

Surgical Technique Guide

Anterior Ring of the Pelvis



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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, 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.

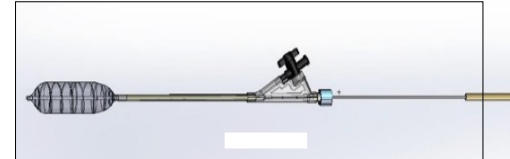
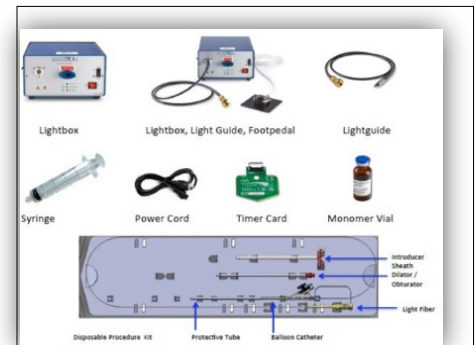
During a percutaneous procedure, a small diameter expandable balloon catheter is inserted into the medullary canal and is positioned across the area requiring stabilization. Once in correct alignment and position, it is infused with a biocompatible light curable liquid monomer, which hardens under the 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 Photodynamic Bone Stabilization Procedure Pack, its container, and any packaging is not made with natural rubber latex.

IlluminOss Bone Stabilization 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 visible 436nm 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. This section provides key or important information about the use of the product in the treatment of traumatic, fragility, fractures of the anterior ring of the pelvis.

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, 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.

Implant Sizes

IlluminOss implants in the treatment of fractures for the Anterior Ring of the Pelvis range in diameter from 8.0mm to 9.0mm and in lengths from 80mm to 160mm. A list of suggested implant sizes is in Table 1.

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 trays have been sterilized and are delivered to the OR suite (see Appendix C for instrumentation detail).

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 proper operation (See Appendix A: Light Box Set-Up Summary) 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 to be supported. The IlluminOss implants for the treatment of anterior ring pelvic fractures are typically between 8 mm & 9 mm in diameter and between 80 – 160 mm long.

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 symphysis, 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.

Determining Implant Diameter

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

General Consideration Points

When any doubt exists about the proper size of the IlluminOss implant to utilize, the selection of a larger implant is usually the correct determination. The implant will only fill and conform to the available intramedullary space provided.

Fracture stabilization cannot be assured when the IlluminOss implant is not in contact with the cortical walls, allowing the implant to move within the intramedullary canal. The implant diameter should be of sufficient size that it achieves conformal contact with the walls of the intramedullary canal.

Select a balloon diameter equal to the largest canal diameter observed over the span of the implant. In cases where there may be some doubt on the correct diameter implant (e.g. eccentrically shaped canal) always use the larger sized implant.

The use of fluoroscopy is mandatory during implantation of the IlluminOss System. It is incumbent upon the surgeon that they use fluoroscopy as they would with the use of standard intramedullary systems and that they take fluoroscopy images throughout the procedure as necessary to ascertain correct instrument positioning as well as correct fracture reduction. thin wall PET balloon.

The IlluminOss implant is constructed from a thin wall PET balloon. Do not bring or allow 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.



Procedural Concept

An antegrade approach to the medullary canal of the superior ramis originating at the pubic symphysis towards the placement of a patient conforming implant. Access to the ramis is made by a ~5mm incision at the pubic symphysis with an IlluminOss implant delivered and formed from the entry pathway spanning the desired length of the canal of the ramus.

The treating an anterior ring fracture procedure is performed in discrete stages;

- creation of a pathway
- preparing the interosseous space with awls and burrs
- 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

Fluoroscopic Imaging

Prior to starting the procedure at minimum fluoroscopic images in the AP, inlet and outlet, obturator should be obtained to ensure adequate visualization of the canal and associated anatomy.

Prior to draping, ensure that the C-arm is able to obtain the necessary images without being obstructed by the table.

The legs should be accessible for possible reduction maneuvers, but not necessarily prepped and draped. A pillow to flex the hip can help to relax the neurovascular structures and iliopsoas muscle if desired for anterior pelvic approach. All pressure points should be padded.

Fracture Reduction

The use of reduction clamps should be considered to achieve and maintain anatomical reduction of the fracture especially in complex fracture patterns.

Incision & Anatomical Landmarks

A small suprapubic incision of approximately 3-4 cm incision is made to gain access to the intraosseous space of the symphysis.

Straight Awl

Make the initial minimally invasive incision at the pubic symphysis to allow for the delivery of a sharp straight awl to make a pathway to the interosseous space. (FIG 1A, B, & C)

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 medullary canal therefore allowing for the initial entry point to be at the symphysis extending the length of the implant rather than the tubercle which is common for rigid implants.

The pathway created must be at least 4.5mm in diameter to accommodate the passage of the sheath and dilator.

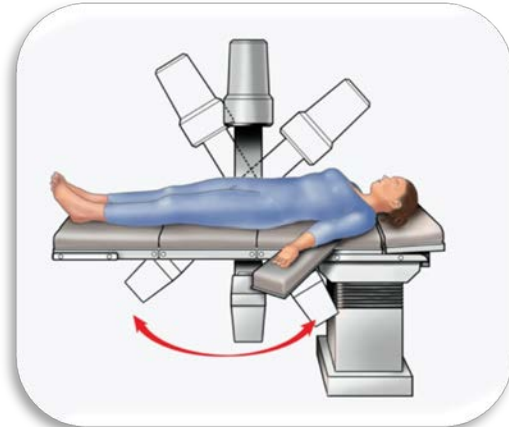


FIG 1A



FIG 1B



FIG 1C

Insert the 4.0 mm Cannulated Awl Into the Canal

The intramedullary canal at the symphysis is then further opened with a 4.0 mm cannulated curved awl in order to make an initial pathway into the intramedullary canal of the superior ramus and introduce a guidewire spanning the fracture and following the anatomic curve of the pelvic bone up to and over the dome of the acetabulum. (Fig 2 A & B)

With the 4.0 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.

Note: The pathway created must be at least 4.5mm in diameter to accommodate the passage of the sheath and dilator.

Note: The cannulated curved awl has a small "1/2 step" on the front of the awl that protrudes in front of the full diameter awl where the guidewire exits the cannulation. 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.

Insert the 1.2mm 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 1.2mm ball tipped guidewire into the medullary canal through the rear cannulation port of the 4.0 mm awl and across the fracture site. (Fig 3)

Verify fracture reduction and the position of the guidewire through the use of X ray guidance in different directions to confirm the correct position of the guidewire.

Leaving the guidewire in position and remove the cannulated awl. (Fig 4A & B)

When the 4.0 mm cannulated awl has been removed only the guidewire shall remain in the canal. (Fig 5A & B)



FIG 2A

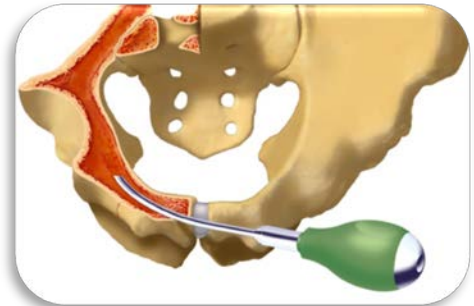


FIG 2B

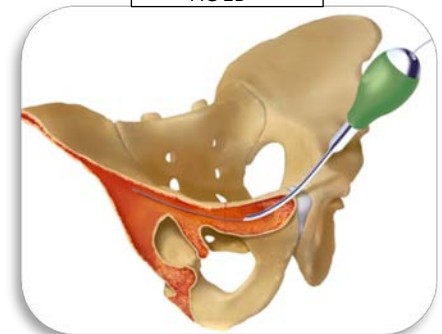


FIG 3

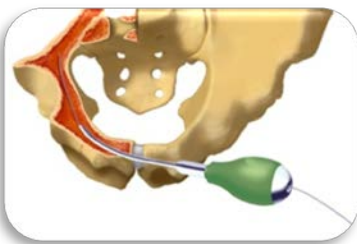


FIG 4A



FIG 4B

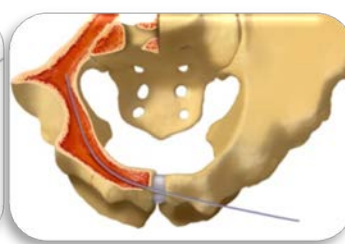


FIG 5A



FIG 5B

Preparation of Canal: Burrs

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 burrs (Fig 6) are provided in 1.0mm increments. The burrs are used to achieve a minimum diameter of 5.5mm pathway into the canal, are sized 4.5mm, 5.5mm & 6.5mm and are designed to clear the canal.

Note: The 4.5mm burr, which is provided as a front cutting is the first size burr to start the canal preparation to allow for the delivery of the sheath and dilator.

Place 4.5mm flexible cannulated burr over the 1.2mm ball tip guide wire to open and prepare the canal providing proper space for delivery of the implant. (Fig 7A & B)

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

When the 4.5 mm burr has been advanced as far forward as desired, the burr is withdrawn, and exchanged for the next sequential larger size. This next sized burr is similarly mounted over the 1.2mm guidewire and either a hand reamer or power drill used to advance the burr within the canal.

If an internal diameter of at least 4.5mm cannot be achieved in the creation of a pathway from the condyle to the canal with the use of the burrs, the 4.5mm 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 burr from the IM canal leaving the 1.2mm ball tip guidewire in place across the fracture. (Fig 8)

At this point there is a guidewire in position; within the superior ramus 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 or larger diameter smaller than the size of the instrument used.

Preparation for Implant Delivery; Component Preparation

Open the outer box containing the following components:

Foam pouch containing:

- individually foil wrapped monomer vials,
- sterile syringes,
- sterile monomer transfer spike,
- Sterile delivery catheter package,

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 non-sterile pink bubble wrapped pouch containing the timer key card and set it aside for insertion into the light box.

Open the individual sterile pouches and introduce the monomer, 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.



FIG 6



FIG 7A



FIG 7B



FIG 8

Balloon Catheter Preparation; Remove Air from the Catheter

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. Attach the empty 20cc syringe provided in the kit to the black stopcock luer and open the valve. 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)

Detach the syringe from the stopcock luer and expel any air out of the syringe. Repeat the process a second time to ensure all the air has been removed from the balloon catheter. Close the luer to maintain the vacuum within the implant.

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 20cc syringe to the transfer spike luer and turn the assembly over. Slowly draw the monomer into the syringe. (Fig 10) Consolidate any air bubbles and expel any residual air from the syringe.

Prime Distal End of Balloon

Attach the syringe containing the monomer to the closed stopcock luer. Slide the white protective tube covering the balloon backwards towards the syringe, about 25mm, exposing the front portion of the balloon. (Fig 11)

Open the stopcock valve on the catheter where the vacuum will assist in pulling in the monomer into the balloon catheter. Apply some pressure to the syringe plunger for several seconds, and the monomer will travel the entire length of the balloon catheter.

The tip of the exposed balloon beyond the end of the protective tube shall start to slightly expand in diameter. (Fig 12A & B)

Note: Do not try and fully inflate the balloon to its full size or diameter. The purpose of this step is to transfer some monomer to the distal end of the implant.

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. 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 13)

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)

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 IllumiOss implant has now been prepared and is ready for implantation.



FIG 9



FIG 10



FIG 11



FIG 12A



FIG 12B



FIG 13

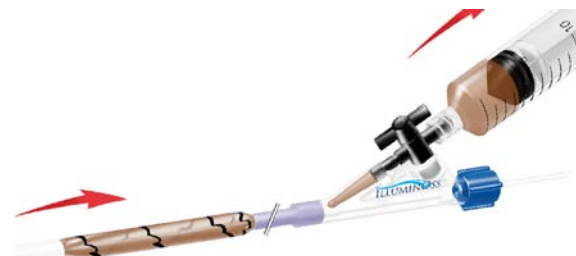


FIG 14

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.

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.

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

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.

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 1.2mm 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)

Confirm positioning of the dilator and sheath assembly 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)

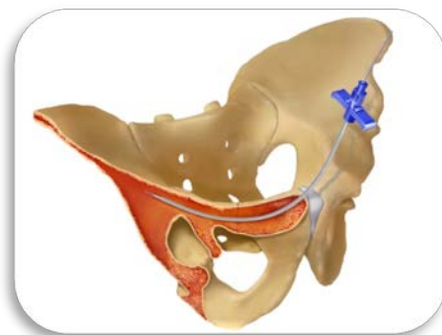


FIG 15

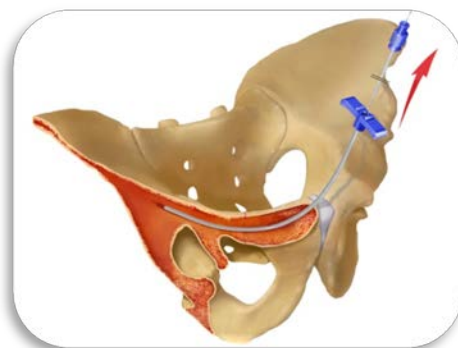


FIG 16

Placement of Balloon Implant into the Sheath

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

Ensure the proper position of the implant through the use of fluoroscopy ensuring that the fracture reduction has been maintained and the sheath is still spanning the fracture site.

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.



FIG 17

Remove Tearaway Sheath

Grasping the sheath break the wings of the tearaway sheath, and slowly separate the sheath in half while withdrawing it from the canal, and discard the sheath. (Fig 18)

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

Use of fluoroscopy to confirm the proper position of the implant (anterior, posterior, and inlet/outlet) 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 syringes by opening the black stopcock on the catheter and applying moderate pressure to the syringe plunger attached to each of the implants. (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 21A, B & C)

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

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 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.

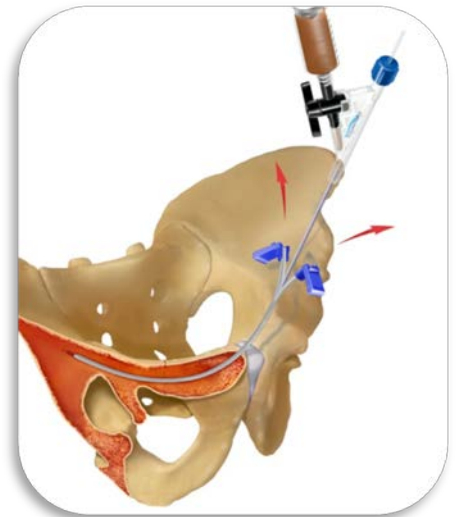


FIG 18

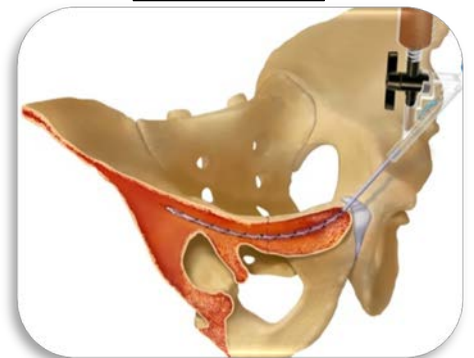


FIG 19

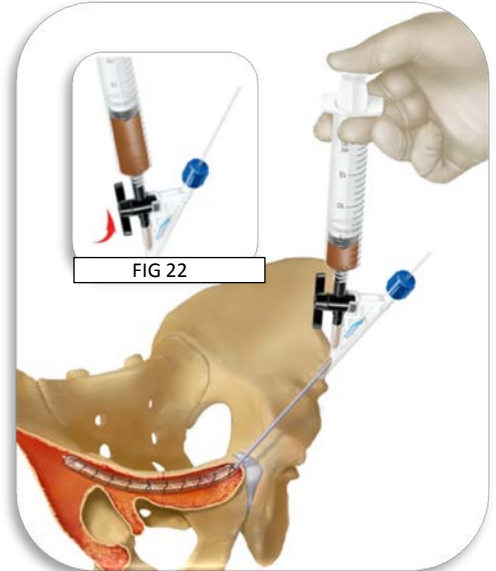


FIG 20

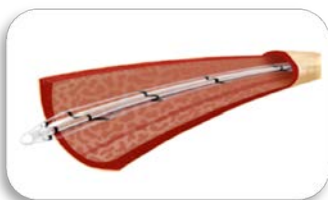


FIG 21A

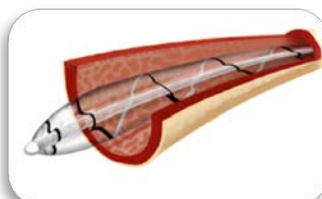


FIG 21B



FIG 21C

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) 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 23

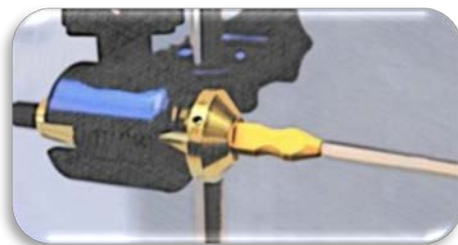


FIG 24

Insert Timer Key Card

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.

Toggle the foot pedal switch on the front of the light box from the standby position to the enabled position. (Fig 25A). in the "System Standby Mode," the Foot Pedal is inoperable and the user will hear an audible beep when the foot pedal is depressed.

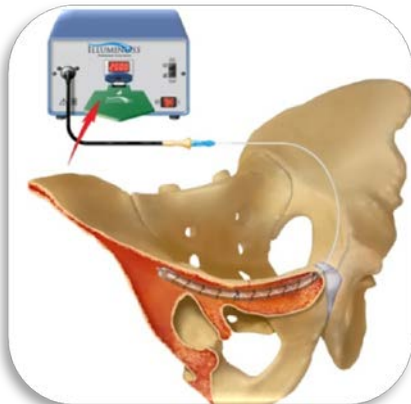


FIG 25



FIG 25A



FIG 26

Activate the light source

Depress and release the foot pedal to initiate the light curing cycle. (Fig 26 & 26A)

The system runs automatically and the timer counts down the residual time until the implant is cured.

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.

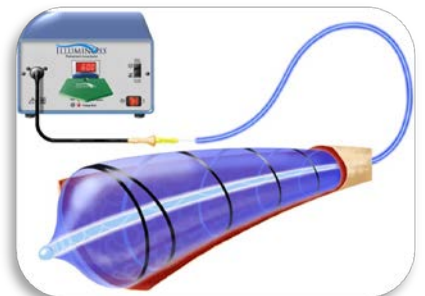


FIG 26A

Separation of Catheter from the Implant

At completion of light cycle, 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.

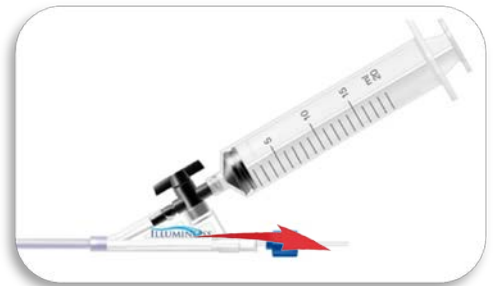


FIG 27

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

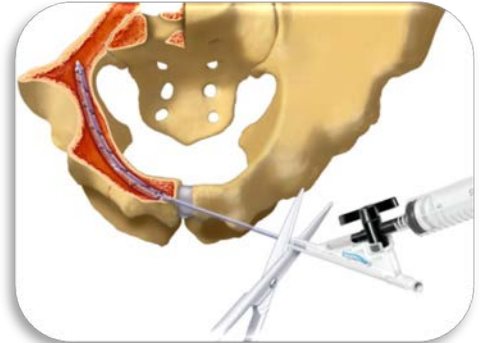


FIG 28

Slide the flex stabilizer instrument over the catheter shaft. (Fig 29)

NOTE: 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.

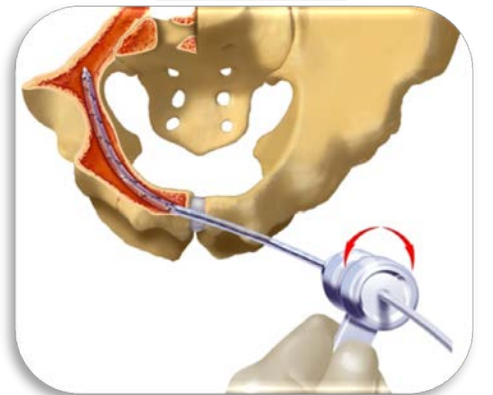


FIG 29

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

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

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)

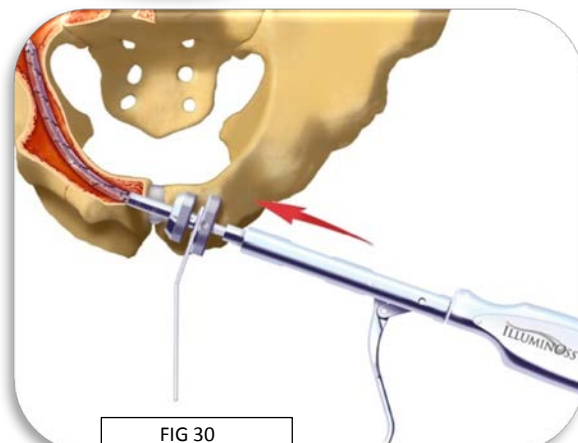
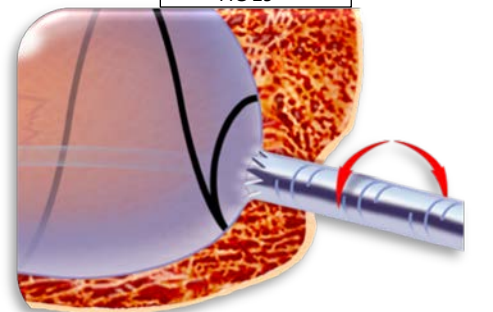


FIG 30

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)

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

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)

Remove the stabilizer from the incision. 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.

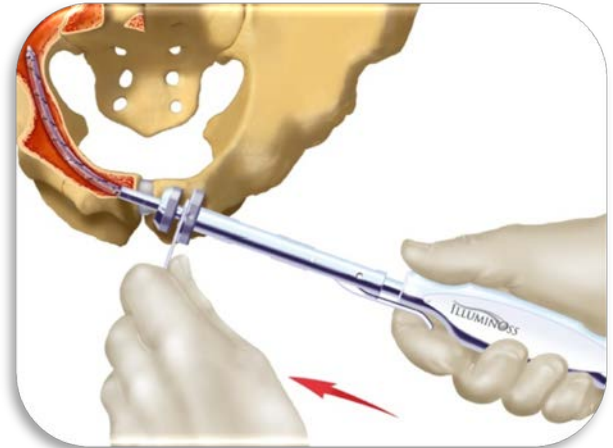


FIG 31

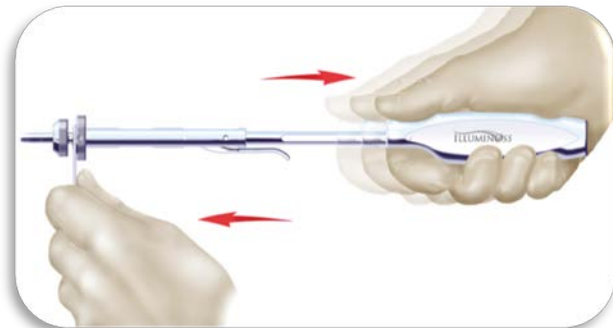


FIG 32

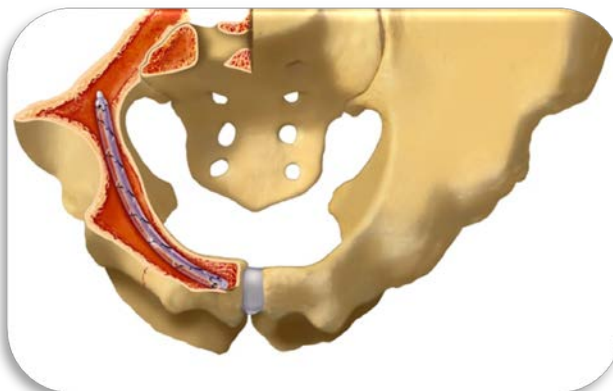


FIG 33

Screw Placement (Optional)

While the implant provides strength and stability to the fracture site, there are occasions where supplemental plate and screw fixation may be required. Examples may include highly comminuted fractures, midshaft humeral fractures, spiral fractures, small canals subjected to higher loads.

After completion of the curing cycle for the IlluminOss implant, supplemental plate and screw fixation of the fractured bone may be performed with the use of cross-locking cortical screws delivered through the IlluminOss implant.

- 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.
- With a powered drill, drill the required screw holes with the appropriate sized drill bit for the screw size chosen.
- Measure the bone hole depth using a depth gauge. Select the proper length screw and use a screwdriver to fully insert the screw into the implant.
- **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 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 suggested.
- **NOTE:** Irrigation may be performed to remove any residual debris.
- 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.

Post-Operative Management

Perform wound closure, sterile dressings as per routine and any post-operative immobilization as required. Postoperative partial or full weight bearing with rollator is allowed and mobilization took place under guidance of a physiotherapist.

Implant Removal

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

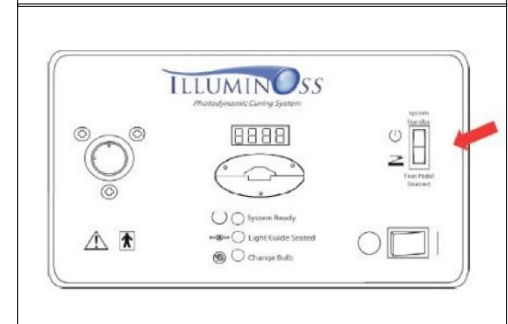
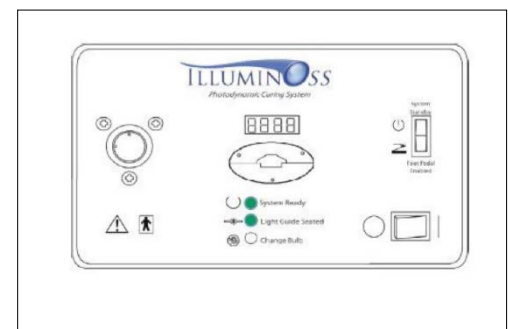
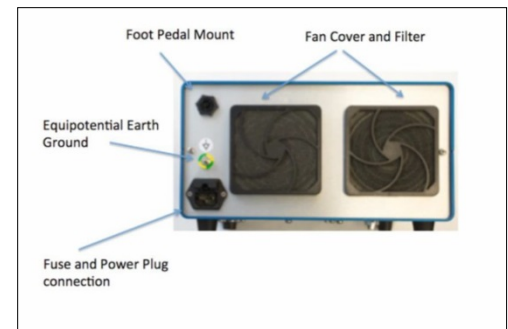
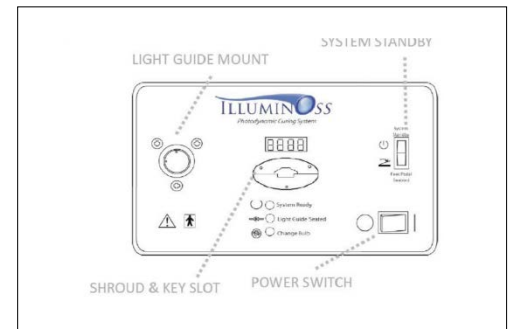
Appendix A: Light Box Preparation

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).

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.
- 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.



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

NOTE: Do not pull on or attempt to stretch the light guide or the single use light fiber attached to the catheter system as damage to the light fiber or light guide may occur, or a significant reduction in the light intensity to the implant resulting in incomplete hardening of the liquid monomer.

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, 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.

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

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; 7-mm to 22-mm in diameter and lengths from 60 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 after 15-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 any supplement screw fixation has not been evaluated in an MR environment.

Appendix C Instrumentation – Small Delivery Set

Part Number

Description

CT-0127	GREEN AWL CURVED
CT-0199	GREEN AWL STRAIGHT
CT-0197	MINI STABILIZER
CT-0301	MINI SLAPHAMMER
05-0901	STRAIGHT AWL
CT-0131	BURR GUIDE SPLIT TUBE STABILIZER
CT-0239	4.5 MM FRONT CUTTING FLEXIBLE BURR *
CT-0241	5.5 MM SIDE CUTTING FLEXIBLE BURR *
CT-0242	6.5 MM SIDE CUTTING FLEXIBLE BURR *
CT-0195	SPARE MINI FLEX STABILIZER TUBES *
CT-0235	RADIOGRAPHIC RULER
CT-0278	CATHETER SCISSORS
CT-0238	AO ADAPTER ASSEMBLY, 1.5 MM GUIDEWIRE

Inspect the instruments for damage upon receipt and after each use and cleaning.

Instruments with dents, burs, signs of corrosion or spotting, or raised surfaces which could cause damage to surgical gloves should be set aside for repair service or returned to IlluminOss. Properly dispose of any used single-use or limited use instruments.

*** Limited Use Instruments may require replacement after use or require replacement when dull or worn.**

Table 1: Implants, Guidewires, Sheaths and Dilators

Implants			
Catalog Number	Implant Dimension – Diameter & Length (mm)	Maximum Monomer Volume (mL)	Timer Key Cure Time (sec)
USML 08080	8mm x 80mm Photodynamic Bone Stabilization Procedure Pack	5	300
USML-08100	8mm x 100mm Photodynamic Bone Stabilization Procedure Pack	6.7	300
USML-08120	8mm x 120mm Photodynamic Bone Stabilization Procedure Pack	7.7	300
USML-09100	9mm x 100mm Photodynamic Bone Stabilization Procedure Pack	8.2	500
USML-09120	9mm x 120mm Photodynamic Bone Stabilization Procedure Pack	9.5	500
USSL-0900160	9mm x 160mm Photodynamic Bone Stabilization Procedure Pack	11	400
USSL-0900180	9mm x 180mm Photodynamic Bone Stabilization Procedure Pack	13	400
Guidewires			
Catalog Number	Description	Packaged	Units
CT-0243-01	1.2mm Ball Tip Guidewire	Sterile	5 pack
Sheaths & Dilators			
Catalog Number	Description	Packaged	Units
CT-0097-01	5.5mm Introducer Sheath & Dilator	Sterile	1 unit each
CT-0299-01	4.5mm Introducer Sheath & Dilator	Sterile	1 unit each
Monomer			
CT-0300-01	20ml Monomer Vial Pouch	Sterile	1 unit



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