



Ulna Surgical Technique Guide



About IlluminOss

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 balloon begin to cure. The cured implant stabilizes the fracture and provides both longitudinal strength and rotational stability to the affected bone.

Features & Benefits

- ▶ A patient conforming implant for rapid repair and stabilization of fractures.
- ▶ A small diameter, flexible catheter allows surgeons to determine the entry position of the implant unlike a rigid metal implant.
- ▶ The implant expands within the patient's intramedullary canal, filling and conforming to the patients unique canal geometry.
- ▶ The procedure to repair and stabilize the bone is a simple and straightforward which may provide faster operative times benefiting the patient.
- ▶ The implant is radiolucent allowing for better visualization of the cortex during the post operative treatment phase.
- ▶ Cures on demand, only through the applications of visible light.
- ▶ Screws and plates can be used anywhere along the implant.

Indication

The IlluminOss System is indicated for use in fracture alignment reduction. It provides stabilization for bone fractures using a minimally invasive technique in which the bone is not subjected to significant weight bearing forces. This document is intended as an outline for the surgical technique of the repair of the ulna. The IlluminOss implant can be used for either the left or the right ulna.

Pre Operative Set Up

- ▶ Ensure that the IlluminOss delivery instrumentation has been sterilized and is delivered to the OR.
- ▶ Set-up and activate the light box prior to start of the procedure to confirm operative status.

Note: The light box must be set-up outside the sterile field and on the same side as the target ulna nearest to pathway being made into the of the patient. The light guide is not sterile it remains outside of the surgical field. The light fiber is a predetermined length (183cm) and ensure that the light box is close enough to make the connection.

Implant Diameter & Length

The IlluminOss implant range in a variety of diameters and lengths. The determination of an implant length and diameter maybe preformed pre-operatively or after the start of the procedure. In determining the appropriate IlluminOss implant length to select, measure the ulna from the ulna styloid or the olecranon to the fracture site. The IlluminOss implant should span across the length of the fracture site in order to stabilize it. Select an implant that achieves cortical contact along the length of the fracture.

Reduce Fracture & Creating Initial Pathway

Position the patient in the supine position and reduce the fracture by traditional methods. 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 1). Check the position with AP and lateral views.

Note: A proximal approach can be performed by accessing the olecranon.

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

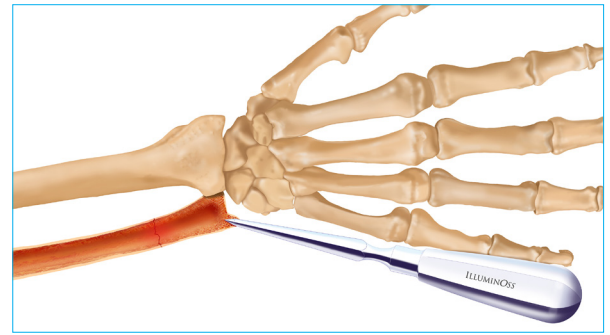


Figure 1

Insert Cannulated Awl Into Canal

Insert the cannulated awl into the initial pathway (Figure 2). The cannulated awl enlarges the canal allowing for the sheath and dilator to be placed within the intramedullary canal.

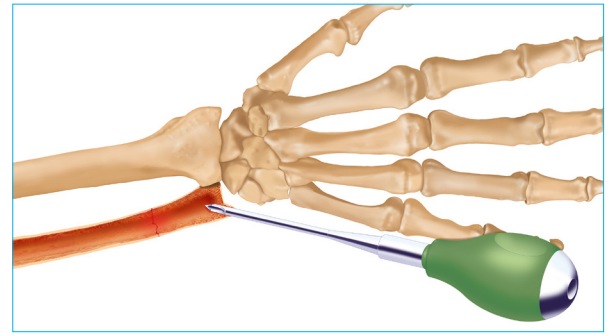


Figure 2

Insert Guidewire Into Cannulated Awl

Deliver the 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 3). Remove the cannulated awl leaving the guidewire in position.

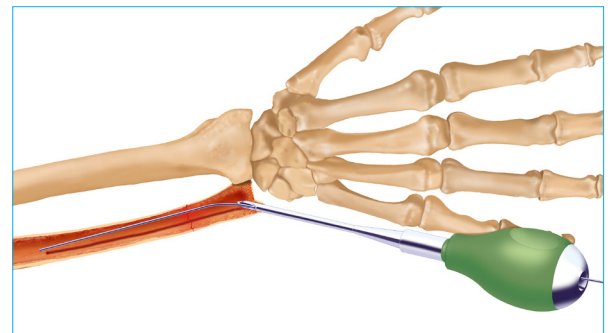


Figure 3

Preparation Of Canal

Place the IlluminOss flexible cannulated burrs over the ball tip guidewire to clean the canal providing proper space for delivery of the implant (Figure 4). 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 3.5mm 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.

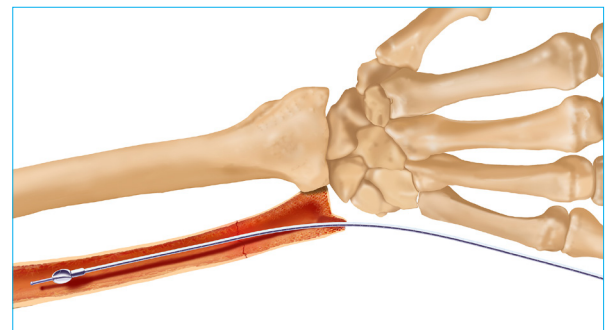


Figure 4

Insert Dilator & Sheath

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 5). 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.

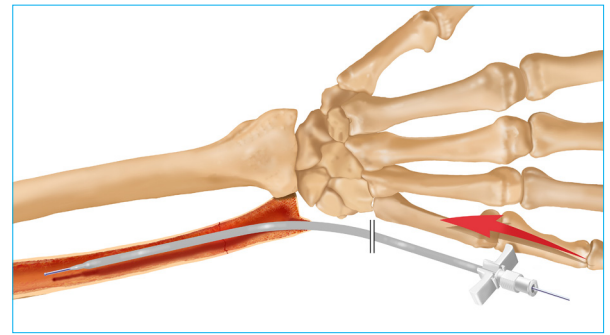


Figure 5

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 6). 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.

Warning: Do not use an implant that will not hold a vacuum. Discard that implant and replace it with a new sterile implant.



Figure 6

Transfer 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 the syringe (Figure 7). Consolidate any air bubbles and expel any residual air from the syringe.



Figure 7

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 8). 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 9).

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



Figure 8



Figure 9

Prime 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 of the syringe. 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 10).

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

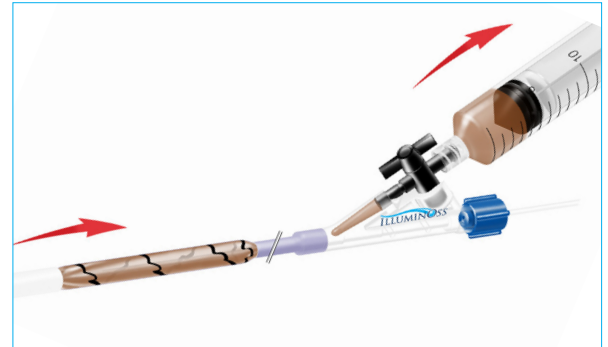


Figure 10

Insert The 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 11). For proper position use fluoroscopy, ensuring that the fracture reduction has been maintained and the sheath is still spanning the fracture site.

Note: Care must be taken when inserting the prepared catheter through the sheath. Support the length of the balloon catheter during insertion. Do not force or significantly bend the balloon during its delivery into the sheath as damage to the implant may occur.

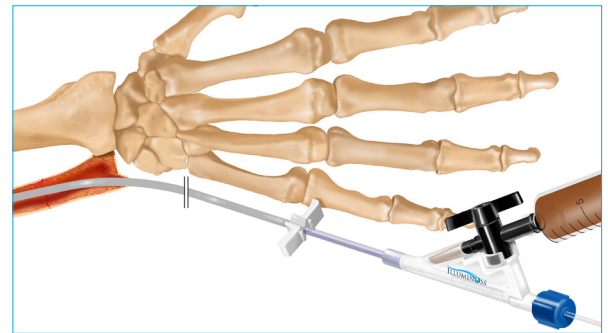


Figure 11

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 and discard the sheath (Figure 12). The removal of the sheath leaves the balloon exposed within the canal. 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.

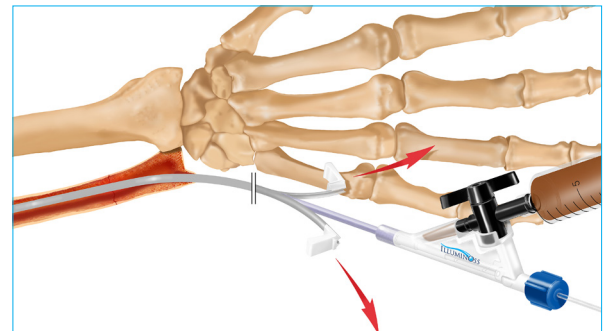


Figure 12

Infuse Balloon With Monomer

Infuse the monomer from the attached 20cc syringe by opening valve and applying moderate pressure to syringe plunger (Figure 13). With the infusion of monomer into the balloon, the spiral radiopaque marker stripe on the outside of the balloon allows visual guidance of implant conforming to the canal as well as its positioning along the length of the bone. Once resistance is felt on the syringe plunger, or it cannot be advanced any further, close the stopcock valve (Figure 14). 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.

Warning: If adjustment of either the balloon position or the bone is required, depressurize balloon by opening the stopcock and aspirating monomer out of the implant 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.

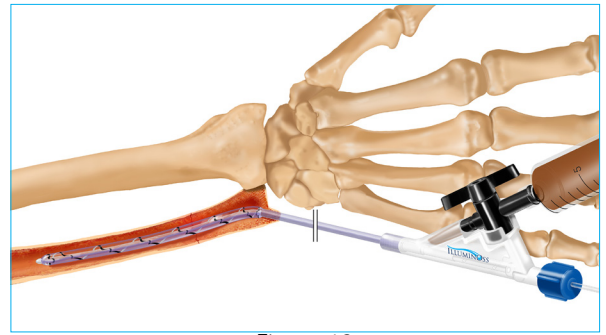


Figure 13

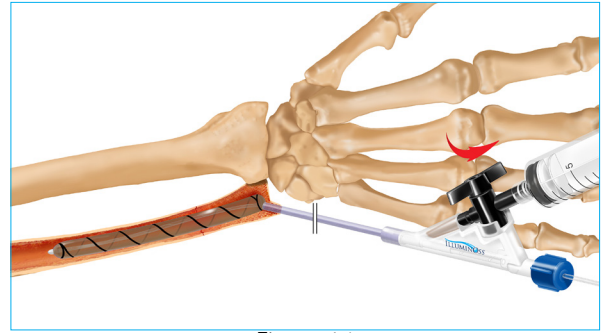


Figure 14

Photodynamic Curing Process

Pass the end of the light fiber off the sterile field and connect it to the light guide until it snaps in place. 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. Toggle the foot pedal switch on the front of the light box from the “standby” position to the “enabled” position.

Depress and release the foot pedal to initiate the light curing cycle (Figure 15). The system runs automatically and the timer counts down the residual time until the implant is cured. At the completion of the curing cycle no further light is delivered to the implant. After the curing process has completed, unscrew the blue cap and remove light fiber from balloon catheter and discard.

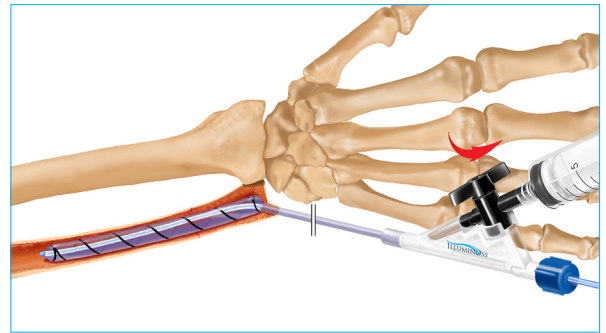


Figure 15

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.

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

Cut The Proximal End Of The Catheter

Using a pair of surgical scissors, cut the braided catheter tube as far back to the plastic connector as possible and then discard (Figure 16).

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

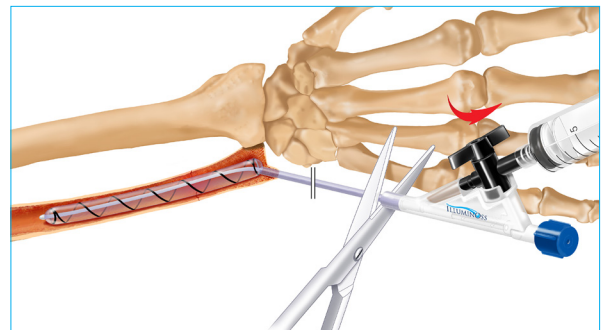


Figure 16

Place Stabilizer Over Catheter

Slide the stabilizer over the catheter shaft and advance it forward to contact the proximal end of the implant (Figure 17). Use fluoroscopic imaging to ensure that the serrated end of the stabilizer is in contact the proximal end of the implant (Figure 17). Rotate the stabilizer knob clockwise several times while applying moderate pressure to the stabilizer to score the end of the PET balloon.

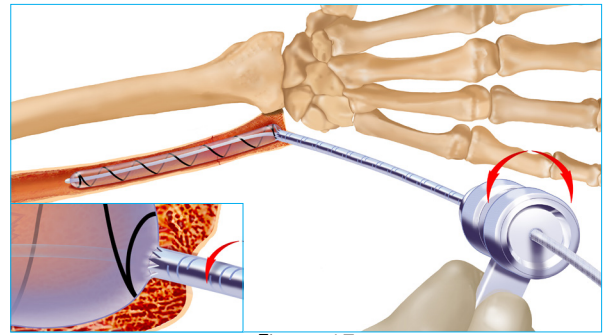


Figure 17

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 protruding from the stabilizer. Once the jaw tips are over the catheter, close the handle lever to close the slap hammer causing it to tighten and grip onto the catheter (Figure 18).

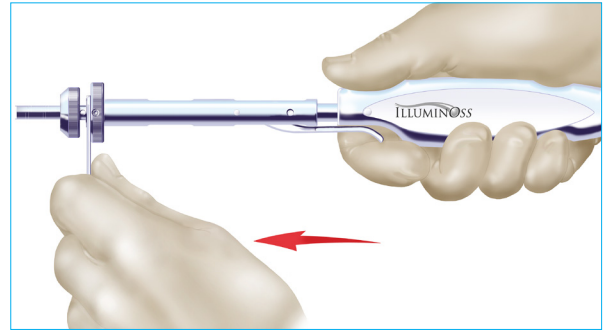


Figure 18

Removal Of Catheter From Implant

Hold the stabilizer handle with one hand and apply forward pressure against the proximal end of the balloon. With the second hand, grasp the sliding "hammer" portion of the slap hammer instrument. Apply in one quick full, sharp stroke, separating the catheter from the implant (Figure 19).

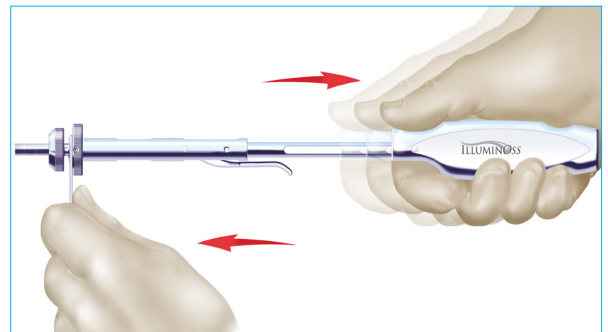


Figure 19

Implant Strength & Stability

The implant provides longitudinal strength and rotational stability over its length (Figure 20). Screws and plates can be used in conjunction anywhere along the length of the implant. Should the use of ancillary fixation be required, do not select a screw size that is greater than one third the diameter of the IlluminOss implant.

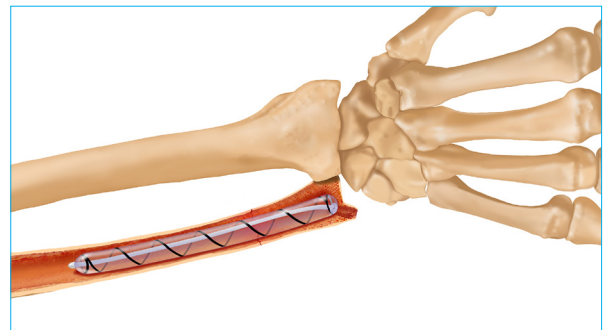


Figure 20

[illegible]

Notes

[illegible]

Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Contraindications

This product is contraindicated in patients who: are considered skeletally immature; 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 sheath provided at the site of the fracture; are uncooperative or who have a neurologic disorder and, or are incapable of following directions; have metabolic disorders which may impair bone formation, have osteomalacia, distant foci of infections which may spread to the implant site, have marked bone loss or bone resorption in the opinion of the surgeon would preclude the use of a stand alone implant, have vascular insufficiency, muscular atrophy, or neuro-muscular disease; have open fractures with severe contamination; have extremely comminuted fractures where insufficient holding power of the balloon on the intramedullary canal is probable; or in patients for whom delivery sheath is unable to cross fracture site after proper fracture reduction and realignment. This 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.



IlluminOss Medical Inc
993 Waterman Avenue
East Providence, RI 02914
Phone: (401) 714-0008
Fax: (401) 714-0009

www.illuminoss.com

This Product Is Investigational In The United States.



EC REP
Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands



ILLUMINOSS MEDICAL INC.
993 Waterman Avenue
East Providence, RI 02914
U.S.A.
+1 (401) 714-0008