Ortholucent Implants

℞ Only

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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
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Important information – please read prior to use

Outline:

Definitions / Description

A. Indications
B. Precautions
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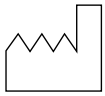
creed™
Ortholucent Implants

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.
R_x 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.