ortho invoice date	Full Credit*
Product subject to a Qualified Recall	Full Credit*

*Less any credits issued by Innov8ortho to customer with respect to such product.

VI. Confidentiality
Customer will not disclose to any third party these terms and conditions, including the Product List, or any other information provided by Innov8ortho to customer, without Innov8ortho's written approval, except as may be required by law or lawful order of any applicable government agency.

VII. Limited Product Warranty; Disclaimer and Limitation of Liability
Innov8ortho warrants to the original purchaser that each Innov8ortho product set forth in the Product List will be free from defects in material and workmanship for the period set forth in the labeling of the particular Innov8ortho product or, if no such period is set forth in the labeling, for a period of one (1) year from date of purchase. If Innov8ortho product proves to be so defective, such Innov8ortho product may be returned to Innov8ortho for repair, replacement, refund or credit at Innov8ortho's option, in accordance with Innov8ortho's return goods and allowance policy. Any alteration, abuse, misuse, further manufacture, packaging, processing, adjustment or repair by any person or entity other than Innov8ortho or a person entity authorized in writing by Innov8ortho shall void this limited product warranty ab initio. THIS LIMITED PRODUCT WARRANTY IS IN LEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REMIDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE SOLE LIABILITY OF Innov8ortho AND REMIDY AVAILBLE TO CUSTOMER FOR Innov8ortho PRODUCTS WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND Innov8ortho WILL NOT BE LIABLE TO CUSTOMER FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE POSSIBILITY OR LIKELYHOOD OF SUCH DAMAGES. IN NO EVENT WILL Innov8ortho BE LIABLE FOR ANY CLAIM, LOSS OR DAMAGE ARISING OUT OF OR RELATING TO, IN WHOLE OR IN PART, ANY PURCHASE ORDER, THERE TERMS AND CONDITIONS OR OTHERWISE, IN EXCESS OF THE AMOUNT PAID BY CUSTOMER TO Innov8ortho PURSUANT TO THE PURCHASE ORDER TO WHICH CLAIM, LOSS OR DAMAGE RELATES.

VIII. Product Changes
All products and product specifications identified in the Product List are based upon the information available to Innov8ortho at the time of publication. Innov8ortho reserves the right to discontinue any product or to change any product specifications without notice.

IX. Termination
Any customer purchase order may be terminated by Innov8ortho as follows: (1) upon 30 days prior written notice to customer; (2) effective immediately, if customer commits a material breach of any provision of the purchase order or these terms and conditions and such breach continues for a period of 30 days following notice; or (3) effective immediately, if the customer files, or has filled against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law or makes or seeks to make a general assignment for the benefit of its creditors or applies for or consents to the appointment of a trustee, receiver, or custodian for its or substantial part of its property.

X. Force Majeure
Innov8ortho will not be liable for its failure to perform or a delay in performance of any order due to strikes, fire, explosion, flood, riot, lock out, injunction, interruption of transportation, unavoidable accidents, acts of government or a public enemy, terrorism, inability to obtain supplies at reasonable prices, or other causes beyond its control.

XI. Choice of Law
All transactions under these terms and conditions shall be governed by and construed in accordance with the laws of the State of New York as applicable to contracts made and to be performed in that state, without regard to conflicts of laws principles.

XII. General
NONE OF THE FOREGOING TERMS AND CONDITIONS MAY BE MODIFIED EXCEPT UPON NOVASTEP'S EXPRESS WRITTEN CONSENT STATING THAT IT IS AN AMENDMENT OT MODIFICATION THERETO.
In the event of any inconsistency between these terms and conditions of sale and those contained in any purchase order, purchase order release, confirmation, acceptance, or any similar document, the terms and conditions set forth above shall prevail.
These terms and conditions of sale constitute the entire understanding between Innov8ortho and customer and supersede all prior terms and conditions of sale published by Innov8ortho, in each case, related to the subject matter hereof.

Creed Part List

ITEM NUMBER	DEVICE DESCRIPTION
CREED CANNULATED IMPLANT SYSTEM	
CREED – STERILE SMALL HEADLESS CANNULATED COMPRESSION SCREW 2.5MM	
F1-0825-014S	CREED Ø2.5 Cannulated Headless Compression Screw 14mm, Thread 8mm
F1-0825-016S	CREED Ø2.5 Cannulated Headless Compression Screw 16mm, Thread 8mm
F1-0825-018S	CREED Ø2.5 Cannulated Headless Compression Screw 18mm, Thread 8mm
F1-0825-020S	CREED Ø2.5 Cannulated Headless Compression Screw 20mm, Thread 8mm
F1-0825-022S	CREED Ø2.5 Cannulated Headless Compression Screw 22mm, Thread 8mm
F1-0825-024S	CREED Ø2.5 Cannulated Headless Compression Screw 24mm, Thread 8mm
F1-0825-026S	CREED Ø2.5 Cannulated Headless Compression Screw 26mm, Thread 8mm
F1-0825-028S	CREED Ø2.5 Cannulated Headless Compression Screw 28mm, Thread 8mm
F1-0825-030S	CREED Ø2.5 Cannulated Headless Compression Screw 30mm, Thread 8mm
CREED – STERILE SMALL HEADED CANNULATED COMPRESSION SCREW 2.5MM	
F2-0825-012S	CREED Ø2.5 Cannulated Headed Screw 12mm, Thread 8mm
F2-0825-014S	CREED Ø2.5 Cannulated Headed Screw 14mm, Thread 8mm
F2-0825-016S	CREED Ø2.5 Cannulated Headed Screw 16mm, Thread 8mm
F2-0825-018S	CREED Ø2.5 Cannulated Headed Screw 18mm, Thread 8mm
F2-0825-020S	CREED Ø2.5 Cannulated Headed Screw 20mm, Thread 8mm
F2-0825-022S	CREED Ø2.5 Cannulated Headed Screw 22mm, Thread 8mm
F2-0825-024S	CREED Ø2.5 Cannulated Headed Screw 24mm, Thread 8mm
F2-0825-026S	CREED Ø2.5 Cannulated Headed Screw 26mm, Thread 8mm
F2-0825-028S	CREED Ø2.5 Cannulated Headed Screw 26mm, Thread 8mm
F2-0825-030S	CREED Ø2.5 Cannulated Headed Screw 30mm, Thread 8mm
CREED – STERILE SMALL HEADLESS CANNULATED COMPRESSION SCREW 4.3MM	
F1-1040-018s	CREED Ø4.3 Cannulated Headless Compression Screw 18mm, Thread 10mm
F1-1040-020s	CREED Ø4.3 Cannulated Headless Compression Screw 20mm, Thread 10mm
F1-1040-022s	CREED Ø4.3 Cannulated Headless Compression Screw 22mm, Thread 10mm
F1-1040-024s	CREED Ø4.3 Cannulated Headless Compression Screw 24mm, Thread 10mm
F1-1040-026s	CREED Ø4.3 Cannulated Headless Compression Screw 26mm, Thread 10mm
F1-1040-028s	CREED Ø4.3 Cannulated Headless Compression Screw 28mm, Thread 10mm
F1-1040-030s	CREED Ø4.3 Cannulated Headless Compression Screw 30mm, Thread 10mm
F1-1040-032s	CREED Ø4.3 Cannulated Headless Compression Screw 32mm, Thread 10mm
F1-1040-034s	CREED Ø4.3 Cannulated Headless Compression Screw 34mm, Thread 10mm
F1-1040-036s	CREED Ø4.3 Cannulated Headless Compression Screw 36mm, Thread 10mm
F1-1040-038s	CREED Ø4.3 Cannulated Headless Compression Screw 38mm, Thread 10mm
F1-1040-040s	CREED Ø4.3 Cannulated Headless Compression Screw 40mm, Thread 10mm
F1-1040-042s	CREED Ø4.3 Cannulated Headless Compression Screw 42mm, Thread 10mm
F1-1040-044s	CREED Ø4.3 Cannulated Headless Compression Screw 44mm, Thread 10mm
F1-1040-046s	CREED Ø4.3 Cannulated Headless Compression Screw 46mm, Thread 10mm
F1-1040-048s	CREED Ø4.3 Cannulated Headless Compression Screw 48mm, Thread 10mm
F1-1040-050s	CREED Ø4.3 Cannulated Headless Compression Screw 50mm, Thread 10mm
F1-1040-055s	CREED Ø4.3 Cannulated Headless Compression Screw 55mm, Thread 10mm
F1-1040-060s	CREED Ø4.3 Cannulated Headless Compression Screw 60mm, Thread 10mm

ITEM NUMBER	DEVICE DESCRIPTION
CREED – STERILE SMALL HEADED CANNULATED COMPRESSION SCREW 4.3MM	
F2-1040-018S	CREED Ø4.3 Cannulated Headed Screw 18mm, Thread 10mm
F2-1040-020S	CREED Ø4.3 Cannulated Headed Screw 20mm, Thread 10mm
F2-1040-022S	CREED Ø4.3 Cannulated Headed Screw 22mm, Thread 10mm
F2-1040-024S	CREED Ø4.3 Cannulated Headed Screw 24mm, Thread 10mm
F2-1040-026S	CREED Ø4.3 Cannulated Headed Screw 26mm, Thread 10mm
F2-1040-028S	CREED Ø4.3 Cannulated Headed Screw 28mm, Thread 10mm
F2-1040-030S	CREED Ø4.3 Cannulated Headed Screw 30mm, Thread 10mm
F2-1040-032S	CREED Ø4.3 Cannulated Headed Screw 32mm, Thread 10mm
F2-1040-034S	CREED Ø4.3 Cannulated Headed Screw 34mm, Thread 10mm
F2-1040-036S	CREED Ø4.3 Cannulated Headed Screw 36mm, Thread 10mm
F2-1040-038S	CREED Ø4.3 Cannulated Headed Screw 38mm, Thread 10mm
F2-1040-040S	CREED Ø4.3 Cannulated Headed Screw 40mm, Thread 10mm
F2-1040-042S	CREED Ø4.3 Cannulated Headed Screw 42mm, Thread 10mm
F2-1040-044S	CREED Ø4.3 Cannulated Headed Screw 44mm, Thread 10mm
F2-1040-046S	CREED Ø4.3 Cannulated Headed Screw 46mm, Thread 10mm
F2-1040-048S	CREED Ø4.3 Cannulated Headed Screw 48mm, Thread 10mm
F2-1040-050S	CREED Ø4.3 Cannulated Headed Screw 50mm, Thread 10mm
F2-1040-055S	CREED Ø4.3 Cannulated Headed Screw 55mm, Thread 10mm
F2-1040-060S	CREED Ø4.3 Cannulated Headed Screw 60mm, Thread 10mm
CREED – STERILE SMALL SCREWS WASHER OPTIONS	
F2-0025-000S	CREED Cannulated Screws / Washer 2.5mm / OD 5.0mm
F2-0043-000S	CREED Cannulated Screws / Washer 4.3mm / OD 7.5mm
CREED – STERILE SMALL K-WIRE KITS	
F4-0013-150S	CREED K-wire Ø1.3 x 150mm Drill Tip (qty 2 per Kit)
F4-0020-150S	CREED K-wire Ø2.0 x 150mm Drill Tip (qty 2 per Kit)
CREED – STERILE SMALL SCREWS INSTRUMENT KIT	
F4-2540-000S	CREED Single-Use Instrument Kit For Ø2.5 And Ø4.3 Screws

ITEM NUMBER	DEVICE DESCRIPTION
CREED – STERILE LARGE HEADLESS CANNULATED COMPRESSION SCREW 5.6MM	
F1-1656-030S	CREED Ø5.6 Cannulated Headless Compression Screw 30mm, Thread 16mm
F1-1656-032S	CREED Ø5.6 Cannulated Headless Compression Screw 32mm, Thread 16mm
F1-1656-034S	CREED Ø5.6 Cannulated Headless Compression Screw 34mm, Thread 16mm
F1-1656-036S	CREED Ø5.6 Cannulated Headless Compression Screw 36mm, Thread 16mm
F1-1656-038S	CREED Ø5.6 Cannulated Headless Compression Screw 38mm, Thread 16mm
F1-1656-040S	CREED Ø5.6 Cannulated Headless Compression Screw 40mm, Thread 16mm
F1-1656-042S	CREED Ø5.6 Cannulated Headless Compression Screw 42mm, Thread 16mm
F1-1656-044S	CREED Ø5.6 Cannulated Headless Compression Screw 44mm, Thread 16mm
F1-1656-046S	CREED Ø5.6 Cannulated Headless Compression Screw 46mm, Thread 16mm
F1-1656-048S	CREED Ø5.6 Cannulated Headless Compression Screw 48mm, Thread 16mm
F1-1656-050S	CREED Ø5.6 Cannulated Headless Compression Screw 50mm, Thread 16mm
F1-1656-055S	CREED Ø5.6 Cannulated Headless Compression Screw 55mm, Thread 16mm
F1-1656-060S	CREED Ø5.6 Cannulated Headless Compression Screw 60mm, Thread 16mm
F1-1656-065S	CREED Ø5.6 Cannulated Headless Compression Screw 65mm, Thread 16mm
F1-1656-070S	CREED Ø5.6 Cannulated Headless Compression Screw 70mm, Thread 16mm
F1-1656-075S	CREED Ø5.6 Cannulated Headless Compression Screw 75mm, Thread 16mm
F1-1656-080S	CREED Ø5.6 Cannulated Headless Compression Screw 80mm, Thread 16mm
F1-3256-042S	CREED Ø5.6 Cannulated Headless Compression Screw 42mm, Thread 32mm
F1-3256-044S	CREED Ø5.6 Cannulated Headless Compression Screw 44mm, Thread 32mm
F1-3256-046S	CREED Ø5.6 Cannulated Headless Compression Screw 46mm, Thread 32mm
F1-3256-048S	CREED Ø5.6 Cannulated Headless Compression Screw 48mm, Thread 32mm
F1-3256-050S	CREED Ø5.6 Cannulated Headless Compression Screw 50mm, Thread 32mm
F1-3256-055S	CREED Ø5.6 Cannulated Headless Compression Screw 55mm, Thread 32mm
F1-3256-060S	CREED Ø5.6 Cannulated Headless Compression Screw 60mm, Thread 32mm
F1-3256-065S	CREED Ø5.6 Cannulated Headless Compression Screw 65mm, Thread 32mm
F1-3256-070S	CREED Ø5.6 Cannulated Headless Compression Screw 70mm, Thread 32mm
F1-3256-075S	CREED Ø5.6 cannulated headless compression screw 75mm, thread 32mm

CREED – STERILE LARGE HEADED CANNULATED COMPRESSION SCREW 5.6MM	
F2-1656-030S	CREED Ø5.6 Cannulated Headed Screw 30mm, Thread 16mm
F2-1656-032S	CREED Ø5.6 Cannulated Headed Screw 32mm, Thread 16mm
F2-1656-034S	CREED Ø5.6 Cannulated Headed Screw 34mm, Thread 16mm
F2-1656-036S	CREED Ø5.6 Cannulated Headed Screw 36mm, Thread 16mm
F2-1656-038S	CREED Ø5.6 Cannulated Headed Screw 38mm, Thread 16mm
F2-1656-040S	CREED Ø5.6 Cannulated Headed Screw 40mm, Thread 16mm
F2-1656-042S	CREED Ø5.6 Cannulated Headed Screw 42mm, Thread 16mm
F2-1656-044S	CREED Ø5.6 Cannulated Headed Screw 44mm, Thread 16mm
F2-1656-046S	CREED Ø5.6 Cannulated Headed Screw 46mm, Thread 16mm
F2-1656-048S	CREED Ø5.6 Cannulated Headed Screw 48mm, Thread 16mm
F2-1656-050S	CREED Ø5.6 Cannulated Headed Screw 50mm, Thread 16mm
F2-1656-055S	CREED Ø5.6 Cannulated Headed Screw 55mm, Thread 16mm
F2-1656-060S	CREED Ø5.6 Cannulated Headed Screw 60mm, Thread 16mm
F2-1656-065S	CREED Ø5.6 Cannulated Headed Screw 65mm, Thread 16mm
F2-1656-070S	CREED Ø5.6 Cannulated Headed Screw 70mm, Thread 16mm
F2-1656-075S	CREED Ø5.6 Cannulated Headed Screw 75mm, Thread 16mm
F2-3256-042S	CREED Ø5.6 Cannulated Headed Screw 42mm, Thread 32mm

ITEM NUMBER	DEVICE DESCRIPTION
CREED – STERILE LARGE HEADED CANNULATED COMPRESSION SCREW 5.6MM	
F2-3256-044S	CREED Ø5.6 Cannulated Headed Screw 44mm, Thread 32mm
F2-3256-046S	CREED Ø5.6 Cannulated Headed Screw 46mm, Thread 32mm
F2-3256-048S	CREED Ø5.6 Cannulated Headed Screw 48mm, Thread 32mm
F2-3256-050S	CREED Ø5.6 Cannulated Headed Screw 50mm, Thread 32mm
F2-3256-055S	CREED Ø5.6 Cannulated Headed Screw 55mm, Thread 32mm
F2-3256-060S	CREED Ø5.6 Cannulated Headed Screw 60mm, Thread 32mm
F2-3256-065S	CREED Ø5.6 Cannulated Headed Screw 65mm, Thread 32mm
F2-3256-070S	CREED Ø5.6 Cannulated Headed Screw 70mm, Thread 32mm
F2-3256-075S	CREED Ø5.6 Cannulated Headed Screw 75mm, Thread 32mm

CREED – STERILE LARGE HEADLESS CANNULATED COMPRESSION SCREW 7.4MM	
F1-1974-040S	CREED Ø7.4 Cannulated Headless Compression Screw 40mm, Thread 19mm
F1-1974-042S	CREED Ø7.4 Cannulated Headless Compression Screw 42mm, Thread 19mm
F1-1974-044S	CREED Ø7.4 Cannulated Headless Compression Screw 44mm, Thread 19mm
F1-1974-046S	CREED Ø7.4 Cannulated Headless Compression Screw 46mm, Thread 19mm
F1-1974-048S	CREED Ø7.4 Cannulated Headless Compression Screw 48mm, Thread 19mm
F1-1974-050S	CREED Ø7.4 Cannulated Headless Compression Screw 50mm, Thread 19mm
F1-1974-055S	CREED Ø7.4 Cannulated Headless Compression Screw 55mm, Thread 19mm
F1-1974-060S	CREED Ø7.4 Cannulated Headless Compression Screw 60mm, Thread 19mm
F1-1974-065S	CREED Ø7.4 Cannulated Headless Compression Screw 65mm, Thread 19mm
F1-1974-070S	CREED Ø7.4 Cannulated Headless Compression Screw 70mm, Thread 19mm
F1-1974-075S	CREED Ø7.4 Cannulated Headless Compression Screw 75mm, Thread 19mm
F1-1974-080S	CREED Ø7.4 Cannulated Headless Compression Screw 80mm, Thread 19mm
F1-1974-085S	CREED Ø7.4 Cannulated Headless Compression Screw 85mm, Thread 19mm
F1-1974-090S	CREED Ø7.4 Cannulated Headless Compression Screw 90mm, Thread 19mm
F1-1974-095S	CREED Ø7.4 Cannulated Headless Compression Screw 95mm, Thread 19mm
F1-1974-100S	CREED Ø7.4 Cannulated Headless Compression Screw 100mm, Thread 19mm
F1-3274-046S	CREED Ø7.4 Cannulated Headless Compression Screw 46mm, Thread 32mm
F1-3274-048S	CREED Ø7.4 Cannulated Headless Compression Screw 48mm, Thread 32mm
F1-3274-050S	CREED Ø7.4 Cannulated Headless Compression Screw 50mm, Thread 32mm
F1-3274-055S	CREED Ø7.4 Cannulated Headless Compression Screw 55mm, Thread 32mm
F1-3274-060S	CREED Ø7.4 Cannulated Headless Compression Screw 60mm, Thread 32mm
F1-3274-065S	CREED Ø7.4 Cannulated Headless Compression Screw 65mm, Thread 32mm
F1-3274-070S	CREED Ø7.4 Cannulated Headless Compression Screw 70mm, Thread 32mm
F1-3274-075S	CREED Ø7.4 Cannulated Headless Compression Screw 75mm, Thread 32mm
F1-3274-080S	CREED Ø7.4 Cannulated Headless Compression Screw 80mm, Thread 32mm
F1-3274-085S	CREED Ø7.4 Cannulated Headless Compression Screw 85mm, Thread 32mm
F1-3274-090S	CREED Ø7.4 Cannulated Headless Compression Screw 90mm, Thread 32mm
F1-3274-095S	CREED Ø7.4 Cannulated Headless Compression Screw 95mm, Thread 32mm
F1-3274-100S	CREED Ø7.4 Cannulated Headless Compression Screw 100mm, Thread 32mm
F1-3274-105S	Creed Ø7.4 Cannulated Headless Compression Screw 105mm, Thread 32mm

ITEM NUMBER	DEVICE DESCRIPTION
CREED – STERILE LARGE HEADED CANNULATED COMPRESSION SCREW 7.4MM	
F2-1974-040S	CREED Ø7.4 Cannulated Headed Screw 40mm, Thread 19mm
F2-1974-042S	CREED Ø7.4 Cannulated Headed Screw 42mm, Thread 19mm
F2-1974-044S	CREED Ø7.4 Cannulated Headed Screw 44mm, Thread 19mm
F2-1974-046S	CREED Ø7.4 Cannulated Headed Screw 46mm, Thread 19mm
F2-1974-048S	CREED Ø7.4 Cannulated Headed Screw 48mm, Thread 19mm
F2-1974-050S	CREED Ø7.4 Cannulated Headed Screw 50mm, Thread 19mm
F2-1974-055S	CREED Ø7.4 Cannulated Headed Screw 55mm, Thread 19mm
F2-1974-060S	CREED Ø7.4 Cannulated Headed Screw 60mm, Thread 19mm
F2-1974-065S	CREED Ø7.4 Cannulated Headed Screw 65mm, Thread 19mm
F2-1974-070S	CREED Ø7.4 Cannulated Headed Screw 70mm, Thread 19mm
F2-1974-075S	CREED Ø7.4 Cannulated Headed Screw 75mm, Thread 19mm
F2-1974-080S	CREED Ø7.4 Cannulated Headed Screw 80mm, Thread 19mm
F2-1974-085S	CREED Ø7.4 Cannulated Headed Screw 85mm, Thread 19mm
F2-1974-090S	CREED Ø7.4 Cannulated Headed Screw 90mm, Thread 19mm
F2-1974-095S	CREED Ø7.4 Cannulated Headed Screw 95mm, Thread 19mm
F2-3274-040S	CREED Ø7.4 Cannulated Headed Screw 40mm, Thread 32mm
F2-3274-042S	CREED Ø7.4 Cannulated Headed Screw 42mm, Thread 32mm
F2-3274-044S	CREED Ø7.4 Cannulated Headed Screw 44mm, Thread 32mm
F2-3274-046S	CREED Ø7.4 Cannulated Headed Screw 46mm, Thread 32mm
F2-3274-048S	CREED Ø7.4 Cannulated Headed Screw 48mm, Thread 32mm
F2-3274-050S	CREED Ø7.4 Cannulated Headed Screw 50mm, Thread 32mm
F2-3274-055S	CREED Ø7.4 Cannulated Headed Screw 55mm, Thread 32mm
F2-3274-060S	CREED Ø7.4 Cannulated Headed Screw 60mm, Thread 32mm
F2-3274-065S	CREED Ø7.4 Cannulated Headed Screw 65mm, Thread 32mm
F2-3274-070S	CREED Ø7.4 Cannulated Headed Screw 70mm, Thread 32mm
F2-3274-075S	CREED Ø7.4 Cannulated Headed Screw 75mm, Thread 32mm
F2-3274-080S	CREED Ø7.4 Cannulated Headed Screw 80mm, Thread 32mm
F2-3274-085S	CREED Ø7.4 Cannulated Headed Screw 85mm, Thread 32mm
F2-3274-090S	CREED Ø7.4 Cannulated Headed Screw 90mm, Thread 32mm
F2-3274-095S	CREED Ø7.4 Cannulated Headed Screw 95mm, Thread 32mm
CREED – STERILE LARGE SMALL SCREWS WASHER OPTIONS	
F2-0056-000S	CREED Cannulated Screws / Washer 5.6mm / OD 11.0mm
F2-0074-000S	CREED Cannulated Screws / Washer 7.4mm / OD 13.0mm
CREED – STERILE LARGE K-WIRE KITS	
F4-0028-230S	CREED K-wire Ø2.8 x 230mm Drill Tip (qty 2 per Kit)
F4-0020-150S	CREED K-wire Ø3.2 x 230mm Drill Tip (qty 2 per Kit)
CREED – STERILE LARGE SCREWS INSTRUMENT KIT	
F4-5674-000S	CREED Single-Use Instrument Kit for Ø5.6 And Ø7.4 Screws

ITEM NUMBER	DEVICE DESCRIPTION
HAMMERTHREAD CUNNULATED HAMMERTOE IMPLANT SYSTEM	
HAMMERTHREAD – STERILE PIP-DIP IMPLANT 2.5MM	
F1-1225-032S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 32mm Thread 12mm
F1-1225-034S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 34mm Thread 12mm
F1-1225-036S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 36mm Thread 12mm
F1-1225-038S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 38mm Thread 12mm
F1-1225-040S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 40mm Thread 12mm
F1-1225-042S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 42mm Thread 12mm
F1-1225-044S	HAMMERTHREAD / Ø2.5 PIP-DIP Implant Length 44mm Thread 12mm
HAMMERTHREAD – STERILE PIP IMPLANT 2.5MM	
F1-1225-P20S	HAMMERTHREAD / Ø2.5 PIP Implant Length 20mm Thread 12mm
F1-1225-P22S	HAMMERTHREAD / Ø2.5 PIP Implant Length 22mm Thread 12mm
F1-1225-P24S	HAMMERTHREAD / Ø2.5 PIP Implant Length 24mm Thread 12mm
F1-1225-P26S	HAMMERTHREAD / Ø2.5 PIP Implant Length 26mm Thread 12mm
F1-1225-P28S	HAMMERTHREAD / Ø2.5 PIP Implant Length 28mm Thread 12mm
F1-1225-P30S	HAMMERTHREAD / Ø2.5 PIP Implant Length 30mm Thread 12mm
F1-1225-P32S	HAMMERTHREAD / Ø2.5 PIP Implant Length 32mm Thread 12mm
HAMMERTHREAD – STERILE INSTRUMENT KIT	
F4-P025-000S	HAMMERTHREAD / Instrument Kit for Lesser Toe Deformities

ITEM NUMBER	DEVICE DESCRIPTION
CREED MEDIAL MALLEOLAR IMPLANT SYSTEM	
CREED – STERILE MEDIAL MAL PARTIALLY THREADED IMPLANT 3.7MM	
F1-0737-020S	CREED Medialmal / Ø3.7 Partially Threaded Screw 20mm, Thread 7mm
F1-0737-022S	CREED Medialmal / Ø3.7 Partially Threaded Screw 22mm, Thread 7mm
F1-0737-024S	CREED Medialmal / Ø3.7 Partially Threaded Screw 24mm, Thread 7mm
F1-0737-026S	CREED Medialmal / Ø3.7 Partially Threaded Screw 26mm, Thread 7mm
F1-0737-028S	CREED Medialmal / Ø3.7 Partially Threaded Screw 28mm, Thread 7mm
F1-1137-030S	CREED Medialmal / Ø3.7 Partially Threaded Screw 30mm, Thread 11mm
F1-1137-032S	CREED Medialmal / Ø3.7 Partially Threaded Screw 32mm, Thread 11mm
F1-1137-034S	CREED Medialmal / Ø3.7 Partially Threaded Screw 34mm, Thread 11mm
F1-1137-036S	CREED Medialmal / Ø3.7 Partially Threaded Screw 36mm, Thread 11mm
F1-1137-038S	CREED Medialmal / Ø3.7 Partially Threaded Screw 38mm, Thread 11mm
F1-1137-040S	CREED Medialmal / Ø3.7 Partially Threaded Screw 40mm, Thread 11mm
F1-1537-042S	CREED Medialmal / Ø3.7 Partially Threaded Screw 42mm, Thread 15mm
F1-1537-044S	CREED Medialmal / Ø3.7 Partially Threaded Screw 44mm, Thread 15mm
F1-1537-046S	CREED Medialmal / Ø3.7 Partially Threaded Screw 46mm, Thread 15mm
F1-1537-048S	CREED Medialmal / Ø3.7 Partially Threaded Screw 48mm, Thread 15mm
F1-1537-050S	CREED Medialmal / Ø3.7 Partially Threaded Screw 50mm, Thread 15mm
F1-1537-055S	CREED Medialmal / Ø3.7 Partially Threaded Screw 55mm, Thread 15mm
F1-2237-060S	CREED Medialmal / Ø3.7 Partially Threaded Screw 60mm, Thread 15mm

ITEM NUMBER	DEVICE DESCRIPTION
CREED – STERILE MEDIAL MAL FULLY THREADED IMPLANT 3.7MM	
F1-0037-020S	CREED Medialmal / Ø3.7 Fully Threaded Screw 20mm
F1-0037-022S	CREED Medialmal / Ø3.7 Fully Threaded Screw 22mm
F1-0037-024S	CREED Medialmal / Ø3.7 Fully Threaded Screw 24mm
F1-0037-026S	CREED Medialmal / Ø3.7 Fully Threaded Screw 26mm
F1-0037-028S	CREED Medialmal / Ø3.7 Fully Threaded Screw 28mm
F1-0037-030S	CREED Medialmal / Ø3.7 Fully Threaded Screw 30mm
F1-0037-032S	CREED Medialmal / Ø3.7 Fully Threaded Screw 32mm
F1-0037-034S	CREED Medialmal / Ø3.7 Fully Threaded Screw 34mm
F1-0037-036S	CREED Medialmal / Ø3.7 Fully Threaded Screw 36mm
F1-0037-038S	CREED Medialmal / Ø3.7 Fully Threaded Screw 38mm
F1-0037-040S	CREED Medialmal / Ø3.7 Fully Threaded Screw 40mm
F1-0037-042S	CREED Medialmal / Ø3.7 Fully Threaded Screw 42mm
F1-0037-044S	CREED Medialmal / Ø3.7 Fully Threaded Screw 44mm
F1-0037-046S	CREED Medialmal / Ø3.7 Fully Threaded Screw 46mm
F1-0037-048S	CREED Medialmal / Ø3.7 Fully Threaded Screw 48mm
F1-0037-050S	CREED Medialmal / Ø3.7 Fully Threaded Screw 50mm
F1-0037-055S	CREED Medialmal / Ø3.7 Fully Threaded Screw 55mm
F1-0037-060S	CREED Medialmal / Ø3.7 Fully Threaded Screw 60mm
F1-0037-065S	CREED Medialmal / Ø3.7 Fully Threaded Screw 65mm
F1-0037-070S	CREED Medialmal / Ø3.7 Fully Threaded Screw 70mm
F1-0037-075S	CREED Medialmal / Ø3.7 Fully Threaded Screw 75mm
F1-0037-080S	CREED Medialmal / Ø3.7 Fully Threaded Screw 80mm

CREED MEDIAL MAL – STERILE INSTRUMENT KIT	
F4-3015-000s	CREED Medialmal / Single-Use Instrument Kit For Ø3.7 Screws

Cannulated compression screws with ortholucent technology for intraoperative and postoperative visualization of bones and joint spaces

Authors: Santiago Suniaga, Lisa Ferrara, PhD, Vytautas M Ringus MD, Shea T. Charbeneau DPM

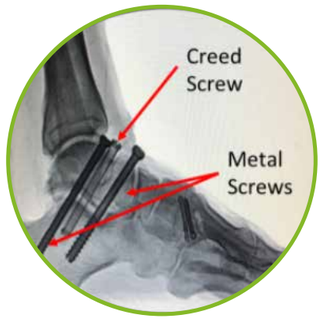


Figure 1. X-Ray image with CREED Screws vs. conventional non-radiolucent implants.

Metallic implants impede visualization of the fusion site due to their radiopaque nature. These visual obstructions make it more difficult for surgeons to assess fracture reduction and can negatively impact patient outcome.

By contrast, implants that allow significant visualization of bone structures by offering less resistance to the passage of X-rays (i.e. radiolucency) are often composed of non-metallic materials that lack the strength of metallic implants. This lower implant strength can increase the risk of breakage and result in suboptimal biomechanical stabilization of the injured site.

Introduction

For end stage ankle arthritis, ankle arthrodesis remains the gold standard treatment. The arthroscopic approach, despite its greater technical difficulty, has the advantage of less wound complications, diminished post-operative pain, earlier patient mobilization, and equivalent or earlier fusion rates when compared to open arthrodesis[1,2]. Because arthrodeses have historically been evaluated by bone bridging on plain radiographs, poor visibility of the fusion site due to the radiopaque properties of metallic implants remains a challenge.

State-of-the-art for internal fixation

The advent of implantable metallic fixation devices provided many advantages for direct internal stabilization and rigid fixation for ankle arthrodesis. To achieve early stability through direct immobilization of the anatomic site, the use of multiple screws, intramedullary nails, and bone plates have been the preferred solution for multiple decades.[3] However, as with any implantable orthopedic device, there are inherent challenges with present fixation systems that require further innovation to be overcome.

The Ortholucent Screw

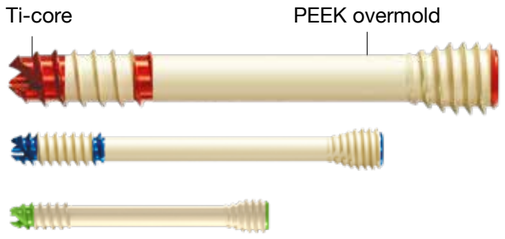
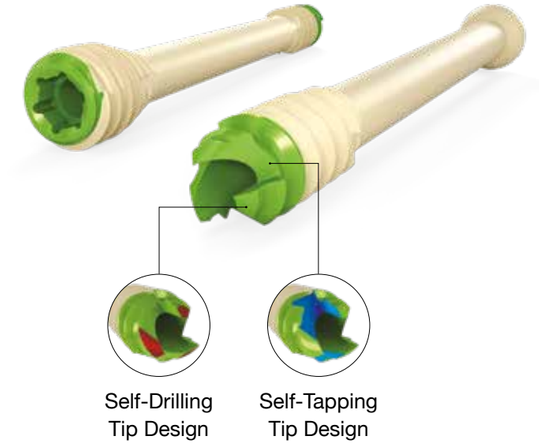


Figure 2. CREED 4.3mm, 5.6mm and 7.4mm Cannulated Headless Compression Screws.

The need to balance radiolucency with screw strength has led to the next generation of innovation. The ortholucent Creed Cannulated Screw is a novel implant designed to overcome the difficulty of poor visualization while maintaining comparable strength to conventional metallic implants. The radiolucent properties of the Creed Screws are the result of an innovative design that combines a thin walled titanium core with an overlay of implant grade Polyether Ether Ketone (PEEK). This composite approach provides a significant clinical advantage over traditional metal implants by radically improving intraoperative and postoperative visualization of bones and joint spaces.

Implant strength and bonding integrity

The strength of the Creed Screws is derived from two essential features: A grade 23 titanium core and a cross-sectional design that maximizes the resistance to torsional and bending loads. The titanium core provides the strength to withstand the biomechanical loads during fracture fixation, while the large and thin-walled shaft diameter allows the Creed Screws to retain the geometric properties of similarly sized metal screws. When tested against commercially available metallic screws, **the Creed Screws show equivalent or better dynamic fatigue strength (bending) and torsional strength (shear).**



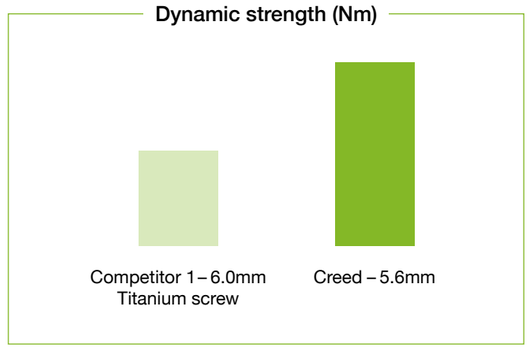


Figure 3. Dynamic fatigue strength in bending. Comparison between 6.0mm Titanium screw and Creed 5.6mm Screw.

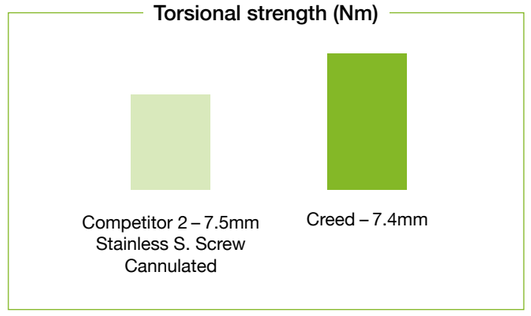


Figure 4. Torsional strength. Comparison between cannulated 7.5mm stainless steel screw and Creed 7.4mm Screw.

In addition, the composite design of the Creed Screw incorporates a proprietary bond technology that is highly resistant to delamination of the PEEK from the Titanium core. Aggressive testing of multiple Creed screw sizes in simulated dense bone under supraphysiological loads demonstrated significant resistance to delamination with no evidence of the PEEK debonding from the Titanium core under multiple test scenarios.

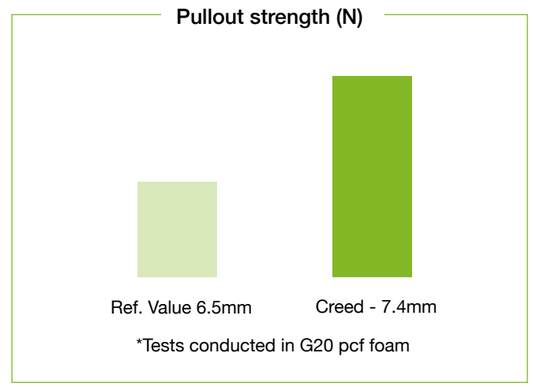


Figure 5. Pullout strength of Creed Screws. Reference value displayed taken from the FDA Guidance document for Orthopedic Non-Spinal Metallic Bone Screws.

Performance in surgery

To facilitate operational steps, Creed Screws have a self-cutting and self-tapping design and do not require predrilling. The optimization of the titanium cutting geometry results in a low insertion torque, a commonly used metric to measure cutting performance. When compared to established competitor implants such as Wright Medical, the insertion torque of Creed Screws is up to 27% lower. Low insertion torque is linked to reduced risk of microfractures and fragment displacement, which favors patient outcome.

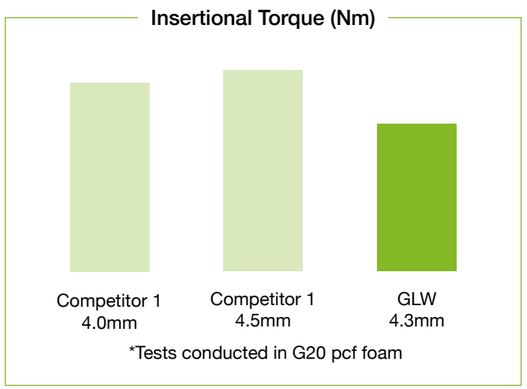


Figure 6. Insertion torque. Comparison between Wright Medical 4.0mm and 4.5mm cannulated screws vs. Creed 4.3mm screws.

Interaction with bone

Titanium and PEEK are known to have favorable biocompatible properties and have been widely used as implant materials. Nevertheless, Titanium has been observed to promote greater osteointegration when compared to PEEK[4,5]. Given that most of the outer surface of the Creed composite screws consists of PEEK, the potentially lower osteointegration could result in an easier extraction of the screw if necessary. Therefore, the ortholucency of the Creed Screws and its removal capabilities provide an innovative and novel screw design that benefits the patient population.

Surgery-ready solution

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

Figure 7. Creed Screws Single Use Instrument Kit – Small.

Case Study: Creed 7.4mm cannulated compression screw

26-year-old male, police officer, presented for a second opinion after stepping through a board in an attic suffering a left ankle bimalleolar fracture. Postoperatively he developed symptomatic posttraumatic arthritis and deformity and elected to have a left ankle arthroscopic arthrodesis with tendoachilles lengthening.

To allow visualization of the fusion site post operatively, without sacrificing compression, it was decided to use the 7.4mm Creed Screw for fixation. A three-screw fixation technique was used, with one headed and two headless screws in a divergent fashion. Appropriate compression was able to be seen on multiple fluoroscopic angles. 2 and 6 weeks post-operative x-rays below show the fusion site visualized through hardware with ankle arthrodesis in acceptable alignment (Figure 8-9).

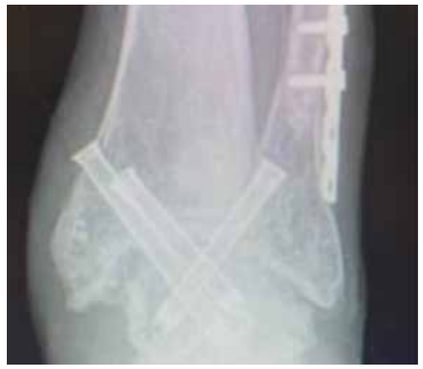


Figure 8. Week 2 post-operative AP ankle radiograph of left ankle arthrodesis using 3 Creed 7.4mm cannulated compression screws in a divergent fashion.

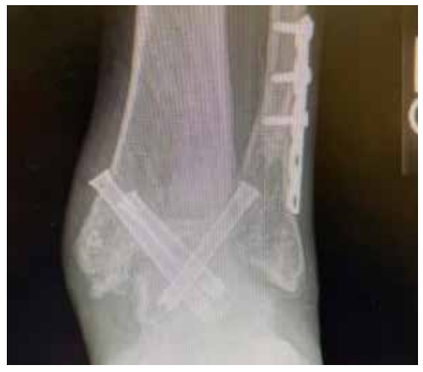


Figure 9. Week 6 post-operative lateral ankle radiograph of left ankle arthrodesis using 3 Creed 7.4mm cannulated compression screws in a divergent fashion.

Conclusion

The novel implant design of the Creed Screws combines a titanium core with a full radiolucent PEEK overlay that offers the unique advantage of improved visualization of the fusion site, while providing the needed strength for successful fusion. This ortholucent design allows surgeons to better orient the joint into the correct position for fusion intraoperatively, with the benefit of post-operative visualization of the fusion status. The surgical procedure is further aided by a self-drilling and self-tapping screw design with a low insertion torque and a PEEK surface that facilitates screw removal due to low osteointegration. By combining these features, the Creed Screws represent a new innovative step in implant design that aims to address surgeons needs and promises to benefit patient outcome.

References

1. Myerson MS, Quill G. Ankle arthrodesis. A comparison of an arthroscopic and an open method of treatment. Clin Orthop Relat Res. 1991 Jul;(268):84-95. PMID: 2060232.

2. Lee MS. Arthroscopic ankle arthrodesis. Clin Podiatr Med Surg. 2011 Jun;28(3):511-21. doi: 10.1016/j.cpm.2011.04.008.

3. Mendicino SS, Kreplick AL, Walters JL. Open Ankle Arthrodesis. Clin Podiatr Med Surg. 2017 Oct;34(4):489-502. doi: 10.1016/j.cpm.2017.05.006.

4. Pelletier M, Cordaro N, Lau A, Walsh WR. PEEK versus Ti interbody fusion devices: resultant fusion, bone apposition, initial and 26 week biomechanics. Clin Spine Surg. 2016;29:E208–214.

5. Wu SH, Li Y, Zhang YQ, Li XK, Yuan CF, Hao YL, Zhang ZY, Guo Z. Porous titanium-6 aluminum-4 vanadium cage has better osseointegration and less micromotion than a poly-ether-ether-ketone cage in sheep vertebral fusion. Artif Organs. 2013;37:E191–201. doi: 10.1111/aor.12153.

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