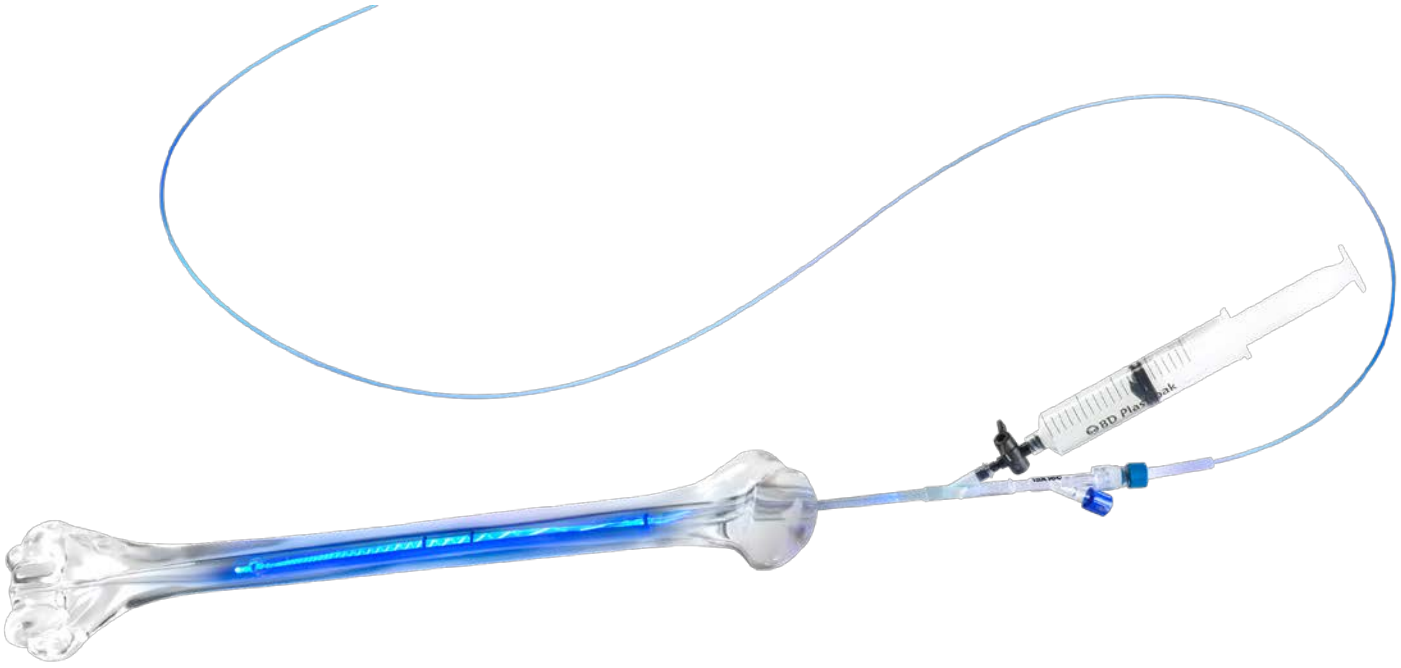
ILLUMINOSS®

Fracture repair at the speed of light

Surgical Technique Guide

Humerus, Radius & Ulna



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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.

1. 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 humerus, radius and ulna.

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.*

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

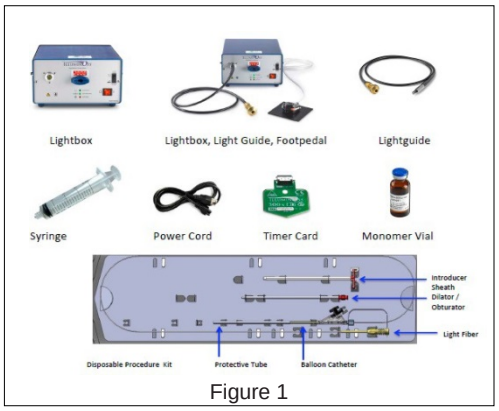


Figure 1

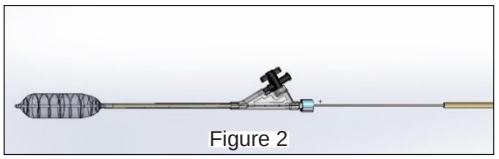


Figure 2

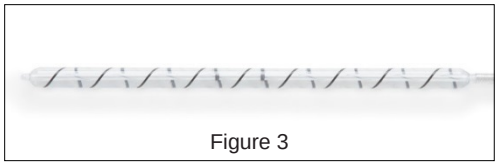


Figure 3

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 17.

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.

2. 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 Sizing

Implant sizing may be done pre-operatively or after the start of the procedure.

Determine Implant Length

In cases of impending fracture the approximate implant length can 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 A/P view of the humerus, radius or ulna.

For Humerus:

- Measure the length of the humerus from its head to the olecranon fossa and deduct 3 cm from the measured distance.
- Hold a radiographic ruler parallel to the humerus with one end at the proximal humerus. 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 A/P image.

For Radius & Ulna:

- Measure the radius from the radial styloid to the fracture site**.**
- Measure the ulna from the entry point to the fracture**.**
- Check the reduction and read off the length from the illustration on the ruler.

Determine Implant Diameter

- Position the image intensifier for views of the affected bone in two planes.
- It is important to view and to measure the bone in two planes so that the largest diameter of the canal can accurately be determined and the correct sized implant chosen.
- An undersized implant not achieving circumferential cortical contact will not be stable.
- Hold the ruler parallel at right angles to the affected bone while positioned over the medullary canal.
- Select the implant diameter sufficient to fill and to achieve contact with the medullary canal/cortex.
- 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 accordance with the individual's x-ray systems.

General Consideration Points

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

Humerus

Patient Positioning & Surgical Approach

For purposes of illustration, a proximal humeral lesion (Figure 4) is described. The Humerus is approached through a minimally invasive deltoid incision to allow for the delivery of an 8 mm cannulated awl to access the canal (Figure 5).

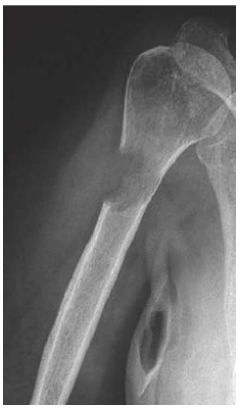


Figure 4

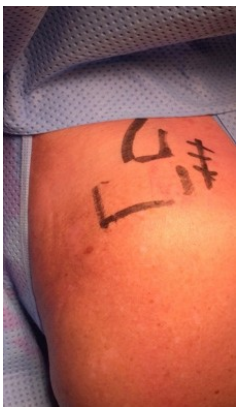


Figure 5

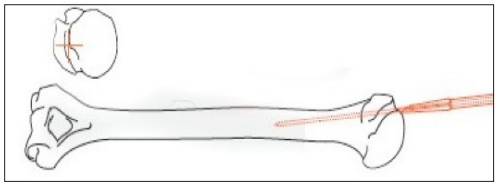
A. Humerus

Fracture Reduction, Incision & Anatomical Landmarks

- Use of reduction clamps to achieve and maintain anatomical reduction of the fracture is recommended in complex fracture patterns.
- Make the initial minimally invasive stab incision to allow for the delivery of an 8mm cannulated awl into the head of the proximal humerus.
- Alternatively make an incision anterolateral to the acromion process and split the deltoid muscle longitudinally.
- The deltoid is split to expose the sub deltoid bursa.
- The supraspinatus tendon is then incised in line with its fibers.
- Palpate the greater tuberosity, identify but do not expose the supraspinatus tendon and split the mid-section lengthwise.
- The antegrade insertion point for the IlluminOss implant is located on the extended axis of the central humeral shaft at the bone cartilage transition of the humeral head and not on the greater tuberosity; otherwise the tendon attachment of the supraspinatus will be affected.
- With the humeral head correctly positioned, the point is located just in front of, or below, the tip of the acromion process. The surgeon may find this position with the use of an image intensifier using a Kirschner Wire or other similar type instrument.
- The orientation between an excessively ventral or dorsal position of the Kirschner wire can be determined where the line of the humeral head intersects the Kirschner wire. The Kirschner wire is located in the desired position if it rests in the middle of the humeral head (Figures 6 and 7).

NOTE: Avoid any additional injury to the rotator cuff at all costs. The arm can be adducted across the chest in order to gain better access to the proximal humerus.

NOTE: As the IlluminOss catheter is flexible, a more lateral approach and delivery of the sheath into the canal may be made to further spare the rotator cuff.



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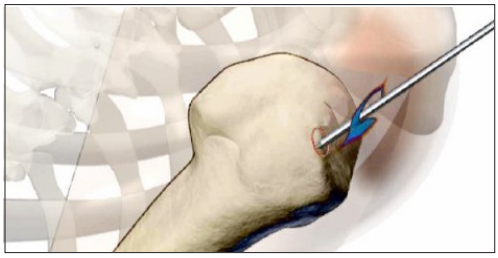
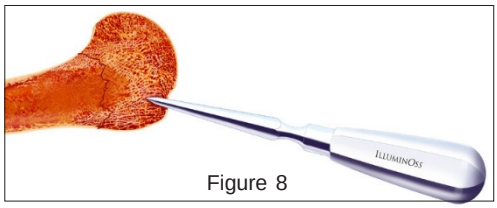


Figure 7

Creating the Entry Portal & Pathway

- 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 8).
- Once the initial pathway to the canal has been created, it should be enlarged by using the curved awl in a +/- 30-degree rotating motion to advance it into the IM canal. (Figure 9)
- **NOTE:** The pathway into the canal must be large enough to accommodate the diameter delivery sheath provided for the balloon catheter. The curved awl is tapered and can create a pathway up to 8mm in diameter.
- Once the awl reaches the midline of the IM canal it is in position to provide access and for the introduction of a 2.0 mm (or 1.2 mm with the 5.5mm sheath) ball tip guidewire into the canal (Figure 10).
- Advance the guidewire so it spans the fracture site.
- Verify fracture reduction and the position of the guidewire in both A/P and lateral views with imaging equipment.



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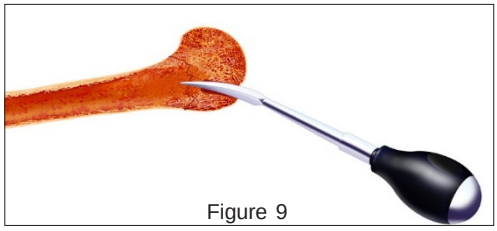


Figure 9

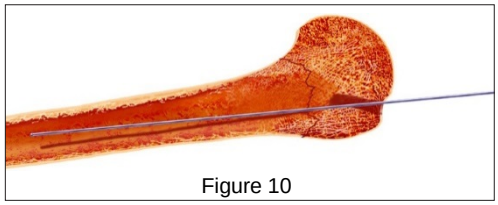


Figure 10

Canal Preparation

- Using manual reduction and fluoroscopic imaging align bone fragments if necessary to assist in canal preparation.
- Utilize the IlluminOss flexible cannulated reamers over the 2.0 mm ball tip guidewire to clean the canal and provide proper space for delivery of the implant. (Figure 11)

NOTE: Flexible cannulated reamers are provided in diameters of 6.0, 6.5, 7.0, 7.5 & 8.0 mm. 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.

Start with the smallest diameter reamer mounted on either a power drill or a hand reamer and clean the desired length of the canal with the reamer. Reaming is commenced in 0.5mm increments to achieve a minimum diameter of 8.0 mm within the canal of the bone.

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

- A flexible reamer support is provided to support the flexible shaft if necessary. Irrigate as needed to clear debris from the intramedullary canal.
- Verify fracture reduction and the position of the guidewire in both A/P and lateral views with imaging equipment.
- After completion of the reaming process, remove the cannulated reamer from the IM canal and leave the 2.0 ball tip guidewire in place across the fracture. (Figure 12)

NOTE: A minimum canal diameter of 13mm is required for the stand-alone use of the implant in load bearing indications. Utilize FDA cleared plates in conjunction with the implant in those cases where the implant will not achieve 13mm in diameter in the area of the fracture.

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

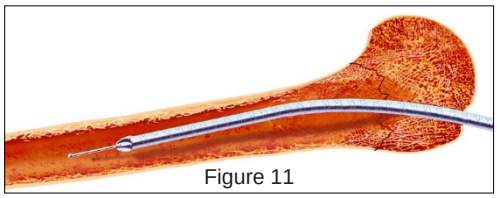


Figure 11

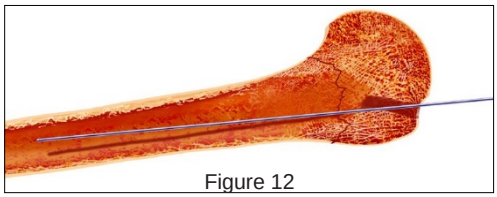


Figure 12

Head Reaming

Curved head reamers (Figure 13) 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 proximal aspects of the humerus.

- Attach the curved head reamer (Figure 13) to the T-handle (Figure 14).
- Insert the assembly through the initial pathway made to access the humeral canal. (Figure 13) 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. The use of a power driver is at the surgeon's discretion.

Warning: Should the clinical indication deem that high speed reaming 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 reamer.

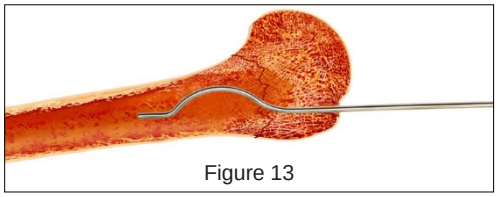


Figure 13


Figure 14

PROCEED TO SECTIONS 3-8 FOR IMPLANT PREPARATION & PROCEDURAL STEPS

SECTIONS 3-8 ARE THE SAME, REGARDLESS OF BONE TREATED.

PICTURES OF THE HUMERUS HAVE BEEN USED THROUGHOUT FOR ILLUSTRATIVE PURPOSES.

B. Distal Radius & Radius

Implant diameter and length refer to section above.

- Position the patient in the supine position and place the arm on a sideboard providing access to the styloid of the radius.
- The use of traction greatly assists in maintaining the reduction of the fracture. Finger trap reduction as shown allows for manipulation of the hand and wrist, and freedom to position the hand accordingly. (Figure 15)
- A stitch incision should be made at the radial styloid. A straight awl is used to make an initial entry portal at the radial styloid. (Figure 16) Check the position with A/P and lateral views.

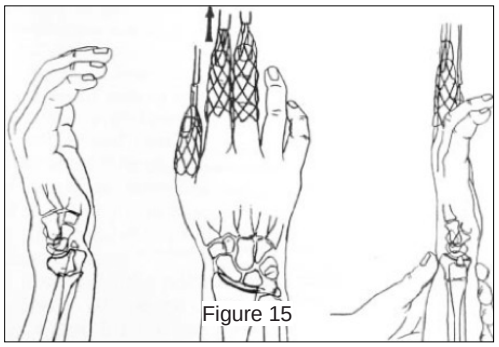
  NOTE: The operating table must be radiolucent as the arm must be visualized in two planes using the image intensifier.
- Insert the cannulated awl into the initial pathway. (Figure 17) The cannulated awl enlarges the canal allowing for the sheath and dilator to be placed within the intramedullary canal.
- Deliver the 1.2 mm guidewire into the medullary canal through the cannulated awl for use with the IlluminOss burrs. (Figure 18)
- Note: If the IlluminOss Reamers are used in canal preparation, the 1.2mm ball tip guidewire must be replaced with the 2.0 mm ball tip guidewire.
- Remove the cannulated awl leaving the guidewire in position.
- 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 (Figure 19). 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 within the medullary canal.
- After clearing the canal, remove the burr from the canal leaving the ball tip guidewire in place across the fracture site.

  NOTE: Select the desired implant size and deliver to the sterile field.
- Insert the dilator into the tear away sheath. Verify that the guidewire is in position crossing the fracture.
- Place the dilator and tear away sheath assembly over the guidewire into the intramedullary canal. (Figure 20)
- Confirm positioning of the sheath assembly via fluoroscopy.
- Once in position, remove the dilator and guidewire, leaving the tear away sheath in place across the fracture site. (Figure 21)

PROCEED TO SECTIONS 3 - 8 FOR IMPLANT PREPARATION & PROCEDURAL STEPS

SECTIONS 3 - 8 ARE THE SAME, REGARDLESS OF BONE TREATED.

PICTURES OF THE HUMERUS HAVE BEEN USED THROUGHOUT FOR ILLUSTRATIVE PURPOSES.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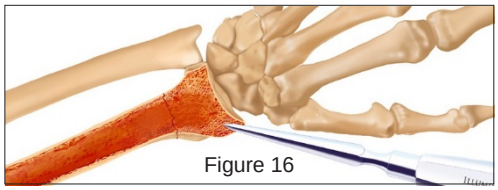
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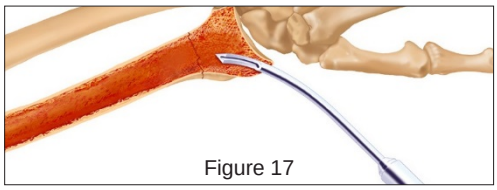
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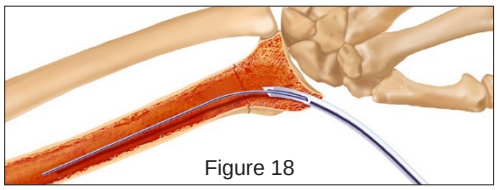
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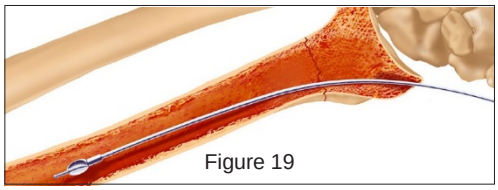
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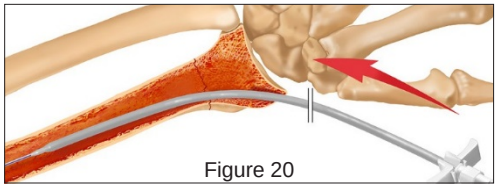
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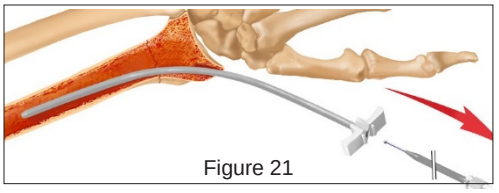


Figure 21

C. Ulna

- Position the patient in the supine position and place the arm on a sideboard providing access to the styloid of the ulna for the distal ulna or access to the olecranon for the proximal ulna.
- A stitch incision should be made at the ulna styloid.
- A straight awl is used to make an initial entry portal at the ulna styloid (Figure 22). Check the position with A/P and lateral views.
- Insert the cannulated awl into the initial pathway (Figure 23). The cannulated awl enlarges the canal allowing for the sheath and dilator to be placed within the intramedullary canal.
- Deliver the 1.2 mm ball tip guidewire into the medullary canal through the cannulated awl. Once in position, remove the stylet from the back of the awl and insert the ball-tipped guidewire through the awl and across the fracture (Figure 23). Remove the cannulated awl leaving the guidewire in position.

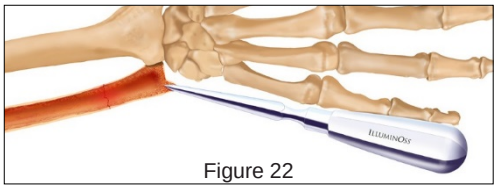
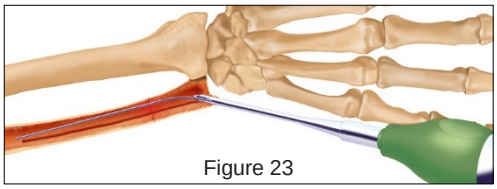


Figure 22

Preparation of Canal

- 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 (Figure 24). 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 4.5mm within the medullary canal.
- After clearing the canal, remove the burr from the canal leaving the ball tip guidewire in place across the fracture site.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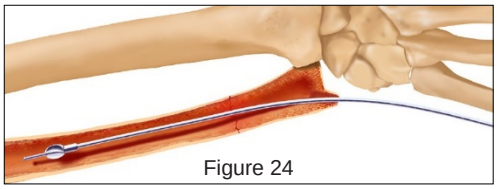
Figure 24

PROCEED TO SECTIONS 3-8 FOR IMPLANT PREPARATION & PROCEDURAL STEPS.

SECTIONS 3-8 ARE THE SAME, REGARDLESS OF BONE TREATED.

PICTURES OF THE HUMERUS HAVE BEEN USED THROUGHOUT FOR ILLUSTRATIVE PURPOSES.

3. Component Preparation

Open the outer box containing the following components:

Foam pouch containing:

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

Sterile delivery catheter pouch

- Remove the pouches containing the monomer vials, sterile transfer spike and sterile syringes from the foam pouch.

NOTE: The contents of these pouches are sterile.

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

NOTE: This is a non-sterile component.

- Open the individual pouches and introduce the monomer vials, syringes, transfer spike and delivery catheter into the sterile field.
- Monomer should be at room temperature when used. If monomer is colder than room temperature, it should be allowed to warm.

4. Balloon Catheter Priming & Preparation

Carefully remove the catheter assembly from the card backing, leaving the white protective tube covering the balloon in place as this will assist in the priming/preparation of the implant.

1- Attach an empty 20cc syringe from the kit to the black stopcock on the implant and open the valve. (Figure 25)

2- Evacuate all of the air out of the implant by drawing a vacuum with the syringe. Close the stopcock to maintain the vacuum.

3- Detach syringe from stopcock luer and expel any collected air out of the syringe

4- Repeat steps 1-3 to ensure all air has been removed from the balloon catheter. Close the stopcock and maintain the vacuum within the implant.

5- Remove the blue cap from the monomer vial and insert the transfer spike into the top of the vial.

6- Attach the syringe to the transfer spike, turn assembly over, and slowly draw the monomer into the syringe. Consolidate any air bubbles and expel the residual air from the syringe. (Figure 26)

7- Attach the syringe containing the monomer to the closed stopcock luer. Slide the white protective tube covering the balloon back about 15 mm, exposing the distal portion of the balloon. (Figure 27)

8- Open the stopcock valve on the catheter, where the residual vacuum will pull monomer slowly into the catheter.

9- Apply some pressure to the plunger on the syringe for several seconds, as the monomer will travel the entire length of the balloon catheter causing the tip of the exposed balloon beyond the protective tube to slightly expand. (Figure 28)

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

10- Reverse the syringe plunger direction and apply suction to withdraw the infused monomer from the implant, collapsing the tip of the balloon implant, along with any air bubbles which are drawn back into the syringe barrel.

11- When sufficient monomer has been withdrawn and the distal end of the balloon has deflated, the protective sheath can be advanced over the tip of the catheter.

12- Advance the protective sheath forward so that the middle portion of the balloon catheter is exposed while the tip of the balloon is still contained within the protective sheath.

13- Infuse just a small amount of monomer into the mid-section of the balloon and with two fingers on the outside of the balloon, gently advance in a wiping motion the monomer forward towards the distal tip.

NOTE: Do not try and fully inflate the balloon to its full size. The purpose of this step is to get monomer into the central section of the implant and to withdraw any residual air or air bubbles from the implant. A fully inflated balloon may be difficult to reinsert into the protective sheath.

14- Pull a vacuum on the syringe and at the same time gently pull the protective sheath backwards covering the entire balloon.(Figure 29) The simultaneous action of a vacuum drawn on the syringe and the compression placement of the protective sheath on the balloon will expel all the air from the balloon catheter into the syringe.

15- Leave the monomer filled syringe attached to the catheter.

16- The IlluminOss implant has now been prepared and is ready for implantation

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

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.

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

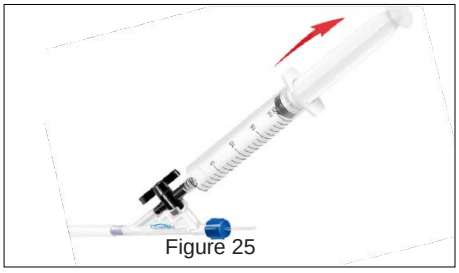
Figure 25


Figure 26

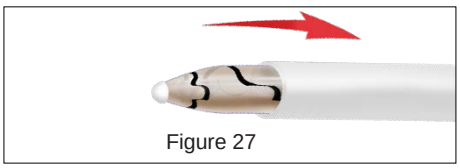
Figure 27

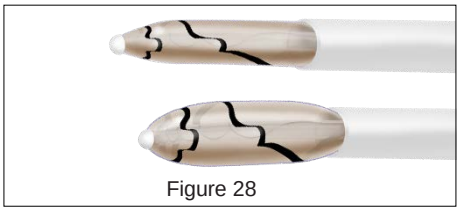
Figure 28

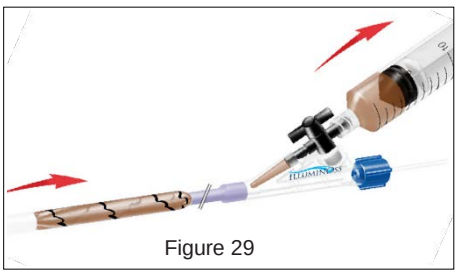
Figure 29

5. Sheath Assembly & Delivery within Canal

Insert the dilator into the tear away sheath assembly. Verify guide wire position in the canal on both sides of the fracture using fluoroscopy (Figure 30)
Insert the dilator/ tear away sheath assembly into the intramedullary canal by sliding it over the guidewire across the fracture site (Figure 31).
NOTE: The tip of the sheath and the dilator may be bent to assist in its delivery through a bend or curvature in the delivery approach.
Confirm positioning of the sheath assembly via fluoroscopy.
Once the sheath and dilator are in position (Figure 31), remove the dilator and guidewire, leaving the tear away sheath assembly in place across the fracture site. (Figure 32)

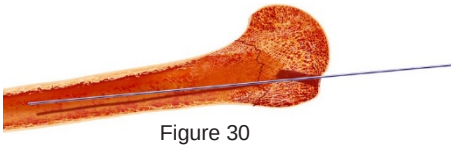
Figure 30

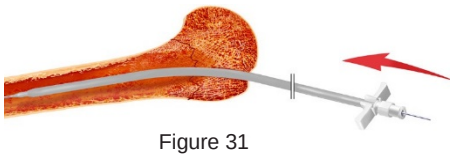
Figure 31

6. Balloon Catheter Insertion & Monomer Infusion

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 sheath from the balloon catheter and introduce the prepared balloon into the tear away sheath previously positioned in the intramedullary canal. (Figure 33)

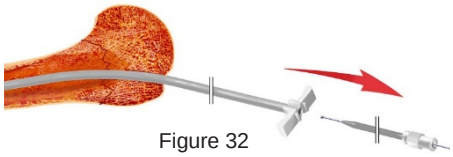
Figure 32

NOTE: Care must be taken when inserting the prepared catheter through the sheath. Support the length of the balloon catheter during insertion with your hand. Do not force or significantly bend the balloon during its insertion into the sheath or damage may occur.

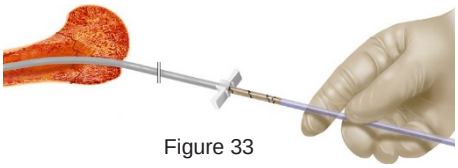
Figure 33

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

Check proper position using fluoroscopy, ensuring that the fracture reduction has been maintained and the sheath is still spanning the fracture site.
While holding the balloon catheter in position within the canal and sheath, break the wings of the tear away sheath and slowly separate the sheath in half while withdrawing it from the canal. Remove the entire sheath and discard. (Figure 34)
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 35)
Once resistance is felt on the syringe plunger, or it cannot be advanced any further, close the stopcock valve. (Figure 36)
Reconfirm fracture alignment with fluoroscopy. Multiple vials of monomer may have to be opened to achieve a fully filled implant.

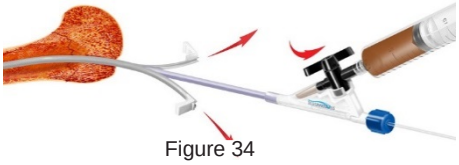
Figure 34

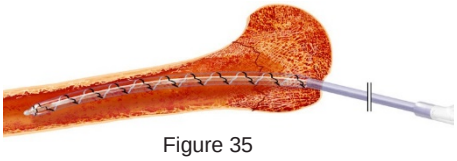
Figure 35

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


Figure 36

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.

Check light pipe to ensure depth stop abuts the blue cap fitting on proximal end of catheter and that the fitting is tightened snugly around light pipe. (Figure 37)

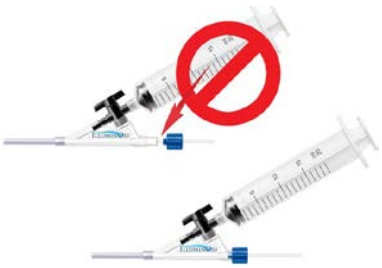
Figure 37

7. Handling of the Light Fiber & Curing Cycle

- **Avoiding damage to the small diameter Plastic Light Fiber extending from the rear of the implant as this delivers light to cure the implant.**
- **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.**

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 38)
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 39)

- Insert timer key into the receptacle on the front of the light console**.** Ensure the timer changes to the prescribed time shown on the key**.** (Figure 40)
- **NOTE:** Ensure that the proper timer key is being used by comparing the timer key setting to the setting on the timer key flag**.**
- Toggle the foot pedal switch on the front of the light box from the **"**Standby**"** position to the **"**Enabled**"** position**.** (Figure 41)
- 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 42)
- **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.**
  When the foot pedal has been depressed, light is transferred to the implant via the light fiber. The fiber will be illuminated in a visible blue light. (Figure 42)
  At completion of light cycle, unscrew the blue cap fitting and slowly remove light fiber from balloon catheter. (Figure 43) Detach it from the light guide connector and discard it.

Figure 38

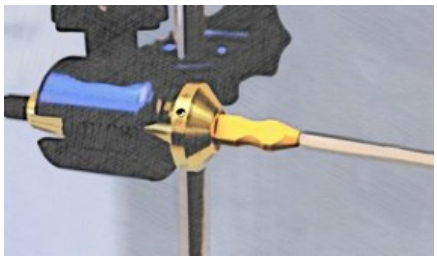
Figure 39

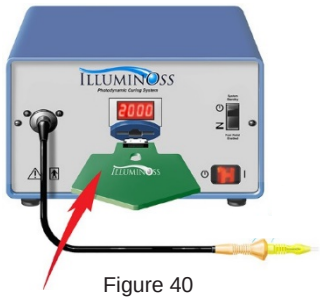

Figure 40

Figure 41

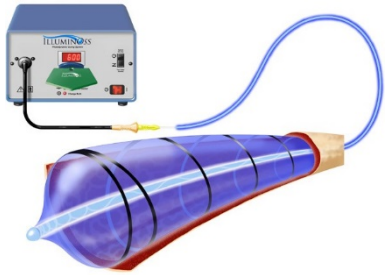
Figure 42

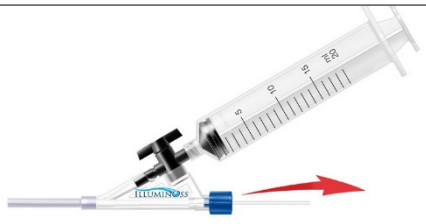
Figure 43

8. Separation of Catheter from Implant

- Using a pair of surgical scissors, cut braided catheter tube immediately adjacent the distal Y-connector and discard Y-connector. (Figure 44)

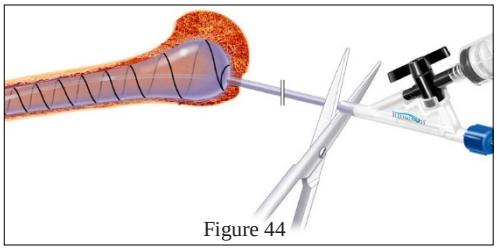
Figure 44

- 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). (Figure 45)
- **NOTE:** Several centimeters of the catheter should protrude out from the knob of the instrument.

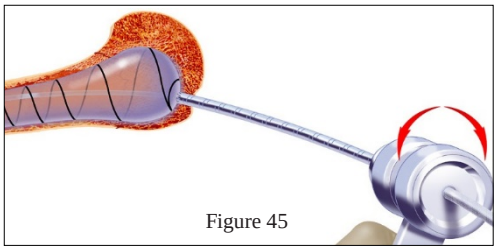
Figure 45

- Rotate the stabilizer back and forth with moderately applied pressure to score the end of the PET balloon covering. (Figure 46)
- 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.

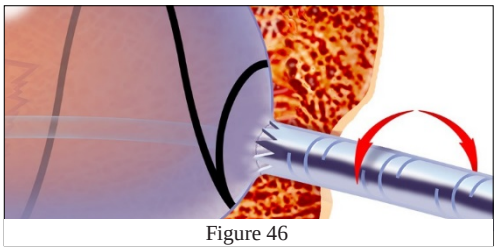
Figure 46

- 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. (Figure 47)
- 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 48)
- Quickly move the hammer from distal to proximal in one quick, full, sharp stroke, separating the catheter from the implant. (Figure 49)
- Remove the stabilizer from the incision. Evaluate the fixation and deployment of the IlluminOss implant in both A/P and Lateral radiographic views. Upon completion of the procedure, remove discard the timer key and turn off the light box.

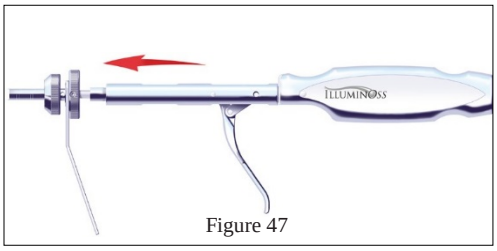

Figure 47

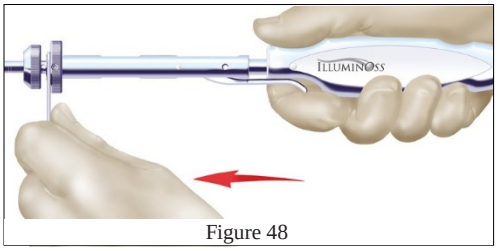

Figure 48

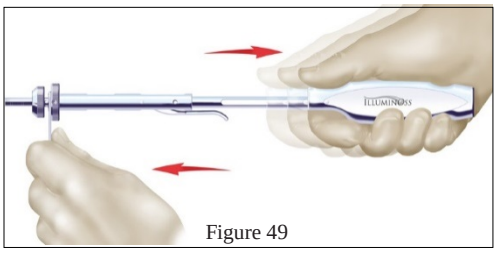

Figure 49

9. 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.

10. Post-Operative Management

Perform wound closure and immobilization as required (sterile dressing, forearm wrapped in an elastic bandage, soft cast or sling as required).

11. 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).

Figure 1. Light Box Components (Front)

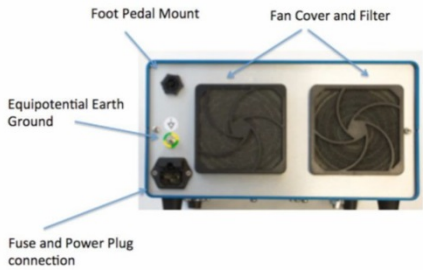

Figure 2. Light Box Components (Rear)

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).

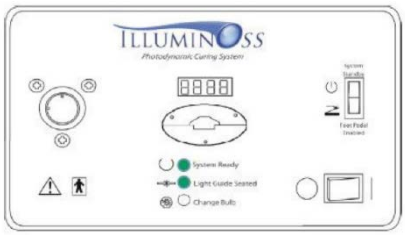
Figure 3. Light Box Ready For Use

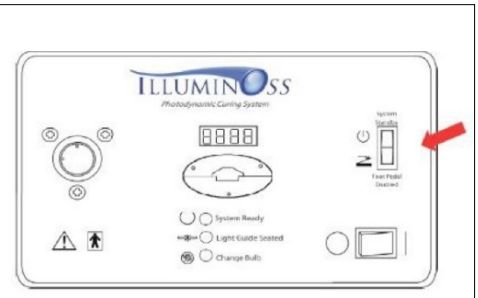
Figure 4. Manual placement in "Standby" mode

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

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

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

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

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

Appendix B: Liquid Monomer Removal Procedure

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

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

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

1. Balloon Catheter Removal:

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

2. Clean the Medullary Canal

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

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

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

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

Indication for use The IlluminOss Photodynamic Bone Stabilization System is indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, 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

Part Number	Description
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			
CT-0300-01	20ml Monomer Vial Pouch	Sterile	1 unit

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