ILLUMINOSS®

Fracture repair at the speed of light

Surgical Technique Overview

Quick Illustrative Guide

For more detailed procedural information including Warnings,Cautions,Risks & Contraindications, please see the respective IlluminOss Surgical Technique Guide, Package insert or www.illuminOss.com.

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, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system.

The IlluminOss Implant, the Product Components, the Container and the Packaging are **"Not Made with Natural Rubber Latex."**

Create Initial Pathway With Straight Awl

(Figure 1)

Figure 1

Insert Curved Awl Into Pathway

(Figure 2)

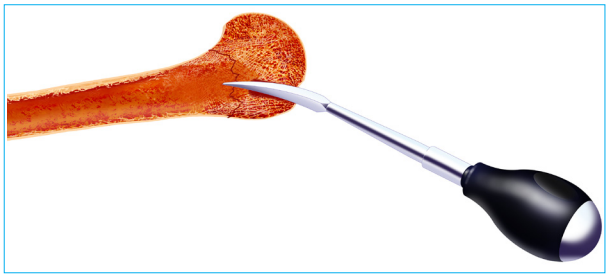

Figure 2

Head Reaming (Humerus specific)

(Figure 3)

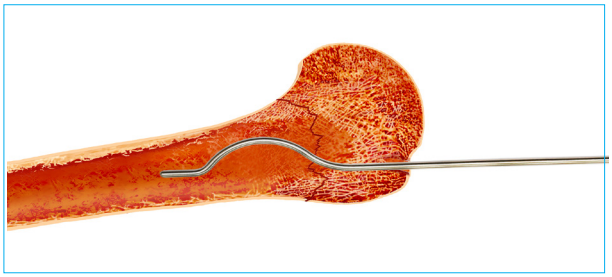

Figure 3

Insert The Guide Wire Into The Canal

(Figure 4)

Figure 4

Preparation Of The Canal - clear canal and or ream as needed

(Figure 5)

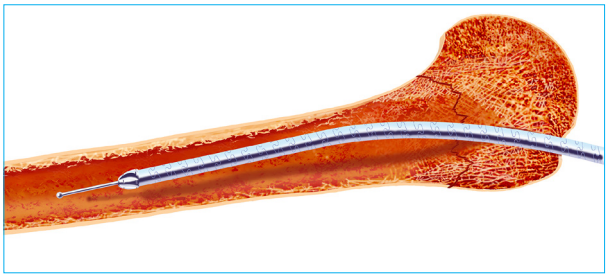

Figure 5

Measure the diameter of the canal in 2 planes (ruler or embedded fluoro measurement)

(Figure 6)

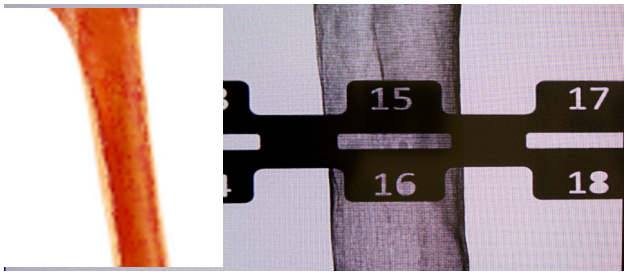

Figure **6**

Insert Dilator & Sheath over Guide Wire

(Figure 7)

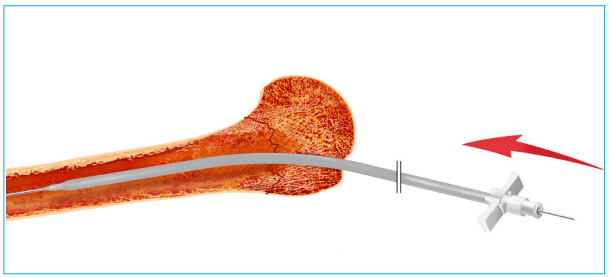

Figure 7

Remove Dilator & Guide Wire leave sheath in place

(Figure 8)

Prevent inadvertent and premature monomer curing in the exposed catheter, OR spot light beams be directed away from aiming at the implant introduction site during catheter positioning.

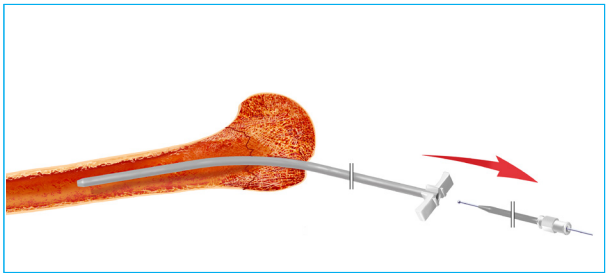

Figure 8

Insert Balloon Catheter Into Sheath

(Figure 9)

Do not bend, kink, pull on or otherwise manipulate the plastic light fiber during insertion.

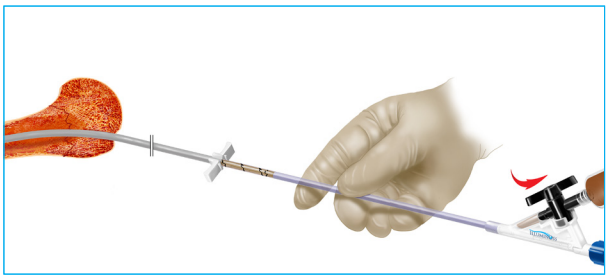

Figure 9

Remove Tear Away Sheath

(Figure 10)

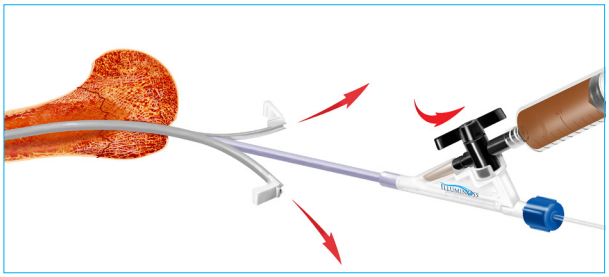

Figure 10

Infuse Balloon With Monomer

(Figure 11)

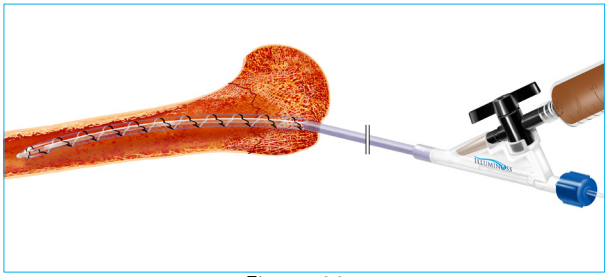

Figure 11

Ensure proper reduction & the implant in contact with the cortical wall. Keep all sharp objects away from uncured implant

(Figure 12)

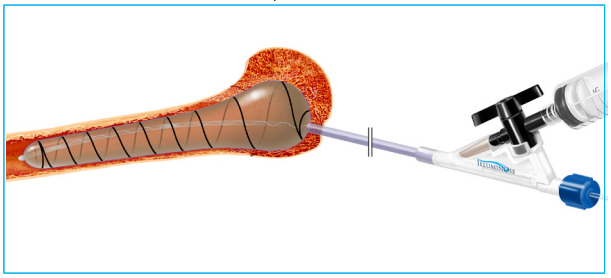

Figure 12

Curing of the Implant

Avoid 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.

Insert Timer Key Card
Attach light fiber to light guide

(Figure 13)

Figure 13

Activate Light Source - Enable foot pedal, depress pedal & timer counts down

(Figure 14)

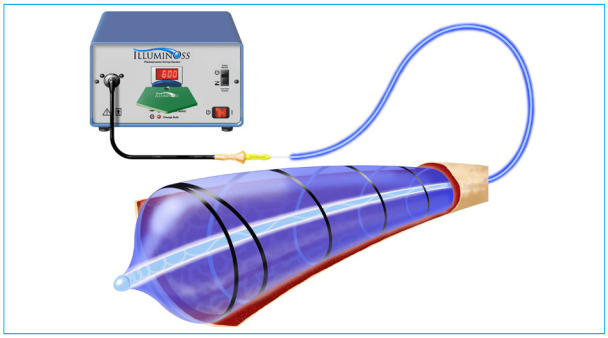

Figure 14

When the light source turns off the implant is cured

(Figure 15)

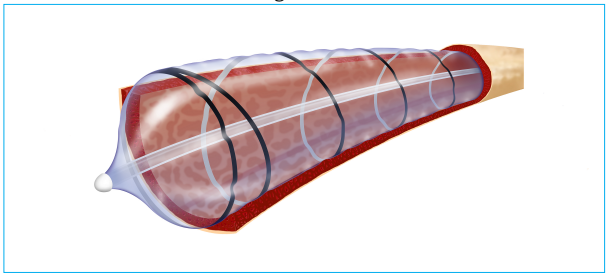

Figure 15

Post cured implant steps

Remove Light Fiber from implant

(Figure 16)

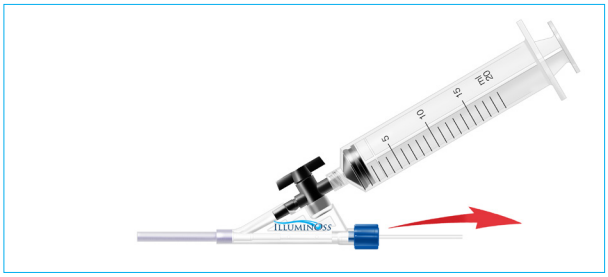

Figure 16

Cut Catheter immediately under Y hub

(Figure 17)

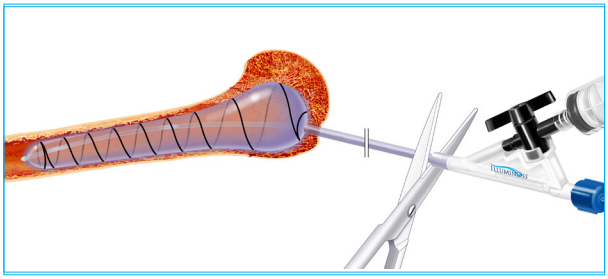

Figure 17

Removal Of Catheter From Implant

Place Stabilizer Over Cut Catheter and slide it forward to make contact with the implant.

(Figure 18)

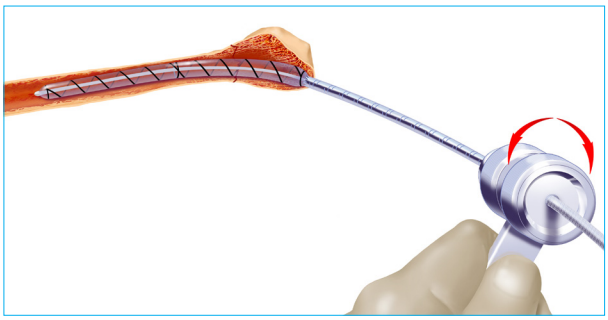

Figure 18

While in firm contact with Implant, rotate the stabilizer several times scoring the balloon.

(Figure 19)

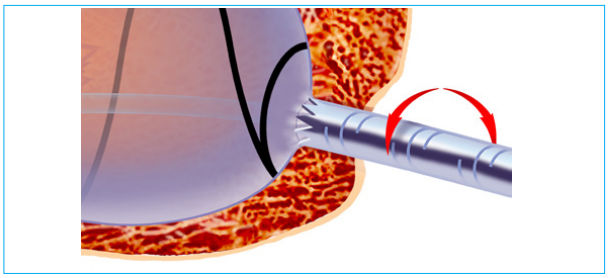

Figure 19

Attach Slap Hammer To the Catheter adjacent to the rear of the stabilizer.

(Figure 20)

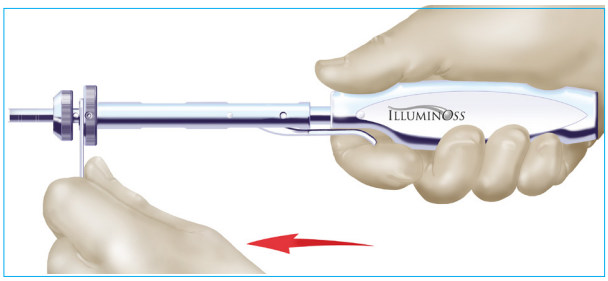

Figure 20

Pushing forward on the stabilizer with one hand, sharply and quickly slide the rear of the slaphammer backwards with the other hand.

(Figure 21)

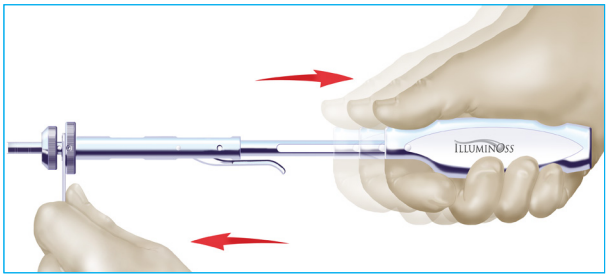

Figure 21

Completed Implant is completely cured, providing longitudinal strength and rotational stability. Optional screws or supplemental hardware can be added as required.

(Figure 22)

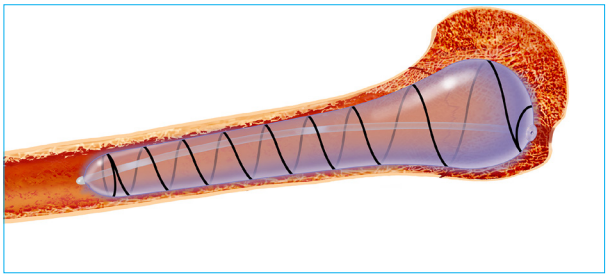

Figure 22

IMPORTANT REMINDERS

Measure the intramedullary canal to determine implant diameter. The implant diameter should be of sufficient size so that it achieves circumferential conformal contact with the walls of the intramedullary canal.

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.

Select a balloon diameter equal to or slightly larger than the largest canal diameter observed.

Reduce the fracture prior to the placement of the IlluminOss 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.

Do not severely bend, kink, pull, compress or twist the plastic light fiber. Do not attach any instruments to the plastic light fiber.

If screws are used, they should be no larger than 1/3 the diameter of the implant. Screws should be a minimum of 30 mm from the fracture line.

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