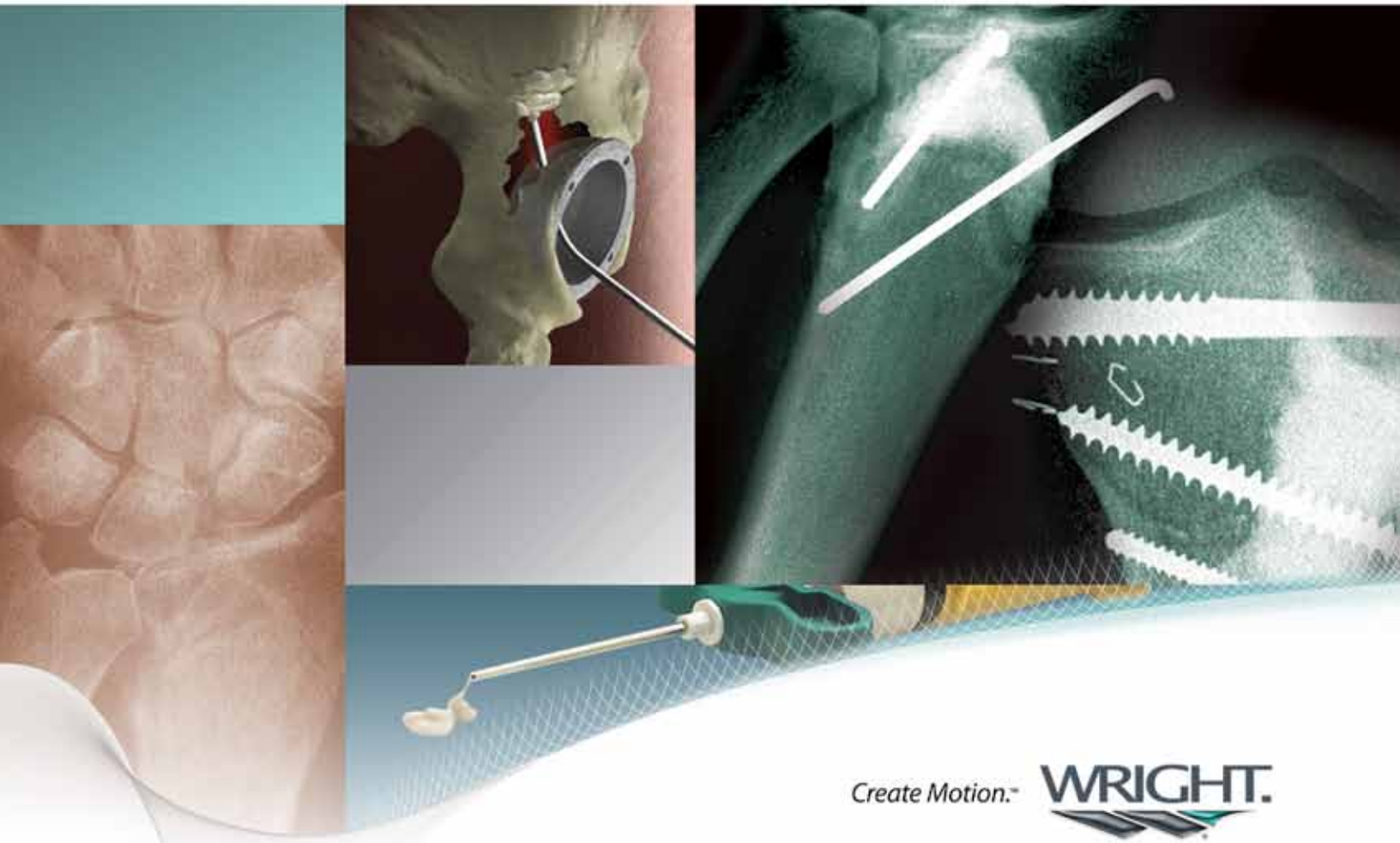
MIIG® X3

High Strength Injectable
Graft for Compression Fractures

SURGICAL TECHNIQUE



Create Motion.™ WRIGHT.

MIIG® X3

HIGH-STRENGTH INJECTABLE GRAFT FOR COMPRESSION FRACTURES

surgical techniques as described by
KEITH RASKIN, MD
J. TRACY WATSON, MD

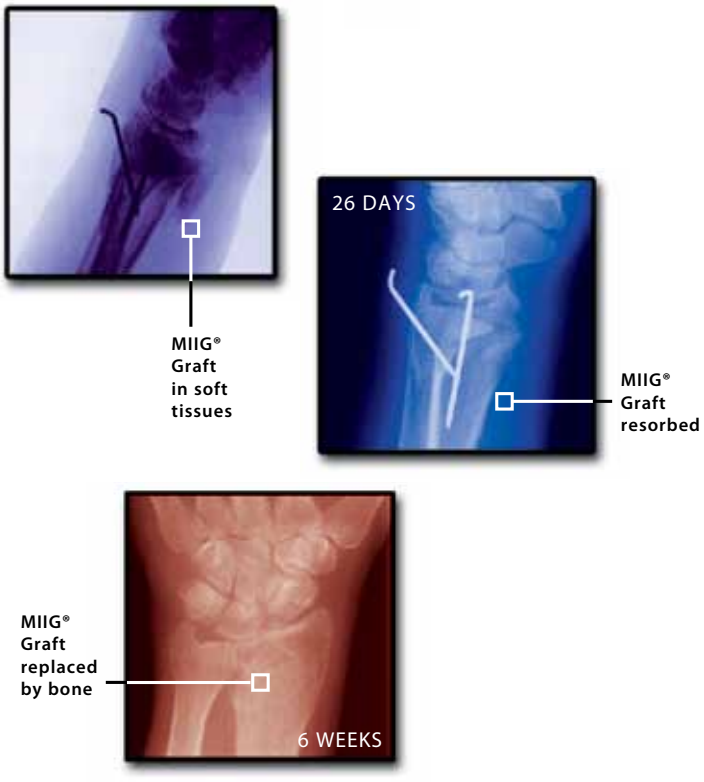
The next generation least-invasive grafting option for compression fractures is an injectable calcium sulfate with significantly higher compressive strength. MIIG® 115 (Minimally Invasive Injectable Graft) was the first injectable graft to provide temporary support and resorb at a predictable rate. Now, MIIG® X3 Graft provides even higher compressive strength with the same reliable resorption.

MIIG® X3 Graft

- **Injects**
- **Resorbs**
- **Remodels into bone**

MIIG® X3 Graft - Resorbable Salt	VS.	Injectable Calcium Phosphate - Slow Resorbing Ceramic
• No Extravasation Issues - Resorbs quickly in soft tissues and synovium		• Ceramic must be removed if leaked into joint space or soft tissues
• Faster resorption and replacement by bone (10-12 weeks)		• Resorption rate 2-3 years
• Straightforward surgical technique: a) Reduce b) Inject graft c) Drill/tap for final hardware		• Backwards technique a) Reduce c) Place final hardware b) Inject graft

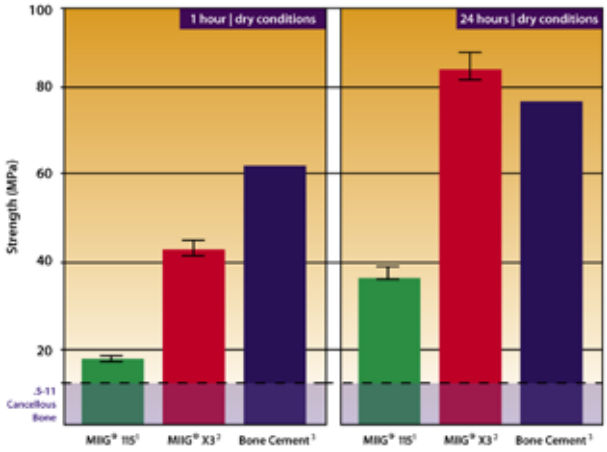
FIGURE 1 |



High-Strength

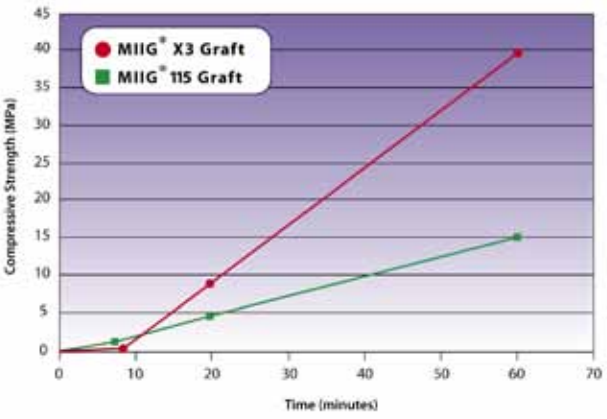
- **MIIG® X3 Graft provides 160% greater compressive strength than MIIG® 115 Graft**

FIGURE 2 | Compressive Strength in a Dry Environment



In a dry environment, MIIG® X3 Graft demonstrates compressive strengths comparable to reported bone cement values.

FIGURE 3 | Compression Strength in a Simulated In Vivo Environment[4]



At one hour in a simulated wet environment, MIIG® X3 Graft maintains 160% greater compressive strength than the MIIG® 115 Graft.

Resorbable

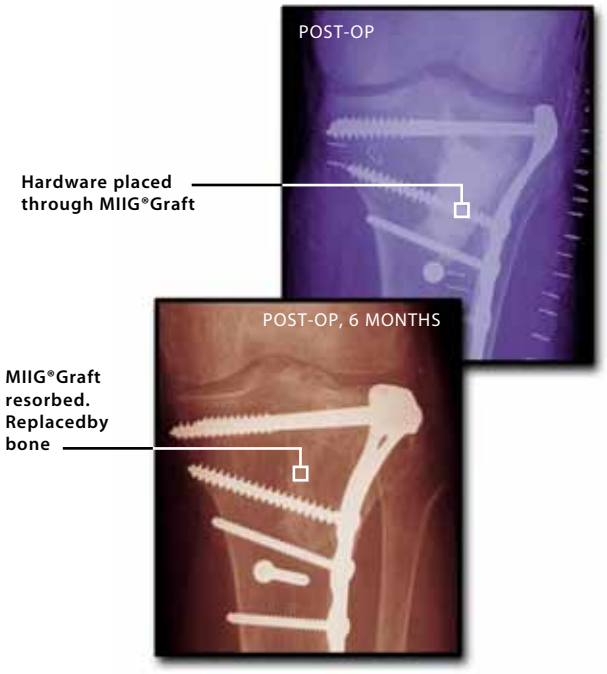
- **Reliable resorption and replacement by bone**

FIGURE 4A |

FIGURE 4B |

A 13x50mm cylindrical defect (outlined) was surgically created in a canine humera model and filled with MIIG® X3 calcium sulfate. Contact radiographs demonstrate an osteoconductive effect through new bone regeneration and subsequent remodeling at 13 weeks.

FIGURE 5 |



MIIG® X3 GRAFT SURGICAL TECHNIQUE

TIBIAL PLATEAU FRACTURE

Presented by J. Tracy Watson, M.D., St. Louis, MO

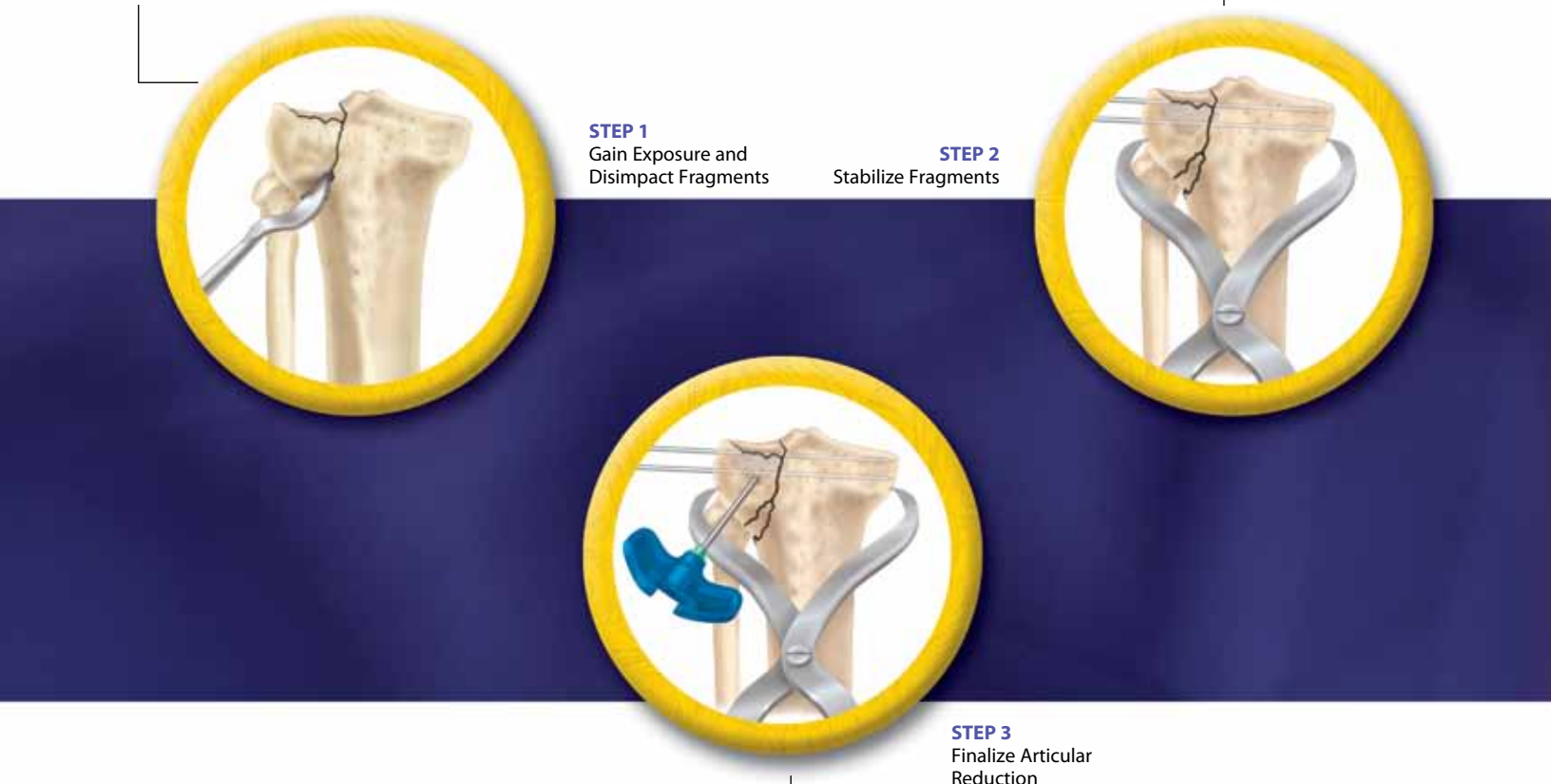
STEP 1 GAIN EXPOSURE AND DISIMPACT FRAGMENTS

Care should be taken to plan a relatively straight full-thicknes incision such that wound necrosis can be minimized. Access to the depressed surface can be obtained directly through the fracture line at the base of the condylar fragment or a cortical window can be made utilizing numerous drill holes and an osteotome.

Once adequate exposure has been obtained, place a curved elevator distal to the fragments to facilitate disimpaction under flouroscopy. Periosteal stripping should be avoided.

STEP 2 STABILIZE FRAGMENTS

Although the depressed fragments can often be elevated *en masse*, the reduction is often tenuous and unstable. In this case, supplemental Kirschner wires or provisional instrumentation can be utilized to stabilize reduction of the larger condylar fragments.



STEP 1
Gain Exposure and Disimpact Fragments

STEP 2
Stabilize Fragments

STEP 3
Finalize Articular Reduction

STEP 3 FINALIZE ARTICULAR REDUCTION

Once the fragments have been reduced and stabilized, insert the appropriate sized injection needle into the compression defect. Positioning of the needle and appropriate reduction of the articular surface can be confirmed via flouroscopy.

STEP 4 INJECT MIIG® X3 GRAFT FOR INTRA-OSSEOUS STABILIZATION

With provisional hardware in position and the MIIG® X3 Graft delivery needle in place, prepare the MIIG® X3 Graft using the mixing instructions provided in the kit. After graft preparation, dock the syringe onto the pre-placed needle. With flouroscopy assistance, begin introduction of the MIIG® X3 Graft material into the compression defect. Injection delivery time is approximately 2 1/2 minutes.

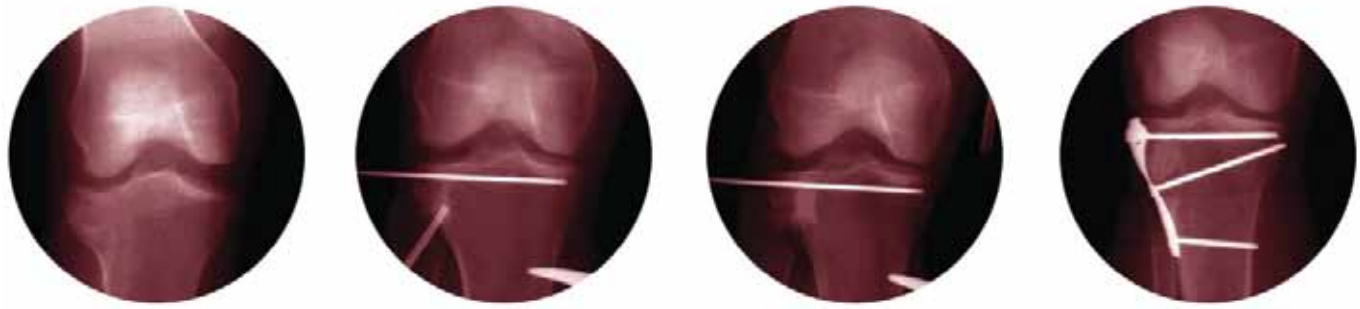
STEP 5 PLACE FINAL HARDWARE

Six to eight minutes after injection, fixation hardware may be placed with standard drilling or use of self-tapping screws. This can be performed through the hardened MIIG® X3 Graft without concern for disrupting the crystalline structure and changing the mechanical properties of the material.

NOTE: Always ensure distal screw fixation is within bone.

STEP 4
Inject MIIG® X3 Graft for intra-osseous stabilization

STEP 5
Place Final Hardware



MIIG® X3 GRAFT SURGICAL TECHNIQUE

CLOSED GRAFTING FOR DISTAL RADIUS FRACTURES

Presented by Keith Raskin, M.D., New York, NY

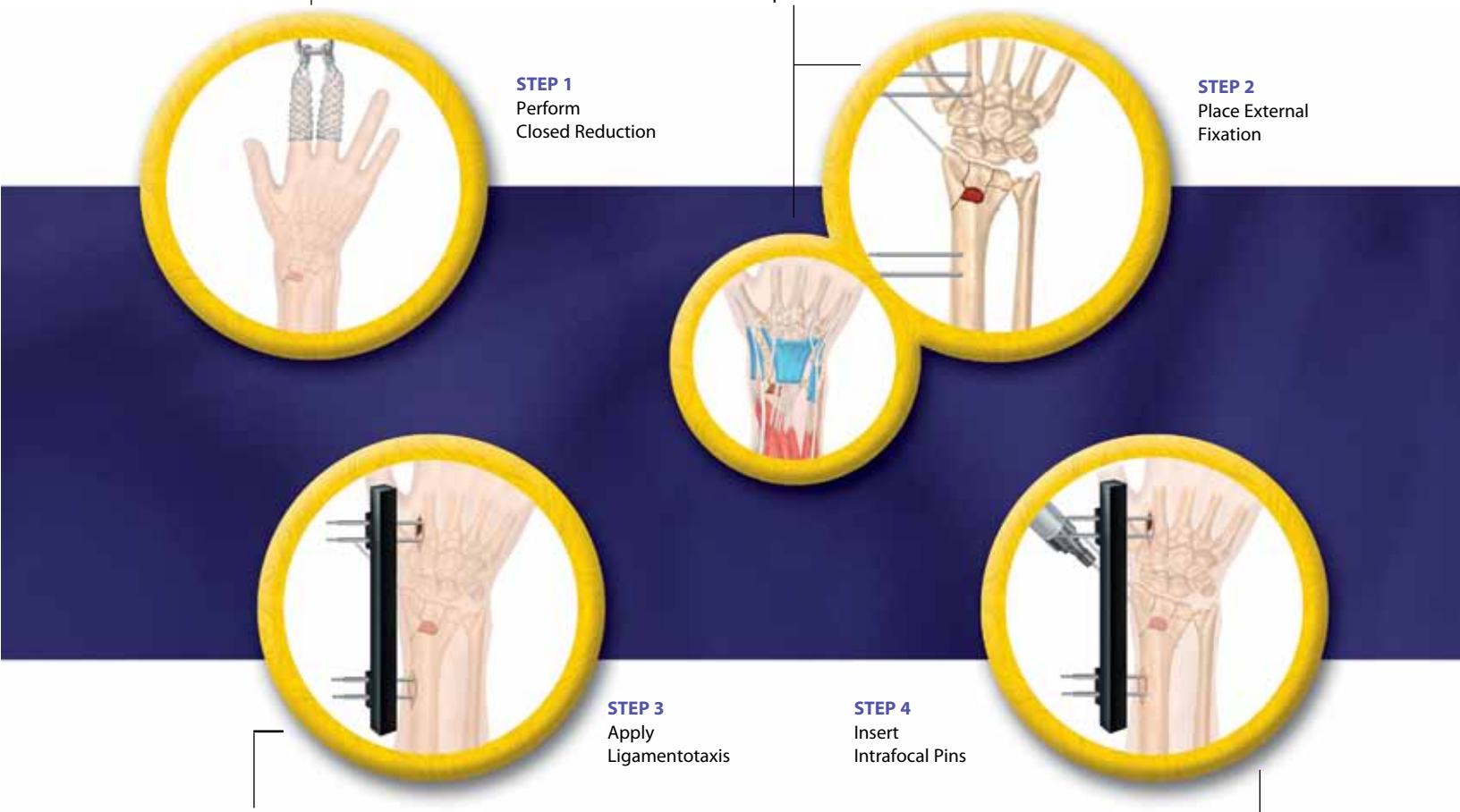
Proper surgical techniques are necessarily the responsibility of the medical professional. The following guidelines are furnished only as recommended techniques. Each surgeon must evaluate the appropriateness of the techniques based on his or her own medical training and expertise.

STEP 1 PERFORM CLOSED REDUCTION

After adequate regional anesthesia, the fracture is grossly realigned through closed manipulation, in preparation for external fixation.

STEP 2 PLACE EXTERNAL FIXATION

The distal pin site is approached through a short longitudinal incision along the dorsoradial border of the index metacarpal. The terminal sensory radial nerve branches are well protected as the pins are inserted with bicortical purchase under direct visualization. The proximal pins are inserted in a similar fashion through a separate incision along the dorsoradial border of the radial shaft approximately 3-5cm proximal to the fracture site. The radial sensory nerve is identified and protected as the pins are inserted under direct visualization.



STEP 3 APPLY LIGAMENTOTAXIS

Ligamentotaxis is applied across the fracture site through the application of the external fixator of choice.

STEP 4 INSERT INTRAFOCAL PINS

Once the deforming force of the carpus has been neutralized through the external fixation, the fracture can be further manipulated with the use of smooth .045" and .062" smooth K-Wires. These wires can be safely inserted from the radial styloid region or through accepted intrafocal pinning technique.

HIGH STRENGTH. INJECTS. REPLACED BY BONE.

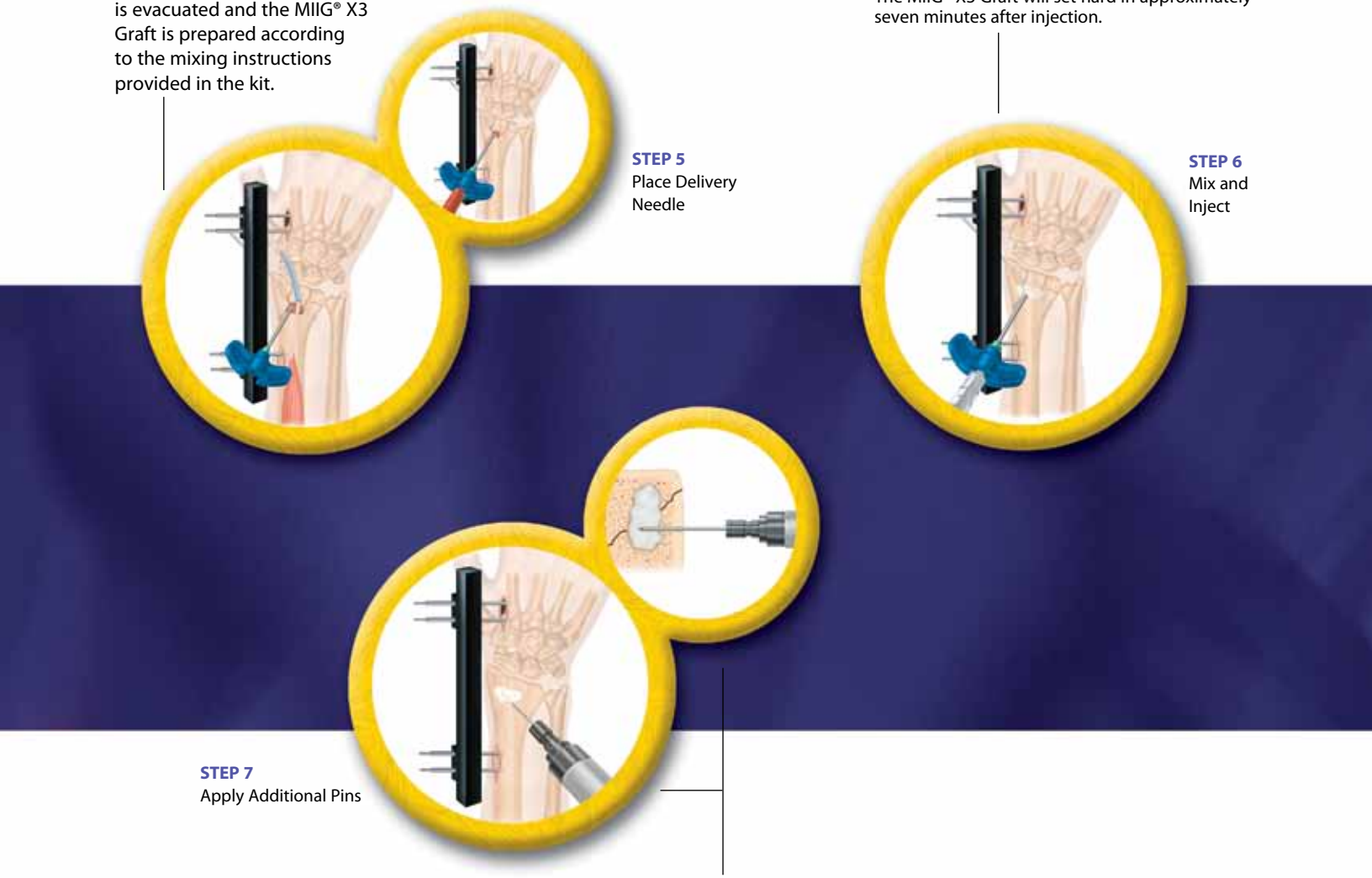
Step 5 PLACE DELIVERY NEEDLE

Once the fracture is stabilized with external fixation and percutaneous K-Wire insertion, the metaphyseal void can be obliterated without the need for open bone grafting technique. The MIIG® X3 Graft injection cannula is safely inserted along the radial border of Lister's Tubercle. This avoids injury to the adjacent thumb extensor tendon and radial sensory nerve branches. Fluoroscopic assistance is recommended. Once the cannula is properly placed, the hematoma is evacuated and the MIIG® X3 Graft is prepared according to the mixing instructions provided in the kit.

STEP 6 MIX AND INJECT

After graft preparation, dock the syringe onto the pre-placed needle and begin injection. A gentle windshield-wiper motion assists in the completion of filling. Injection delivery time is approximately 2 1/2 minutes.

The MIIG® X3 Graft will set hard in approximately seven minutes after injection.



STEP 5
Place Delivery Needle

STEP 6
Mix and Inject

STEP 7
Apply Additional Pins

STEP 7 APPLY ADDITIONAL PINS

As the MIIG® X3 Graft is hardening, final fine adjustment of the fracture can be performed. Additional wires can be inserted through the MIIG® X3 Graft bolus after the material has set hard.

Ordering Information

84XS-0405 5cc
84XS-0415 15cc

For Open Reduction, Internal Fixation, Try:

ALLOMATRIX® DR GRAFT

86DR-0300	3cc

ALLOMATRIX® CUSTOM PUTTY

86XC-0560	5cc
86XC-1000	10cc

Design Features

- High-Strength
- Injects through small gauge needle
- Hardens in defect
- Replaced by bone
- Temporary support medium
- May be drilled or tapped for hardware

References

1 Hand-mixed; data on file.

2 Vacuum-mixed; data on file.

3 Belkoff SM, et al. The effect of the monomer-to-powder ratio on the material porperties of acrylic bone cement. J Biomed Mater Res (Appl Biomater) 2002; 63:396-399. Monomer-to powder ratio was 0.45 ml/g.

4 Data on file.

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