ILLUMINOSS
Fracture repair at the speed of light

Femur & Tibia Surgical Technique Guide

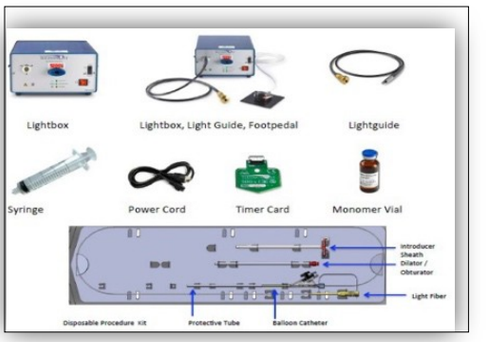
IlluminOss Supplemental Use; in combination with approved fracture fixation systems

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.

During a percutaneous procedure, a small diameter expandable balloon catheter is inserted into the medullary canal and is positioned across the area requiring stabilization. Once in correct alignment and position, it is infused with a biocompatible light curable liquid monomer, which hardens under the application of blue visible light. The monomer is cured and remains within the PET balloon, which conforms to the anatomic contours of the medullary canal making it a customized intramedullary rod, providing longitudinal and rotational stability.

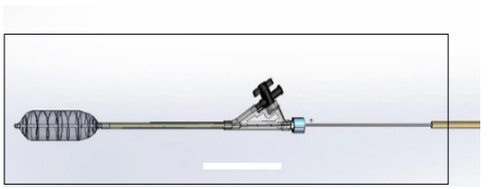
The IlluminOss System, its container, and any packaging is not made with natural rubber latex.

System Description



The IlluminOss Photodynamic Bone Stabilization System is comprised of a single use disposable procedure pack, along with a reusable curing system and instrument set. Surgical stabilization is recommended for patients at risk for fracture and in whom stable fixation can be achieved with an intramedullary implant.

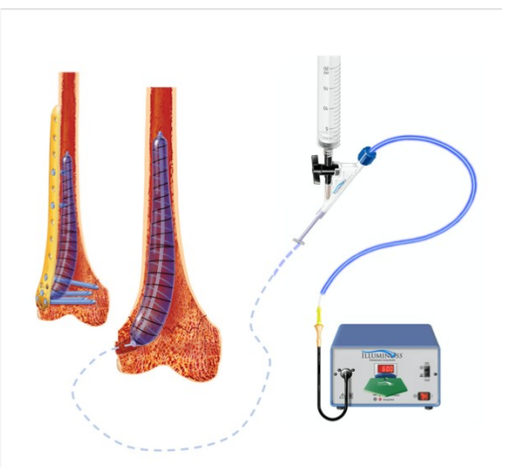
During a percutaneous procedure, a small diameter expandable balloon catheter is inserted into the medullary canal and is positioned across the area requiring stabilization. Once in correct alignment and position, it is infused with a biocompatible light curable liquid monomer which hardens under the application of visible (436 nm) light. The monomer is cured and remains within the PET balloon, which conforms to the anatomic contours of the medullary canal making it a customized intramedullary rod, providing longitudinal and rotational stability to the affected bone. In indications in the lower extremity (Femur & Tibia) the IlluminOss implant is used as a supplement to cleared fracture fixation devices.



This section provides key or important information about the use of the product in the treatment of traumatic, fragility, pathological and impending pathological fractures of the lower extremity where an IlluminOss implant shall be utilized in conjunction with cleared fracture fixation systems. For purposes of illustration a plate & screw has been chosen.

NOTE: The following document does not attempt to discern between different types of cancers, fractures, anatomic locations and or treatment options associated with specific disease states. The information contained within should not constrain nor restrict medical judgment and is not intended to impinge upon the practice of medicine. It is instead intended to augment the professional skills of the surgeon and to serve as a ready reference source in the use of the product.

Indication 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.

Implant Sizes

IlluminOss implants range in diameter from 4.0mm to 22.0mm and in lengths from 40mm to 280mm. IlluminOss implants for the treatment of lower extremity fractures in conjunction with FDA-cleared fracture fixation systems typically range in diameter from 15 mm to 22 mm and in lengths from 140 mm to 280 mm.

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 diameters of the delivery sheath provided with the implant; 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.

Pre-Operative Set-up

Ensure that the appropriate instrumentation kits have been sterilized and are delivered to the OR suite.
Ensure that a sufficient range of implants are brought to the OR suite as well as ancillary guidewires and sheaths.
Set-up and activate the light box prior to the start of the procedure to ensure operation. (See Appendix A: Light Box Preparation) or the light box specific instructions for use PN #900368 for more detailed information on the lightbox.

NOTE: The light box must be set up outside the sterile field and should be on the same side as the target site to be treated.

NOTE: The light guide is not sterile it remains outside of the surgical field. The light fiber is a predetermined length (183cm). Ensure that the light box is close enough to make the connection.

Implant Diameter and Length

The IlluminOss implants range in a variety of diameters and lengths. The determination of an implant length and diameter may be performed pre- operatively or after the start of the procedure. In determining the appropriate IlluminOss implant length to select, the implant should span the entire length of the fracture site in order to stabilize it, plus a sufficient length within bone that has not been compromised.

Note: Select an implant that achieves cortical contact along the entire length of the bone requiring support.

Determining Implant Length

Implant sizing may be done pre-operatively or after the start of the procedure. Use of the IlluminOss radiographic ruler (CT-0235) may assist measurement during the operative process. In cases of an impending fracture the approximate implant length may be determined pre-operatively. Holding the radiographic ruler at the end of the bone measure the distance to the point in the canal that the implant should reach, as this provides an estimated implant length. Alternatively, utilizing pre-operative films and the embedded software in the x-ray programs, measurements for the implant length and diameter can be made. Ensure that the implant is of sufficient length relative to the length of the hardware being utilized.

Determining Implant Diameter

Position the image intensifier for views of the lower extremity in two planes. Hold the ruler parallel and at right angles while positioned over the canal. Select an implant sufficient to fill and to achieve contact with the medullary canal and cortex.

General Consideration Points

- Fracture stabilization cannot be assured when the IlluminOss implant is not in contact with the cortical wall or if the implant is moving within the intramedullary canal. The implant diameter should be of sufficient size so that it achieves circumferential conformal contact with the walls of the intramedullary canal. Select a balloon diameter equal to or slightly larger than the largest canal diameter observed.
- In cases where there may be some doubt on the correct diameter implant (e.g. eccentrically shaped canal) , always use the next larger size diameter implant.
- Reduce the fracture prior to the placement of the implant; the inflation of the IlluminOss implant will not reduce a fracture. Do not attempt to reduce a fracture or adjust the rotational alignment with an implant inflated and in contact with the cortical walls as this may cause a tear in the implant. Reduce the volume of an implant by withdrawing some of the monomer prior to adjusting the reduction. The IlluminOss implant is constructed from a thin wall PET balloon. Do not bring instruments (K wires, screws, suture needles, clamps or other instruments) to come in contact with the implant prior to it being fully cured as it may damage or compromise the implant.
- 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.

Patient Positioning - Fluoroscopic Imaging

Position the patient in the supine position and place the leg in a position providing access to the fracture. The operating table must be radiolucent as the leg must be visualized in two planes using the image intensifier. Prior to draping, ensure that the C-arm is able to obtain the necessary images without being obstructed by the table. Adequately support the knee, but allow the leg to move freely. It may be helpful to place a small bump under the patient's buttock on the injured side. It is also important to ensure a true lateral fluoroscopy of the femur or tibia can be obtained in this position. Prior to starting the procedure at minimum fluoroscopic images in the AP, and lateral should be obtained to ensure adequate visualization of the canal and associated anatomy.

Procedural Concept

The IlluminOss implant can be used to provide supplemental fixation to 510(k)-cleared fracture fixation devices in either the femur or tibia.
A minimally invasive approach to the medullary canal of either the femur or the tibia in conjunction with the placement of an intramedullary IlluminOss implant provides screw holding power for cleared fracture fixation systems. Access to the femur or tibia is typically made originating at the condyle by means of a small incision and a pathway to the canal is made with an awl. An IlluminOss implant is delivered through the entry pathway filling the desired length of the canal.

The procedure for treating a fracture with hardware with supplemental fixation provided by the IlluminOss implant is performed in discrete stages;

a small incision at the condyle
creation of a pathway
preparing the inner osseous space with awls and reamers
the preparation of the implant
the insertion and filling of the IlluminOss implant
the activation of the light box & implant curing
the separation of the catheter from the implant

Hardware is positioned and placed in accordance with the specific instructions of the appropriate hardware, but in general:

Positioning of the jig & fixtures for the plate
Placement of the plate in the drilling jig
Temporary placement of the plate with K wires Drilling
of the first hole through the bone and IlluminOss Screw
placement within the hole
Repeat as necessary

Fracture Reduction

FIG 1A

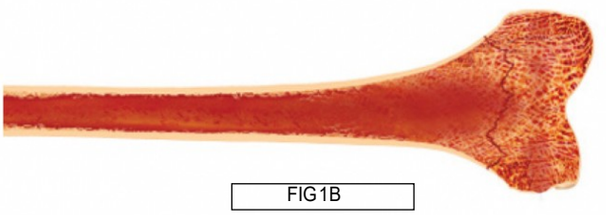


FIG 1B

The initial reduction of the fracture is accomplished by external manipulation under fluoroscopic guidance.

Patient is placed on the Operating Table in the supine position. When supine, the leg rests in an externally rotated or neutral position. A small bump may be placed under the ipsilateral hip to slightly internally rotate the leg. Adequately support the knee, but allow the leg to move freely. It may be helpful to place a small bump under the patient's buttock on the injured side.

Avoid strong traction and a fully extended knee because forces of the gastrocnemius muscle may create recurvatum of the distal fragment. To reduce the muscle forces of the gastrocnemius, flex the leg approximately 20°–40°.

Note: Open reduction and exposure of the fracture may be required and the use of reduction instrumentation may be considered to achieve and maintain anatomical reduction of the fracture especially in complex fracture patterns.

Incision & Anatomical Landmarks

An incision should be made at an appropriate point on the condyle allowing for entry to the canal while spanning the fracture , area requiring stabilization and support. A lateral incision is recommended when a simple articular (AO classification 33-C1) or extra-articular fracture (AO classification 32- or 33-A) is present.

Note: The incision can be extended, if necessary, to improve visualization of the articular surface or lateral metaphysis and diaphysis. It may not always be appropriate to use limited incisions and closed reduction techniques.

Articular fracture reduction must be complete prior to placement of the plate.

FIG 2

Straight Awl

A straight awl is used to make an initial entry portal at the condyle for the creation of a pathway to the interosseous space. (Fig 2). Check the position with AP and lateral views. When the correct position is achieved, rotate the awl to create an initial entry portal. (Fig 2)

Because the IlluminOss catheter is flexible, the insertion point of the implant can be made at a point that is not a straight line with the axis of the canal.

Insert the 8.0 mm Cannulated Awl Into the Canal

The intramedullary canal of the femur is then further opened with the 8.0 mm cannulated curved awl in order to make an initial pathway into the intramedullary canal and to introduce a guidewire spanning the fracture and following the anatomic curve of the femur into the shaft. (Fig 3)

With the 8.0 mm awl in place, rocking it +/- 30 degrees will enlarge the originally tapered pathway created by the straight awl and will assist in the placement of the sheath and dilator within the medullary canal. X-ray guidance is used in different directions to confirm the correct position of the awl.

FIG 3

Note: Ensure that the full diameter of the awl has passed through and has exited into the canal to ensure passage of the guidewire can be made.

Note: The final pathway created must be at least 7.5 mm in diameter to accommodate the passage of the sheath and dilator.

Insert the 2.0 mm Guidewire into the Cannulated Awl

Once the cannulated awl is in position, remove the stylet from the rear cannulation port of the 4.0 mm cannulated awl.

Deliver the 2.0 mm ball tipped guidewire into the medullary canal through the rear cannulation port of the 8.0 mm awl and across the fracture site. (Fig 4)

Verify fracture reduction and the position of the guidewire in both A/P and lateral views with imaging equipment.

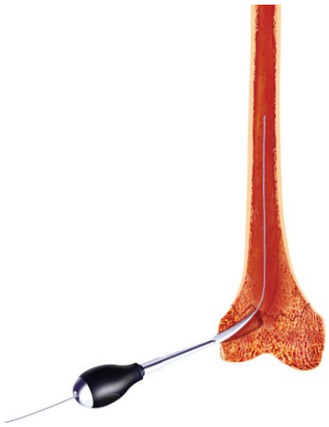


FIG 4

Remove Curved Awl

Leave the guidewire in position and remove the cannulated awl. Verify fracture reduction and the position of the guidewire in both A/P and lateral views with imaging equipment. Remove curved awl (Fig 5A).

FIG 5A

FIG 5B

When the 8.0 mm cannulated awl has been removed only the guidewire shall remain in the canal. (Fig 5B)

Preparation of Canal: Reamers

The medullary canal must be enlarged to allow for the placement of the delivery sheath and obturator and then the expansion of the IlluminOss implant.

The IlluminOss flexible reamers (Fig 6) are provided in .5 mm increments. The reamers are used to achieve a minimum diameter of 7.5 mm pathway into the canal to allow for the delivery of the introduction sheath of 7.0 mm.

FIG 6

The 6.0 mm reamer, which is provided as front cutting, is the size to start the canal preparation for subsequent reamers and to allow for the delivery of the 7.0 mm sheath & dilator.

Place 6.0 mm flexible cannulated reamer over the 2.0 mm ball tip guide wire to open and prepare the canal providing proper space for delivery of the implant. (Fig 7)

Mount the reamer on either a power drill or a hand reamer and introduce the reamer into the pathway advancing it in a forward motion. The flexible shaft stabilizer (CT-0131) is provided for use with the reamer shafts during use.

When the first reamer has been advanced as far forward as desired, the reamer is withdrawn, and exchanged for the next sequential larger size. This new reamer is similarly mounted over the 2.0 mm guidewire and either a hand reamer or power driver used to advance the reamer within the canal. (Fig 7B)

Note: If an internal diameter of at least 7.0 mm cannot be achieved in the creation of a pathway from the initial pathway to the canal with the use of the reamers, the 7.0mm delivery sheath cannot be inserted into the canal and the use of the IlluminOss implant is contraindicated.

After completion of the canal preparation process, remove the cannulated reamer from the IM canal leaving the 2.0mm ball tip guidewire in place across the fracture. (Fig 8)

At this point there is a guidewire in position; from the styloid to the shaft which shall be utilized in the delivery and positioning of the implant.

WARNING: If other reamers or instruments are utilized in the preparation of the medullary canal, ensure that the IlluminOss implant is an equal to or a larger diameter than the size of the instrument used.

FIG 7

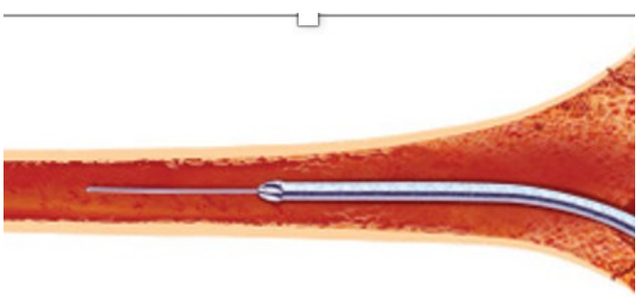


FIG 7B

FIG 8

Preparation for Implant Delivery; Component Preparation

Open the outer box containing the following components:
Foam pouch containing:

- individually foil wrapped monomer vials; sterile,
- sterile syringes
- sterile monomer transfer spike
- timer key card

Sterile delivery catheter pouch

- Remove the pouches containing the monomer vials, sterile transfer spike and sterile syringes from the foam pouch.
  NOTE: The contents of these pouches are sterile.

- Remove the pink bubble wrapped pouch containing the timer key card and set it aside for insertion into the light box.
  NOTE: This is a non-sterile component.
- Open the individual pouches and introduce the monomer vials, syringes, transfer spike and delivery catheter into the sterile field.
- Monomer should be at room temperature when used. If monomer is colder than room temperature, it should be allowed to warm.

Balloon Catheter Preparation; Remove Air from the Catheter

1. Carefully remove the catheter assembly from the sterile package. Leave the white protective flared tube covering the balloon in place as this will assist in the preparation and priming of the implant. 1-Attach the empty 20cc syringe provided in the kit to the black stopcock luer and open the valve.
2. Evacuate all of the air out of the implant by drawing a vacuum on the syringe and then closing the stopcock maintaining the vacuum. (Fig 9)
3. Detach syringe from stopcock and expel any collected air out of the syringe.
4. Repeat steps 1-3 to ensure all air has been removed from the balloon catheter. Close the stopcock and maintain the vacuum within the implant.

FIG 9

Warning: Do not use an implant that will not hold a vacuum. Discard that implant and replace it with a new sterile implant.

Transfer Monomer into the 20cc Syringe

Remove the blue cap from the monomer vial and insert the transfer spike into the top of the vial. Attach the syringe to the transfer spike, turn assembly over, and slowly draw the monomer into the syringe. Consolidate any air bubbles and expel the residual air from the syringe. (Fig 10)

FIG 10

Prime Distal End of Balloon

Attach the syringe containing the monomer to the closed stopcock luer. Slide the white protective tube covering the balloon back about 15 mm, exposing the distal portion of the balloon. (Fig 11)

FIG 11

Open the stopcock valve on the catheter, where the residual vacuum will pull a small amount of monomer slowly into the catheter.

Apply some pressure to the plunger on the syringe for several seconds, as the monomer will travel the entire length of the balloon catheter causing the tip of the exposed balloon beyond the protective tube to slightly expand. (Fig 12A & B)

FIG 12 A

NOTE: Do not try and fully inflate the distal end of the balloon to its full size. The purpose of this step is to get monomer down to the distal end of the implant.

FIG 12 B

Prime the Proximal Portion of the Balloon

Aspirate the monomer that is in the distal end of the balloon to reduce the diameter of the balloon. (Fig 13)

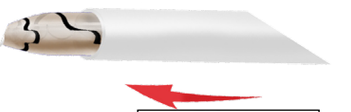


FIG 13

When a sufficient amount of monomer has been withdrawn from the balloon causing it to deflate, the white protective tube is advanced forward, away from the syringe and over the distal tip of the catheter. (Fig 14)
Leave approximately 20mm of the white protective tube remaining over the distal tip of the balloon. The middle portion of the balloon catheter is exposed while the tip of the balloon is still contained within the confines of the white protective tube.
Gently infuse a small amount of monomer into the balloon by depressing the plunger of the syringe.

With two fingers on the outside of the balloon gently advance in a wiping motion the monomer towards the distal tip of the implant. Pull a vacuum on the syringe again and at the same time gently pull the white protective tube back towards the syringe covering the entire balloon. (Fig 14)

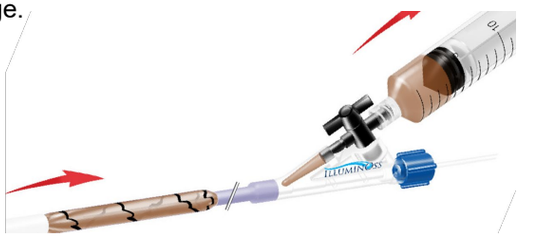


FIG 14

The simultaneous action of a vacuum drawn on the syringe and the compression of the protective tube on the balloon will expel all the air from the balloon catheter into the syringe. Leave the monomer filled syringe attached to the catheter. The IlluminOss implant has now been prepared and is ready for implantation.

NOTE: Do not attempt to fully inflate the balloon during preparation as it may be difficult to fully deflate and reinsert into the protective tube, and inadvertent damage to the balloon may occur.

NOTE: Do not attempt to perform the balloon catheter preparation while the implant is located within the medullary canal as the elimination of air and air bubbles within the implant cannot be verified.

NOTE: Once the implant has been prepared for use, and the catheter primed with monomer, it should be immediately delivered to the surgical site. If the implant is prepared prior to use, ensure that the entire implant and attached syringe is covered with a sterile drape or other sterile material to prevent light from coming in contact with the implant and or syringe.

Insert Dilator & Sheath into the Canal

Insert the dilator into the tear away sheath, and lock the two components together by engaging the hub of the dilator into the wings of the tear away sheath.

Verify that the 2.0mm guidewire is in position crossing the fracture. Place the assembled dilator and tear away sheath over the guidewire and slide it into the pathway and medullary canal. (Fig 15)

FIG 15

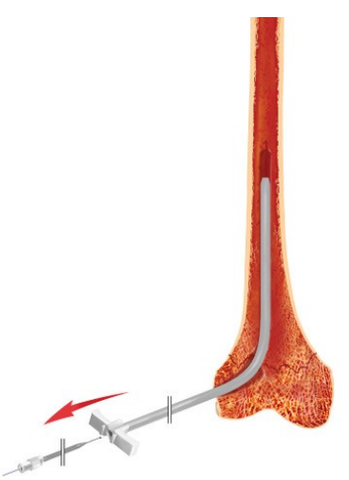


FIG 16

NOTE: The tip of the sheath and the dilator may be bent to assist in its delivery through a bend or curvature in the delivery approach.

Confirm positioning of the dilator and sheath assembly within the canal via fluoroscopy. Once their position of the sheath & dilator has been confirmed, remove the dilator and guidewire from the sheath, leaving the tear-away sheath in position across the fracture site. (Fig 16)

Placement of Balloon Implant into the Sheath

As a precaution against inadvertent and premature monomer curing within the exposed catheter, it is suggested that the OR spot light beams be directed away from aiming at the implant introduction site during catheter positioning.

Remove the white protective tube from the balloon catheter and introduce the previously prepared balloon implant into the tear-away sheath positioned in the femur. (Fig 17)

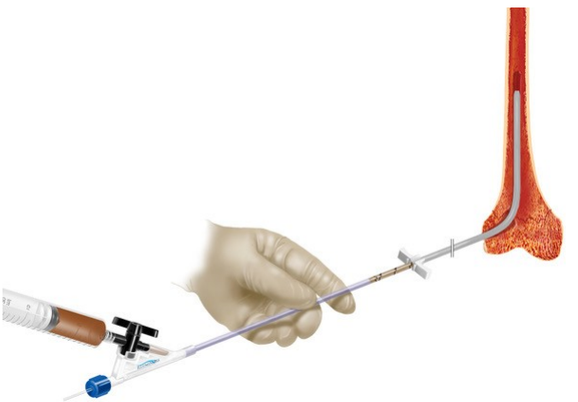


FIG 17

Note: Care must be taken when inserting the prepared catheter through the sheath to support the length of the balloon catheter during insertion.

Do not force or significantly bend the balloon catheter assembly or light fiber during its delivery into the sheath as damage to the implant may occur.

NOTE: A spiral radiopaque marker stripe of about 1.0 mm width has been applied to the outside circumference of the implant. The radiopaque marker is used to provide positioning guidance for the implant within the medullary canal. It also provides the surgeon with a visual cue towards the position of the implant within the canal, as well as the relative size of the inflated implant.
Check proper position using fluoroscopy, ensuring that the fracture reduction has been maintained and the sheath is still spanning the fracture site.

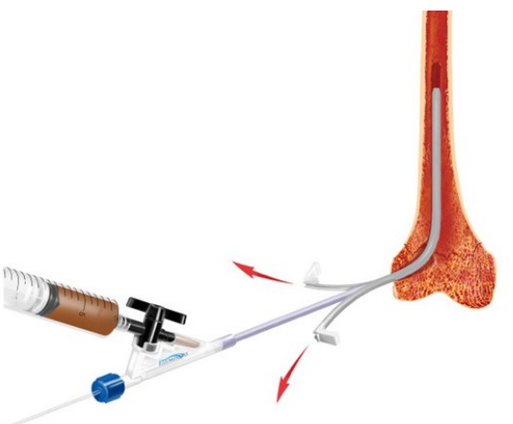


FIG 18

Remove Tear-away Sheath

While holding the balloon catheter in position within the canal and sheath, grasping the sheath break the wings of the tear away sheath and slowly separate the sheath in half while withdrawing it from the canal. Remove the entire sheath and discard. (Fig 18)

The removal of the sheath leaves the balloon exposed within the canal. (Fig 19)

FIG 19

Use fluoroscopy to confirm the position of the implant spanning the fracture site and ensure that the fracture remains sufficiently reduced or adjustments to the position of the balloon may be required.

Infuse Balloon with Monomer

Infuse the monomer from the attached 20cc syringe by opening valve and applying moderate pressure to syringe plunger. (Fig 20)

FIG 20

With the infusion of monomer into the implant the spiral radiopaque marker stripes on the outside of the balloon will start to expand and provide visual guidance of implant conforming to the canal.

(Fig 21 A B & C)

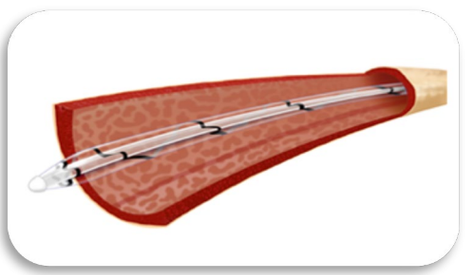


FIG 21A

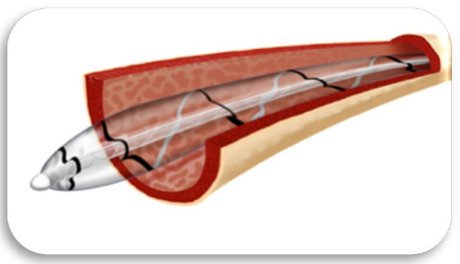


FIG 21B

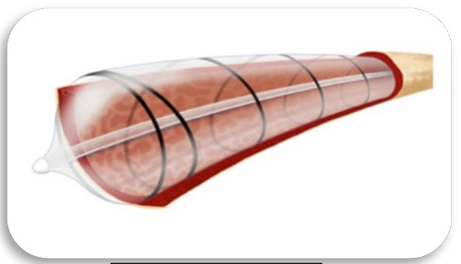


FIG 21C

Once resistance is felt on the syringe plunger, or it cannot be advanced any further, close the stopcock valve. (Fig 22)

FIG 22

Reconfirm fracture alignment with fluoroscopy. Multiple vials of monomer may have to be opened to achieve a fully filled implant. The syringes may be left in position attached to the catheter during the curing process.

NOTE: If adjustment of either the balloon position or the bone is required, depressurize balloon by opening the stopcock and aspirating monomer out of the implant(s) with the syringe to reduce the size of the implant and to disengage it from contact with the cortex of the canal.

Carefully reposition balloon(s) or reduce the fracture. Attempts at repositioning a fully filled balloon in contact with the cortical wall may cause damage to the implant.

NOTE: If a constant pressure cannot be established after infusing the monomer into the balloon, there may be a leak. Please refer to Appendix B for remediation steps.

Handling of the Light Fiber

Do not severely bend or kink the light fiber, catheter or balloon implant.
Handle the components with care.
Severe bends or kinks in the implant assembly will substantially reduce the light intensity delivered to the implant causing incomplete hardening of the liquid monomer.
Do not pull or tug on the light fiber or place the light fiber under any strain when attaching it to the Light Guide.
Do not apply instruments or clamps onto the Light Fiber and avoid contact with sharp objects.
Damage to the light fiber may result in fiber breakage or a significant reduction in the light intensity to the implant resulting in incomplete hardening of the liquid monomer.

Implant Curing Cycle

Remove the end of the light fiber from the paper tether that secures it to the catheter.
Pass the end of the light fiber off the sterile field and connect it to the light guide until it snaps in place and is fully seated. (Fig 23)

FIG 23

For convenience, a light guide pole clamp adapter has been provided. This allows the light guide to be held stably while affixed to a pole clamp or other fittings in the Operating Room. (Fig 24)

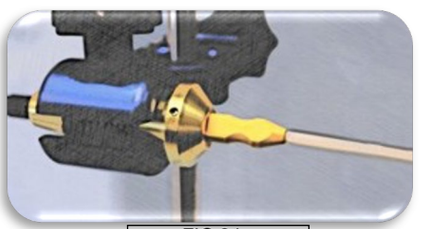


FIG 24

Light Box Preparation

Insert the timer keycard into the slot on the front of the light box. (Fig 25) Ensure the timer changes to the prescribed time shown on the timer key card.
NOTE: Ensure that the proper timer key is being used by comparing the timer key setting to the setting on the timer key flag.

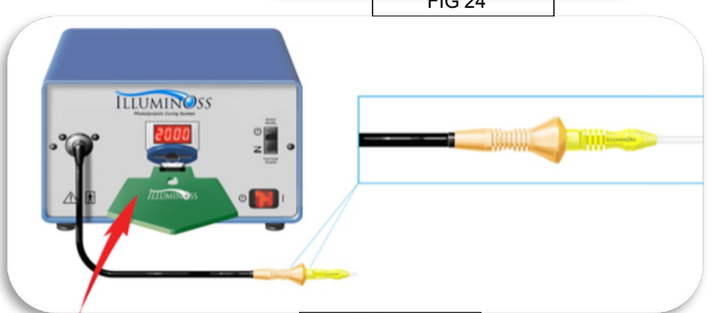


FIG 25

Toggle the foot pedal switch on the front of the light box from the standby position to the enabled position. (Fig 25A)

FIG 25A

Activate the light source

Depress and release the foot pedal to initiate the light curing cycle. This will open the shutter on the light box and the polymerization process will be activated (Fig 26A&B). Light is transferred to the implant via the light fiber. The fiber will be illuminated in a visible blue light. (Fig 26B)

Note: Once the foot pedal has been depressed, the system runs automatically and the timer counts down the residual time until the implant is cured. At the completion of the curing cycle, the shutter on the light box closes and no further light is delivered to the implant.

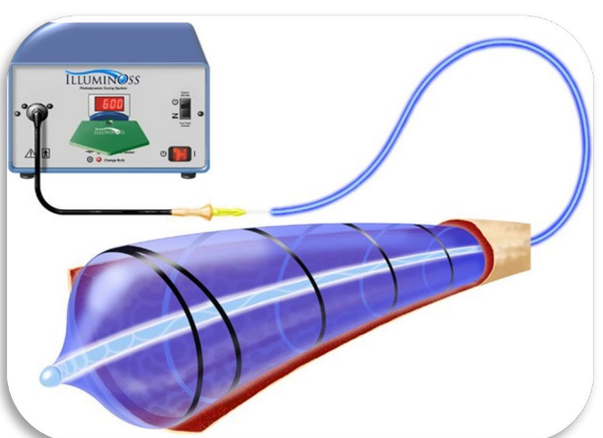
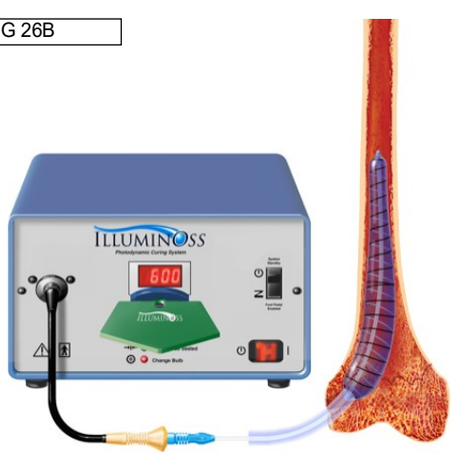


FIG 26A

FIG 26B



Caution: Do not stop the curing process or remove the light fiber prior to the completion of the curing cycle.
At the completion of the curing cycle the light source shutter is closed and no further light is delivered to the implant.

Separation of Catheter from the Implant

At completion of light cycle, the catheter must be removed from the implant.

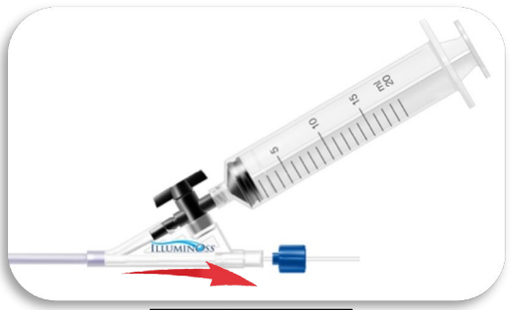


FIG 27

Remove the light fiber

Unscrew the blue cap fitting and slowly remove light fiber from balloon catheter. (Fig 27) Detach the light fiber from the light guide connector and discard it.

Cut the Catheter

Using a pair of surgical scissors, cut braided catheter tube immediately adjacent the distal Y-connector (there is a small scissor image on the Y connector) and discard Y connector assembly (and syringe of residual monomer if it is still attached). (Fig 28)

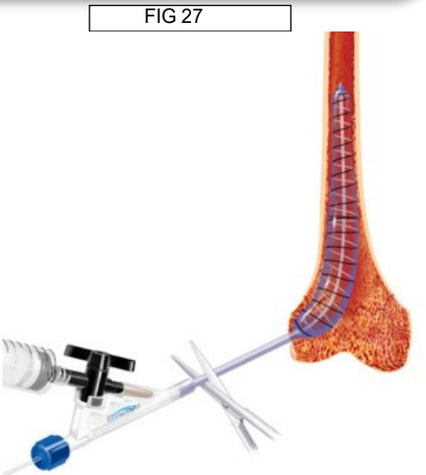


FIG 28

Slide the flex stabilizer instrument over the catheter shaft

Advance the stabilizer over catheter and advance it forward using fluoroscopic imaging to ensure that the serrated end of the instrument touches and aligns closely with the proximal end of the implant (within several millimeters of the radiopaque marker). (Fig 29)

The surgical scissors may have deformed the catheter shape and the flex stabilizer shaft may require some assistance in being initially positioned over the catheter.

Several centimeters of the catheter should protrude out from the knob of the stabilizer instrument.

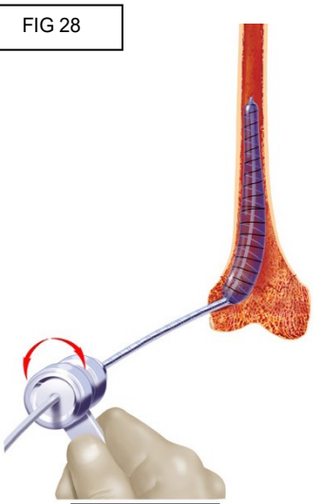


FIG 29

Rotate the stabilizer back and forth multiple times with moderate forward pressure applied, engaging the serrated teeth and scoring the end of the PET balloon covering the implant. (Fig 30)

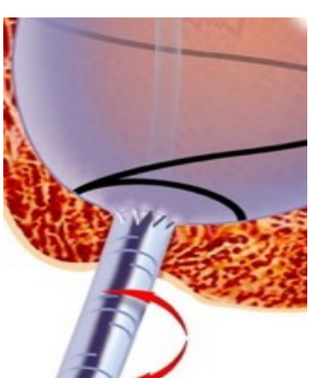


FIG 30

Open the slap hammer by pulling on the lever exposing the jaw tips.
Slide the jaw tips over the catheter that is protruding from the rear of the stabilizer.

Once the jaw tips of the separation slap hammer are over the catheter and have been advanced so that they are adjacent to the rear knob of the stabilizer, push up on the handle lever to close the slap hammer causing the jaw tips to tighten and grip onto the catheter. (Fig 31)

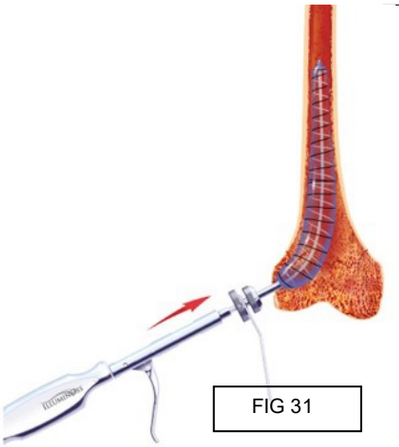


FIG 31

Grasp the stabilizer handle with one hand and apply slight forward pressure against the proximal end of the balloon.

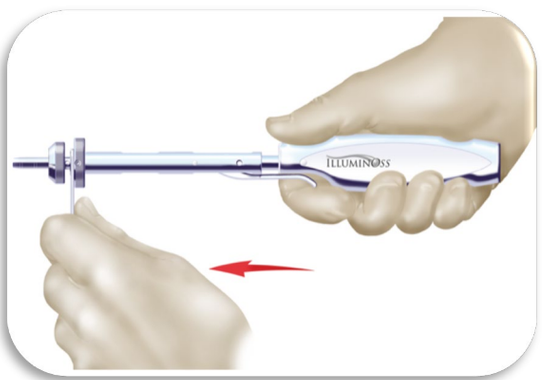


FIG 32

With the second hand, grasp the sliding “hammer” portion of the slap hammer instrument. (Fig 32)

Maintaining forward pressure on stabilizer handle with the first hand, QUICKLY move the hammer from distal to proximal in one quick, full, sharp stroke, separating the catheter from the implant. (Fig 33)

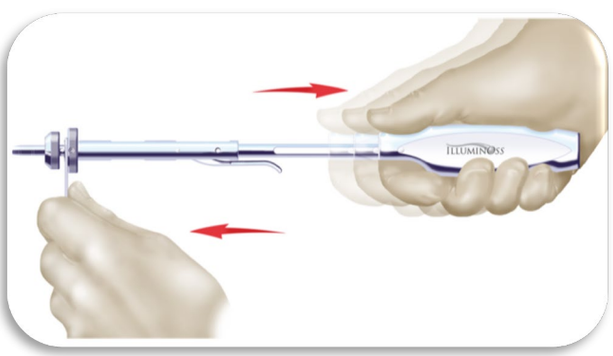


FIG 33

Completed Implant prior to the application of cleared Fracture Fixation Systems

Remove the stabilizer from the incision. Ensure that the end of the implant where the catheter has been removed is smooth and not in contact with any soft tissue which could cause irritation to surrounding tendons or ligaments.

Evaluate the fixation and deployment of the IlluminOss implant in both A/P and Lateral radiographic views. Upon completion of the procedure, remove and discard the timer key and turn off the light box.

Once the IlluminOss implant is in place, the cleared fracture fixation systems shall be implanted. (Figure 34)

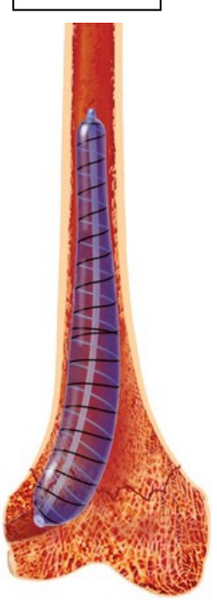


FIG 34

IlluminOss as a Supplement to cleared Fracture Fixation Systems

The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation systems. The IlluminOss implant can be used to provide supplemental fixation to 510(k)-cleared fracture fixation devices in either the femur or tibia. 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.

After completion of the curing cycle for the IlluminOss implant, the chosen plate and screw system shou ' be implanted. The screws should be placed into the IlluminOss implant.
The specific details from the manufacturer of the product, plate and insertion systems should be followe in the attachment of a plate and screw system to a fracture with an IlluminOss.

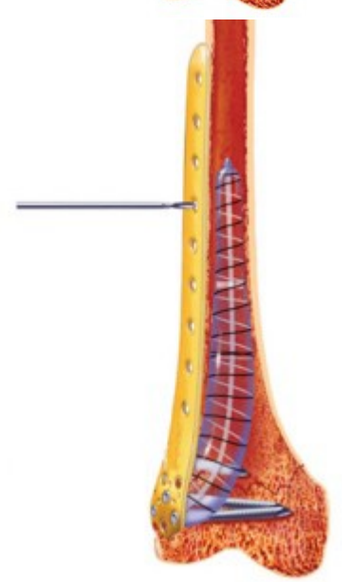
The steps indicated below are general and for illustration purposes. The user should rely upon the spec product instructions for use and delivery of the specific cleared fracture fixation system .

Before a plate and locking screws are placed onto the fracture site for attachment to the bone, fragment length, rotation, varus-valgus and recurvatum correction should be achieved.

Assemble the main components of the hardware delivery and alignment systems used to position the placement and attachment of the plate in accordance with the specific manufacturer and product instructions.

Assemble the radiolucent extensions of the insertion guide. (not shown)

Attach the plate to the appropriate insertion guide and place the plate in the correct anatomic location.
Ensure that the plate maintains contact with the bone during insertion and positioning.
Ensure the proper position of the plate and the frame when the bone is in a properly reduced position
Maintaining the frame in the correct anatomic position, affix the frame into position with K wires.



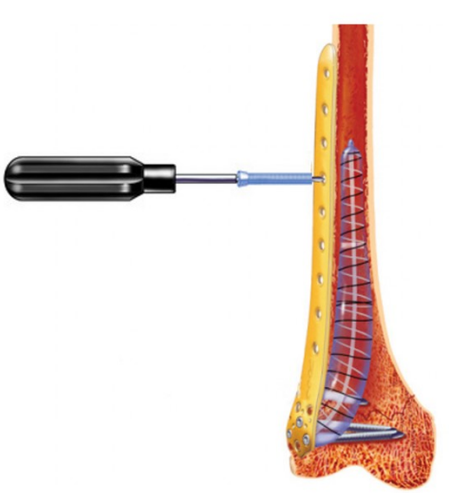
Screw Placement

Using fluoroscopic imaging, identify the locations of the radiopaque markers around the length of the cured IlluminOss implant as well as the inner walls of the cortex on both sides of the implant.
Identify anatomic safe locations for the desired screw(s) avoiding vascular and nerve structures.

Screw placement depends on the type of fracture. The position of the screws should be chosen in accordance with established biomechanical principles for internal fixation. The screws should be inserted close to and remote from the fracture gap in the main fragments.

The recommended distal screw lengths and angles ensure that screws do not penetrate the far cortex or the inter- condylar notch when the plate is placed properly. The screw lengths may be adjusted as necessary based on plate position and patient anatomy.

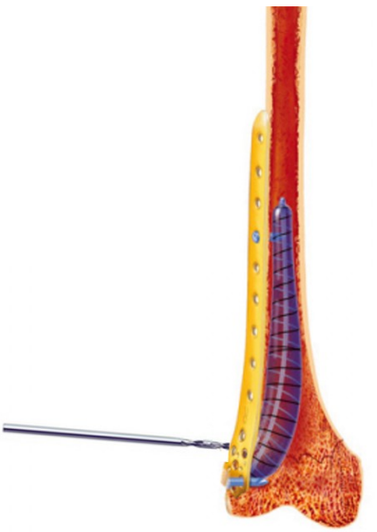
NOTE: When using screws with the IlluminOss implant, do not use a screw larger than one third of the implant diameter. For instance, if an implant of 15mm in diameter is implanted, do not use a screw size larger than 5mm.



NOTE: Screw placement should be a minimum of 3cm from the fracture line.

Drilling and Screw Placement

Standard drilling techniques and precautions should be applied when drilling a bone with an IlluminOss implant.



There are no special techniques, pressure, drill speed, or drill bits required to accomplish the drilling of the IlluminOss implant

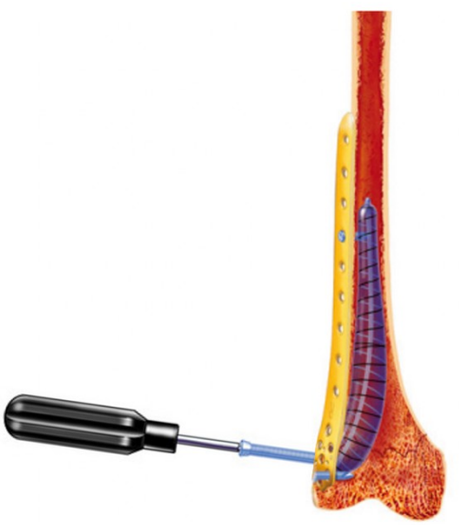
With a powered drill, drill the required screw holes with the appropriately sized drill bit for the screw size chosen.

Drilling of bone for the placement of screws should be accomplished in a manner that prevents thermal injury from the heat caused by powered surgical instruments. The thermal effects of powered drills are well documented as is the use of external cooling to combat the issue.

As with the creation of any drilled hole in bone, some form of external cooling should be applied. This is no different with the use of IlluminOss.
The use of a saline drip irrigation, applied at the surgical site where the drill holes are being created, is sug

NOTE: Irrigation may be performed to remove any residual debris.

To insert the locking screw using a power tool, fit a torque limiter to the power tool and insert the screwdriver shaft into the torque limiter.



With a drill sleeve in position and attached to the plate, drill through the bone and the IlluminOss implant with the correct sized drill bit.

Once the hole has been created, measure the depth of the hole with a screw measurement

gauge. Choose a self-tapping screw according to the measured length.

To insert the locking screw using a power tool, fit a torque limiter to the power tool and insert the screw-driver shaft into the torque limiter.

To insert the screw, start the power tool slowly, increase the speed and then reduce it again before the screw is fully tightened.

The screw position at the condyles should avoid intercondylar notch and patellofemoral joint thereby maximizing the purchase of the screws within bone. The recommended distal screw lengths
and angles ensure that screws do not penetrate the far cortex or the inter- condylar notch when the plate is placed properly. The screw lengths may be adjusted as necessary based on plate position and patient anatomy.

Once the required screws are placed, the plate securely affixed to the bone and the stability verified, the incision can be closed .

Post-Operative Management

Perform wound closure and immobilization as required (sterile dressing, elastic bandage, soft cast or other means as required).

Implant Removal

In a case where the implant should be removed, please refer to the Implant Removal Technique Guide

Appendix A: Light Box

Preparation First Time Set-Up of Light Box

Unpack the light box from the shipping container and place it on a stable table. Remove the silver cap from the light guide mounting receptacle and discard.
Remove the light guide from the box and remove the red protective caps and discard them.
Attach the power cord to the power plug mount on the rear of the light box. Connect plug to wall power supply outlet.
Attach foot pedal to the rear of the light box by pushing the tubing on the foot pedal over the black barb on the foot pedal mount (stepping on or depressing the foot pedal will cause a light clicking noise, which is the activation of the shutter).

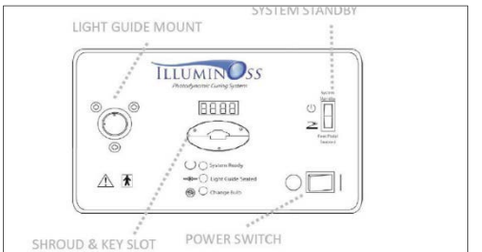


Figure 1. Light Box Components (Front)

In The Operating Room

Determine an appropriate position for the IlluminOss light box. Make certain that the light box is convenient to the operating table and that the light guide is in proximity to the surgical site. Ensure that the distance from the light guide (if attached to a pole clamp) is not further than~ 4 ft. to the surgical site.
Turn on the unit by pressing the red power switch on the lower right front of the light box. The unit will turn on and begin a self-diagnosis. The following displays will be illuminated on the faceplate: 2000 in the illuminated timer.
Insert the light guide into the light guide mount on the front of the light box, pushing it forward until the detent position is reached, and the guide cannot be advanced any further.
A green light for the Light Guide Seated will illuminate (if light guide is properly inserted).If the light guide is not fully inserted, the Light Guide Seated light will not be illuminated, and the system cannot be activated.
And after about 4 minutes of system warm up, a green light on the System Ready will illuminate. (Figure 3)
If not ready for use, the system may be manually placed into “Standby” mode which turns off the foot pedal and prevents accidental activation of the light source. (Figure 4).

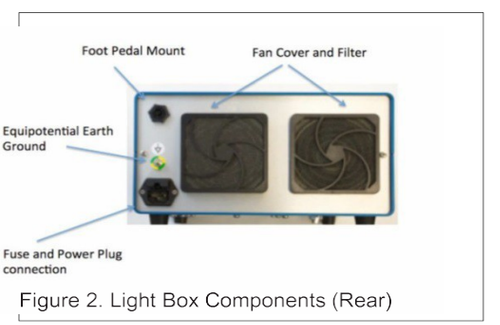


Figure 2. Light Box Components (Rear)

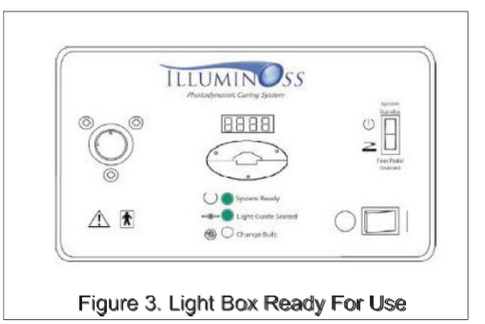


Figure 3. Light Box Ready For Use

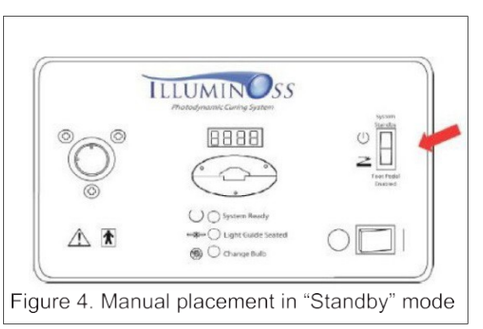


Figure 4. Manual placement in “Standby” mode

Set-up and activate the light box prior to the start of the procedure to ensure correct system operation.

WARNING: Do not pull on or attempt to stretch the light guide or the single use light fiber attached to the catheter system.

NOTE: It is always advisable to have the light box on the side of the patient that is being treated.

NOTE: Do not repeatedly turn the light box on and off as it will shorten the life of the bulb.

NOTE: If the Red " Change Bulb" light is illuminated the system will not function as the bulb has been self-diagnosed as inoperable or has reached its defined 500 hour useful life and needs to be changed by trained IlluminOss personnel.

Appendix B: Liquid Monomer Removal Procedure

The IlluminOss Photodynamic Bone Stabilization System has been designed and tested to provide the surgeon with a reliable means towards the repair and stabilization of certain bone fractures. However, no system testing can take into account all potential issues and problems. In the event that the surgeon experiences a situation where the IlluminOss balloon catheter has been compromised in some fashion, with potential egress of the liquid monomer into the medullary canal, the following steps are recommended:

NOTE: The uncured IlluminOss photodynamic monomer cannot be imaged radiographically. The uncured liquid monomer is a light honey color, semi-viscous, insoluble in water, and radiolucent.

A potential polymer leak should be suspected if either of the following conditions is met: A vacuum cannot be established when retracting the syringe plunger; A constant pressure cannot be established after infusing the monomer into the balloon.

1. Balloon Catheter Removal:

   A. Reduce Pressure: Retract the syringe plunger. This action will reduce pressure allowing aspiration of the monomer back into the syringe from the balloon and catheter assembly.
   B. Remove from Canal: When the balloon is sufficiently deflated to minimize resistance, retract the balloon and catheter assembly from the medullary canal.

2. Clean the Medullary Canal

   A. Aspirate: Apply a hospital-based suction line to a small diameter suction tip or catheter (13Fr or smaller), which in the opinion of the surgeon will provide appropriate access to the canal. Alternatively, an instrument with integrated irrigation and aspiration functions may be selected. Using a slow forward and backward motion, thoroughly aspirate any residual monomer from the confines of the canal. Remove the suction instrument from the canal.
   B. Lavage: Using a syringe, lavage the canal with sterile isotonic saline. (Repeat: Aspirate and Lavage) Repeat the aspiration and lavage process until, in the opinion of the surgeon, all polymer and saline has been removed from the canal.
   C. Swab: With a small diameter sterile swab or pledget, insert the tip of the swab into the canal and advance and retract it in a twirling fashion to clean and dry the medullary wall. (Repeat: Swab). Repeat the process with new swabs until, in the opinion of the surgeon, the canal is free of any residual liquids, debris or other materials that were present while the balloon catheter was present in the canal.

NOTE: Depending upon the location of the pathway into the canal, a flexible shaft swab may provide easier access to the distal aspects of the canal.

Once the canal cleaning is finished, the surgeon may repair and stabilize the fracture with a new IlluminOss device.

Caution Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Indication 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 Do not use on 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 post-operative fixation or unanticipated post-operative 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 post-operative 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 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 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.

MRI SAFETY INFORMATION

MR Conditional

The IlluminOss Photodynamic Bone Stabilization System (PBSS) is MR Conditional and this information applies to the entire family of IlluminOss Photodynamic Bone Stabilization System (PBSS; 4-mm to 22-mm in diameter and lengths from 30 to 280-mm). Nonclinical testing and MRI simulations were performed to identify the worst-case conditions that were used to demonstrate that the IlluminOss Photodynamic Bone Stabilization System (PBSS) is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:
Static magnetic field of 1.5-Tesla and 3-Tesla, only
Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence).

Under the scan conditions defined, the IlluminOss Photodynamic Bone Stabilization System (PBSS) is expected to produce a maximum temperature rise of 2.3°C after15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the IlluminOss Photodynamic Bone Stabilization System (PBSS) extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

This MR Conditional labeling is only applicable for the IlluminOss Photodynamic Bone Stabilization System (PBSS). The use with a fracture fixation system has not been evaluated in an MR environment.

993 Waterman Avenue
East Providence, Rhode Island
02914
Phone: (401) 714-0008
www.IlluminOss.com