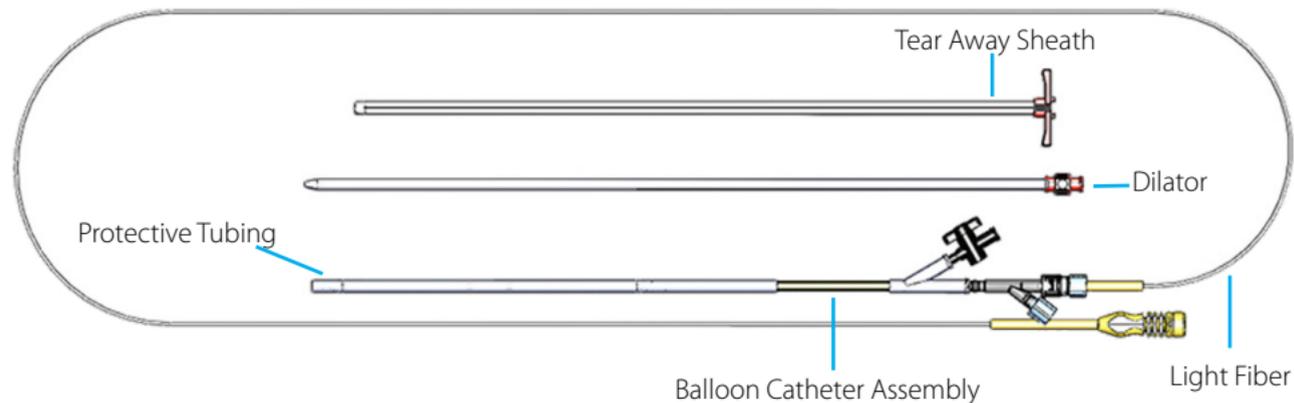




## Quick Setup Guide

The IlluminOss Photodynamic Bone Stabilization Procedure Pack, its container, and any packaging is not made with natural rubber latex.

# 1. Disposable Procedure Pack



Timer Key Card



Monomer



Syringe



Vented Spike

## 2. Light Box Components

Light Box

Light Guide

Foot Pedal

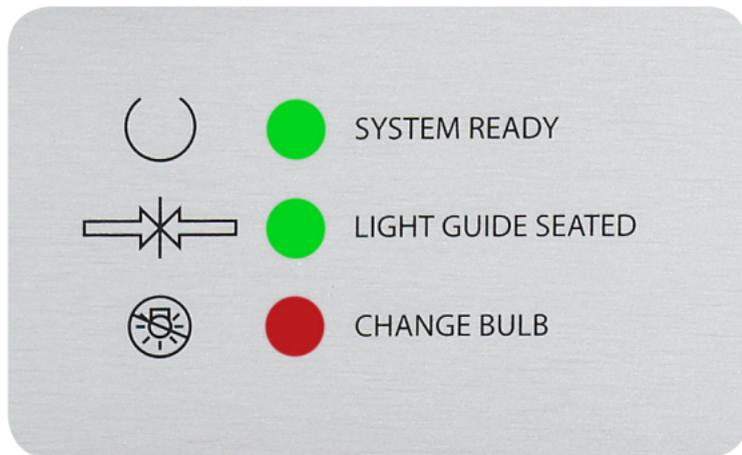


Pole Clamp



### 3. Light Box Setup

- ▶ Plug in the power supply.
- ▶ Attach the foot pedal and light guide into the light box.
- ▶ The light box will perform a self diagnosis.
- ▶ When the light box is ready to be used, the light guide and system ready light will be illuminated green.



**Set-up and activate the light box prior to the start of the procedure to ensure proper function.**

## 4. Reduce The Fracture

- ▶ Reduce the fracture using traditional methods.



## 5. Initial Approach Made With Straight Awl

- ▶ Identify the greater tuberosity of the humerus.
- ▶ Use the straight awl to create initial access to the canal.



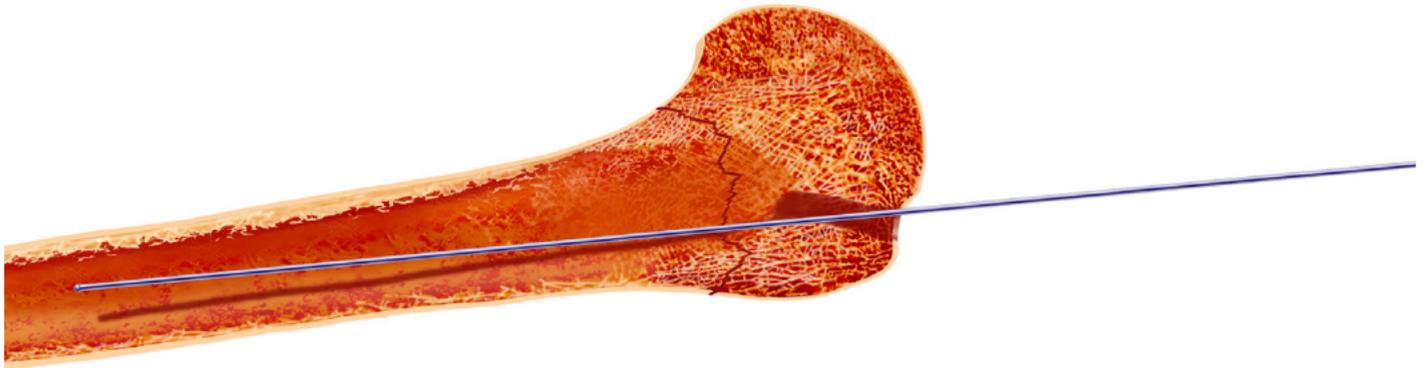
## 6. Insert Curved Awl Into Initial Pathway

- ▶ Insert the appropriate curved awl into the initial pathway.
- ▶ The initial pathway is enlarged to .5mm greater than the size of the sheath by the curved awl in order for the sheath to be positioned within the canal.
- ▶ Once the pathway is enlarged, removed the curved awl.



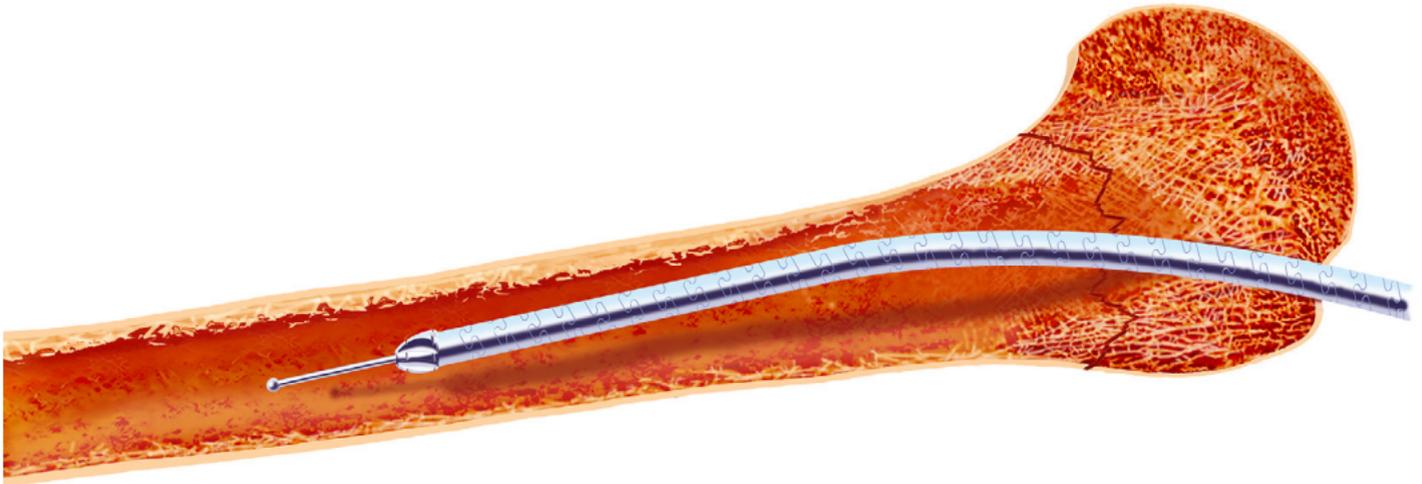
## 7. Insert The Guide Wire Into The Canal

- ▶ Insert the appropriate sized guide wire into the canal, crossing the fracture site.
- ▶ Confirm the positioning of the guide wire by fluoroscopy.
- ▶ Leave the guide wire in position.



## 8. Clear The Canal

- ▶ A series of flexible cannulated burrs & reamers; Burrs (4.5mm 5.5 mm 6.5mm) Reamers (6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm) are used to clear the canal.
- ▶ Reamers are placed over the guide wire and used in sequential order of 0.5mm intervals until the appropriate diameter is cleared within the canal.
- ▶ After the canal has been cleared leave the guide wire in position in the canal.



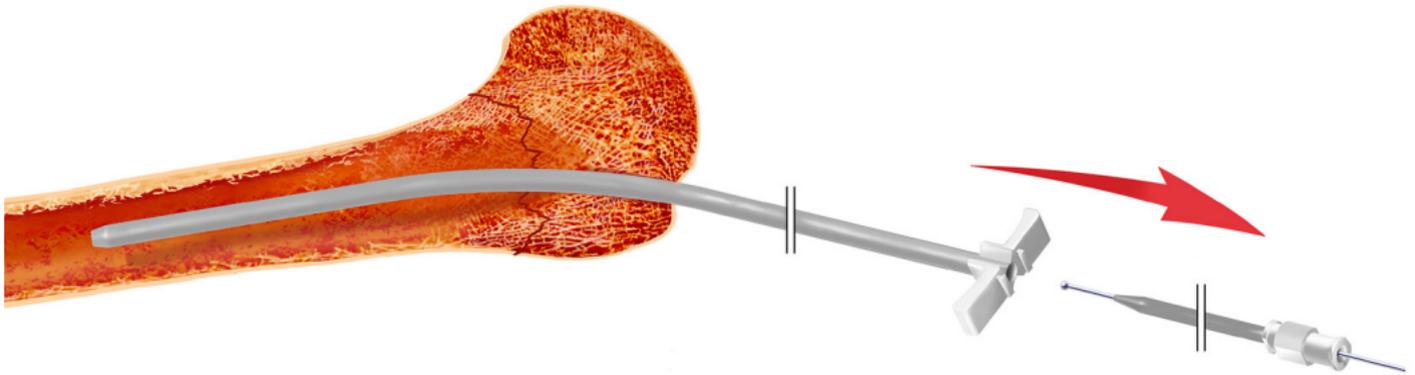
## 9. Insert Dilator & Sheath

- ▶ Insert the dilator and sheath over the guide wire crossing the fracture site.
- ▶ Note: Curving the distal end of the sheath and dilator may assist in it's delivery into the canal.



## 10. Remove Dilator & Guide Wire

- ▶ Remove the dilator and guide wire leaving the sheath in position.



## 11. Remove Air From The Catheter

- ▶ Attach the 20cc syringe to the luer on the catheter.
- ▶ Leave the protective tube over the balloon.
- ▶ Open the stopcock and evacuate all air from the balloon catheter.
- ▶ Close the stopcock, remove the syringe and expel the air from the syringe.
- ▶ Reattach the syringe and repeat the process.
- ▶ Leave the stopcock closed.



## 12. Transfer Of Monomer

- ▶ Attach the vented spike to the syringe.
- ▶ Remove the blue plastic top on vial and insert vented spike through stopper.
- ▶ Transfer the monomer to the syringe.
- ▶ Minimize the air bubbles in the syringe by holding it vertically and pulling slowly on the syringe plunger.



## 13. Prime The Distal End Of The Balloon

- ▶ Attach the monomer filled syringe to the catheter.
- ▶ Pull the protective tube back ~15mm to expose the tip of the balloon.
- ▶ Infuse the monomer slowly to the distal end of the balloon expanding the tip of the balloon slightly.



## 14. Prime The Proximal End Of The Balloon

- ▶ Pull back on the syringe plunger and aspirate the monomer or any air bubbles back in the syringe.
- ▶ Advance the protective tube forward over the distal end of the balloon and infuse a small amount of monomer.
- ▶ Advance the monomer down the balloon by lightly using ones fingers.
- ▶ Reposition the protective tube back over the balloon while drawing a vacuum, making sure all the air bubbles are evacuated.



NOTE: In priming the implant, do not try to inflate the balloon to its full size. The purpose of this step is to deliver monomer to the distal end of 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.

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

NOTE: Once the implant has been prepared for use, and the catheter primed with monomer, it should be immediately delivered to the surgical site.

If the implant is prepared prior to use, ensure that the entire implant and attached syringe is covered with a sterile drape or other sterile material to prevent light from coming in contact with the implant and or syringe.

## 15. Insert Balloon Catheter Into Sheath

- ▶ Insert the prepared implant into the sheath while supporting it during delivery.
- ▶ Confirm positioning by fluoroscopy.



## **PROTECT THE IMPLANT FROM BEING EXPOSED TO EXTRANEOUS OR INTENSE LIGHT**

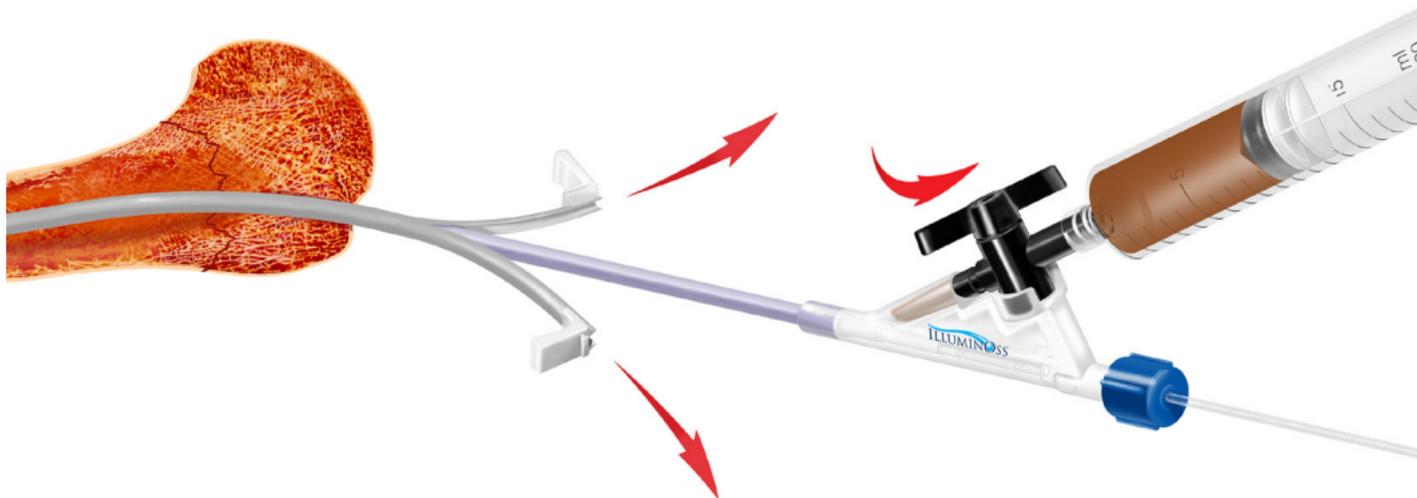
During the delivery and positioning of the implant, as a precaution against inadvertent and premature monomer curing within in the exposed catheter, which may impede the infusion of monomer, it is suggested that the OR spot light beams be either turned off or directed away from aiming at the implant introduction site.

## **PROTECT THE IMPLANT FROM SHARP OBJECTS**

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.

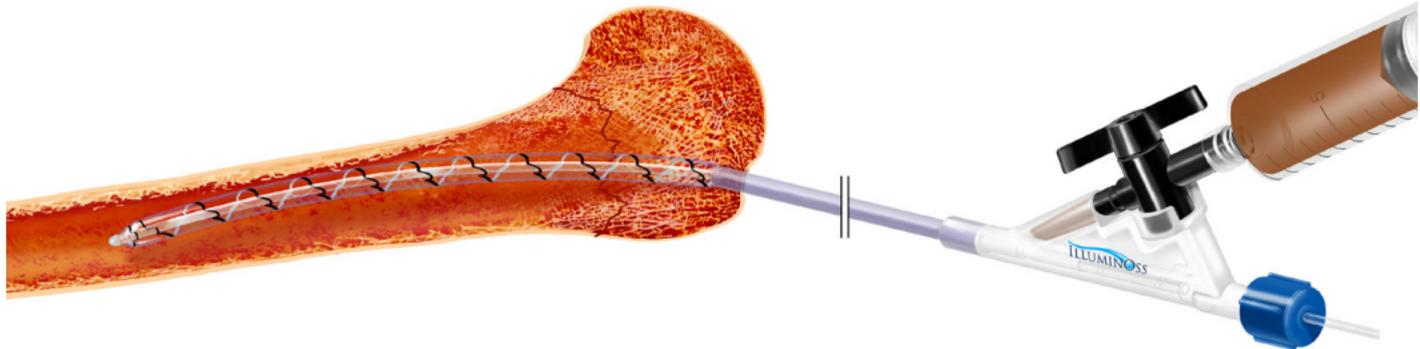
## 16. Remove Tear Away Sheath

- ▶ Remove the sheath by breaking the wings and slowly pulling them apart.
- ▶ Removing the sheath will expose the balloon within the canal.



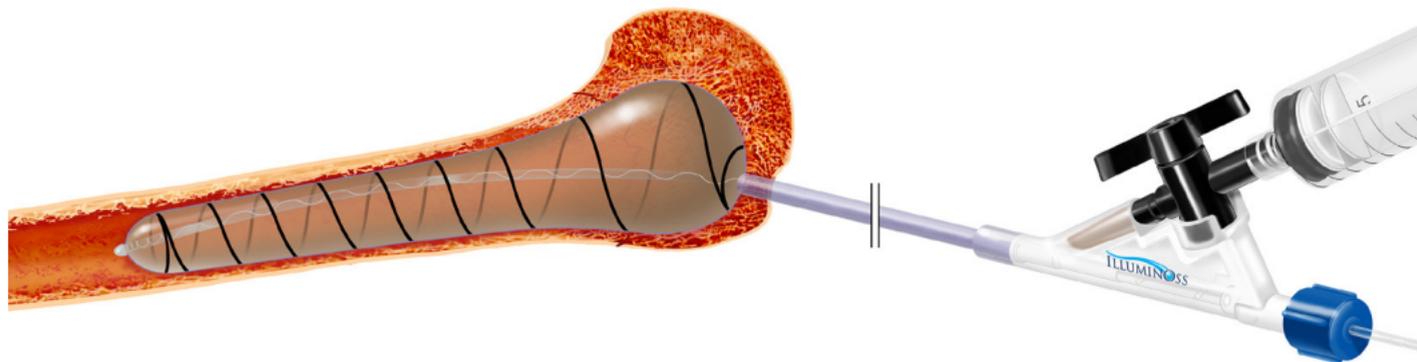
## 17. Confirm Position Of Balloon

- ▶ Confirm positioning of balloon using fluoroscopy.



## 18. Infuse The Balloon With Monomer

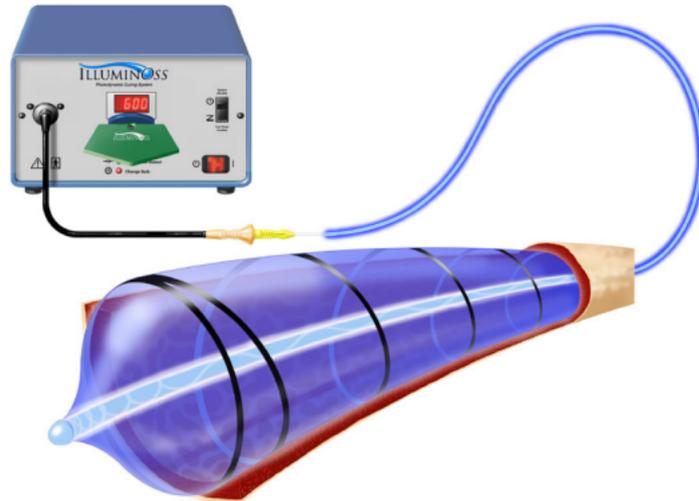
- ▶ Infuse the balloon with the monomer, by pressing on the syringe plunger.
- ▶ When additional pressure cannot be applied to the syringe the balloon is fully inflated.
- ▶ Close the stopcock.
- ▶ Confirm reduction through the use of fluoroscopy.
- ▶ Reposition if necessary by reducing the volume of monomer in the balloon prior to movement.



- 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 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 larger size.
- 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.

## 19. Cure The Implant

- ▶ Attach the plug on the light fiber to the gold connector on the light guide.
- ▶ Insert the timer key card into the light box.
- ▶ Switch the system from “standby” to “foot pedal enabled”.
- ▶ Depress the foot pedal to provide illumination and start the curing process.
- ▶ A beep will signal that the curing process has been completed and the light will shut off.



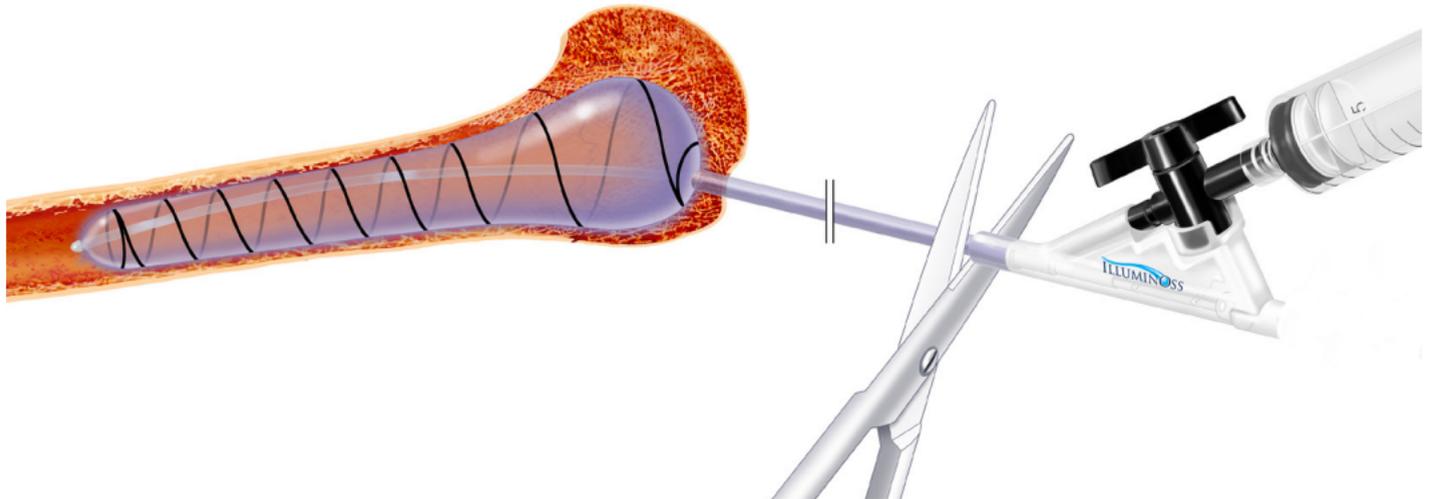
## 20. Remove The Light Fiber

- ▶ Open the blue cap fitting and remove the light fiber from the catheter.



## 21. Cut The Catheter

- ▶ Use a scissor and cut the catheter directly below the Y-Connector.



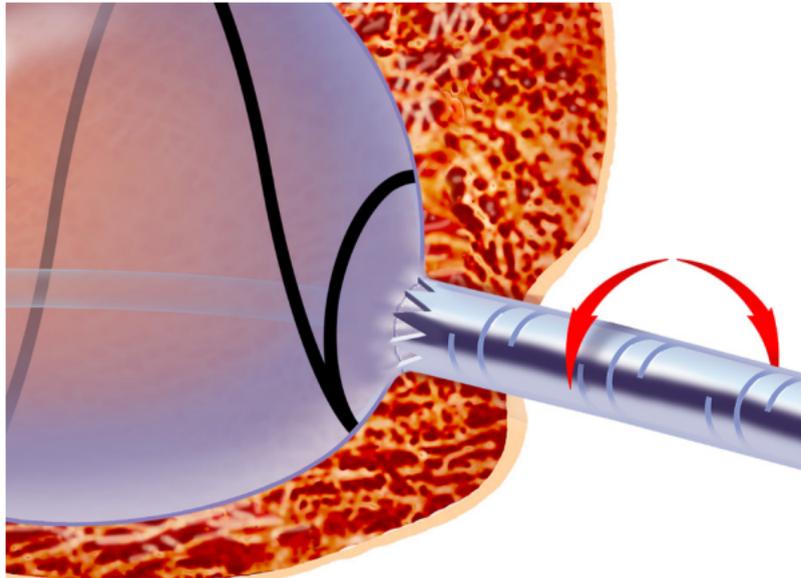
## 22. Place The Stabilizer Over Catheter

- ▶ Place the stabilizer tube over the cut end of the catheter and under fluoroscopy slide the stabilizer forward to come in contact with the implant.



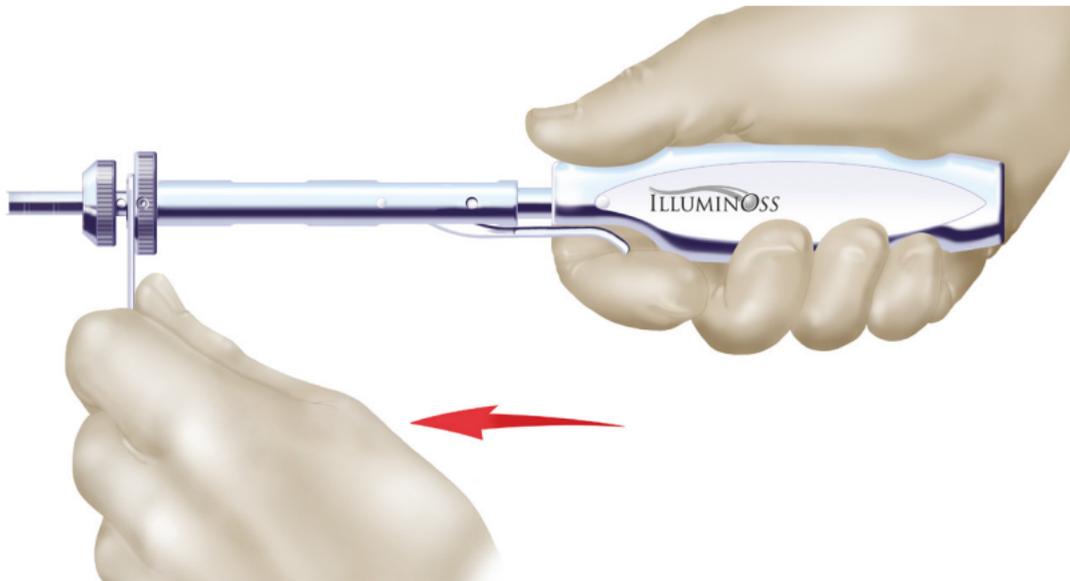
## 23. Ensure Stabilizer Is In Contact With Implant

- ▶ The stabilizer's serrated tip should be in direct contact with the proximal end of the implant to be able to "score" the balloon.
- ▶ Confirm contact of stabilizer and implant by fluoroscopy.
- ▶ Rotate the stabilizer 3-4 times with moderate forward pressure to engage the serrated tips into the implant.



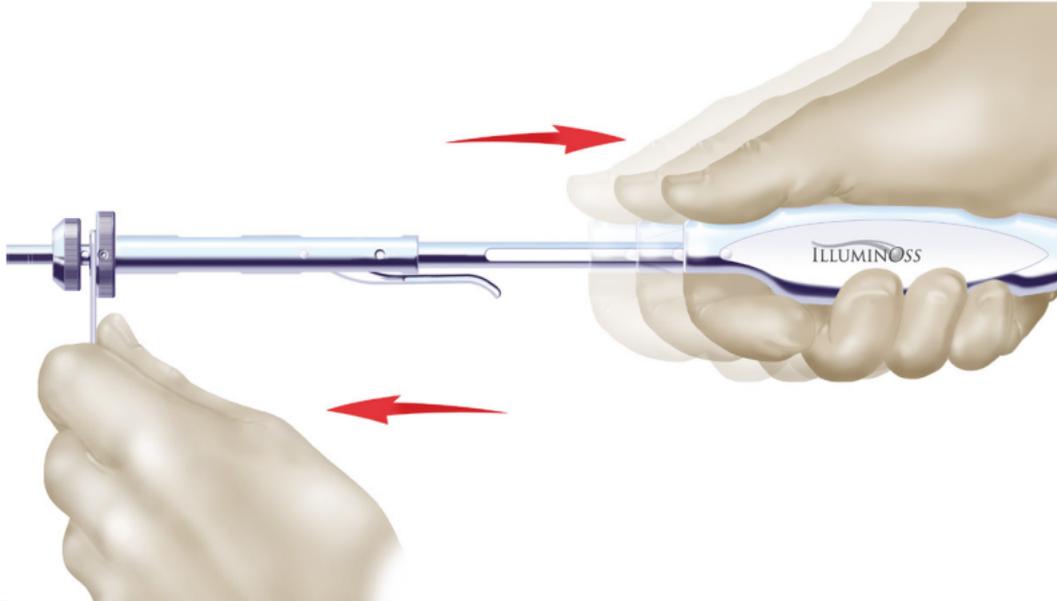
## 24. Attach Slap Hammer To Stabilizer

- ▶ Open the slap hammer by pulling on the lever exposing a bit clamp.
- ▶ Slide the bit clamp over the catheter that is exposed by the stabilizer.
- ▶ Once the bit clamp is over the catheter, slide it forward and adjacent to the stabilizer, and pull up on the handle lever to close the slap hammer causing the bit clamp to tighten and grip onto the catheter.



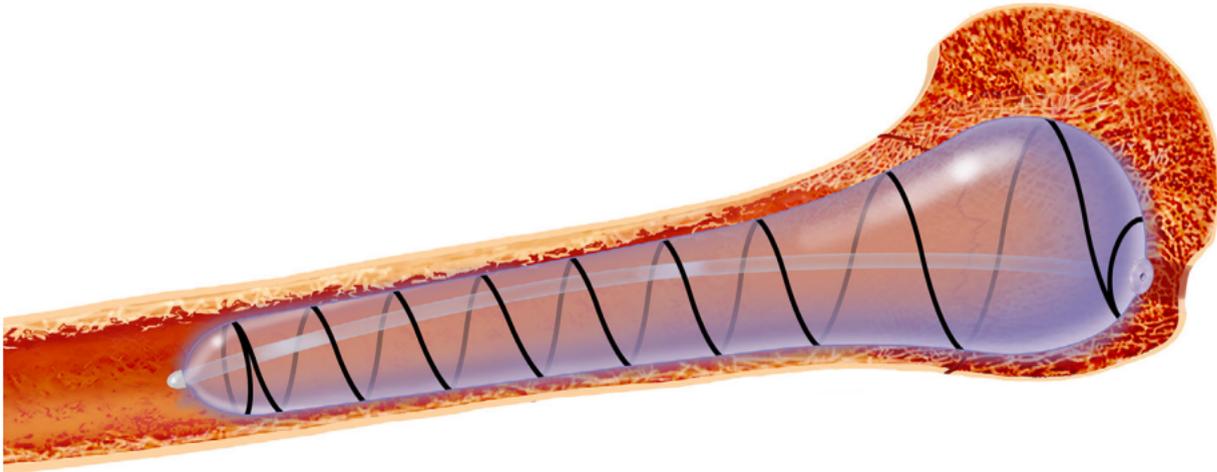
## 25. Separate Catheter From Implant

- ▶ Place one hand forward holding the stabilizer and lock your elbow holding the stabilizer in position. With your other hand grab the back handle of the slap hammer.
- ▶ With one swift forceful motion, pull back on the slap hammer.
- ▶ This quick motion will separate the catheter from the implant



## 26. Cured Implant Provides Strength & Stability

- ▶ The cured implant stabilizes the fracture and provides longitudinal strength and rotational stability.
- ▶ Screws and plates can be used in conjunction with the implant if needed.



## MRI SAFETY INFORMATION



### MR Conditional

The IlluminOss Photodynamic Bone Stabilization System is MR Conditional and this information applies to the entire family of IlluminOss Photodynamic Bone Stabilization System (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 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 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 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. 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 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



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**For more detailed information about  
the set up, preparation and or use of  
the IlluminOss product please refer to  
the Surgical Technique Guide**