Device Description

The IlluminOss Photodynamic Bone Stabilization System is comprised of a Sterile (EtO), single use, disposable kit, along with a reusable curing system and instrument kit. The IlluminOss Monomer is contained within a sterile foil pouch and is sterilized by aseptic processing.

Indications for Use

The IlluminOss Photodynamic Bone Stabilization System is indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system.

Contraindications

This product is contraindicated in patients who have an active or incompletely treated infection that could involve the site where the device will be implanted; are allergic to any of the implant materials or to dental glue; have an intramedullary canal measuring smaller than the diameter of the delivery sheath provided at the site of the fracture; distant foci of infections which may spread to the implant site, have open fractures with severe contamination; or in patients for whom delivery sheath is unable to cross fracture site after proper fracture reduction and realignment.

Warnings

- This device has not been studied in patients who are skeletally immature.
- Do not reuse or attempt to re-sterilize the disposable components.
- Discard and do not use opened or damaged packages. Do not use if there is a loss of sterility of the monomer or other kit components.
- Do not utilize any component after the expiration date.
- Correct selection of the implant diameter and length is extremely important, and should be determined before implantation:
- Ensure the implant is long enough to span the fracture, and is not longer than the canal
- Ensure that the implant diameter is large enough to ensure cortical contact.
- Ensure the separation instrument can reach the balloon.
- The polymerization (curing cycle of implant) is a short term exothermic reaction.
- Do not insert or affix sutures, K-wires, or other hardware to or through the stabilization balloon until after it has cured.
- Do not attempt to inflate the balloon catheter by use of any ancillary inflation equipment. Properly sized inflation syringes and the amount of monomer necessary to accomplish the appropriate inflation are provided. The balloon is made of a non-compliant, thin walled PET and does not expand larger than its prescribed size.
- Do not add any material or fluids to the monomer.
- Do not expose monomer to any light source other than the IlluminOss Photodynamic Curing System, shield the monomer from light after removal from vial.
- If, upon fluoroscopic examination, the user determines that the inflated balloon is not in contact with the intramedullary canal of the bone, the user should remove the balloon prior to curing the monomer, reassess sizing, and replace it with the appropriately sized balloon.
- Do not activate the light source until the balloon catheter is in the appropriate position and the bone fracture is reduced and ready for stabilization. Activation of the light source in the presence of the monomer will initiate polymerization, an irreversible process.
- The monomer must be exposed to the IlluminOss Photodynamic Curing System for a specific amount of time in order to activate and fully cure the implant. A partially cured implant cannot be used to complete a procedure. If an uncured, or partially cured implant is suspected, or if a curing cycle is interrupted, additional curing cycles should be completed
- Inadequate postoperative fixation or unanticipated postoperative events may affect the interface between the bone and stabilization balloon, which may lead to micro-motion of the implanted balloon and balloon surface. Periodic follow up examinations and radiographs are advised for all patients.
- Deep wound infection is a serious postoperative complication and may require total removal of the stabilization system and embedded polymer. Deep wound infection may be latent and not manifest itself for several years post- operatively.

Risks

As with any IM fixation system or rod the following can occur:

- loosening, bending, cracking, fracture, or mechanical failure of the components or loss of or inadequate fixation in bone attributable to delayed union, nonunion, insufficient quantity or quality of bone, markedly unstable comminuted fractures, or insufficient initial fixation
- loss of anatomic position with nonunion or malunion with rotation or angulation
- adverse tissue reaction
- infection, including wound complications
- thromboembolic event or fat embolism (blood clot, fat, or other material that could result in organ damage or failure)
- implantation-related bone fracture
- soft tissue damage
- pain and/or loss of function
- revision
- inability to properly deploy or remove device

Risks specific to a photodynamic curing system can include:

- malfunction of photodynamic process
- lack of electrical safety or electromagnetic compatibility
- unacceptable exothermic reaction
- balloon leakage

Precautions

- Read instructions prior to use.
- Prior to using the IlluminOss Photodynamic LED Light Curing System, surgeons should, through specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of the system.
- Strict adherence to good surgical principles and technique are required during the use of the IlluminOss Photodynamic Bone Stabilization System.
- The monomer in liquid form may cause sensitization by skin contact. In case of contact with skin, wash immediately with soap and water
- In the tibia and femur, the IlluminOss implant is intended only as a means of providing supplemental fixation for FDA-cleared fracture fixation devices. In the tibia and femur, IlluminOss cannot be used as a stand-alone implant.

Instructions for Use

The following are general instructions. Please refer to the current version of the Surgical Technique guide for detailed instructions.

- Setup the Photodynamic LED Light Curing System, System (light console, power cord)
- Position patient as required for desired surgical exposure.
- Make soft tissue incision and create bone entry hole to intramedullary canal.
- Clear the canal from the entry hole across the fracture to prepare a pathway for the implant.
- Determine the canal diameter and length and select the desired balloon catheter size.
- Bring the RFID Timer Card (non-sterile) from the Implant Kit to the RFID Target Point on the Console to set the appropriate cure time for the selected balloon implant
- Reduce the fracture using guidewire; the dilator and sheath are inserted into the canal from the entry hole. Remove the guidewire and dilator leaving the sheath spanning the fracture.
- Prepare balloon catheter for implantation:
- Evacuate all the air out of the implant using the 20cc Air Evacuation syringe.
- With the protective tube covering the balloon, use syringe filled with monomer to prime the balloon catheter with monomer and evacuate the system of air bubbles.
- Remove the primed balloon catheter from the protective tube. Insert the tip of the balloon catheter into the sheath previously positioned in the canal. Insert the balloon fully into the sheath checking proper position across the fracture using fluoroscopy.
- Remove the tear away sheath from canal leaving balloon in position.
- Use monomer filled syringe(s) to fully infuse balloon. Re-check fracture alignment with fluoroscopy. If adjustment is required, depressurize balloon first and carefully re-position balloon and/or reduce fracture.
- Transfer the Hub of the Light fiber from the sterile field to the circulating nurse and insert the light fiber hub into the nosecone of the Light Console.
- With the balloon implant filled, the alignment of the fracture confirmed, activate the LED Light Console by pressing the “ACTIVATE“ button on the LCD screen to initiate light delivery to cure the monomer.
- At completion of light cycle, unscrew cap from Y-Connector and remove Light fiber.
- Cut braided catheter tube immediately adjacent the distal Y-connector and discard Y-connector.
- Use instruments to separate catheter from cured, implanted balloon.
- Perform wound closure and immobilization as required.
- Remove the Light Fiber Hub from the nosecone of the Light Console and turn off the light console.
- **Refer to the IlluminOss Medical Surgical Technique Guides for additional information.**

MRI Safety Information

MRI modeling and physical testing were performed to consider the entire family of the IlluminOss Photodynamic Implants (4mm to 22mm in diameter and lengths from 30mm to 280mm).
Every version of the IlluminOss Photodynamic Implant is MR Conditional.

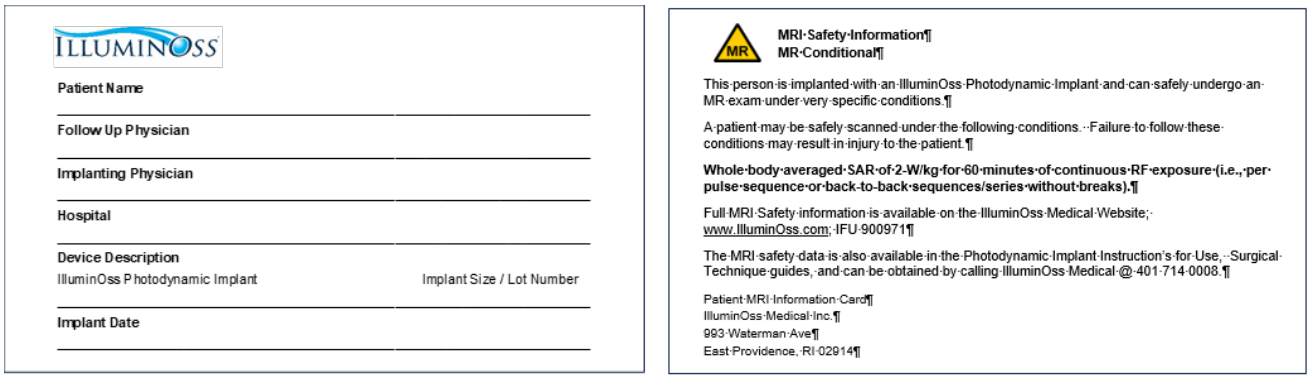
A patient implanted with the IlluminOss Photodynamic Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	***Condition of Use/Information***
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	20-T/m (2,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	Any transmit RF coil may be used.
Receive RF Coil Information	Any receive RF coil may be used.
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks).
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.
Additional Information	This MR Conditional labeling is only applicable for the IlluminOss Photodynamic Implant. The use of this implant in combination with any other fracture fixation system (Screws, Plates, IM Nails or other devices) for supplemental fixation has not been evaluated for MRI-related issues. Patients who have other MR Conditional devices can be scanned as long all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met. If information about a specific parameter is not included, there are no conditions associated with that parameter.

Patient Implant Card

To improve patient safety in the MR environment, as well as MRI patient workflow a “Patient Implant Card” that provides the conditions for safe use for the implanted device has been provided. Without a “ Patient Implant Card” many MR imaging services are not equipped to quickly obtain the necessary implant information to safely conduct MR imaging. An example of the Patient Implant Card is shown below.



System Components

Photodynamic Curing System (Model SY-2100-01)

The Photodynamic Curing System is supplied non-sterile and remains outside the sterile field:

QTY.	Description
(1)	Photodynamic LED Light Curing System
(1)	10 ft Power Cable

Photodynamic Bone Stabilization Implant and Delivery Kit – Sterile (EtO) Packaged containing

Balloon Stabilization Catheter Tray and Lid

QTY.	Description
(1)	Balloon Stabilization Catheter (with Protective Tube & Light Fiber)
(1)	Introducer Sheath with Dilator
(0) or (1)	10 ml Syringes Ring handle
(1) (2) or (3)	20 ml Syringes
(1)	Vented Transfer Spike
(1)	20 ml Air Evacuation Syringe

Photodynamic Monomer Pouch – Sterilized by Aseptic Processing - Packaged separately

QTY.	Description
(1) (2) (3) or (4)	20ml Photodynamic Monomer Vials in Multipack with tray

Additional Item

(1)	Non-Sterile RFID Timer Card

The IlluminOss Implant is constructed from the following materials;

Balloon	PET
Radiopaque ink (if applicable)	TPU (thermoplastic polyurethane) Tungsten
Radiopaque marker (if applicable)	Tantalum
Monomer	multifunctional methacrylates

NOTE: The IlluminOss Photodynamic Bone Stabilization Kit, its container, and any packaging is not made with natural rubber latex.

Instrumentation

IlluminOss Medical recommends that the bone stabilization device be used with associated IlluminOss Medical instrument kits.

Balloon Implant Size.

Catalog #	Description Diameter x Length (mm)	Maximum Monomer Volume (ml)	Timer Card Duration (sec)	Delivery Sheath Diameter (mm)
UM-04040	4 x 40	1.5	300	3.5
UM-05040	5 x 40	1.8	300	3.5
UM-05050	5 x 50	2.0	300	3.5
UM-06040	6 x 40	2.1	300	3.5
UM-06050	6 x 50	2.4	300	3.5
UM-06060	6 x 60	2.7	300	3.5
UM-07050	7 x 50	2.9	300	3.5
UM-07060	7 x 60	3.3	300	3.5
UM-07070	7 x 70	3.7	300	3.5
US-0700160	7 x 160	7	300	5.5
US-0700200	7 x 200	9	300	5.5
UM-08050	8 x 50	3.5	300	3.5
UM-08060	8 x 60	4.0	300	3.5
UM-08070	8 x 70	4.5	300	3.5
UM-08080	8 x 80	5.0	300	4.5
UM-08100	8 x 100	6.7	300	4.5
UM-08120	8 x 120	7.7	500	4.5
UM-09100 AC-09100	9 x 100	8.2	500	4.5
UM-09120 AC-09120	9 x 120	9.5	500	4.5
US-0900160	9 x 160	11	350	5.5
US-0900180	9 x 180	13	350	5.5
US-0900220	9 x 220	15	350	5.5
US-1100160	11 x 160	16	400	5.5
US-1100180	11 x 180	18	400	5.5
US-1100220	11 x 220	21	400	5.5
UM-1310070 AC-1310070	13/10 x 70	7.0	600	4.5
UM-1310090 AC-1310090	13/10 x 90	9.0	600	4.5
UM-1310120 AC-1310120	13/10 x 120	12	600	4.5
US-1500180	15 x 180	33	600	7.0
US-1500220	15 x 220	40	600	7.0
US-1500260	15 x 260	46	600	7.0
US-1500280	15 x 280	49	600	7.0
US-1700180	17 x 180	42	700	7.0
US-1700220	17 x 220	51	700	7.0
US-1700260	17 x 260	60	700	7.0
US-1700280	17 x 280	65	700	7.0
US-1822080	18/22 x 80	26	350	7.0
US-1822090	18/22 x 90	31	350	7.0
US-2213140	22/13 x 140	46	650	7.0
US-2213160	22/13 x 160	51	650	7.0
US-2213220	22/13 x 220	60	650	7.0
US-2213240	22/13 x 240	58	650	7.0
US-2213260	22/13 x 260	60	700	7.0
US-2200100	22 x 100	33	500	7.0
US-2200120	22 x 120	40	500	7.0

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Caution: Federal law restricts this device to sale by or on the order of a physician