ILLUMINOSS®

Fracture repair at the speed of light

Humerus Surgical Technique

Quick Reference Guide

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.

About IlluminOss

IlluminOss Medical, produces minimally invasive conforming orthopedic implants leveraging it's proprietary bone stabilization technology, the IlluminOss System. Through the unique combination of balloons, light activated monomers and flexible catheters, IlluminOss has created the world's first patient conforming intramedullary implant. The IlluminOss System has been used successfully in international markets for a wide variety of clinical indications since 2010.

Technology

IlluminOss' minimally invasive procedure incorporates a PET or Dacron® balloon catheter that is delivered through a small pathway into the intramedullary canal transiting the fracture site. Using a standard syringe, IlluminOss' light activated, bio-compatible monomer is infused into the balloon, causing it to expand, fill and conform to the patients intramedullary canal. Only upon the activation of IlluminOss' visible light source (436NM) will the monomer infused into the balloon begin to cure. The cured implant stabilizes the fracture and provides both longitudinal strength and rotational stability to the affected bone.

Note: The following document does not attempt to discern between different types of cancers, locations , and treatment options associated with specific disease states or fracture patterns . The information should not constrain the surgeon 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.

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. The IlluminOss implant can be used for either the left or the right humerus.

The Quick Reference Guide provides the user with a generalized overview to the steps and techniques used in the delivery and creation of an IlluminOss Implant. For a complete review and greater understanding of all of the specific steps associated with the IlluminOss device* rfc nmqgrgm l g l e _ l b qcr sn md rfc Jge fr @mv* _ jgqrg l e md rfc qspega_j g l qrps k c l rq _q ucjj _q jgosgb k m l m k cp pc k mt_j rcaf l goscq* njc_qc pcdcp rm rfc Qspega_j Rcaf l gosc Esgbc &0. /7' Nfmrmbw l _ kga @m l c Qr_ `gjgx_rgm l Qwqrc k\* N_pr Ls k `cp 7 . . 3 / .]@

Preoperative Set Up

- Ensure that the IlluminOss delivery and humerus specific instrumentation has been sterilized and is delivered to the OR.
- Ensure that a sufficient range of IlluminOss implant sizes are brought to the OR.
- Set-up and activate the light box prior to start of the procedure to confirm operative status [1].

Note: The light box must be set-up outside the sterile field and on the same side as the target Humerus nearest to pathway being made into the humerus the of the patient.

- Example: if the approach is being made from the shoulder have the light box nearest to the head or shoulder of the patient. If the approach is being made via the elbow have the light box more to the middle of the patient.
- The light guide is not sterile it remains outside of the surgical field.
- The light fiber is a predetermined length and cannot be stretched. Ensure that the light box is close enough to make the connection.

[1] Appendix A: Light Box Set-Up instructions for use-part #900093

Implant Sizes

The IlluminOss humeral implants range in diameters from 15mm to 22mm and in lengths from 160mm to 280mm.

Diameter	Length
15mm	**180mm**
15mm	**220mm**
15mm	**260mm**
15mm	**280mm**
17mm	**180mm**
17mm	**220mm**
17mm	**260mm**
17mm	**280mm**
22/13mm	**160mm**
22/13mm	**220mm**
22/13mm	**240mm**
22/13mm	**260mm**

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 during the operative process.

- In cases of impending fracture the approximate implant length may be determined pre-operatively.
- If the arm is fractured, the correct length can only be determined if the fracture is correctly reduced.
- Position the image intensifier for an AP and Lateral views of the humerus.
- Measure the length of the humerus from its head to the olecranon fossa and deduct 3cm from the measured distance.
- Hold a radiographic ruler parallel to the humerus with one end at the proximal humerus and mark the skin at the proximal end of the ruler.
- Position the image intensifier over the distal humerus , place the proximal end of the ruler next to the marked skin site and record an AP image.
- Alternatively utilizing pre operative films, and x-ray measurement programs, can be made in accord with the individual's x-ray systems.

Determining Implant Diameter

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

Note: 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. Alternatively utilizing pre-operative radiographic films, and embedded software in the x ray programs, measurements for the implant length and diameter can be made in accord with the individual's x-ray systems.
Warning: 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.

[2] Appendix B: Maximum monomer for IlluminOss implants and cure times.

Patient Positioning

Position the patient in a supine position, or with the upper body raised at an angle of ~30° and support the shoulder with pads.

Note: The operating table must be radiolucent in the shoulder area, or else it should be possible to remove the corresponding table section. The whole upper arm, including the elbow and humeral head, must be visualized in two planes using the image intensifier.

Surgical Approach

The attached is a generic surgical approach and is provided only as an illustration of an IlluminOss Implant being inserted in an antegrade manner. The antegrade delivery and implantation of IlluminOss in the humerus is made through a lateral deltoid splitting incision.

A 2-3cm incision is made from the edge of the acromion to the edge of the head of humerus, anterolateral to the tip of the acromion. The deltoid is divided down to the sub-deltoid bursa. The deltoid muscle is then retracted. Visualize the rotator cuff insertion into the greater tuberosity. The biceps tendon is palpated anteriorly. Entry portal is made just medial to the tendon insertion and centered midway between the biceps groove anteriorly and the posterior humeral head.

The information should not constrain the surgeon 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 IlluminOss product.

Create Initial Pathway With Straight Awl

Place the awl at the junction of the articular cartilage and the greater tuberosity. Check the position with A/P and lateral views. When the correct position is achieved, rotate the awl to create an initial entry portal (Figure 1).

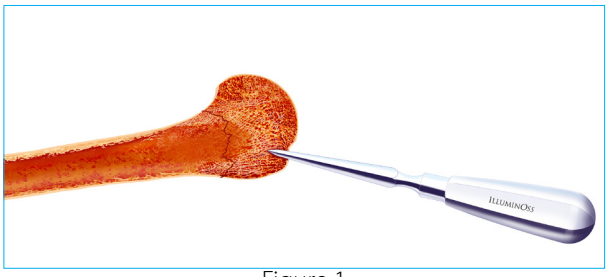

Figure 1

Insert 8.0mm Curved Awl Into Pathway

Insert the 8.0mm solid curved awl fully into the bone to enlarge the pathway up to 8.0mm (Figure 2).

Note: The pathway into the canal must be large enough to accommodate the 7.0mm diameter delivery sheath and dilator for the balloon catheter. The curved awl is tapered and can create a pathway up to 8.0mm in diameter.

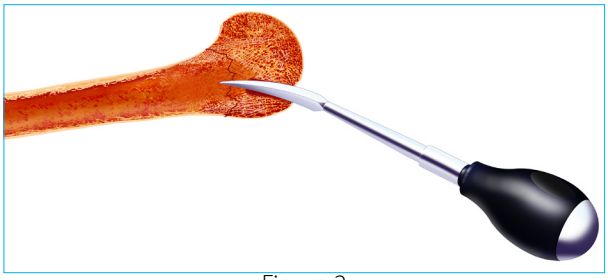
Figure 2

Head Reaming

Curved head reamers are provided if proximal or metaphyseal aspects of the affected humerus require additional reaming to enlarge the intramedullary space. The curved head reamers are specifically designed for the removal of cancellous bone or other soft particulate within the aspects of the humerus (Figure 3). The curved head reamers come in four different sizes 16mm, 18mm, 20mm, and 22mm.

Attach the curved head reamer to the T-handle. Insert the curved aspect of the instrument through the pathway accessing the proximal aspect of humeral canal. Rotate the T-handle in a back and forth manner frequently changing the orientation of the instrument within the desired location to achieve the desired reaming effect.

Note: Surgeons should start with the smallest sized curved head reamer (16mm) and continue to use sequentially larger curved head reamers (18, 20, & 22) until the desired size and shape has been achieved.

Warning: Should the clinical indication deem that high speed burring of the bone is necessary it should be done prior to the insertion and or placement of the IlluminOss Implant to protect the balloon from errant contact with the burr head.

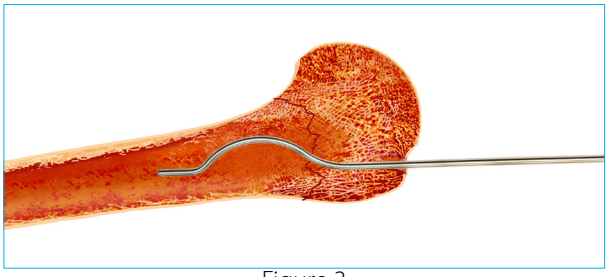

Figure 3

Insert The Guide Wire Into The Canal

Once the curved awl reaches the midline of the intramedullary canal it is in position to provide access and the introduction of a 2.0mm ball tip guidewire into the canal (Figure 4). Advance the guidewire so it spans the fracture, verify fracture reduction and the position of the guidewire in both A/P and lateral views with imaging equipment.

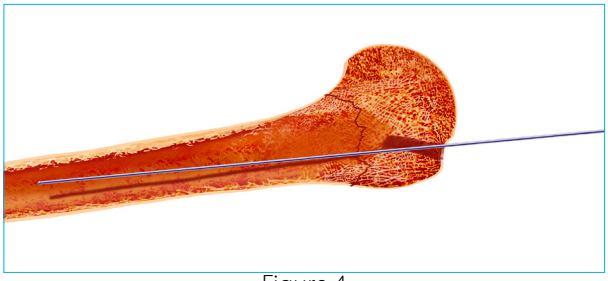

Figure 4

Preparation Of The Canal

Using manual reduction and fluoroscopic imaging align bone fragments if necessary to assist in canal preparation. Utilize the IlluminOss flexible cannulated reamers (6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm) over the 2.0mm ball tip guidewire to clean the canal and provide proper space for delivery of the implant (Figure 5). Start with the smallest diameter reamer mounted on either a power drill or T-Handle and prepare the desired length of the canal with the reamer. Reaming is commenced in 0.5mm increments to achieve a minimum diameter of 8.0mm within the canal of the bone.

Verify fracture reduction and the position of the guide wire in both A/P and Lateral views with imaging equipment. After completion of the reaming process, remove the cannulated reamer from the intramedullary canal and leave the 2.0mm ball tip guidewire in place across the fracture.

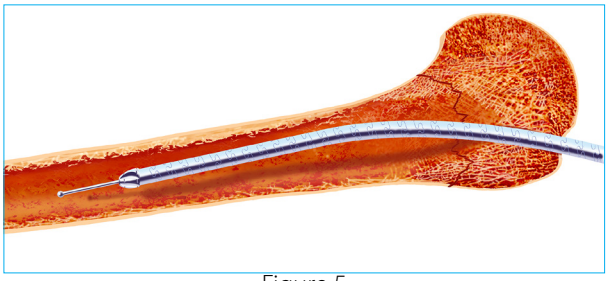

Figure 5

Preparation Of The Canal (Cont)

Note: If an internal diameter of 7.0mm cannot be achieved with the use of the burrs, the delivery sheath cannot be delivered into the canal, and the use of the IlluminOss implant is contraindicated.

Warning: If other orthopedic reamers are utilized in the preparation of the medullary canal, to ensure adequate bone stability, when the canal has been reamed do not use an IlluminOss implant with a diameter smaller than the largest reamer used.

Note: Select the desired implant size.

Insert Dilator & Sheath

Insert the dilator into the tear away sheath assembly over the guide wire. Verify guide wire position in the canal on both sides of the fracture. Insert the dilator and tear away sheath assembly into the intramedullary canal by sliding it over guidewire across fracture site (Figure 6).Confirm positioning of the sheath assembly via fluoroscopy.

Note: The sheath and dilator may be manually bent and curved to assist in delivery.

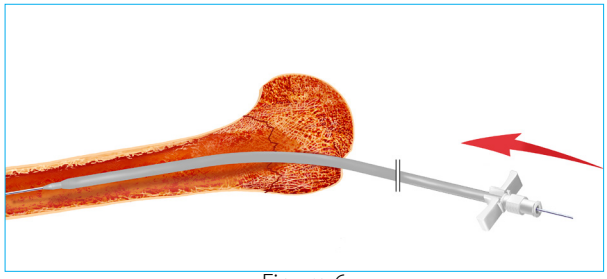

Figure 6

Remove Dilator & Guide Wire

Remove the dilator and guidewire, leaving the tear away sheath assembly in place across the fracture site (Figure 7).

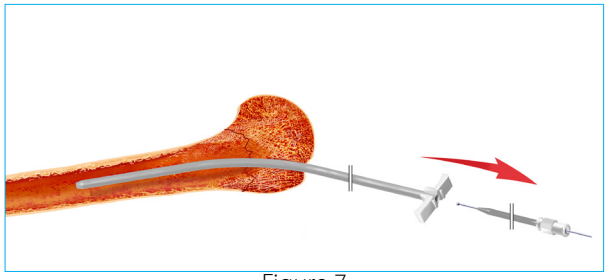

Figure 7

Remove Air From Catheter

Carefully remove the catheter assembly from the sterile packaging. Leave the protective tube covering the balloon in place as this will assist in the priming preparation 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 with the syringe, and then close the stopcock to maintain the vacuum (Figure 8). Detach syringe from stopcock luer and expel any collected air out of the syringe. Repeat this process to ensure all air has been removed from the balloon catheter. Close the luer to maintain the vacuum within the implant.

Note: If a vacuum cannot be achieved with a specific implant, it may have been compromised in some fashion. Do not use an implant that will not hold a vacuum. Discard that implant and replace it with a new sterile implant.

Figure 8

Transfer Of Monomer Into Syringe

Remove the blue cap from the monomer vial and insert the transfer spike into the top of the vial. Attach the syringe to the transfer spike and, turn assembly over, and slowly draw the monomer into it the syringe (Figure 9). Consolidate any air bubbles and expel any residual air from the syringe.

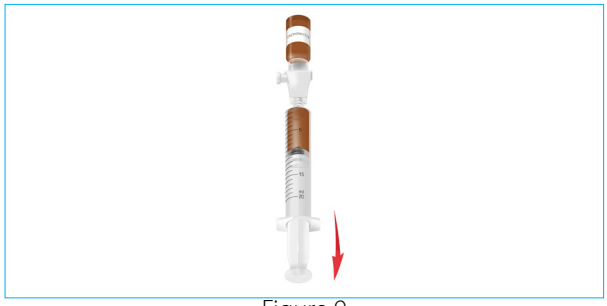

Figure 9

Prime Distal End Of Balloon

Attach the syringe containing the monomer to the closed stopcock luer. Slide the protective tube covering the balloon back towards the syringe about 15mm, exposing the front portion of the balloon (Figure 10).

Figure 10

Open the stopcock valve on the catheter, where the residual vacuum will pull and infuse monomer slowly into the catheter. Apply some pressure to the plunger on the syringe for several seconds, the monomer will travel the entire length of the balloon catheter. The tip of the exposed balloon beyond the protective tube shall start to slightly expand in diameter (Figure 11).

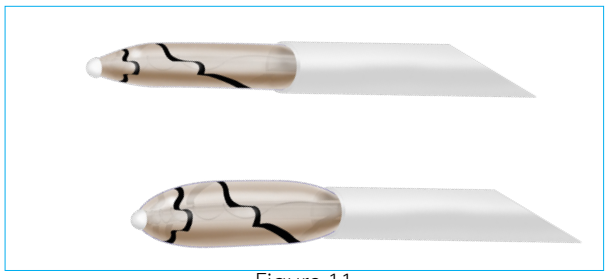

Figure 11

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

Prime The Proximal End Of Balloon

When sufficient monomer has been withdrawn from the distal end of the balloon, causing the balloon to deflate, the 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 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 on the syringe plunger. With two fingers on the outside of the balloon gently advance in a wiping motion the monomer forward towards the distal tip. Pull a vacuum on the syringe again and at the same time gently pull the protective tube back towards the syringe into position covering the entire balloon (Figure 12).

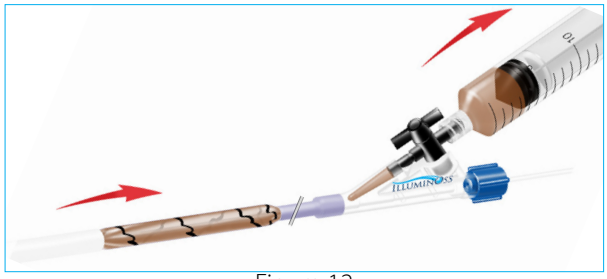

Figure 12

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

Note: Do not attempt to fully inflate the balloon as it may be difficult to fully deflate and reinsert into the tube. The purpose of this step is to deliver monomer into the central section of the implant and to withdraw any residual air or air bubbles from the implant.

Warning: Do not attempt to perform the balloon catheter preparation within the medullary canal.

Insert Balloon Catheter Into Sheath

Remove the protective tube from the balloon catheter and introduce the prepared balloon into the tear away sheath previously positioned in the intramedullary canal (Figure 13). For proper position use fluoroscopy, ensuring that the fracture reduction has been maintained and the sheath is still spanning the fracture site (Figure 14).

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.

Note: A spiral radiopaque marker stripe of about 1.0mm width has been applied to the outside circumference of the implant. The radiopaque marker is used to provide positioning guidance for the implant within the medullary canal and to provide the surgeon with a visual cue towards the position of the implant within the canal as well as the relative size of the inflated implant.

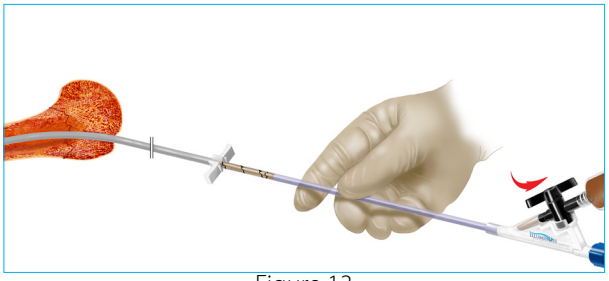

Figure 13

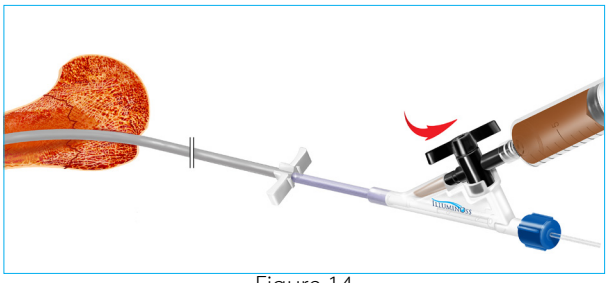

Figure 14

Remove Tear Away Sheath

While holding the balloon catheter in position, break the wings of the tear away sheath and slowly separate the sheath in half while withdrawing it from the canal. Remove the entire sheath and discard (Figure 15). The removal of the sheath leaves the balloon exposed within the canal (Figure 16). Use fluoroscopy to confirm the position of the balloon spanning the fracture site and ensure the fracture remains sufficiently reduced. Minor adjustments to the balloon position may be required.

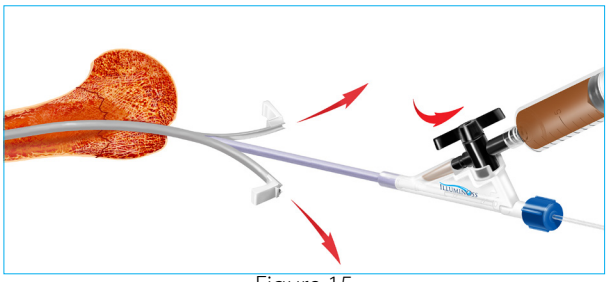

Figure 15

Infuse Balloon With Monomer

Using the syringes provided along with the vented spike, transfer monomer from the vials as needed. Infuse the monomer from the attached 20cc syringe by opening valve and applying moderate pressure to syringe plunger (Figure 17).

Once resistance is felt on the syringe plunger, or it cannot be advanced any further, close the stopcock valve. Reconfirm fracture alignment with fluoroscopy. Multiple vials of monomer may have to be opened to achieve a fully filled implant. Leave the syringe attached to the catheter.

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 with the syringe to disengage it from contact with the cortex of the canal. Carefully reposition balloon or reduce the fracture. Attempts at repositioning a fully filled balloon may cause damage to the implant.

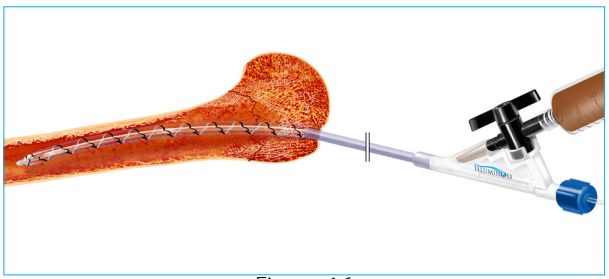

Figure 16

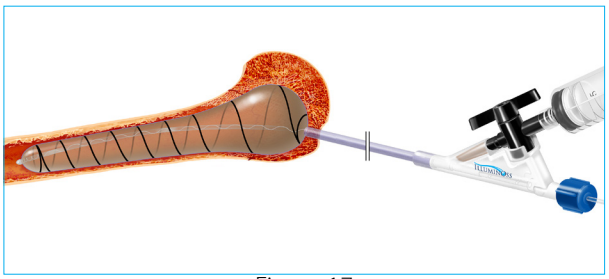

Figure 17

Confirm Proper Position Of Light Fiber

Check light fiber to ensure depth stop abuts the blue cap fitting on proximal end of catheter and that blue cap fitting is tightened snugly around the light fiber (Figure 18).

Figure 18

Photodynamic Curing Process

Remove the end of the light fiber, from the 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 19). Insert the timer key into the slot on the front of the light box. Ensure the timer changes to the prescribed time shown on the timer key (Figure 19).Toggle the foot pedal switch on the front of the light box from the "standby" position to the "enabled" position .

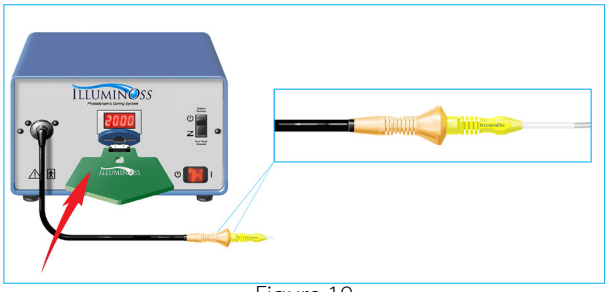

Figure 19

Note: Ensure that the proper timer key is being used by comparing timer key setting to the setting on the timer key flag located on the light fiber tether.

Depress and release the foot pedal to initiate the light curing cycle of the implant. This will open the shutter on the light box and the polymerization process will be activated (Figure 20).

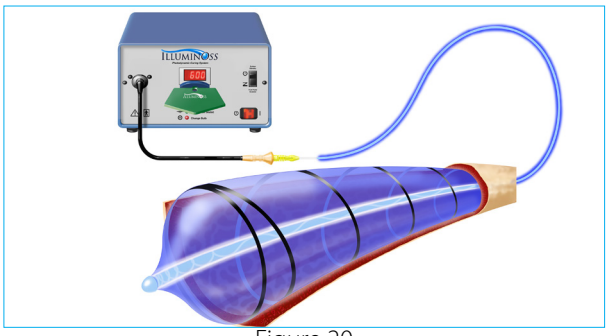

Figure 20

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

Caution: Do not stop the curing process or remove the light fiber prior to the completion of the curing cycle.

Remove Light Fiber

At completion of light cycle, unscrew the blue cap fitting and slowly remove light fiber from balloon catheter (Figure 21). Detach it from the light guide connector and discard it.

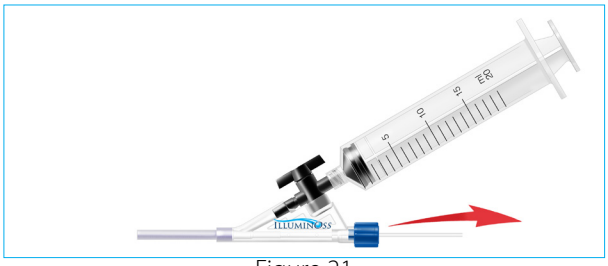

Figure 21

Cut Catheter

Using a pair of surgical scissors, cut the braided catheter tube immediately distal to the Y-connector and then discard (Figure 22).

Note: Cutting the braided catheter shorter than the described above will cause difficulty in separating it from the implant.

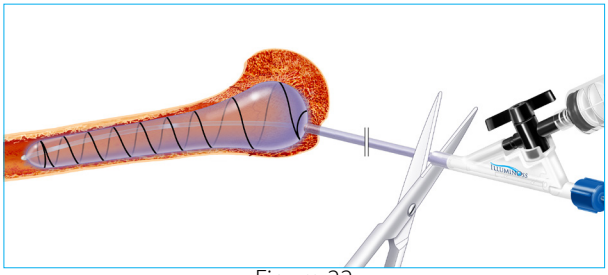

Figure 22

Place Stabilizer Over Catheter

Slide the stabilizer over the catheter shaft, advance it forward to contact the proximal end of the implant (Figure 23).Use fluoroscopic imaging to ensure that the serrated end of the instrument is in close contact the proximal end of the implant (Figure 23). Approximately 50mm of the catheter should protrude from the knob on the stabilizer. Rotate the stabilizer knob back and forth several times while applying moderate pressure to the stabilizer to score the end of the PET balloon.

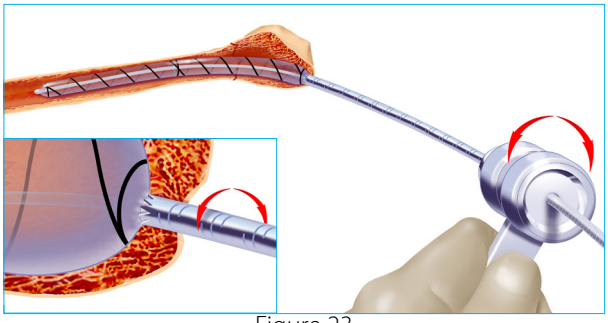

Figure 23

Attach Slap Hammer To Stabilizer

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. Once the jaw tips are over the catheter, push up on the handle lever to close the slap hammer causing the jaw tips to tighten and grip onto the catheter (Figure 24).

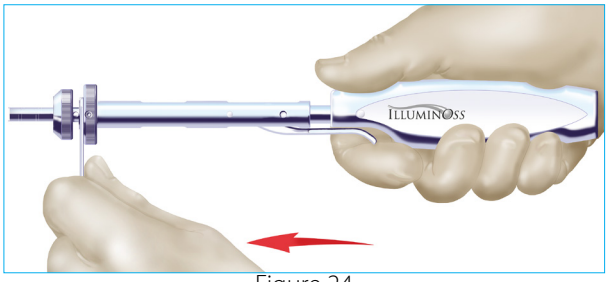

Figure 24

Removal Of Catheter From Implant

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. Quickly move the hammer from distal to proximal in one quick full, sharp stroke, separating the catheter from the implant (Figure 25). Remove the stabilizer from the incision. Evaluate the fixation and deployment of the IlluminOss implant in both AP and Lateral radiographic views.

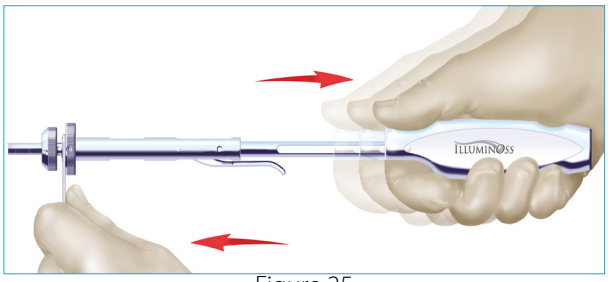

Figure 25

Implant Provides Strength & Stability

The implant provides longitudinal strength and rotational stability over the length of the implant (Figure 26). Screws and plates can be used in conjunction anywhere along the length of 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.

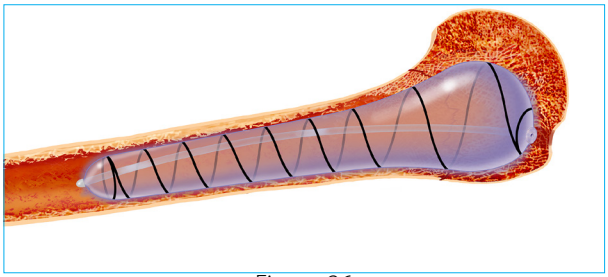

Figure 26

Appendix A: Light Box Setup

Positioning Of Light Box

Unpack the light box from the shipping container and place it on a stable table (Figure 27). Determine an appropriate position for the IlluminOss Light box. Make certain that the light box is convenient to the operating table to reach the surgical site, preferably on the side of the patient that is being treated. Ensure that the distance from the light guide (if attached to a pole clamp) is not further than ~4 ft to the surgical site.

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

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

Figure 27

Connecting Power Cord & Foot Pedal

Remove the silver cap from the light guide mount 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 (Figure 28). 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 (Figure 28). Stepping on or depressing the foot pedal will cause a light clicking noise, which is the activation of the shutter.

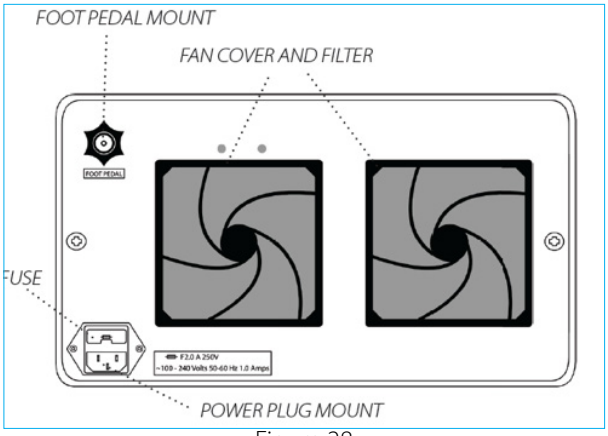

Figure 28

Light Box Self Diagnosis

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. Once the self diagnosis is performed, the LED screen on the light box will display "2000" (Figure 29).

Figure 29

Insert Light Guide

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, which indicates that it was properly inserted (Figure 30). If the light guide is not fully inserted, light guide seated light will not be illuminated, and the system cannot be activated.

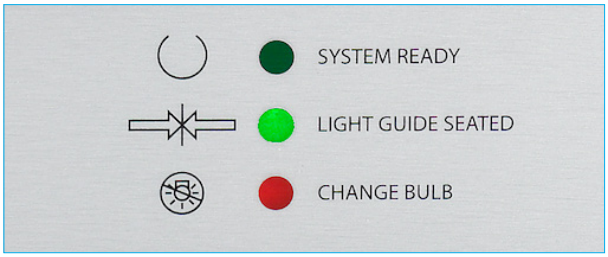

Figure 30

Appendix A: Light Box Setup

System Ready

After about 4 minutes of system warm up, the green light next to the "system ready" will illuminate (Figure 31). If not ready for use the system may be manually placed the into "Standby" mode which turns off the foot pedal and prevents accidental activation of the light source (Figure 32).

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.

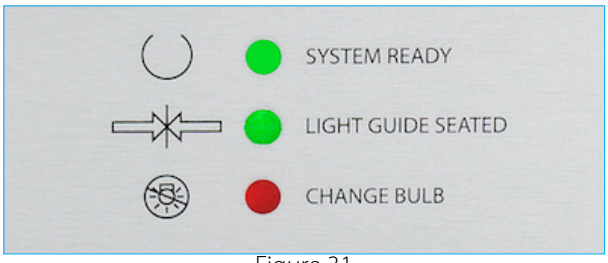

Figure 31

Figure 32

Prior to use, please see the complete "Directions for Use" and "Surgical Technique Guide" for more information on Indications, contraindications, Warnings, Precautions, Adverse Events, and Operator Instructions.

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.

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 6.5 mm 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 resterilize the disposable components. Discard and do not use opened or damaged packages. Do not use if there is a loss of sterility of the polymer or other kit components. Do not utilize any component after the expiration date. Correct selection of the implant diameter and length is extremely important, 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 polymer necessary to accomplish the appropriate inflation are provided. The balloon is made of a non-compliant, thin walled PET and does not expand larger than its prescribed size. Do not add any material or fluids to the polymer. Do not expose polymer to any light source other than the IlluminOss Photodynamic Curing System, shield the polymer from light after removal from vial. If, upon fluoroscopic examination, the user determines that the inflated balloon is not in contact with the intramedullary canal of the bone, the user should remove the balloon prior to curing the polymer, reassess sizing, and replace it with the appropriately sized balloon. Do not activate the light source until the balloon catheter is in the appropriate position and the bone fracture is reduced and ready for stabilization. Activation of the light source in the presence of the polymer will initiate polymerization, an irreversible process. The polymer must be exposed to the IlluminOss Photodynamic Curing System for a specific amount of time in order to activate and fully cure the implant. A partially cured implant cannot be used to complete a procedure. If a uncured, or partially cured implant is suspected, or if a curing cycle is interrupted, additional curing cycles should be completed Inadequate postoperative fixation or unanticipated postoperative events may affect the interface between the bone and stabilization balloon, which may lead to micro-motion of the implanted balloon and balloon surface. Periodic follow up examinations and radiographs are advised for all patients. Deep wound infection is a serious postoperative complication and may require total removal of the stabilization system and embedded polymer. Deep wound infection may be latent and not manifest itself for several years post-operatively.

Risks: As with any IM fixation system or rod the following can occur: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to delayed union, nonunion, insufficient quantity or quality of bone or markedly unstable comminuted fractures loss of anatomic position with nonunion or malunion with rotation or angulation.

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