



# ILLUMINOSS<sup>®</sup>

*Fracture repair at the speed of light*



# **IlluminOss® for the Treatment of Fragility Fractures: Patient Customized Polymer Implants Provide Durable Results**

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# Overview

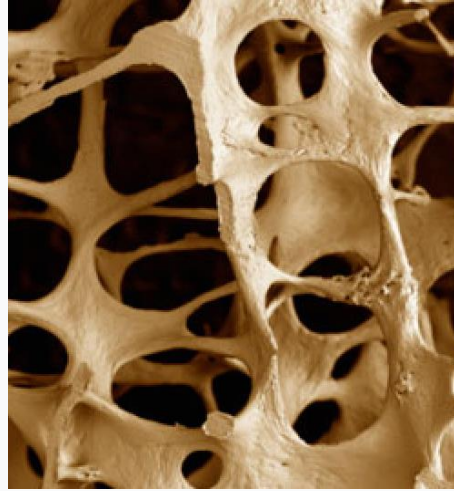
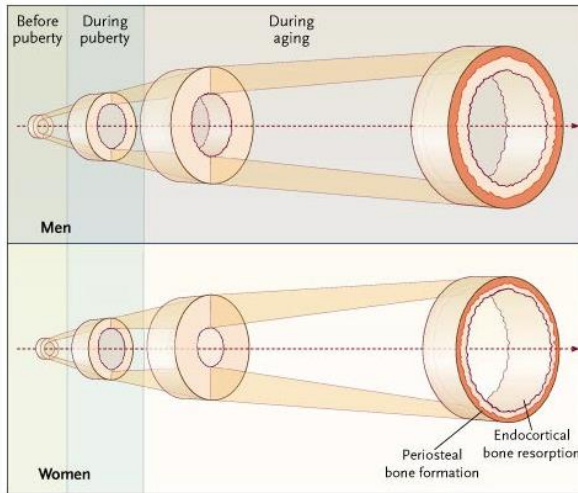
- The IlluminOss Bone Stabilization System
- Challenges in Osteoporotic and Pathologic Fracture Repair
- System Concept and Components
- Supplemental Hardware Use
- Clinical Experience
- Case Examples
  - Metastatic Humerus
  - Distal Radius
  - Proximal Humerus
- Supplemental Hardware
- Advantages of IlluminOss
- Conclusion

# *The IlluminOss Bone Stabilization System*

- A minimally invasive polymer implant designed specifically for the repair and stabilization of compromised or weakened bone including:
  - Osteoporotic fractures
  - Pathological and impending pathological fractures associated with metastatic disease
- Customized to conform to an individual patient's intramedullary canal
- Can be utilized as a stand alone implant or as a supplement to conventional hardware
- Utilized in over 6,000 patients worldwide since 2010



# Challenges in Osteoporotic and Pathologic Fracture Repair



- Loss of cortical bone and bone geometry leads to difficult repair with conventional hardware.
- Pullout strength of hardware is reduced due to poor quality bone, and screw locations.

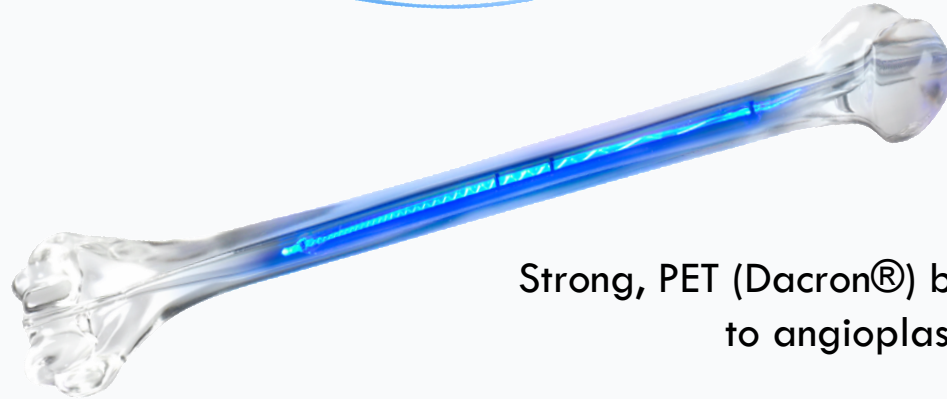


One year later collapse of humeral head

# System Concept and Components



Proprietary, 3 part multi-functional, methacrylate, photodynamic monomer



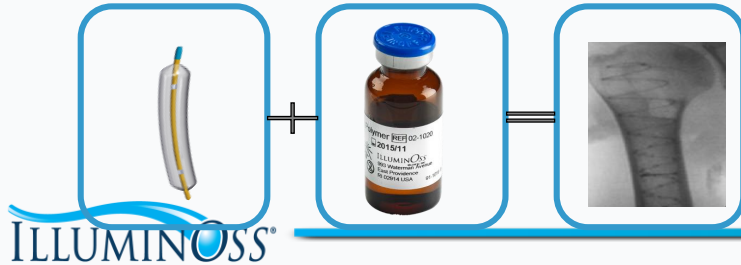
Strong, PET (Dacron®) balloon similar to angioplasty



Small diameter flexible delivery catheter



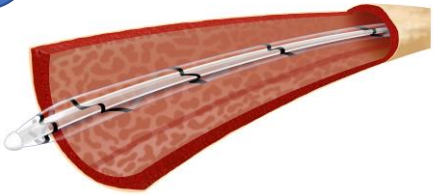
Light Box that emits visible 436nm light





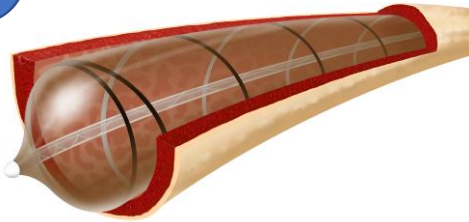
# A Simple Procedure

1



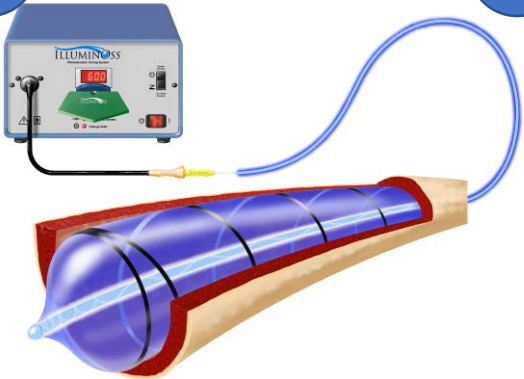
Balloon catheter inserted into the intramedullary canal

2



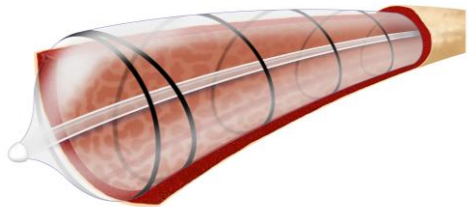
Liquid monomer infused to expand implant

3



Visible blue light delivered to polymerize the implant

4



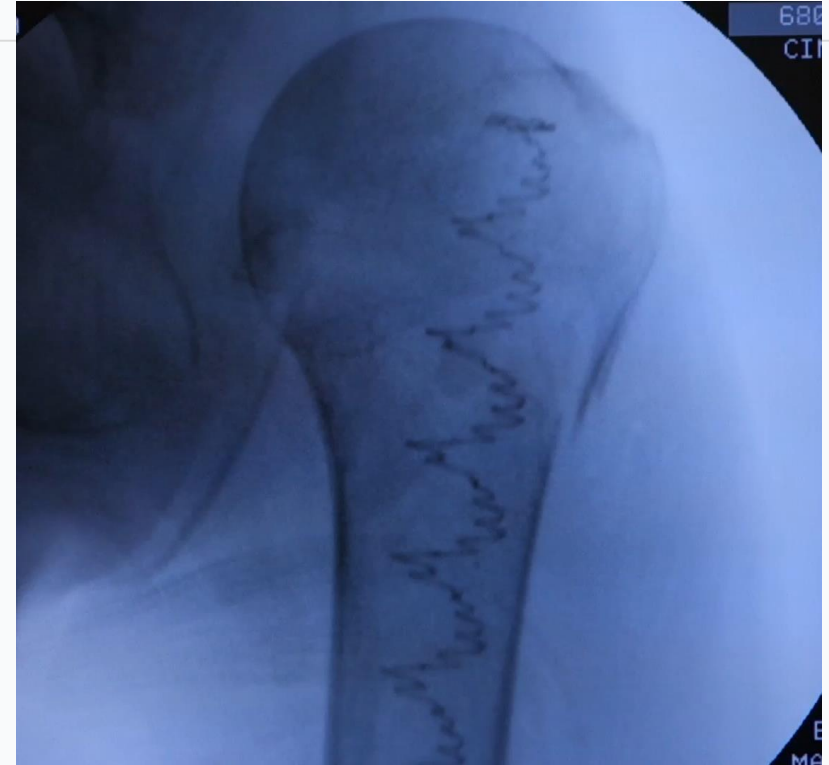
Implant provides immediate strength and rotational stability to the bone



**Implant diameters of 22mm can be achieved from a sub 7mm implant**

# Implant Expansion Movies

*Implant delivered small and expanded within the canal*



360 degree radial contact to the circumference of the canal providing Rotational Stability, may negate the need for cross locking screws



# *Indications for IlluminOss*



Stand Alone Fracture Care



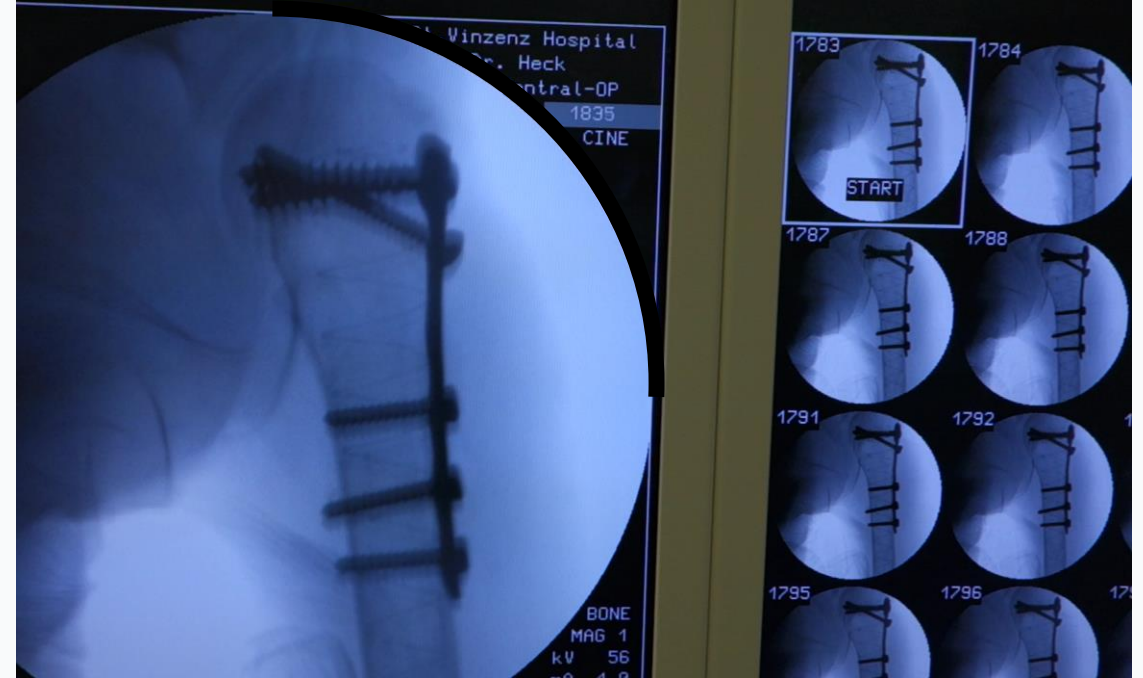
Metastatic Bone Disease



Supplemental Hardware

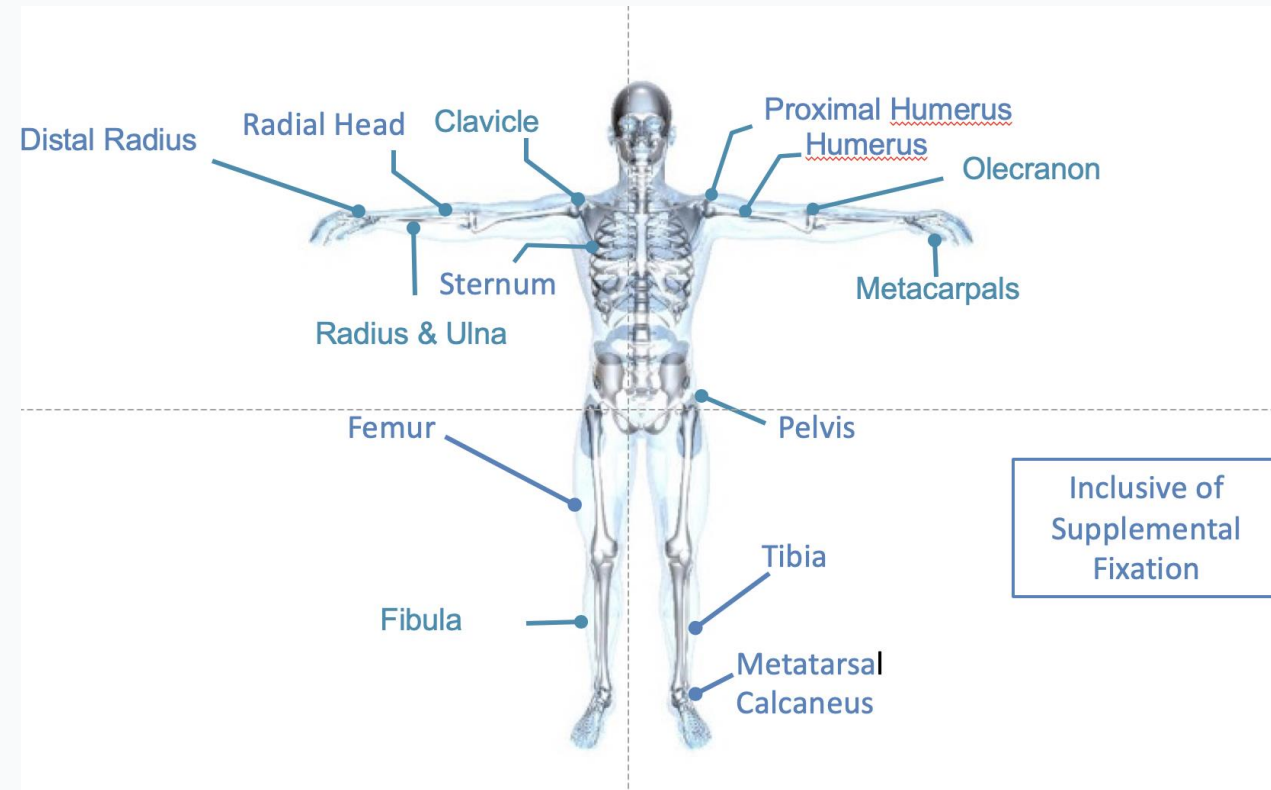
# Supplemental Hardware Use

- IlluminOss is easily drilled and provides a substantial benefit in providing substantially increased holding power to screws & plates – 3x-5x
- Flexibility and freedom in the placement of screws may allow for faster procedures, and less fluoro.



# European Clinical Experience

- In clinical use since 2010 with over 6,000+ cases
- Product use proven in multiple indications
- Established, Confirmed and Validated the appropriate procedural steps and performance metrics
- Experience provided the US clinical efforts with an excellent basis of knowledge



# Lightfix Trial – Metastatic Humerus

The largest prospective, industry sponsored clinical trial for metastatic fractures;

## ***“The Treatment of Impending and Actual Pathological Fractures in the Humerus from Metastatic Bone Disease”***

13 Centers 81 Patients

Age: 35 – 84 years old, mean 64.4

Gender: 57% male, 43% female

Follow up out to 1 year

VAS Pain Score

MSTS Function Score

The Lightfix Trial showed both:

- a Significant Reduction in Pain
- a Substantial Increase in Function

## *Metastatic Humerus – Pre-Op*



# Metastatic Humerus with IlluminOss



## Recovery:

Single view demonstrates  
implant in good position with  
acceptable alignment



# Metastatic Humerus with IlluminOss



## 3 month Post-Op:

- Good alignment
- Progressive healing
- Minimal pain



# Metastatic Humerus with IlluminOss



## 1 year Post-Op:

- Complete healing with reossification
- Minimal symptomatology

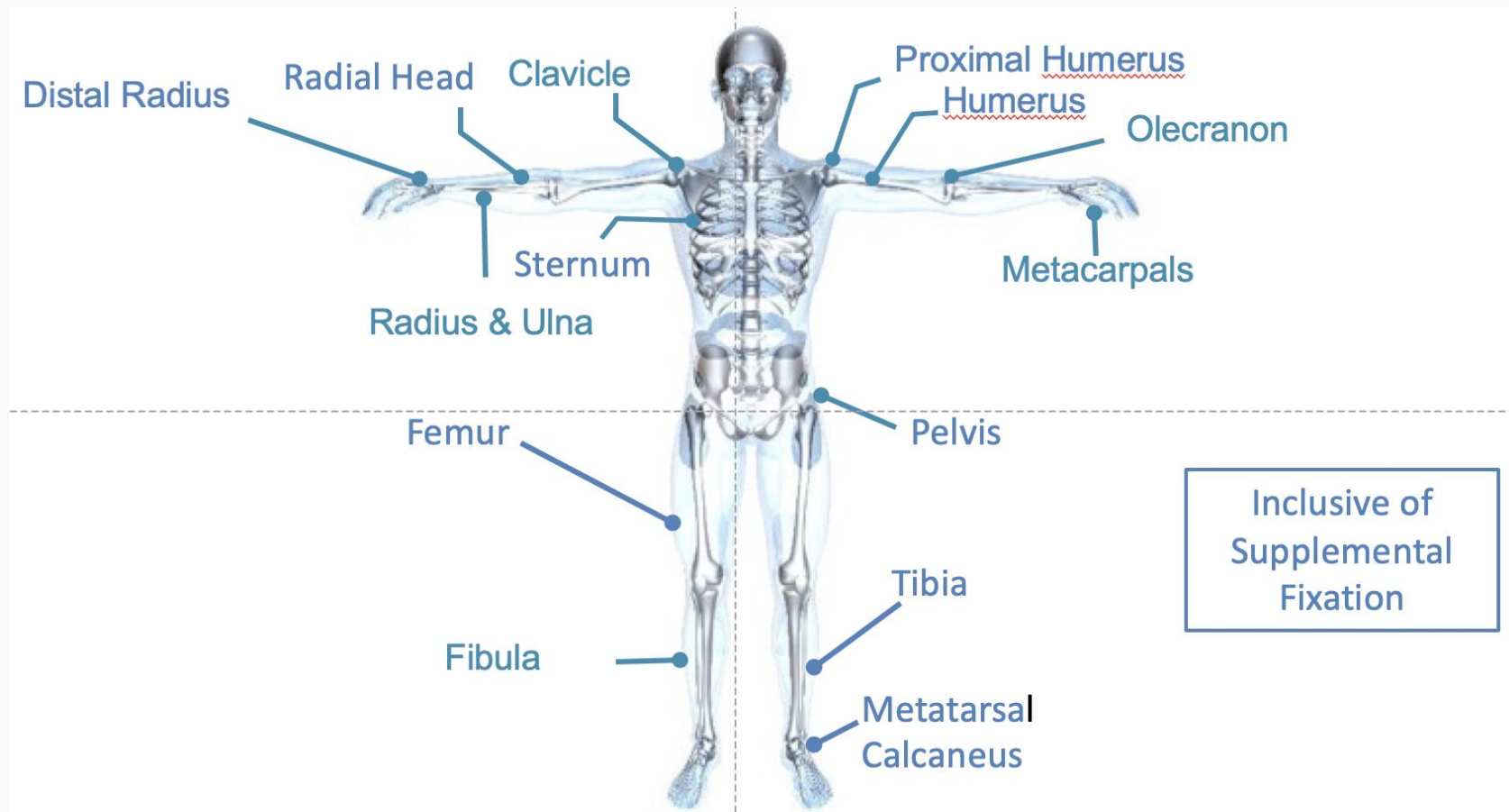


## *Lightfix Trial: Anecdotal Results*

- Typically a smaller sized incision
- Delivery system, which is a small diameter flexible catheter, provides the ability to spare the rotator cuff; a lateral approach can be made which seems to result in less postoperative pain and a faster recovery
- Less procedural estimated blood loss
- May also obviate pre-operative embolization for highly vascular tumors as it acts as a tamponade within the bone.
- Shorter hospital stay (half discharged same or next day)
- Procedure allows higher rate of post operative X ray therapy within 24 hours (almost half)

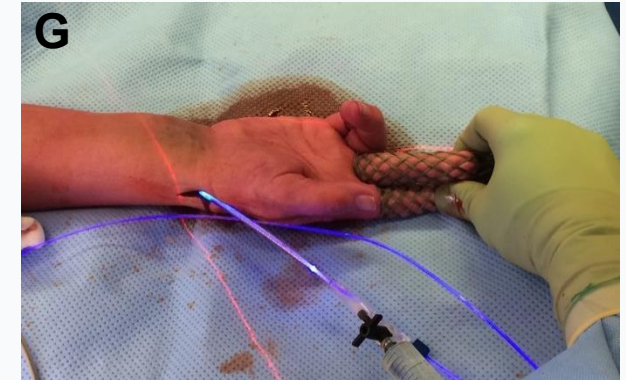
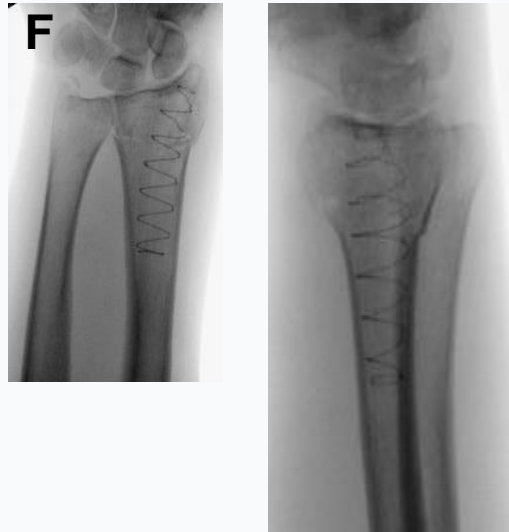
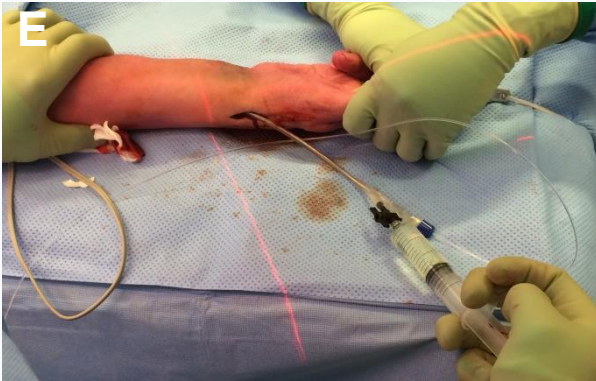
# *EU Clinical Experience: Trauma*

Osteoporotic, Poor Quality Compromised Bone, Typically an Older Population





# Procedural Simplicity



# Case: Bi-lateral Distal Radius Fracture

65 year old female bi-lateral distal radius and distal ulna fracture

Pre-Operative



Post Operative





## *Case: Distal Radius*

Day 2 post-op:



## *Distal Radius Trial*

- 5 Centers
- 50 Patients
- Mean Age: 75 years
- Gender: 94% female, 6% male
- Length of Study: 1 year
- Endpoints: DASH score PRWE score, Health-Related Quality of Life, Time to ADL independence, Time to activities/work resumption, range of motion of the wrist, radiological outcome, and complications.

# *Distal Radius Study: Interim Results*

- Average Procedure time = 49.9 min
- Incision size = 6 mm
- 82% of the patients were in the hospital 1 day or less
- No hard casts were used Post Operative. Exclusive to Soft Cast; air or light compressive bandage
- Minimal Use of Post Operative Opioids
- 60% of the patients returned to full function within 1 week and all patients returned to full function within 2 weeks

## Conclusions:

1. IlluminOss shows good radiological results and no secondary loss of reduction at six weeks after surgery.
2. IlluminOss allows them to resume their activities of daily living early, which is of the utmost importance in an elderly population.

# Case: Proximal Humerus



## Pre-Operative:

- 79 year old female
- proximal humeral fracture
- treated in day care



## Case: Proximal Humerus



Pre Op



Implant delivery



Implant filling



Post-operative

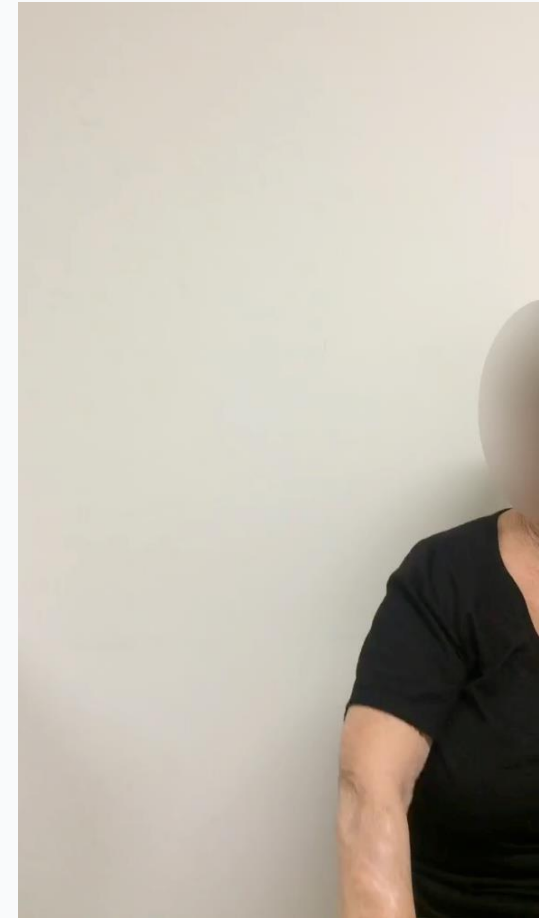
## Case: Proximal Humerus



Pre-op



Post-op 1 year



Full ROM



## *Proximal Humerus*

- IlluminOss for the older proximal humerus population provides both rotational and longitudinal stability while allowing for the use of supplementary hardware.
- Excellent rates of fracture healing were observed at 90-days, 180-days, and one-year post-surgery.
- Study showed that pts treated were much older than in the majority of other studies.
- Fracture healing rates of 96%.
- The ideal construct for bones that have compromised structural integrity, as is the case of elderly and potentially osteoporotic population.

## *Supplemental Fixation*

- IlluminOss can be easily drilled for the placement of ancillary screws.
- Not only does it drills like a plastic, it does not adhere to the drill bit like PMMA
- In combination with screws, IlluminOss provides a substantial 3 - 5x increase in holding / pullout force
- This holding power has shown to be of substantial benefit, providing purchase to screws in compromised, poor quality bone where none previously existed.

## *Indications for Use: USA*

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.

***For a complete list of contraindications, warnings, risks and precautions refer to the implant instructions for use, surgical technique guide or contact your IlluminOss Medical sales representative.***

# *Advantages of IlluminOss*

- Smaller incisions with less potential soft tissue damage, yet with the ability to expand the implant substantially
- Stable fixation can be achieved in poor quality bone
- Faster return to function and resumption of daily living activities
- Short procedure times
- Reduced hospital stays
- Less post-operative pain
- Less use of pain medication
- Relatively radiolucent
- Ability to work as either a stand alone implant or as a supplement to traditional hardware, as well as drilling anywhere

# Conclusions

- A much needed new approach to the treatment of fragility fractures
- Provides a patient customizable implant
- Experience in over 6,000 patients worldwide
- Based on WW experience, IlluminOss expands the surgeon fracture implant options to:
  1. Traditional hardware
  2. IlluminOss
  3. Supplemental; the combination use of hardware plus IlluminOss
- More studies are necessary but as time progresses, I expect to see the adoption of IlluminOss in a much broader range of patients

