Device Description

The IlluminOss Photodynamic Bone Stabilization System is comprised of a single use disposable procedure pack, along with a reusable curing system and instrument kit.

Intended Purpose / Indication

The Photodynamic Bone Stabilization System is indicated for use in fracture alignment and reduction. It provides stabilization for bone fractures using a minimally invasive technique in which the bone is not subjected to significant weight bearing forces. This IlluminOss procedure pack is intended for use in treatment of the metacarpal, phalange, clavicle, radius, ulna, distal radius, olecranon and fibula. It is also intended for use in treatment of acute fractures of the humerus, and impending and actual pathological fractures of the humerus from metastatic bone disease.

Contraindications

For all bones:

- Patients who are considered skeletally immature.
- Presence of active or incompletely treated infections that could involve the site where the device will be implanted.
- Patients allergic to any of the implant materials, or to dental glue.
- Patients whose intramedullary canal at site of fracture measures smaller than the diameter of the sheath provided.
- Uncooperative patient or patient with neurologic disorder, incapable of following directions.
- Distant foci of infections which may spread to the implant site.
- Vascular insufficiency.
- Open fractures with severe contamination.
- Extremely comminuted fractures where insufficient holding power of the balloon on the intramedullary canal is probable.
- Delivery sheath is unable to cross fracture site after proper fracture reduction and realignment.

For acute Humerus fractures:

- Patients who are under the age of Fifty (50)

For all bones excluding pathologic Humerus:

- Metabolic disorders which may impair bone formation.
- Osteomalacia.
- Vascular insufficiency, muscular atrophy, or neuro-muscular disease.

Warnings

⚠ Do not reuse or attempt to re-sterilize the disposable components, doing so may result in injury or death.

⚠ Discard and do not use opened or damaged packages. Do not use if there is a loss of sterility of the polymer or other kit components.

⚠ Do not utilize any component after the expiration date.

⚠ Correct selection of the implant diameter and length is extremely important, before implantation:

- ⚠ Ensure the implant is long enough to span the fracture, and is not longer than the canal.
- ⚠ 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 cured.

⚠ If simultaneous fractures of the tibia and fibula of the lower extremity require surgical reduction and stabilization: the tibial fracture should be adequately treated using conventional methods prior to use of the IlluminOss device to treat the fibular fracture.

⚠ Do not utilize the system for treatment of tibial fractures.

⚠ If simultaneous fractures of the radius and ulna of the upper extremity require surgical reduction and stabilization: the surgeon should consider use of conventional methods of fixation for one bone fracture, and the IlluminOss device to treat the fracture of the other bone.

⚠ Do not attempt to inflate the balloon catheter by use of any ancillary inflation equipment. Properly sized inflation syringes and the amount of polymer 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 polymer.

⚠ Do not expose polymer to any light source other than the IlluminOss Photodynamic Curing System, shield polymer 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 polymer, 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 polymer will initiate polymerization, an irreversible process.

⚠ The polymer 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.

Precautions

- Read instructions prior to use.
- Prior to using the IlluminOss Photodynamic Bone Stabilization 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 polymer in liquid form may cause sensitization by skin contact. In case of contact with skin, wash immediately with soap and water.

Risks

For all bones

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

- loosening, bending, cracking or 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 or 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 would complications,
- implantation-related bone fracture,
- soft tissue damage,
- pain and/or loss of function, revision,
- inability to properly deploy or remove device.

Specific to a photodynamic curing system the following can occur:

- lack of electrical safety or electromagnetic compatibility,
- unacceptable exothermic reaction,
- balloon leakage.

Specific to the Humerus

- The risk of thromboembolic event or fat embolism (blood clot, fat, or other material that could result in organ damage or failure) in this patient population should be addressed and monitored.

System Components

The elements of the IlluminOss Photodynamic Bone Stabilization System are:

Photodynamic Bone Stabilization Procedure Pack

Balloon Stabilization Catheter Pouch

QTY.	Description
(1)	Balloon Stabilization Catheter (with Sheath & Light Fiber)
(1)	Introducer Sheath with Dilator
(1)	Protective Tube

Photodynamic Polymer Pouch

QTY.	Description
(1,2,3, or 4)	20ml Photodynamic Polymer Vial

Additional Components

QTY.	Description
(0) or (1)	10 ml Sterile Syringes
(1) (2) or (3)	20 ml Sterile Syringes
(1)	Vented Transfer Spike
(1)	Non-Sterile Timer Key

Photodynamic Curing System (Model SY-2000)

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

QTY.	Description
(1)	Photodynamic Curing System light console
(1)	Power Cable
(1)	Light Guide with Light Fiber Connector
(1)	Foot Pedal
(1)	Pole Clamp

Instrument Kits (Model SY-3000, SY-4000, SY-5000, SY-9100)

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

Instructions For Use

The following are general instructions, refer to the most current version of the Surgical Technique Guide for detailed instructions.

- Setup Photodynamic Curing System (light console, light guide, power cord, and foot pedal).
- 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.
- Insert Timer Key from the Procedure Pack into Light Console to set the appropriate cure time for the selected balloon.
- Using fluoroscopic or radiographic imaging assistance, reduce the fracture using guidewire, dilator and sheath 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 of the air out of the implant using 20cc syringe.
  - Transfer monomer from vial to syringe by using the Vented Transfer Spike.
  - With the protective sheath covering the balloon, secure male luer fitting of syringe filled with 3-5cc of monomer to the female luer fitting of the black stopcock by turning the syringe clockwise. Prime the balloon catheter with monomer and evacuate the system of air bubbles. Close the stopcock valve by turning the black lever horizontal to the axis of the stopcock. Remove the syringe from the stopcock luer fitting by turning the syringe counterclockwise.
- Remove the primed, depressurized balloon catheter from the protective sheath. 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 fluoroscopic or radiographic imaging assistance.
- Remove the sheath from canal leaving balloon in position.

- Use monomer filled syringe(s) to fully infuse balloon. Re-check fracture alignment with fluoroscopic or radiographic imaging assistance. If adjustment is required, depressurize balloon first and carefully re-position balloon and/or reduce fracture.
- Once balloon is filled, depress foot pedal to activate light source and fully cure 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. Use fluoroscopic or radiographic imaging assistance to check instrument positioning.
- After completion of the curing cycle for the IlluminOss implant, supplemental screw fixation of the fractured bone may be performed with the use of cross-locking cortical screws delivered through the IlluminOss implant. When using screws with the IlluminOss implant, do not use a screw larger than one third of the final cured implant diameter. The minimum acceptable distance that a 4.0mm or smaller diameter bone screw should be placed from the fracture line is 30mm.
- The use of fluoroscopic or radiographic imaging assistance for drilling and screw placement is recommended. With a powered drill, drill the required screw holes with the appropriately sized drill bit for the screw size chosen. Use saline irrigation and suction to cool the drill site and remove debris. Measure the screw hole depth using a depth gauge. Select the proper length screw and use a screwdriver to fully insert the screw through the bone and into or across the implant.
- Perform wound closure and immobilization as required.
- Remove Timer Key from Light Console and discard.
- Refer to the IlluminOss Medical Surgical Technique Guide for additional information.

BALLOON IMPLANT SIZES

Catalog #	Description Diameter x Length (mm)	Maximum Monomer Volume (ml)	Timer Card Duration (sec)	Delivery Sheath Diameter (mm)
MS-04040	4 x 40	1.5	300	3.5
MS-05040	5 x 40	1.8	300	3.5
MS-05050	5 x 50	2.0	300	3.5
MS-06040	6 x 40	2.1	300	3.5
MS-06050	6 x 50	2.4	300	3.5
MS-06060	6 x 60	2.7	300	3.5
MS-07050	7 x 50	2.9	300	3.5
MS-07060	7 x 60	3.3	300	3.5
MS-07070	7 x 70	3.7	300	3.5
SL-0700160	7 x 160	7	300	5.5
SL-0700200	7 x 200	9	300	5.5
MS-08050	8 x 50	3.5	300	3.5
MS-08060	8 x 60	4.0	300	3.5
MS-08070	8 x 70	4.5	300	3.5
ML-08080	8 x 80	5.0	300	4.5
ML-08100	8 x 100	6.7	300	4.5
ML-08120	8 x 120	7.7	300	4.5
ML-09100	9 x 100	8.2	500	4.5
ML-09120	9 x 120	9.5	500	4.5
ML-09160	9 x 160	12	500	4.5
SL-0900160	9 x 160	11	400	5.5
SL-0900180	9 x 180	13	400	5.5
SL-0900220	9 x 220	15	400	5.5
SL-1100160	11 x 160	16	500	5.5
SL-1100180	11 x 180	18	500	5.5
SL-1100220	11 x 220	21	500	5.5
ML-1310070	13/10 x 70	7.0	500	4.5
ML-1310090	13/10 x 90	9.0	600	4.5
ML-1310120	13/10 x 120	12	600	4.5
SL-1500180	15 x 180	33	700	7.0
SL-1500220	15 x 220	40	700	7.0
SL-1500260	15 x 260	46	800	7.0
SL-1500280	15 x 280	49	800	7.0
SL-1700180	17 x 180	42	800	7.0
SL-1700220	17 x 220	51	800	7.0
SL-1700260	17 x 260	60	1000	7.0
SL-1700280	17 x 280	65	1000	7.0
SL-1822080	18/22 x 80	26	600	7.0
SL-1822090	18/22 x 90	31	700	7.0
SL-2213160	22/13 x 160	51	800	7.0
SL-2213220	22/13 x 220	60	1000	7.0
SL-2213240	22/13 x 240	58	1000	7.0
SL-2213260	22/13 x 260	60	1000	7.0

NOTE: THE ILLUMINOSS PHOTODYNAMIC BONE STABILIZATION PROCEDURE PACK, ITS CONTAINER, AND ANY PACKAGING IS NOT MADE WITH NATURAL RUBBER LATEX.

MRI Safety Information

MRI modeling and physical testing were performed to consider the entire family of the **IlluminOss Photodynamic Bone Stabilization System (PBSS)**(4-mm to 22-mm in diameter and lengths from 30- to 280-mm). Every version of the **IlluminOss Photodynamic Bone Stabilization System (PBSS)** is MR Conditional. A patient with the **IlluminOss Photodynamic Bone Stabilization System (PBSS)** 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*
Static Magnetic Field Strength (T)	1.5-Tesla or 3.0-Tesla
Static Magnetic Field Orientation	Horizontal
Maximum Spatial Field Gradient (T/m and gauss/cm)	20-T/m (2,000-gauss/cm)
RF Excitation Polarization	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
MR System Operating Mode	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Scan Duration and Wait Time	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 the IlluminOss Photodynamic Bone Stabilization System (PBSS) may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.
Additional Information	This MR Conditional labeling is only applicable for the IlluminOss Photodynamic Bone Stabilization System (PBSS). The use of this implant with any supplemental screw fixation has not been evaluated for MRI-related issues.

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