creed™

℞ Only

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INSTRUCTIONS FOR USE CREED IMPLANTS

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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
	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.
℞ 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 (single sterile barrier) pack contains a ready-to-use implant.

STERILE SINGLE USE IMPLANT – DO NOT REUSE OR RESTERILISE.

A. Indications

CREED™ 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.

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 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.

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.

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 Edge and Creed HammerThread implants are manufactured from Ti6Al4V.

The Creed Headed and Headless 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. Implant Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriately sized trephine drill.

J. 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.

K. 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.

L. Caution

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

M. 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.