

Surgical Technique Guide

Distal Humerus-
Single or Dual Implants



Table of Contents

System Description & Indication for Use	1
Pre-Operative Setup	2
Procedural Concept	3
Canal Preparation	4
Sheath Assembly and Delivery within the Canal	6
Balloon Catheter Priming and Preparation	7
Balloon Catheter Insertion and Monomer Infusion	9
Handling of the Light Fiber & Curing Cycle	11
Separation of Catheter from Implant	12
Screw Placement (optional)	13
Post-Operative Management	13
Implant Removal	13
Appendix A: Light Box Preparation	14
Appendix B: Liquid Monomer Removal Process	15
Indication for Use, Cautions, Contraindications, Warnings & Risks	16
MRI Safety Information	17
Appendix C: Instrumentation	18
Implants, Guidewires, Sheaths and Dilators	19

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, and ulna.

The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with an FDA cleared fracture fixation system to provide supplemental fixation in the humerus, radius and ulna.

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.

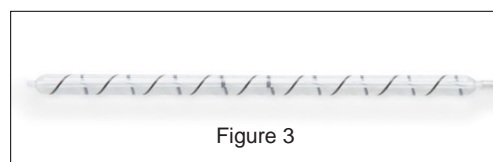
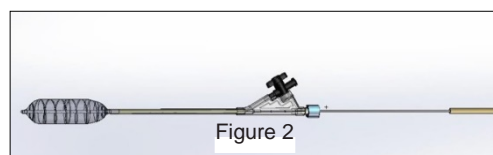
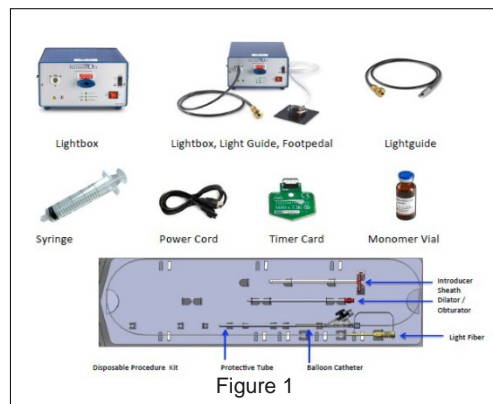
System Description

The IlluminOss Photodynamic Bone Stabilization System is comprised of a single use disposable procedure pack, along with a reusable curing system (Figures 1-3) and instrument set (Appendix C). 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.

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 distal humerus.

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 the use in skeletally mature patients in the treatment of traumatic, fragility, pathological and impending pathological fractures of the humerus, radius and ulna.

The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with an FDA-cleared fracture fixation system to provide supplemental fixation in the humerus, radius and ulna.

Implant Sizes

IlluminOss implants range in diameter from 7.0mm to 22.0mm and in lengths from 70mm to 280mm. For currently available sizes refer to Table 1 on page 19.

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 (Delivery and/or Humerus Specific) 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 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.

Implant Diameter and Length

The IlluminOss implants range in a variety of diameters and lengths. The determination of an implant length and diameter maybe 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 distal humerus and distal shaft range in diameters from 9 mm to 17mm and in lengths from 160 mm to 280mm.

In the distal humerus, typically two implants are utilized; one from the medial and one from the lateral condyle, although anatomic considerations may alter this proposal.

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. If the arm is fractured, the correct length can only be estimated unless the fracture is correctly reduced. Position the image intensifier for AP and Lateral views of the distal humerus.

Holding the radiographic ruler at the condyle, measure the distance to the medullary canal and to the desired distance in the shaft that the implant should reside 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 distal humerus in two planes. Hold the ruler parallel and at right angles to the distal humerus while positioned over the medullary canal. Select an implant or combination of implant diameters sufficient to fill and to achieve contact with the medullary canal and cortex.

NOTE: The sum of two implant diameters is not sufficient to achieve the filling of a canal measurement of an equal canal diameter measurement. The combination of two larger implants is required.

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 size.

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.

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

A retrograde approach to the medullary canal with two balloons positioned; one from the medial condyle and one from the lateral condyle spanning the distal humeral segment and intersecting at a point above the fracture within the medullary canal.

The Distal Humerus procedure is performed in discrete stages; preparing each pathway (lateral and medial), the preparation of the two implants and then the insertion and simultaneous filling of the IlluminOss implants, followed by the activation of the light box and the curing of the implants. Once the implants are cured, the light fibers are removed, the catheter separated from the implant and the incision(s) closed.

Reduce Fracture and Create Initial Pathway - Lateral Side

Position the patient in the supine position and reduce the fracture by traditional methods.

Note: The operating table must be radiolucent as the arm must be visualized in two planes using an image intensifier.

A stitch incision should be made on the first condyle (for purposes of example the lateral condyle has been chosen first.)

A straight awl is used to make an initial pathway in a superior direction from the condyle towards the medullary canal. Check the position with AP and Lateral views. (Figure 4 A & B)

Note: When using the straight awl in the creation of the pathway from the condyle, please take note that the taper of the awl is substantial and that a deep penetration of the awl is necessary to achieve a diameter of 5.5mm to achieve the passage of the sheath.

Note: Take care when fully inserting the straight awl that the contralateral side of the bone is not penetrated. (Figure 4 C)

Alternative Access Approach Technique

Using a 1.6mm K wire, deliver it into position with a power driver. Starting from the desired access point on the condyle, directed to the entry into the medullary canal. Position the K wire with the assistance of an image intensifier.

Once the K wire is in position from the condyle to the canal, mount a 5.5mm cannulated drill bit on a power driver. Insert the 1.6mm K wire into the cannulated drill bit and follow the path of the k wire into the medullary canal.

Note: A 5.5mm drill is sufficient for the delivery of implants of up to 11mm.

Larger implant diameters require a pathway of 7.0mm and a larger drill bit shall be required.

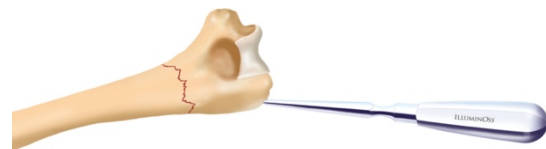
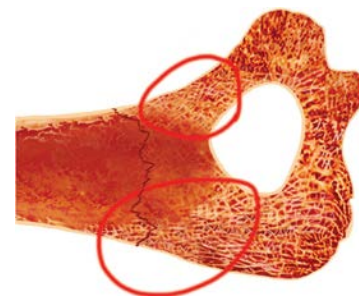


Fig 4 A



Fig 4 B

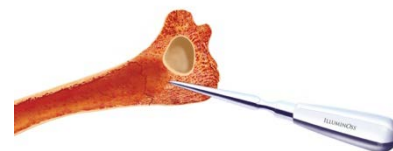


Fig 4 C

Insert Cannulated Awl into Canal

Once the pathway has been made, insert the cannulated awl into the pathway. (Figure 5)

Rocking the cannulated awl +/- 30 degrees will enlarge the originally tapered pathway created allowing for the sheath and dilator to be placed within the medullary canal

Note: The pathway created must be at least 5.5mm 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.

Insert Guidewire into Cannulated Awl

Once the cannulated awl is in position, remove the stylet from the back of the cannulated awl. Deliver the 1.2mm ball tipped guidewire into the medullary canal through the rear of the awl and across the fracture site. (Figure 6)

Leaving the guidewire in position and remove the cannulated awl. (Figure 7)

Note: if implant diameters of up to 11 mm are utilized a 1.2 mm ball tip guidewire is utilized. If implant diameters of 15mm or larger are used a 2.0 mm guidewire may be used. A 2.0mm guidewire requires the use of the 8mm cannulated awl.

Preparation of Canal: Burrs

Place the IlluminOss flexible cannulated burrs over the 1.2mm ball tip guidewire to clean the canal providing proper space for delivery of the implant / sheath & dilator. (Figure 8 A & B)

Start with the smallest diameter burr mounted on either a power drill or a hand reamer to clear the canal.

Burrs are used in 1.0mm increments to achieve a minimum diameter of 5.5mm pathway into the medullary canal.

The flexible shaft stabilizer (CT-0131) is provided for use with the burr and reamer shafts during use.

After clearing the pathway to the medullary canal remove the burr from the 1.2mm ball tip guidewire, leaving the guidewire in position across the fracture.

Note: If an internal diameter of at least 5.5 mm cannot be achieved in the creation of a pathway from the condyle to the canal with the use of the burrs, the 5.5mm delivery sheath cannot be inserted into the canal and the use of the IlluminOss implant is contraindicated.



Fig 5



Fig 6



Fig 7

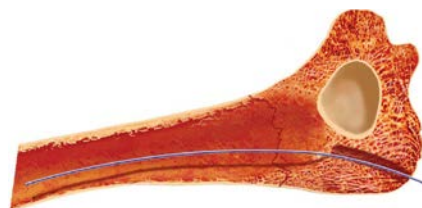


Fig 8A

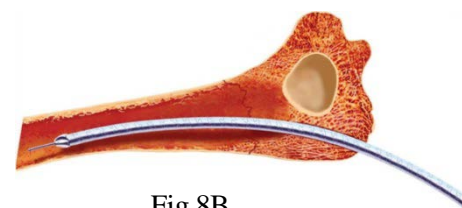


Fig 8B



Fig 9

Preparation of canal: Reamers

If the IlluminOss Reamers are utilized in lieu of the IlluminOss burs, use of the 2.0mm ball tip guidewire is required. (Figure 10)
The IlluminOss reamers are designed to be used only with the IlluminOss 2.0 mm ball tip guidewires. Use with other guidewires may cause damage to the reamer or result in other failures

Place or exchange the 1.2mm ball tip guide wire with a 2.0mm guidewire prior to utilizing the IlluminOss reamers.

Start with the smallest diameter reamer mounted on either a power drill or a T handle to clear the canal.

Reamers are used in .5 mm increments to achieve a minimum diameter of 7.0 mm pathway into the medullary canal. (Figure 11)

After clearing the pathway to the medullary canal remove the reamer from the 2.0 mm ball tip guidewire, leaving the guidewire in position across the fracture site. (Figure 12)

Preparation of canal - Medial Condyle

A stitch incision should be made at the medial condyle.

A straight awl is used to make an initial pathway in a superior direction from the condyle towards the medullary canal. Check the position with AP and Lateral views. (Figure 13)

WARNING: Do not introduce an IlluminOss Implant into the canal prior to the preparation of the contralateral condyle as inadvertent damage to the implant may transpire.

Note: When using the straight awl in the creation of the pathway from the condyle, please take note that the taper of the awl is substantial and that a deep penetration of the awl is necessary to achieve a diameter of 5.5mm to achieve the passage of the sheath.

Note: Take care when fully inserting the straight awl into the bone that the contra lateral side of the bone is not penetrated. (Figure 13A)

Alternative Access Approach Technique

Using a 1.6mm K wire, deliver it into position with a power driver. Starting from the desired access point on the condyle, directed to the entry into the medullary canal, position the K wire with the assistance of an image intensifier.

Once the K wire is in position from the condyle to the canal, mount a 5.5mm cannulated drill bit on a power driver. Insert the 1.6mm K wire into the cannulated drill bit and with the drill bit follow the path of the k wire into the medullary canal.

Note: a 5.5mm drill is sufficient for implants of up to 11mm. Larger implant diameters require a pathway of 7.0mm and a larger drill bit shall be required.



Fig 10

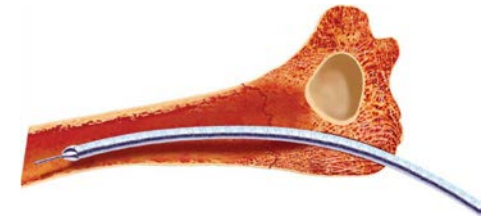


Fig 11

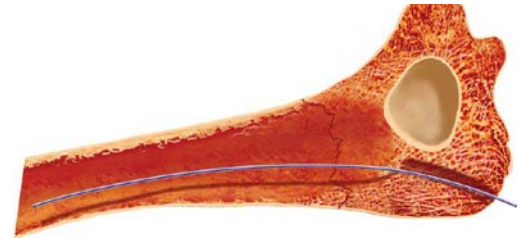


Fig 12



Fig 13



Fig 13A

Insert the cannulated awl into the initial pathway

Once the pathway has been made, insert the cannulated awl into the pathway. (Figure 14)

With the awl placed in the pathway to the canal, gently rocking the cannulated awl +/- 30 degrees will enlarge the pathway to allow the dilator to be delivered within the medullary canal.

Note: The pathway created must be at least 5.5mm to accommodate the passage of the sheath and dilator.

Note: The cannulated curved awl has a "step" on the front of the awl that protrudes in front of the full diameter awl where the guidewire exits. Ensure that the full diameter of the awl has passed through the canal to ensure passage of the guidewire.

CAUTION: Do not use a burr or reamer while the opposing guidewire is in position as it may become engaged with the rotating burr or reamer.

Note: If an internal diameter of at least 5.5mm cannot be achieved in the creation of a pathway from the condyle to the canal, the 5.5mm delivery sheath cannot be inserted into the canal and the use of the IlluminOss implant is contraindicated.

Remove the cannulated awl leaving the guidewire in position. (Figure 15)

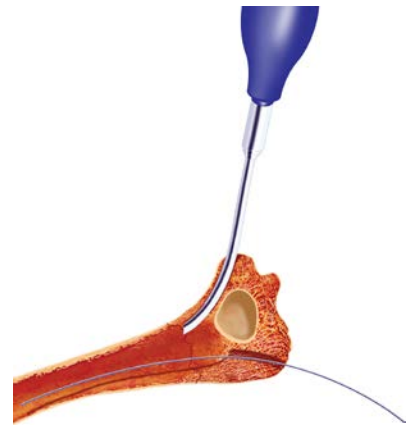


Fig 14

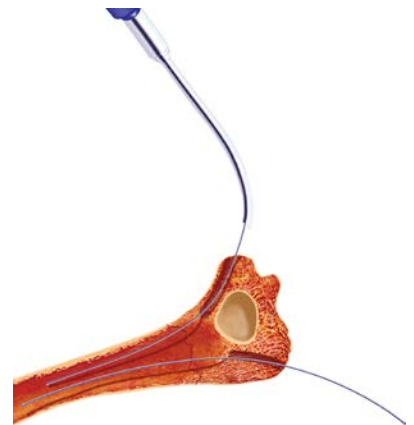


Fig 15

Preparation for Implant delivery

At this point there are two (2) guidewires in position; one in each of the lateral and medial condyle pathways. (Figure 16)

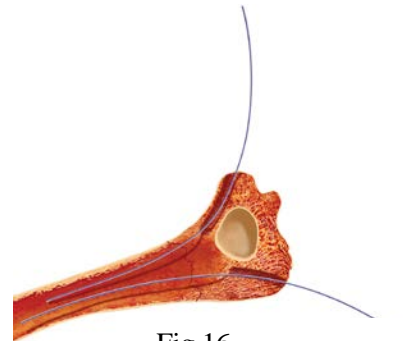


Fig 16

Insert Dilator & Sheath -Lateral Side

Insert the dilator into the tear away sheath, and lock the two 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. (Figure 17)

Confirm positioning of the sheath assembly via fluoroscopy.

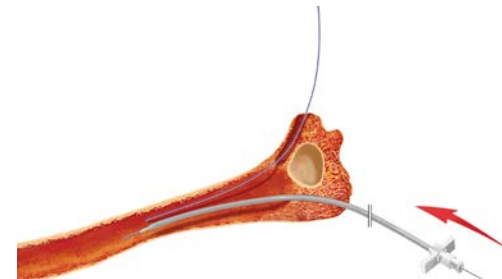


Fig 17

Insert Dilator & Sheath - Medial Side

Insert the dilator into the tear away sheath, and lock the two 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. (Figure 18)

Confirm positioning of the sheath assembly via fluoroscopy.

At this point there are two complete sheaths, dilators and guidewires in position from the condyles leading into the canal.

Note: Confirm positioning of the sheath assemblies medial and lateral via fluoroscopy.

Once their position has been confirmed, remove the dilator and guidewires from the sheaths leaving the two tear-away sheaths in position across the fracture site; one tear away sheath in the medial and lateral condyle. (Figure 19)



Fig 18

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

Open the individual 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.

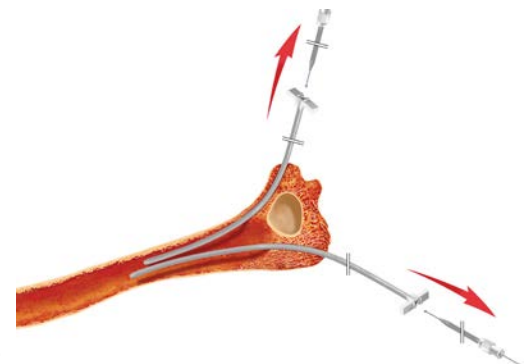


Fig 19

Balloon Catheter Preparation; Remove Air from the Catheter

Carefully remove the catheter assembly from the sterile package. Leave the white protective 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. (Figure 20)

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.



Fig 20

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. (Figure 21) 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 25 mm, exposing the front portion of the balloon. (Figure 22)

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. (Figure 23 A & 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 tip of the catheter.

Leave approximately 20mm of the protective tube on the 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 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 syringe. 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. (Figure 24)

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.

- 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 elimination of air and air bubbles 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.



Fig 21



Fig 22



Fig 23 A & B

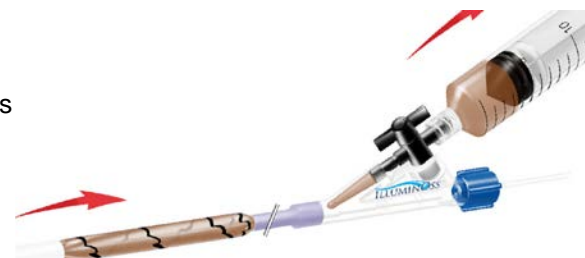


Fig 24

Placement of Balloon Implants; Insert the Balloon Catheter into Lateral 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 lateral condyle. (Figure 25)

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 during its delivery into the sheath as damage to the implant may occur.

Insert the Balloon Catheter into Medial Sheath

Remove the white protective tube from the previously prepared balloon catheter and introduce the balloon into the medial tear away sheath positioned in the medial condyle. (Figure 26)

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 support the length of the balloon catheter during insertion.

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

Remove Tearaway Sheaths

While holding on to one of the two balloon catheters in position within the canal, break the wings of the first tear away sheath, and slowly separate the sheath in half while withdrawing it from the canal, and discard the sheath. (Figure 27)

Repeat this process on the remaining sheath in the bone. (Figure 28)

The removal of the two sheaths leaves both of the balloons exposed within the canal. (Figure 29)

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

Enhanced stability to the distal segment can be achieved by extending the effective length of the implant, positioning the proximal aspect of the implant just at the surface of the condyle, so that the balloon extends from the intramedullary canal all the way to the created pathways.

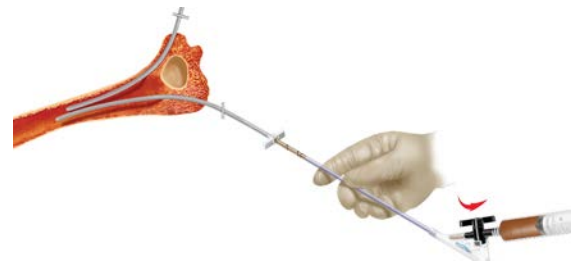


Fig 25



Fig 26

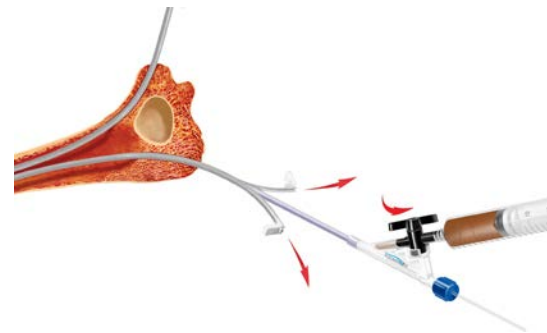


Fig 27

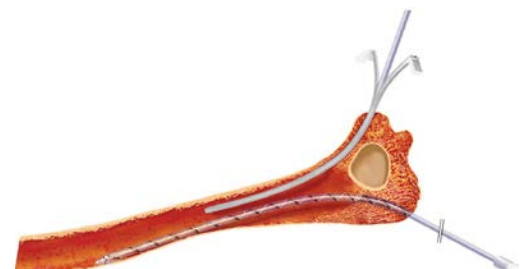


Fig 28

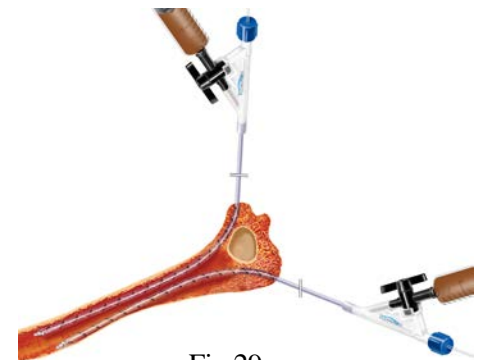


Fig 29

Infuse Balloons with Monomer Simultaneously

NOTE: To ensure that each implant is filled with monomer, and that one implant does not inadvertently preclude the filling of the other implant, both implants should be infused with monomer simultaneously.

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. (Figures 30 & 31)



Fig 30 & 31

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. (Figures 32 A & B)

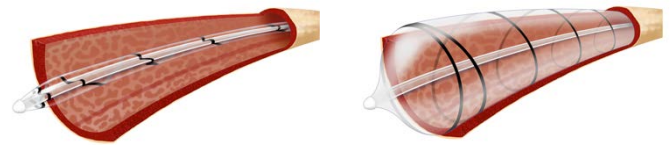


Fig 32 A & B

Once resistance is felt on the syringe plunger or it cannot be advanced any further close the black stopcock. (Figure 33)

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.

WARNING: 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.

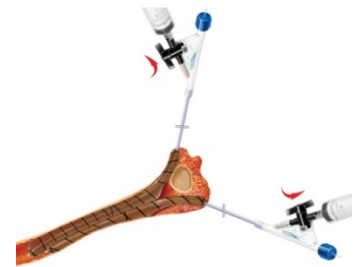


Fig 33

Handling of the Light Fiber and Implant Curing Cycle

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.



Fig 34

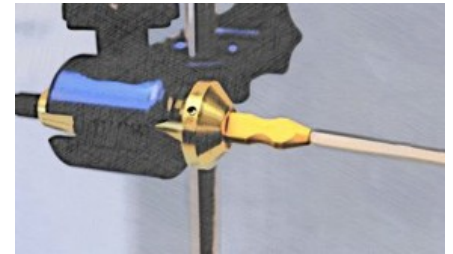


Fig 35

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. (Figure 34)

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. (Figure 35)



Fig 36 & 37

Insert the timer keycard into the slot on the front of the light box. (Figure 36)

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. (Figure 37)

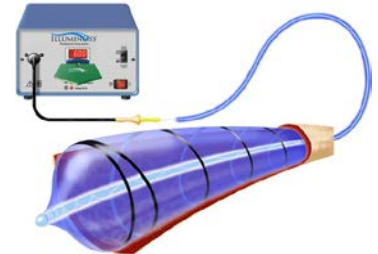


Fig 38

Activate the light source

Depress and release the foot pedal to initiate the light curing cycle. (Figure 38)

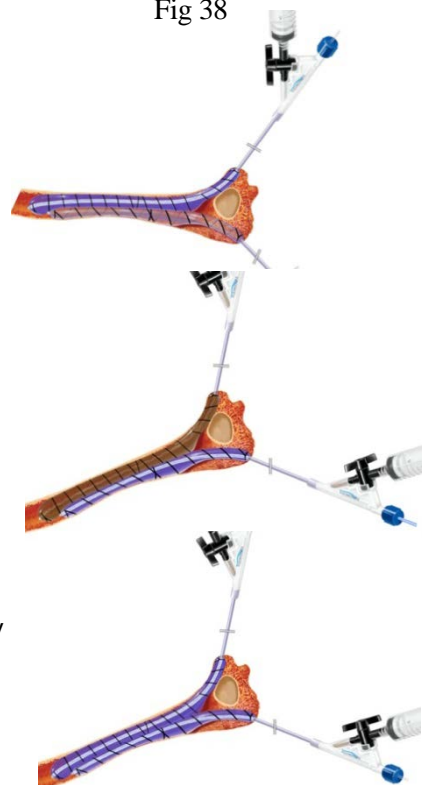
The system runs automatically and the timer counts down the residual time until the implant is cured.

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.

NOTE: Implants must be cured sequentially; if two implants have been used each implant must be cured individually if only one light box is available.

If two implants have been used, and there are two light boxes available, both implants may be cured at the same time.



Separation of Catheter from Implant

At completion of light cycle, unscrew the blue cap fitting and slowly remove light fiber from balloon catheter. (Figure 39)



Fig 39

Detach it from the light guide connector and discard it.

Using a pair of surgical scissors, cut braided catheter tubes (medial and lateral) immediately adjacent the distal Y-connector and discard Y connector. (Figures 40 A & B)

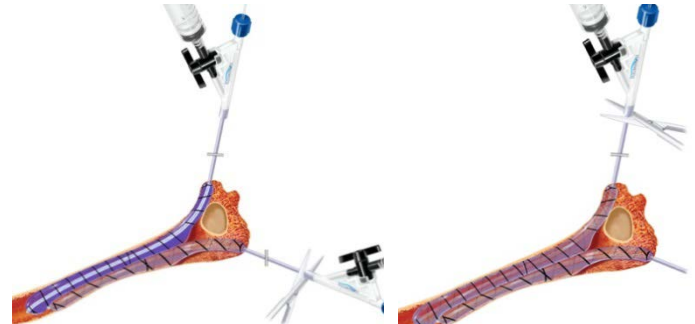


Fig 40 A & B

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

Rotate the stabilizer back and forth with moderately applied pressure to score the end of the PET balloon covering. (Figure 41)

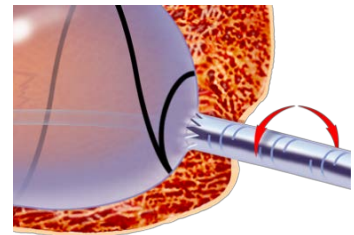


Fig 41

- 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 stabilizer. (Figure 43)

- Once the jaw tips of the separation slap hammer are over the catheter and adjacent to the stabilizer, push up on the handle lever to close the slap hammer causing the jaw tips to tighten and grip onto the catheter.

- 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. (Figure 44)

- Quickly move the hammer from distal to proximal in one quick, full, sharp stroke, separating the catheter from the implant. (Figure 45)

Remove the stabilizer from the incision and position it on the other catheter shaft and repeat the same procedural steps on the remaining implant.

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.

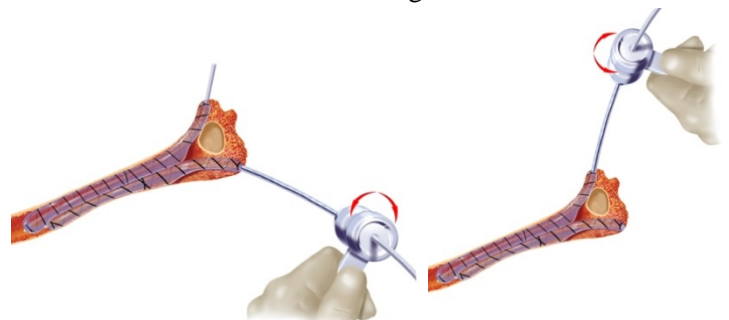


Fig 42 A & B



Fig 43

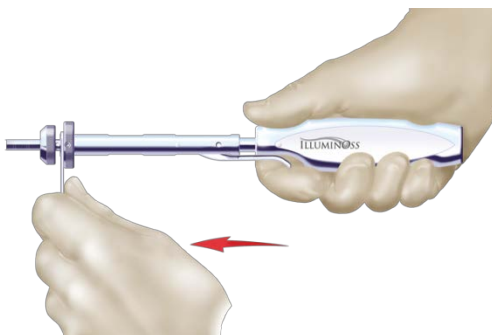


Fig 44

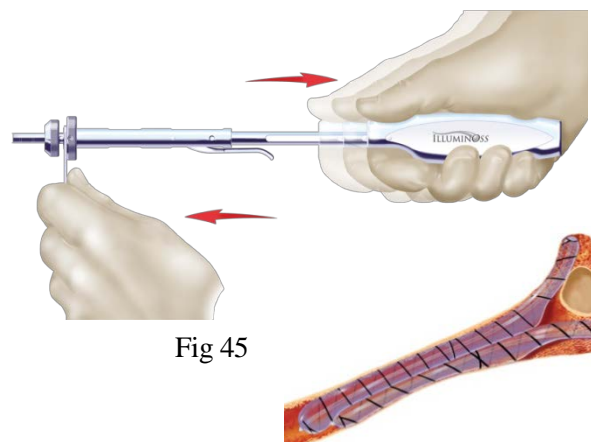


Fig 45

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 and immobilization as required (sterile dressing, forearm wrapped in an elastic bandage, soft cast or sling 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

1. Unpack the light box from the shipping container and place it on a stable table.
2. Remove the silver cap from the light guide mounting receptacle and discard.
3. Remove the light guide from the box and remove the red protective caps and discard them.
4. Attach the power cord to the power plug mount on the rear of the light box. Connect plug to wall power supply outlet.
5. 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

1. 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.
2. Ensure that the distance from the light guide (if attached to a pole clamp) is not further than ~ 4 ft. to the surgical site.
3. Turn on the unit by pressing the red power switch on the lower right front of the light box.
4. The unit will turn on and begin a self-diagnosis. The following displays will be illuminated on the faceplate:
 - A. 2000 in the illuminated timer.
 - B. 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.
 - C. 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.
 - D. And after about 4 minutes of system warm up, a green light on the System Ready will illuminate. (Figure 3)
5. 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).

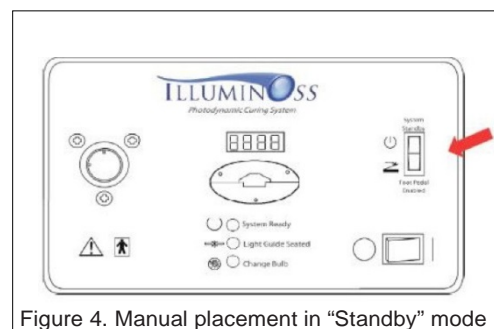
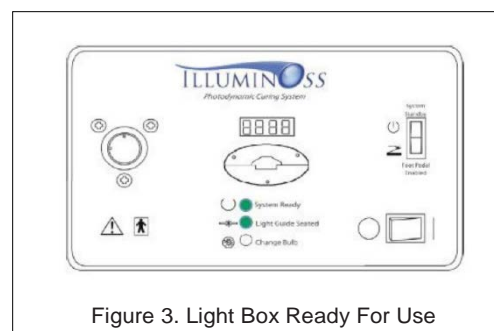
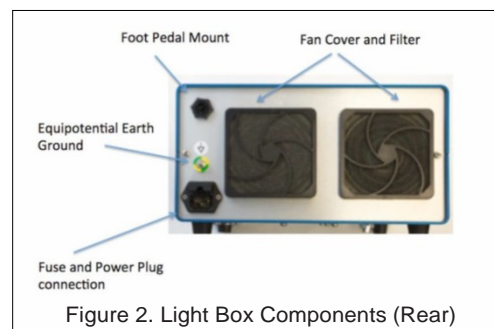
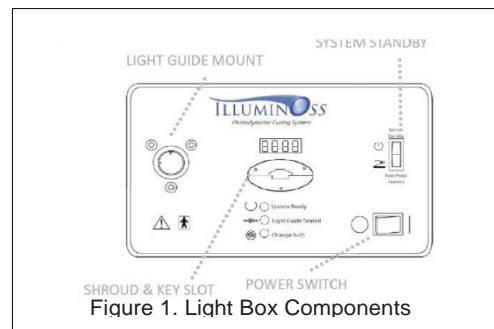
Set-up and activate the light box prior to the start of the procedure to ensure correct system operation.

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, and ulna. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with an FDA-cleared fracture fixation system to provide supplemental fixation in the humerus, radius and ulna.

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

<i>Part Number</i>	<i>Description</i>
CT-0109	2.5 MM STIFF GUIDEWIRE
05-0901	STRAIGHT AWL
CT-0129	6 MM CURVED CANNULATED AWL w/ OBTURATOR
CT-0131	FLEXIBLE SHAFT STABILIZER
CT-0239	4.5 MM FRONT CUTTING FLEXIBLE BURR *
CT-0240	4.5 MM SIDE CUTTING FLEXIBLE BURR *
CT-0241	5.5 MM SIDE CUTTING FLEXIBLE BURR *
CT-0242	6.5 MM SIDE CUTTING FLEXIBLE BURR *
CT-0196	SEPARATION SLAPHAMMER
CT-0188	FLEX STABILIZER *
CT-0186	SPARE FLEX STABILIZER TUBES *
CT-0203	8 MM SOLID AWL
CT-0267	8 MM CANNULATED STRAIGHT AWL
CT-0266	8 MM CANNULATED CURVED AWL
CT-0237	DRILL GUIDE 7 & 8 MM
CT-0205	2.0 MM STERILE BALL TIP GUIDEWIRE
CT-0243	1.2 MM STERILE BALL TIP GUIDEWIRE
CT-0207	GUIDEWIRE PUSHER ROD
CT-0230	16 MM HEAD REAMER
CT-0231	18 MM HEAD REAMER
CT-0232	20 MM HEAD REAMER
CT-0233	22 MM HEAD REAMER
CT-0225	6.0 MM FLEX REAMER, FIXED HEAD *
CT-0226	6.5 MM FLEX REAMER, FIXED HEAD *
CT-0227	7.0 MM FLEX REAMER, FIXED HEAD *
CT-0228	7.5 MM FLEX REAMER, FIXED HEAD *
CT-0229	8.0 MM FLEX REAMER, FIXED HEAD *
CT-0235	RADIOGRAPHIC RULER
CT-0215	DRILL BIT-7.0 MM *
CT-0216	DRILL BIT-8.0 MM *
CT-0206	T HANDLE
CT-0268	CANAL DEPTH GAGE
CT-0270	T HANDLE REDUCER

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)
USSL-0700160	7mm x 160mm Photodynamic Bone Stabilization Procedure Pack	7	300
USSL-0700200	7mm x 200mm Photodynamic Bone Stabilization Procedure Pack	9	300
USSL-0900160	9mm x 160mm Photodynamic Bone Stabilization Procedure Pack	11	400
USSL-0900180	9mm x 180mm Photodynamic Bone Stabilization Procedure Pack	13	400
USSL-0900220	9mm x 220mm Photodynamic Bone Stabilization Procedure Pack	15	400
USSL-1100160	11mm x 160mm Photodynamic Bone Stabilization Procedure Pack	16	500
USSL-1100180	11mm x 180mm Photodynamic Bone Stabilization Procedure Pack	18	500
USSL-1100220	11mm x 220mm Photodynamic Bone Stabilization Procedure Pack	21	500
USML-1310070	13/10mm x 70mm Photodynamic Bone Stabilization Procedure Pack	7	500
USML-1310090	13/10mm x 90mm Photodynamic Bone Stabilization Procedure Pack	9	600
USML-1310120	13/10mm x 120mm Photodynamic Bone Stabilization Procedure Pack	12	600
USSL-1500180	15mm x 180mm Photodynamic Bone Stabilization Procedure Pack	33	700
USSL-1500220	15mm x 220mm Photodynamic Bone Stabilization Procedure Pack	40	700
USSL-1500260	15mm x 260mm Photodynamic Bone Stabilization Procedure Pack	46	800
USSL-1500280	15mm x 280mm Photodynamic Bone Stabilization Procedure Pack	49	800
USSL-1700180	17mm x 180mm Photodynamic Bone Stabilization Procedure Pack	42	800
USSL-1700220	17mm x 220mm Photodynamic Bone Stabilization Procedure Pack	51	800
USSL-1700260	17mm x 260mm Photodynamic Bone Stabilization Procedure Pack	60	1000
USSL-1700280	17mm x 280mm Photodynamic Bone Stabilization Procedure Pack	65	1000
USSL-1822080	18/22mm x 80mm Photodynamic Bone Stabilization Procedure Pack	26	600
USSL-1822090	18/22mm x 90mm Photodynamic Bone Stabilization Procedure Pack	31	700
USSL-2213140	22/13mm x 140mm Photodynamic Bone Stabilization Procedure Pack	46	800
USSL-2213160	22/13mm x 160mm Photodynamic Bone Stabilization Procedure Pack	51	800
USSL-2213220	22/13mm x 220mm Photodynamic Bone Stabilization Procedure Pack	60	1000
USSL-2213240	22/13mm x 240mm Photodynamic Bone Stabilization Procedure Pack	58	1000
USSL-2213260	22/13mm x 260mm Photodynamic Bone Stabilization Procedure Pack	60	1000
Guidewires			
Catalog Number	Description	Packaged	Units
CT-0205-01	2.0mm Ball Tip Guidewire	Sterile	5 pack
CT-0243-01	1.2mm Ball Tip Guidewire	Sterile	5 pack
CT-0200-01	1.0mm Ball Tip Guidewire	Sterile	5 pack
Sheaths & Dilators			
Catalog Number	Description	Packaged	Units
CT-0264-01	7.0mm Introducer Sheath & Dilator	Sterile	1 unit each
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			
Catalog Number	Description	Packaged	Units
CT-0300-01	20ml Monomer Vial Pouch	Sterile	1 unit



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