



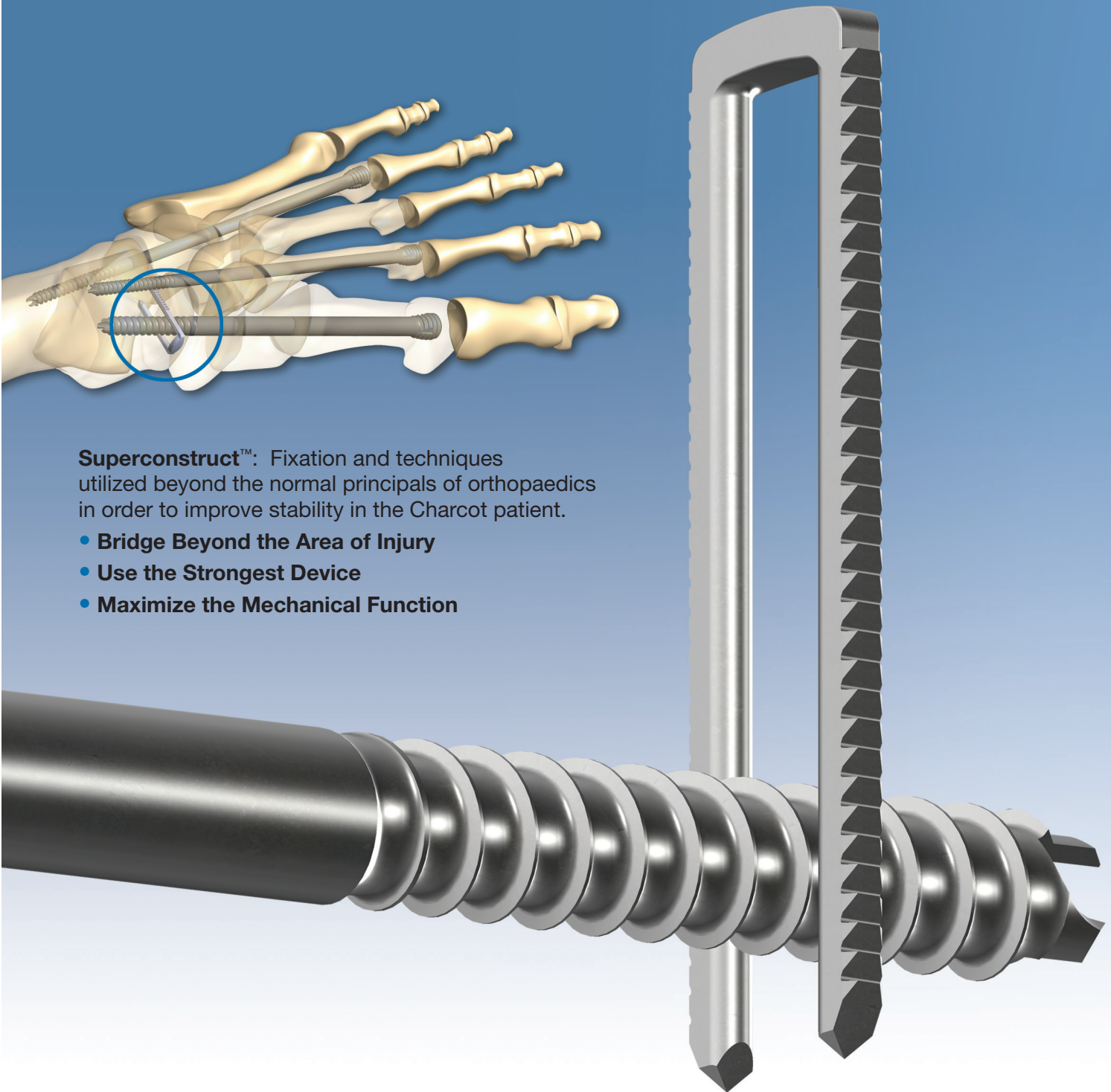
A Superconstruct™* for the Treatment of Charcot Deformity

Bridging Advances in Technology and Technique



A Superconstruct™* for the Treatment of Charcot Deformity

Bridging Advances in Technology and Technique



Superconstruct™: Fixation and techniques utilized beyond the normal principals of orthopaedics in order to improve stability in the Charcot patient.

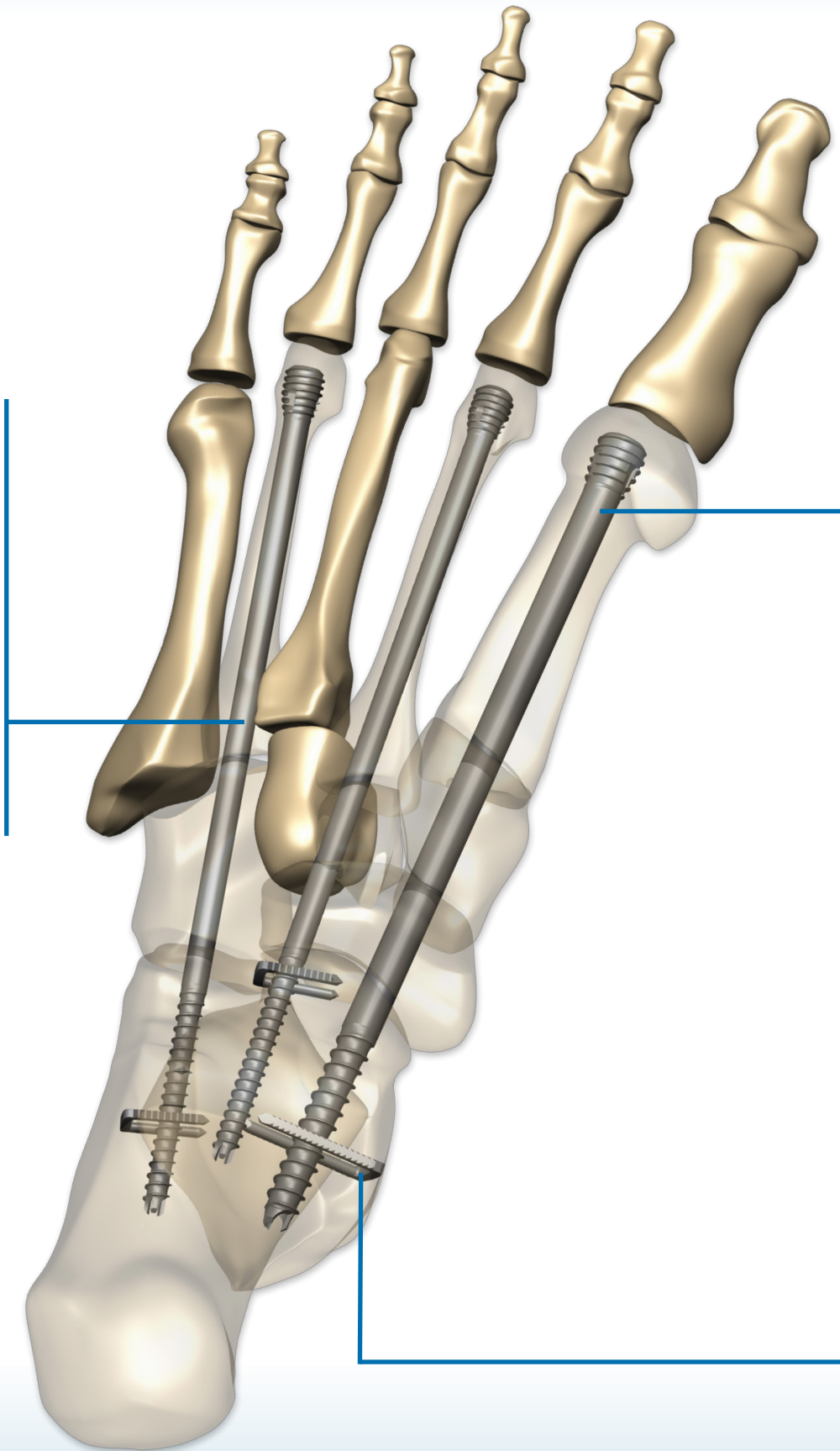
- **Bridge Beyond the Area of Injury**
- **Use the Strongest Device**
- **Maximize the Mechanical Function**

The AXIS Superconstruct™ ... Evolution of Charcot Fixation

Bridge beyond the Area of Injury

"...fusion is extended beyond the zone of injury to include joints that are not affected to improve fixation...the fixation is dramatically improved"¹

- **AXIS Beams from 70-160mm**



¹ V. James Sammarco MD, Superconstructs in the Treatment of Charcot Foot Deformity: Plantar Plating, Locked Plating and Axial Screw Fixation, *Foot Ankle Clin N AM* 12 (2009) 393-407, 399.

The AXIS Superconstruct™ ... Evolution of Charcot Fixation

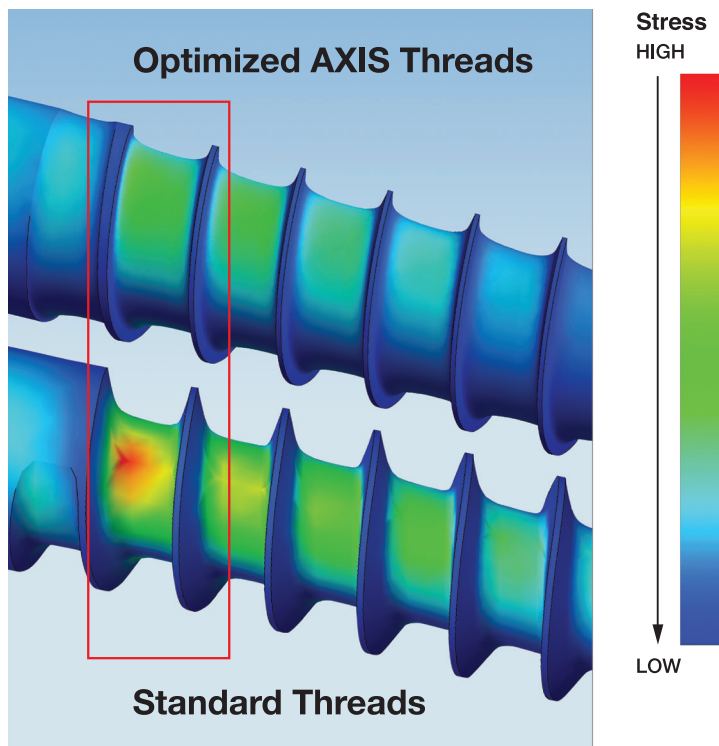
Use the Strongest Device

*"...the strongest device is used that can be tolerated by the soft tissue"*¹

- Large Shank Beams with Sizes up to 7.5mm
- Thread Design Optimized to Handle Higher Bending Forces
- Type II Anodized Titanium Alloy for Enhanced Fatigue Strength

AXIS Strength Advantage

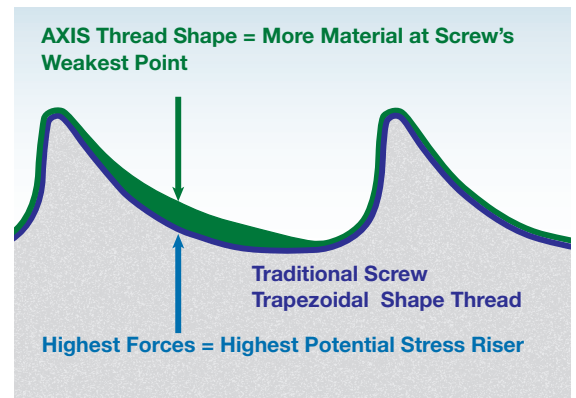
39% Reduction in Stress Risers



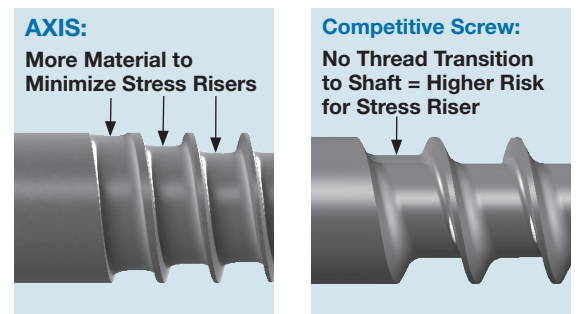
Data on file

More Material Where Needed Most

AXIS: Novel Parabolic Thread Shape



Optimized Thread Transition of Minor Diameter To Shaft

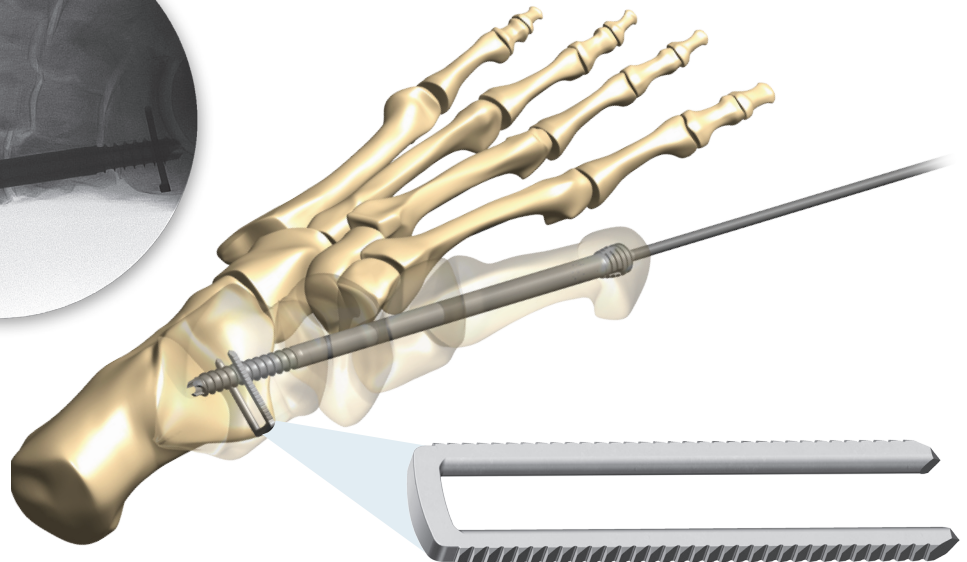
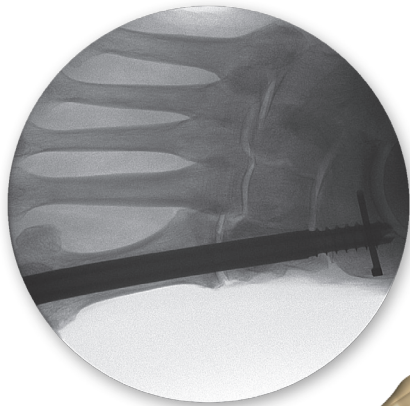


The AXIS Superconstruct™ ... Evolution of Charcot Fixation

Maximize the Mechanical Function

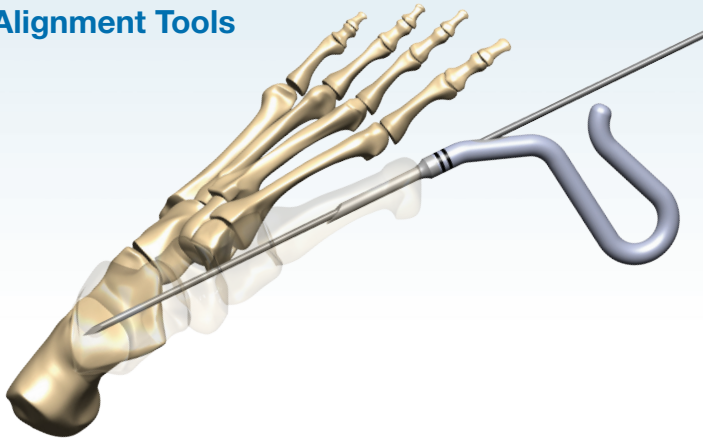
*"...devices are applied in a position that maximizes mechanical function"*¹

- **Intramedullary Beaming Minimizes Stress Risers in Cortical Bone as Seen from Placement of Plates and Oblique Screws**
- **X-Clip Acts as an "Intraosseous Anchor" to create a Superconstruct™**
 - Improves Thread Purchase
 - Improves Construct Stability Through Maintenance of Compression
 - Increases Surface Area to Dissipate Shear Forces

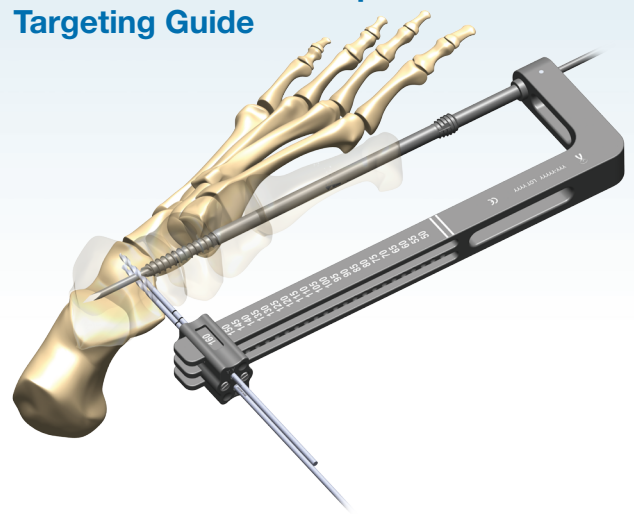


Specialized Instrumentation Facilitates Alignment and Hardware Insertion

Robust Guidewires and Alignment Tools



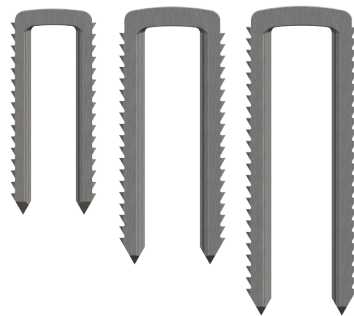
Precision Guided X-Clip Targeting Guide



AXIS™: Fully Cannulated Fusion Beams



Beam Size	Lengths
5.5mm	70-150mm
6.5mm	70-160mm
7.5mm	70-160mm



X-Clip Size	Lengths
5.5mm	15 & 20mm
6.5mm	25 & 30mm
7.5mm	25 & 30mm

300 Interpace Parkway
Suite 410
Parsippany, NJ 07054
Phone: 973.588.8980
Customer Service: 888.499.0079
Fax: 888.499.0542
www.extremitymedical.com



Indications For Use: The AXIS Charcot Fixation System in diameters of 5.5, 6.5 and 7.5mm is indicated for reconstruction procedures, non-unions and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: medial and lateral column fusion resulting from neuropathic osteoarthopathy (Charcot).

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LBL-130-99105-EN Rev A 07/2017

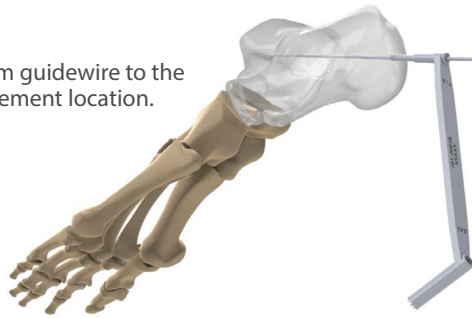
Technique Guide

4.5/6.5mm Headless Compression Screw



STEP 1

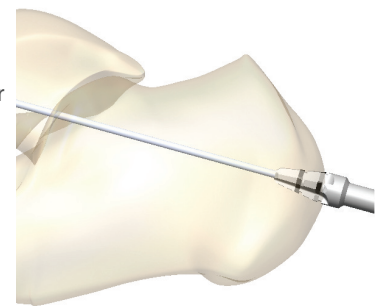
Advance the 1.6mm guidewire to the desired screw placement location.



STEP 4

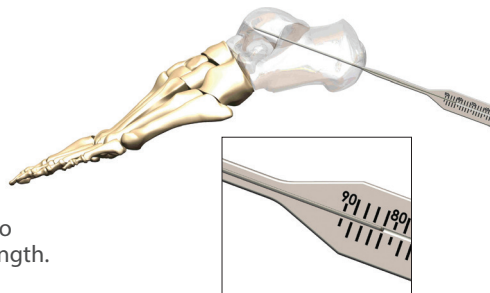
Advance the countersink over the guidewire until the depth line is no longer visible.

- 1st line is for 4.5mm screws
- 2nd line is for 6.5mm screws



STEP 2

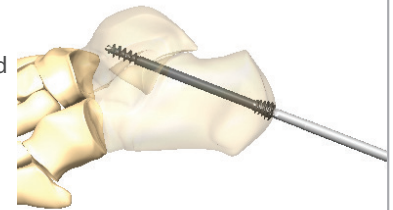
Slide the screw measuring device over the 1.6mm guidewire and down to the bone to determine screw length.



STEP 5

Insert the screw to the desired position with the appropriate driver.

Screw	Driver
4.5mm	3.0mm Hex
6.5mm	4.0mm Hex



STEP 3

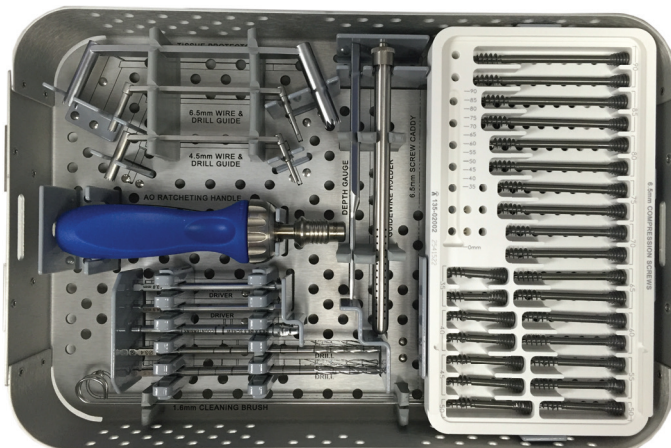
Select the appropriate sized drill, advance to the measured screw length.

Screw	Drill
4.5mm	3.4mm
6.5mm	4.5mm



REMOVAL

Clear the bone from the proximal end of the screw. Insert the appropriate driver into the screw and turn the driver counterclockwise to remove. Inserting a 1.6mm guidewire into the cannulation of the screw may help to align the head of the screw to its corresponding driver.



Instrument	Description	Qty
Disposable Instruments		
101-00006	Guidewire - 1.6mm	5
101-00012	Cannulated Drill - 3.4mm	2
101-00013	Cannulated Drill - 4.5mm	2
101-00023	Cleaning Brush - 1.6mm	2
Reusable Instruments		
101-00009	Guidewire Holder - 1.6mm	1
101-00010	Screw Measuring Device	1
101-00017	4.5mm Guide - Drill and Guide Pin	1
101-00018	6.5mm Guide - Drill and Guide Pin	1
101-00019	Tissue Protector	1
118-00039	AO Ratcheting Handle	1
135-00111	Countersink (AO) - 4.5/6.5mm	2
135-00130	Hex Driver (AO) - 3.0mm	2
135-00140	Hex Driver (AO) - 4.0mm	2
135-00000	Instrument Tray	1

4.5/6.5mm Headless Compression Screws



Headless:

Reduces soft tissue irritation

Cannulated:

Accurate insertion

Tapered Proximal Threads:

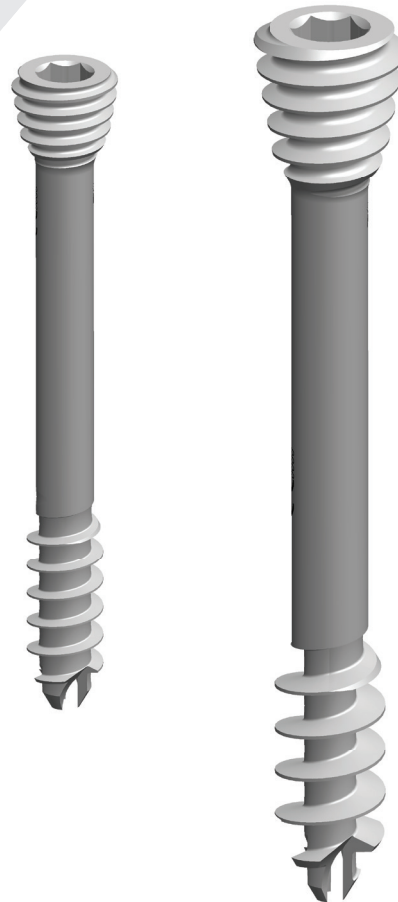
Enhances compression

Type 2 Titanium Anodizing:

Improves fatigue strength

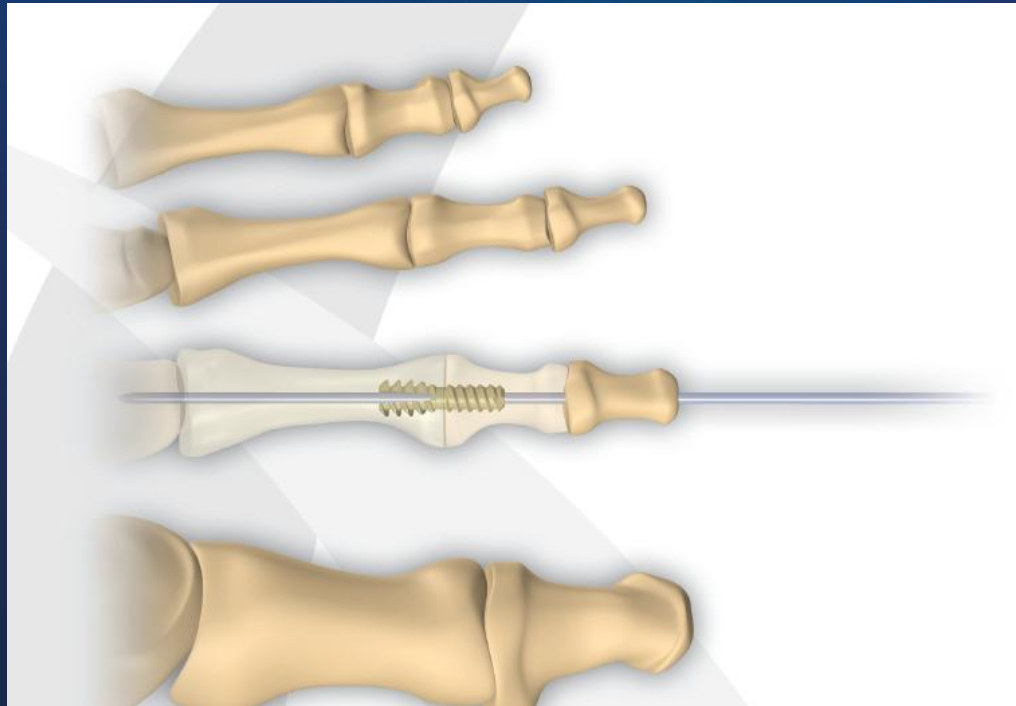
Aggressive Distal Threads:

Designed to maximize purchase



Implant	Description	Qty
4.5mm Compression Screws (Cannulated)		
101-45026-2	4.5x26mm	1
101-45028-2	4.5x28mm	1
101-45030-2	4.5x30mm	1
101-45032-2	4.5x32mm	1
101-45034-2	4.5x34mm	1
101-45036-2	4.5x36mm	1
101-45038-2	4.5x38mm	1
101-45040-2	4.5x40mm	2
101-45044-2	4.5x44mm	2
101-45048-2	4.5x48mm	2
101-45052-2	4.5x52mm	2
101-45056-2	4.5x56mm	2
101-45060-2	4.5x60mm	2

Implant	Description	Qty
6.5mm Compression Screws (Cannulated)		
101-65030-2	6.5 x 30mm	2
101-65035-2	6.5 x 35mm	2
101-65040-2	6.5 x 40mm	2
101-65045-2	6.5 x 45mm	2
101-65050-2	6.5 x 50mm	2
101-65055-2	6.5 x 55mm	2
101-65060-2	6.5 x 60mm	2
101-65065-2	6.5 x 65mm	2
101-65070-2	6.5 x 70mm	2
101-65075-2	6.5 x 75mm	2
101-65080-2	6.5 x 80mm	2
101-65085-2	6.5 x 85mm	2
101-65090-2	6.5 x 90mm	2



TRAINING

Hammertoe Market



- 600,000 + Hammertoe Procedures per Yr US
- 60mm people suffer from Hammertoe deformity
 - majority not DX or treated
- +\$500mm market and growing

Extremity Medical Customer Survey 2013

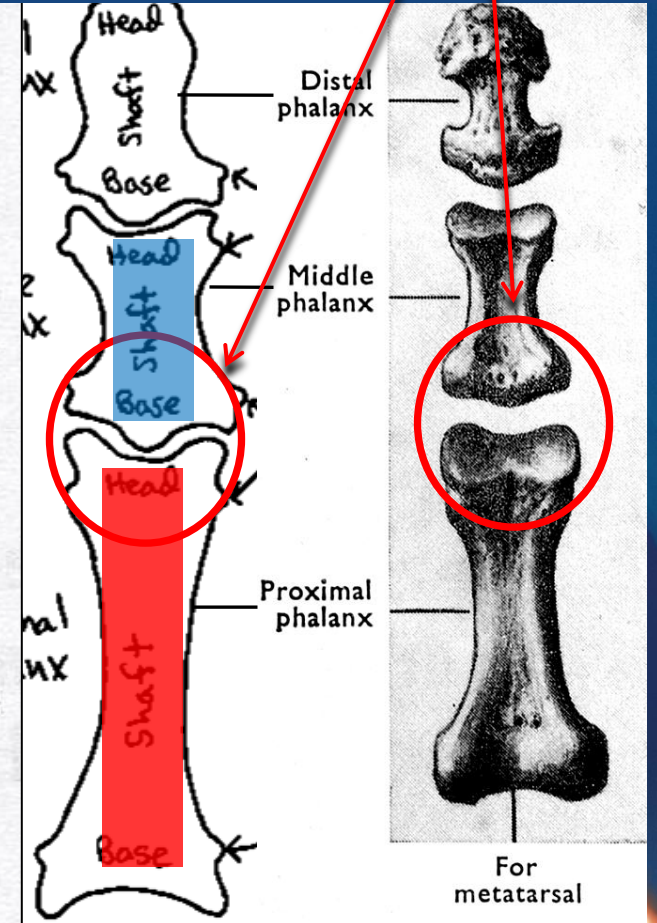
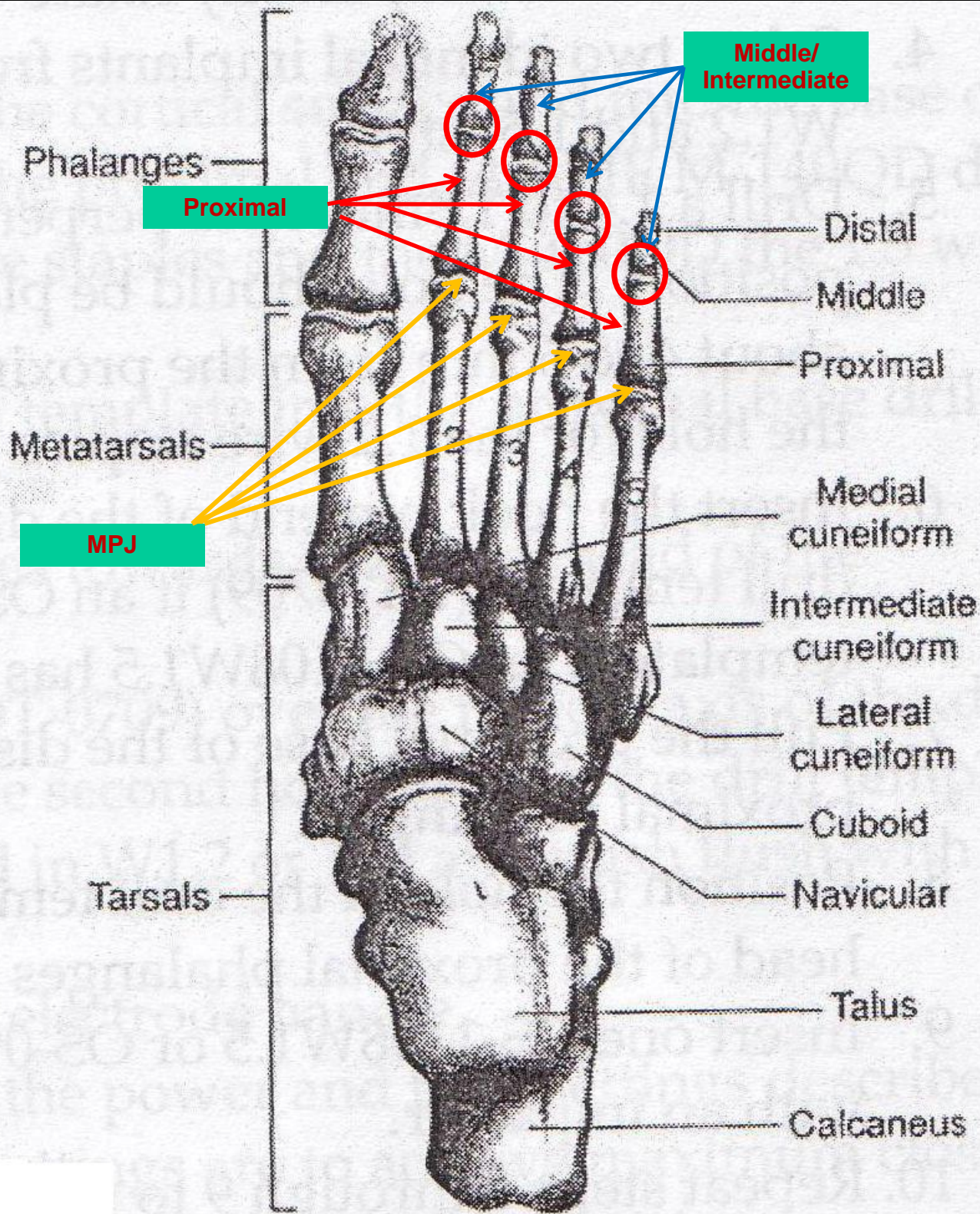
- 50% 3-6 per month
- 25% 6-12 per month
- 25% 12 or more per month



Anatomy

Lesser IP Joint =

Joint between Middle/
Proximal Phalanx



Indications

Forefoot Deformity

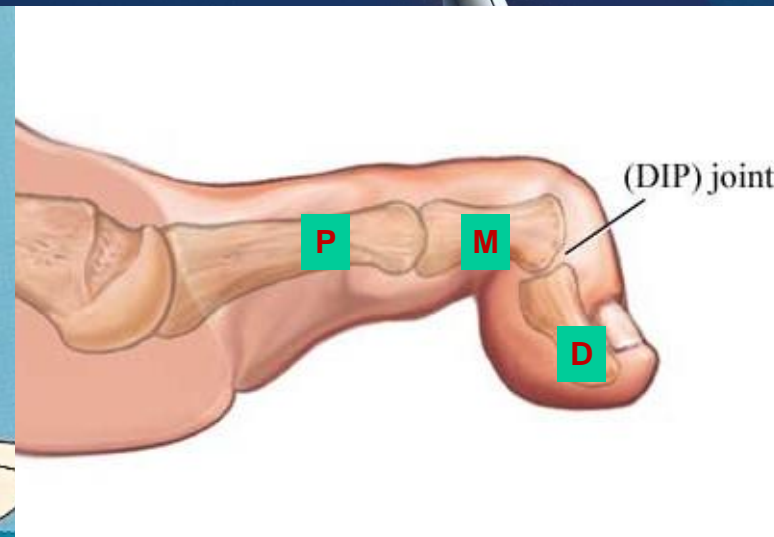
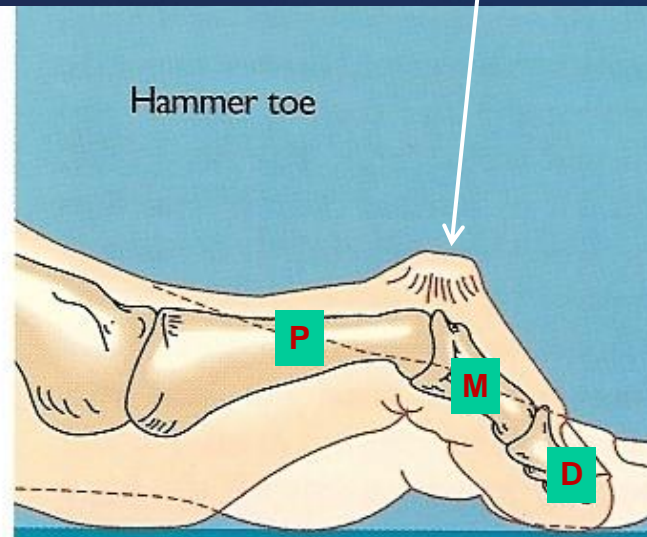
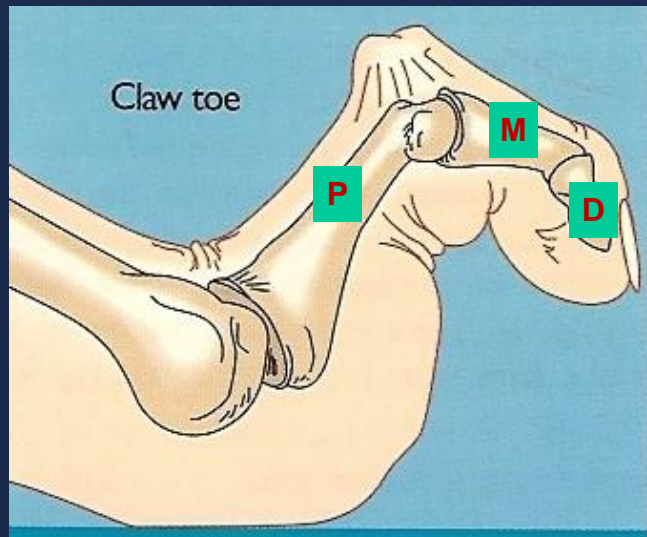
Hammertoe (toe is bent at the middle knuckle of the toe)

- flexion contracture at the IP joint
- extension at the MPJ

Claw toe (toe is bent at both the middle knuckle and tip of the toe)

- hammertoe deformity + flexion at DIP joint

Mallet Toe – deformity at the DIP joint



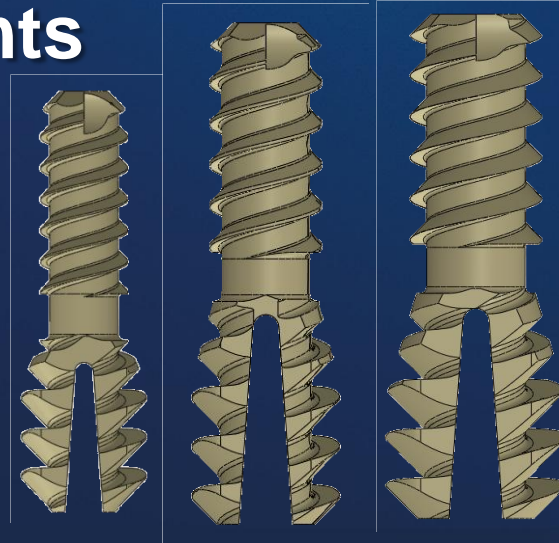
Best in Class!

Differentiated – Material & Design



Design Inputs

- Stability – Maintenance of Correction
- Ability to Simultaneously Address MP Joint
- Ability to Compress Joint
- Sized for All Lesser Joints
- Easy to Use
- Easy to Remove



XM Survey Results 2013

82% Perceived Need for improved technology to improve outcomes

A grayscale photograph of a hand holding a large metal screw. The hand is positioned in the center, with the thumb and index finger gripping the handle of the screw. The screw is oriented horizontally, with its head on the left and its threaded shaft extending to the right. The background is a soft, out-of-focus landscape with rolling hills and a bright sky. The overall tone is professional and clinical.

HammerFi[®]

IP Fusion System

What You *Don't*
See is Just the
Beginning...

The logo for Extremity Medical, featuring a stylized human figure with arms raised in a 'V' shape, positioned above the company name.

EXTREMITY
MEDICAL[™]



**What You *Don't*
See is Just the
Beginning...**



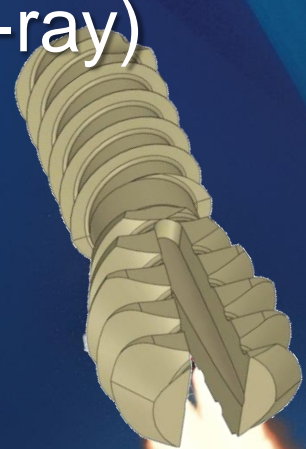
PEEK

Differentiated – Material



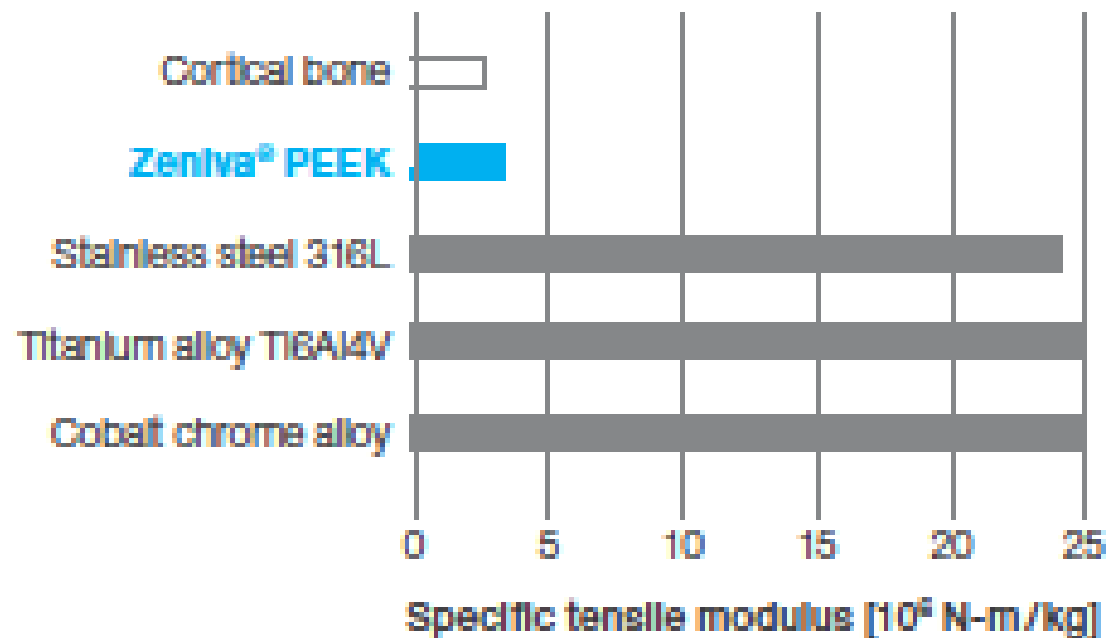
What is & Why PEEK?

- Non-resorbable polymer
- Great Biocompatibility – long track record
 - used medical device over a decade
- Radiolucent – clear visualization of fusion site(x-ray)
- Excellent toughness & fatigue strength
- Stiffness = very similar to cortical bone
- Polymer – can be easily cut for removal
- **PEEK material allows for unique design**



Stiffness very similar to cortical bone

Comparison of stiffness-to-weight ratios
Tensile modulus/density



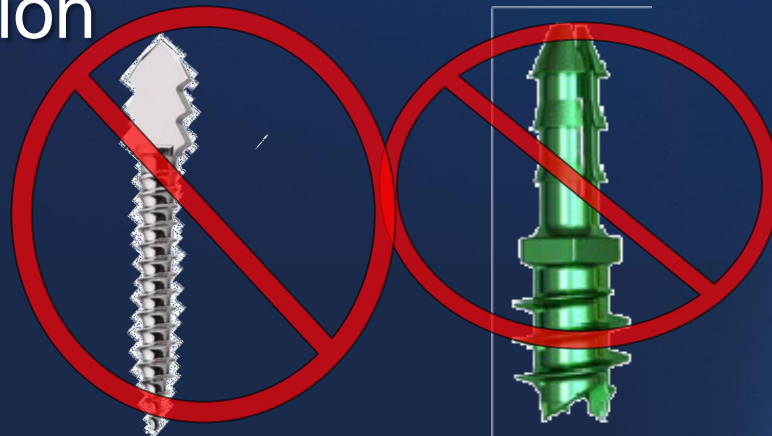
**moment applied
decreases risk of implant cut-out**

Stability

Differentiated – Unique Design



- PEEK –elasticity allows for unique design
 - ❖ **Barbed section**
 - ease of insertion
 - **designed to open & grab cortex**
- Barbs – Reverse Helical Threads
 - opposing threads = able to generate compress joint
- Monolythic – cannot unlock
easy insertion

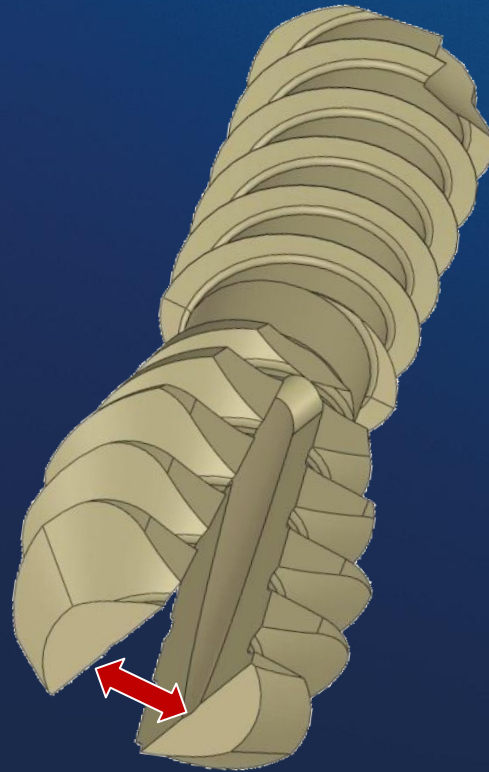


Stability Barbed Segment



Differentiated Feature

- Designed to open & grab cortex



Balanced pull-out threaded & barbed segment

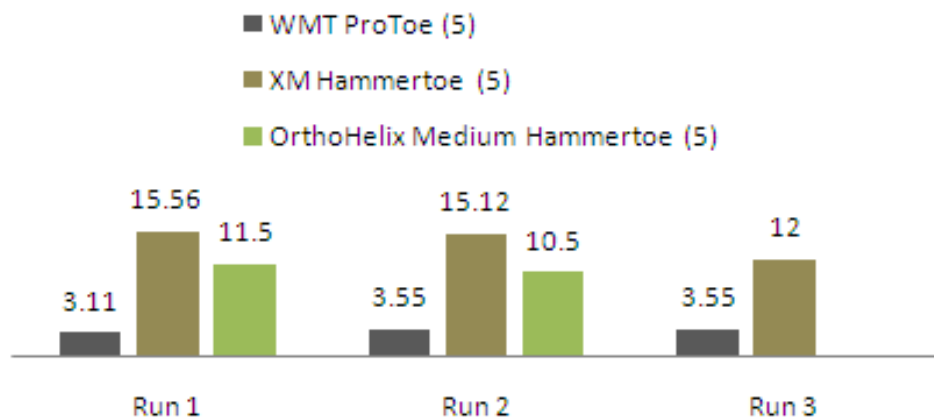


Stability Pull Out Testing

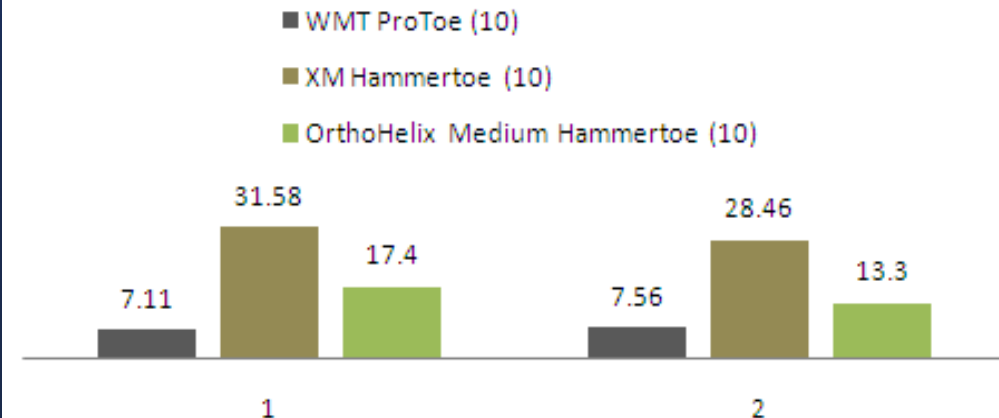
- Favorable Pull Out testing results
 - very low & low density foam
 - non threaded side tested
 - no wire

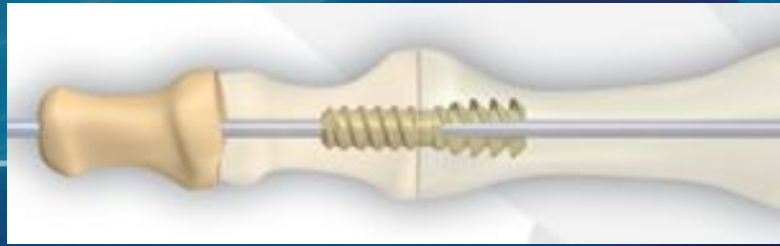
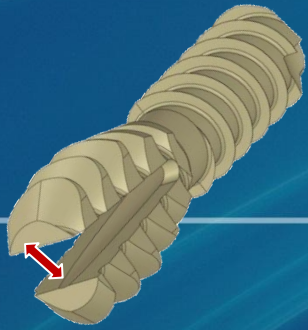


**Pull Out Force(N)
5 pcf foam**

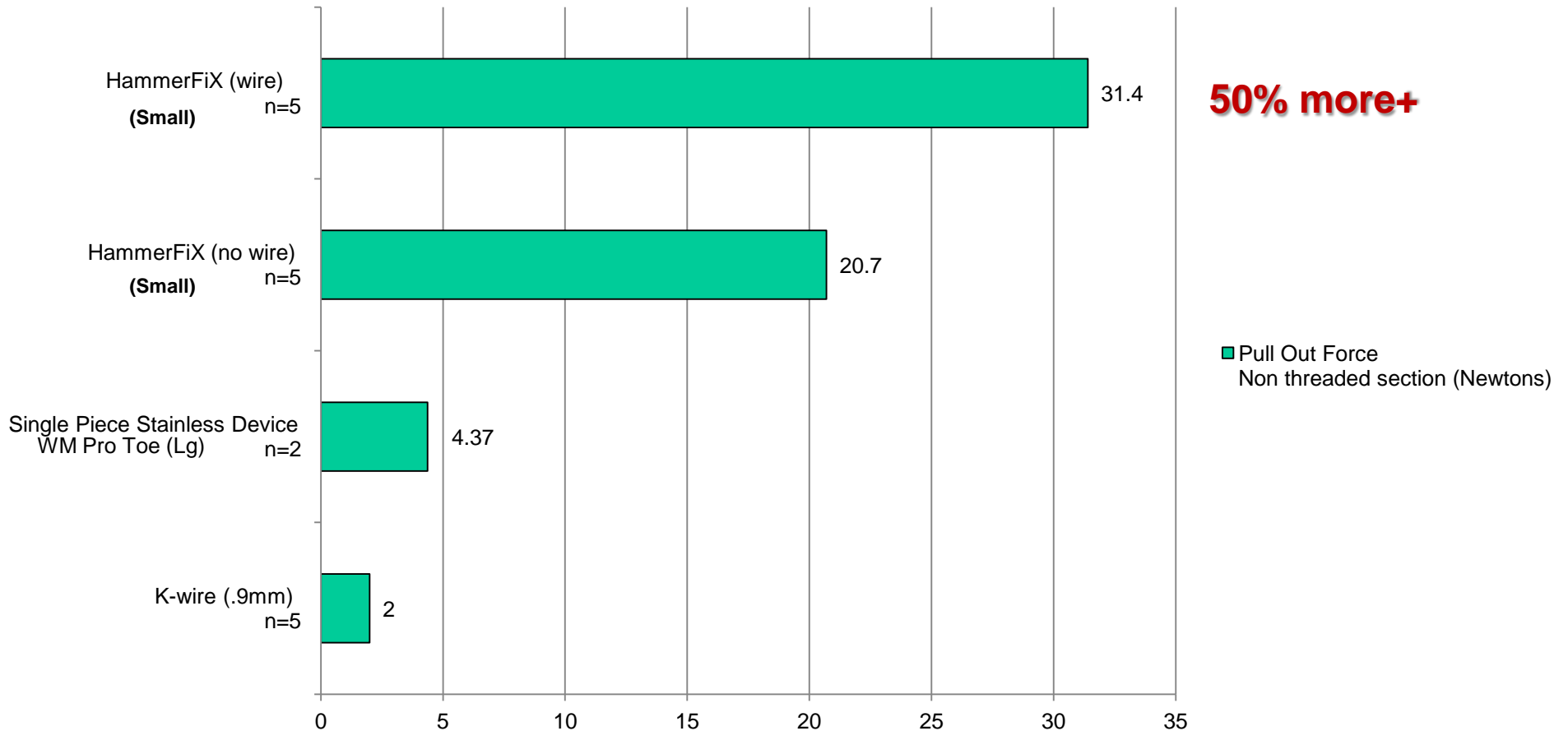


**Pull Out Force(N)
10 pcf foam**





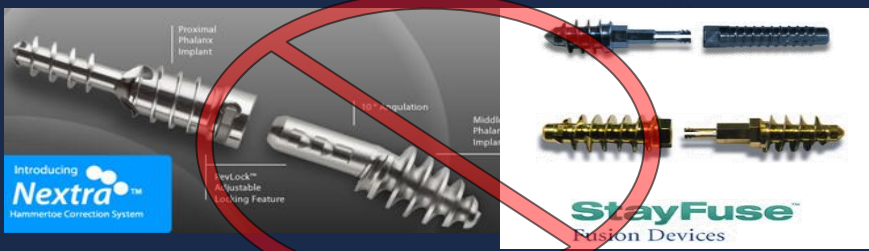
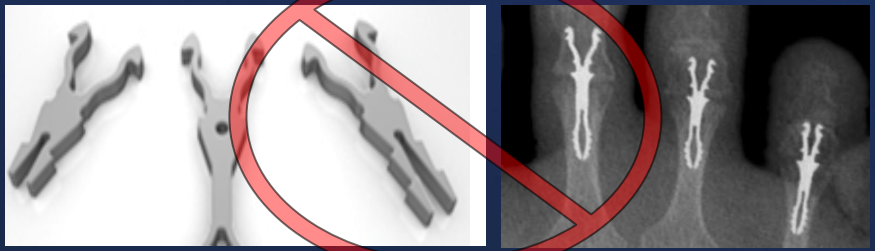
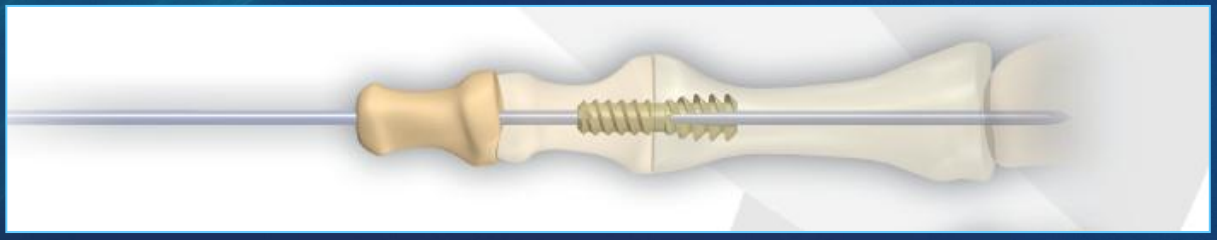
Pull Out Force Non threaded section



Cannulated Address MP Joint

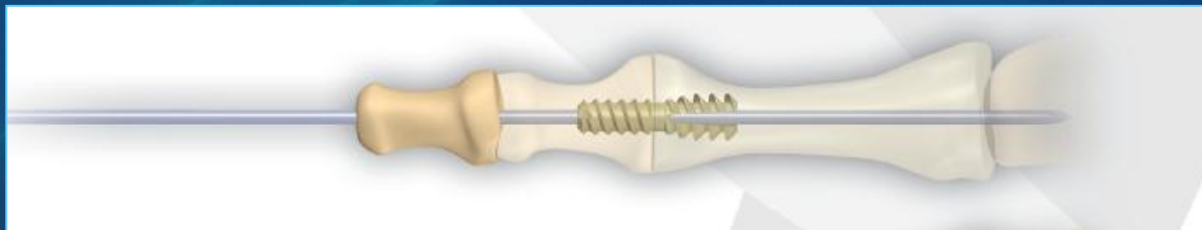
50-70% cases need to address MP Joint*

* 2013 XM Survey results



Cannulated Address MP Joint

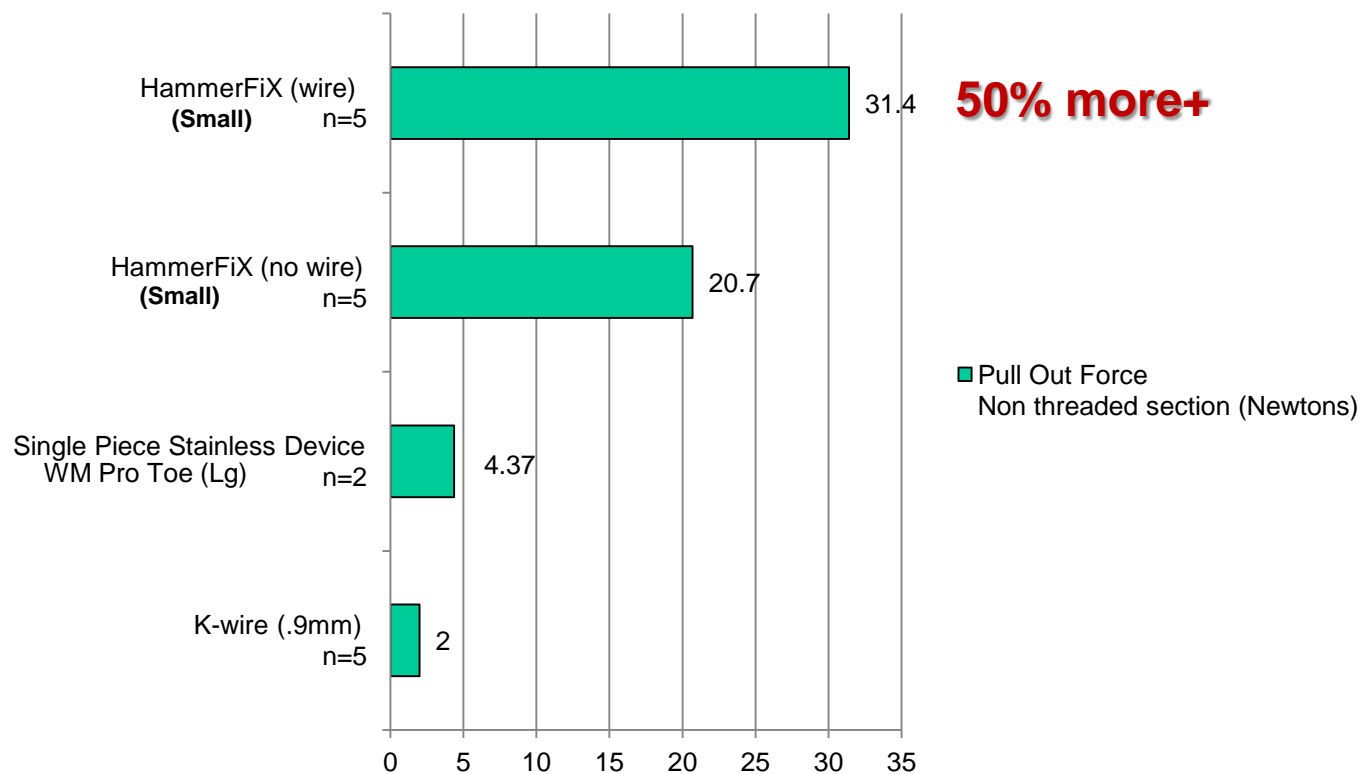
- Ability to address MP Joint* (stabilize temporarily)



ALSO

- + 50% More Pull-Out Strength!
- Rescue Option

Pull Out Force Non threaded section



Address MP Joint



1. Orthohelix – Cannulink

(Tornier → Wright)

1. Orthopro IFuseHT

(Wright)

• MPJ
for Med & Lg only

• Only other devices MPJ

Ti 1-Piece

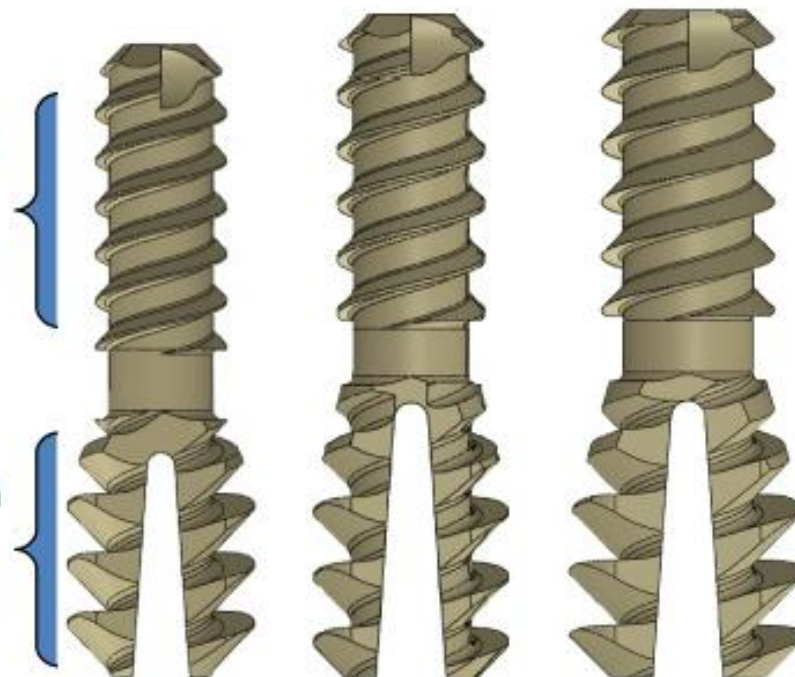


Sized for All Lesser Joints



Threaded Length
(Middle Phalanx)

Barb Length
(Proximal Phalanx)



Size	Small - 2.8	Medium - 3.4	Large - 4.0
Overall Length (mm)	13.5	15	15
Major Diameter Screw (mm)	2.8	3.4	4.0
Major Diameter Barb (mm)	4.0	4.5	5.5
Barb Length (mm) Proximal	5.5	6.8	6.8
Threaded Length (mm) Middle	6.5	7.0	7.0
Guidewire (mm) Compatibility	1.1 (.045 in)	1.4 (.054in)	1.6 (.062 in)

Fast & Easy Technique

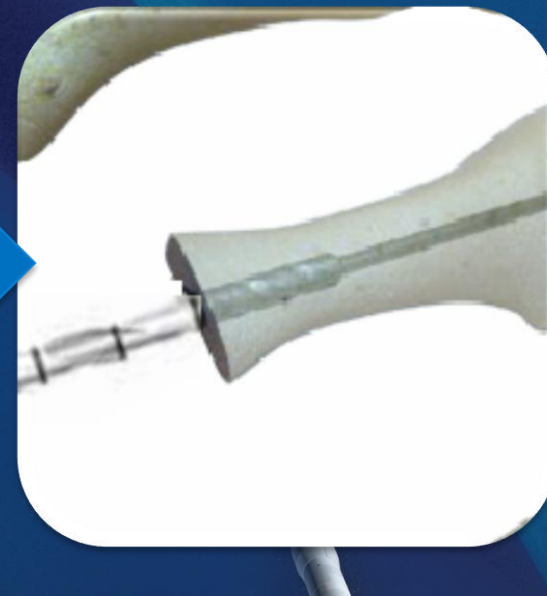
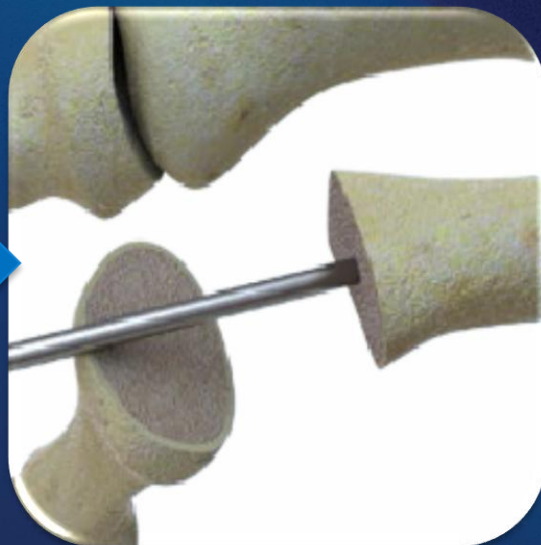
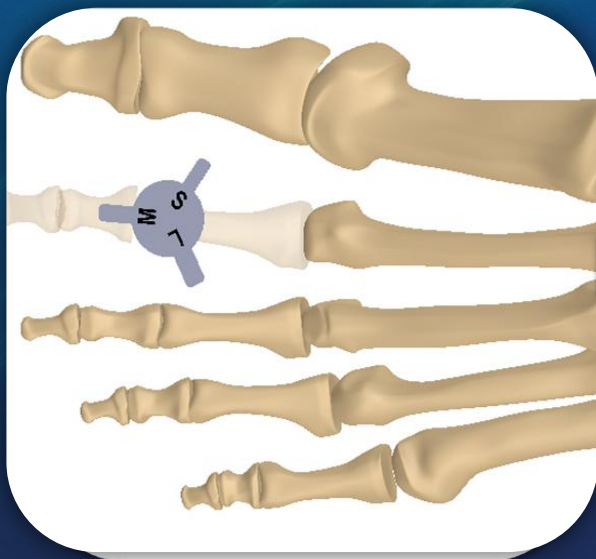
Nitinol =Freezer

BME
Stryker

2-Part
Fussy Intraoperatively



Surgical Technique Overview



Step 1

- Incision
- Prepare the joint
- Perform soft tissue releases as necessary

Step 2

- Advance k-wire into proximal phalanx (retrograde)

Step 3

- Drill over wire to create space for barbed section of implant

Common soft tissue releases

- Extensors that overlay the PIP joint
- MTP joint release – cut capsule dorsally
- Extensor tension lengthening- especially with a bad contracture

Surgical Technique Overview



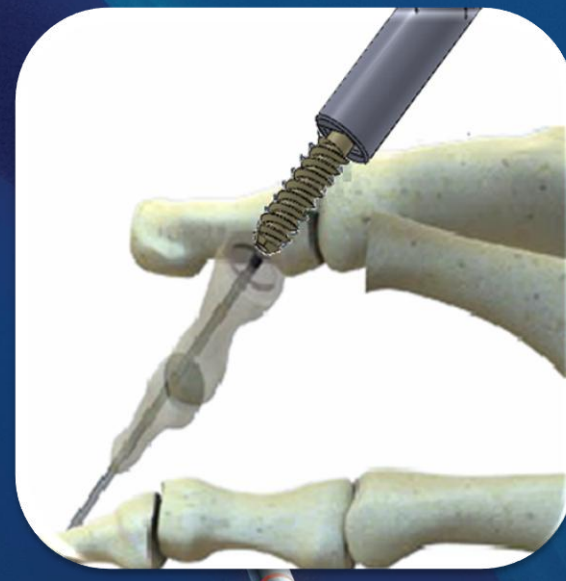
Step 4

- Insert K-wire into middle phalanx
- Drive till exits toe



Step 5

- Tap the middle phalanx (prepare for threaded side)



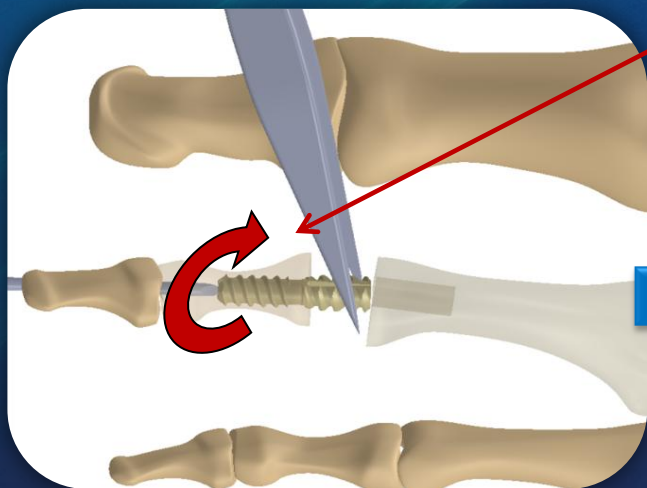
Step 6

- Insert threaded portion implant over kwire



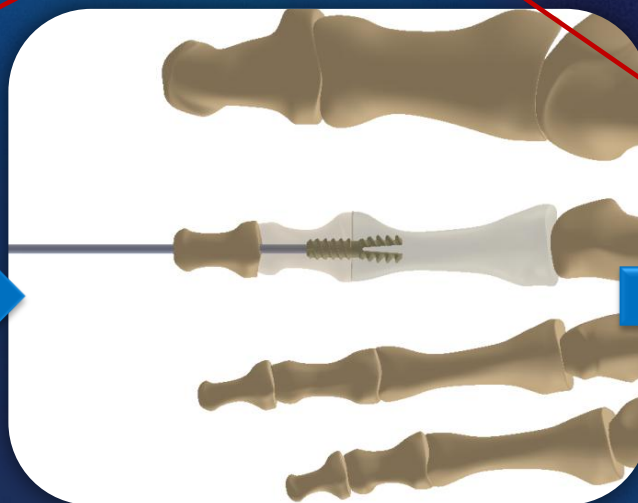
Surgical Technique Overview

Extra Compression



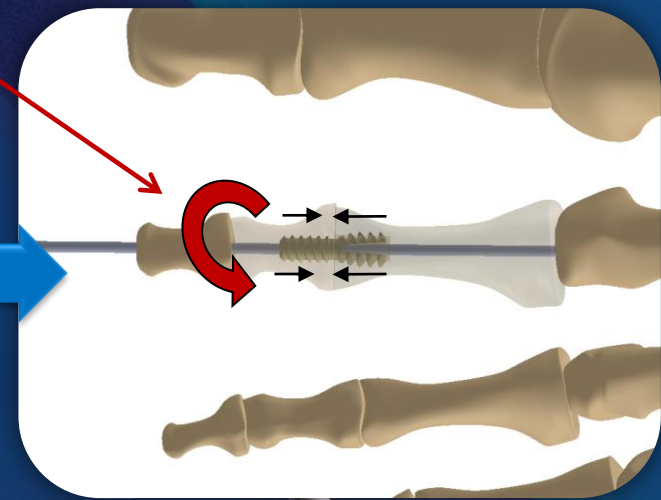
Step 7

- Pinch barb section with Forceps
- Insert into pre-drilled hole of proximal Phalanx



Step 8

- Firmly compress joint until implant is completely buried



Step 9 (Optional)

Pin MP Joint

- Recommended: run wire Through barbs to maximize deployment

10° angle option –YES!!!



Technique not implant

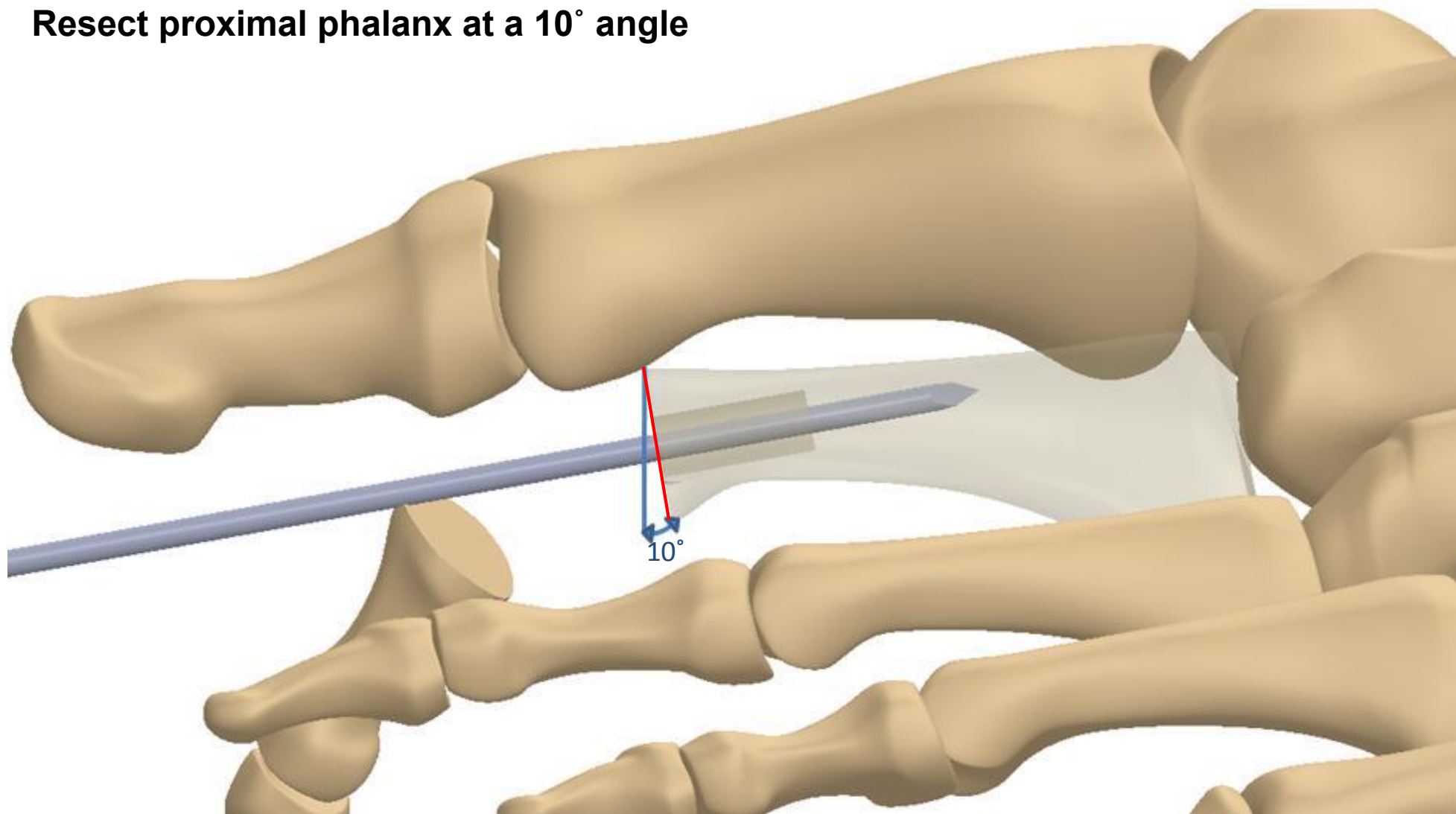
- Resect the distal aspect of the proximal phalanx at a 10° angle
- Advance Guidewire and drill (proximal phalanx) perpendicular to the 10° resection
- All other steps exactly the same

(It may not be possible to utilize the Guidewire for fixation of the MPJ joint)

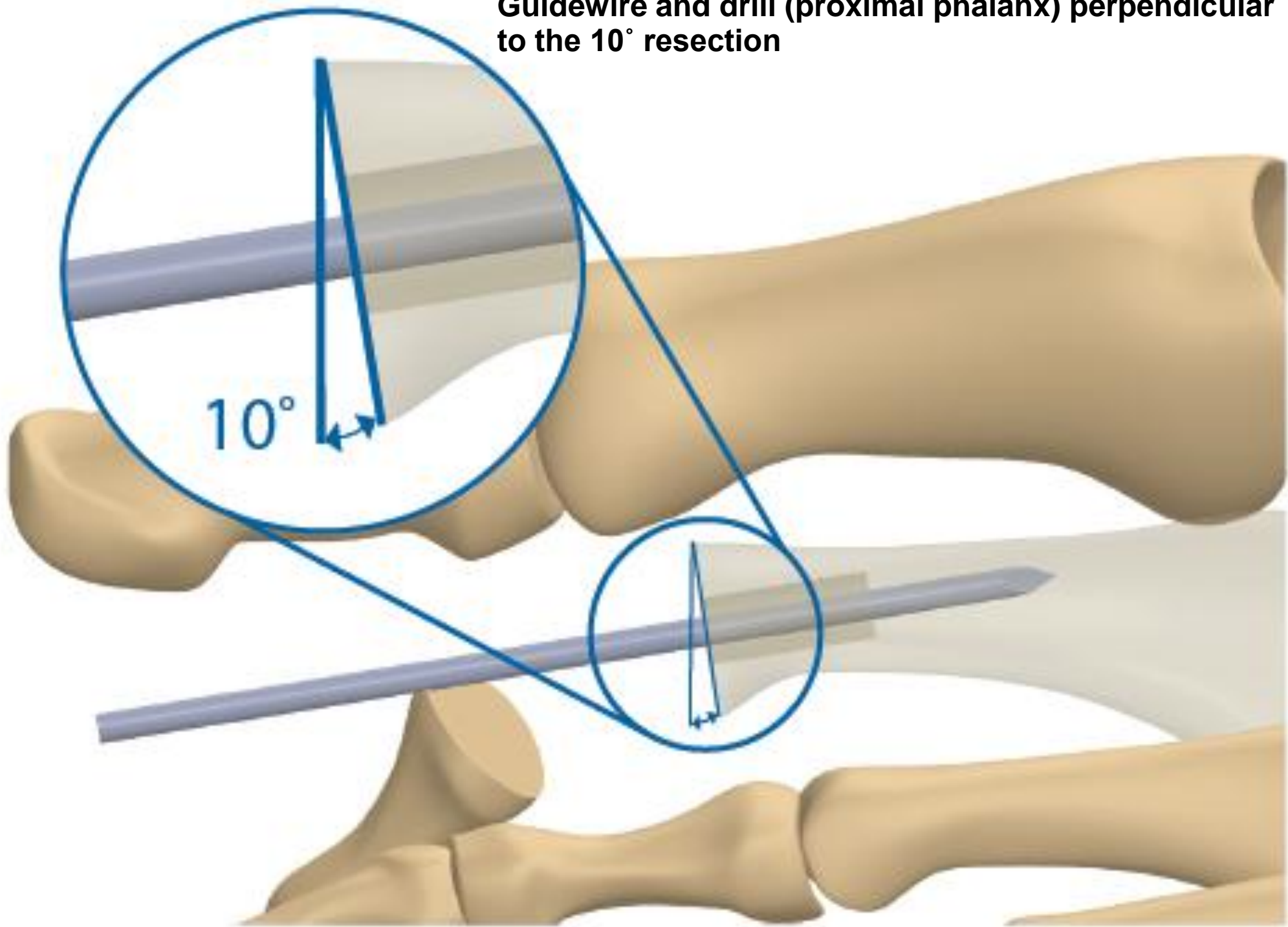


10° angle option

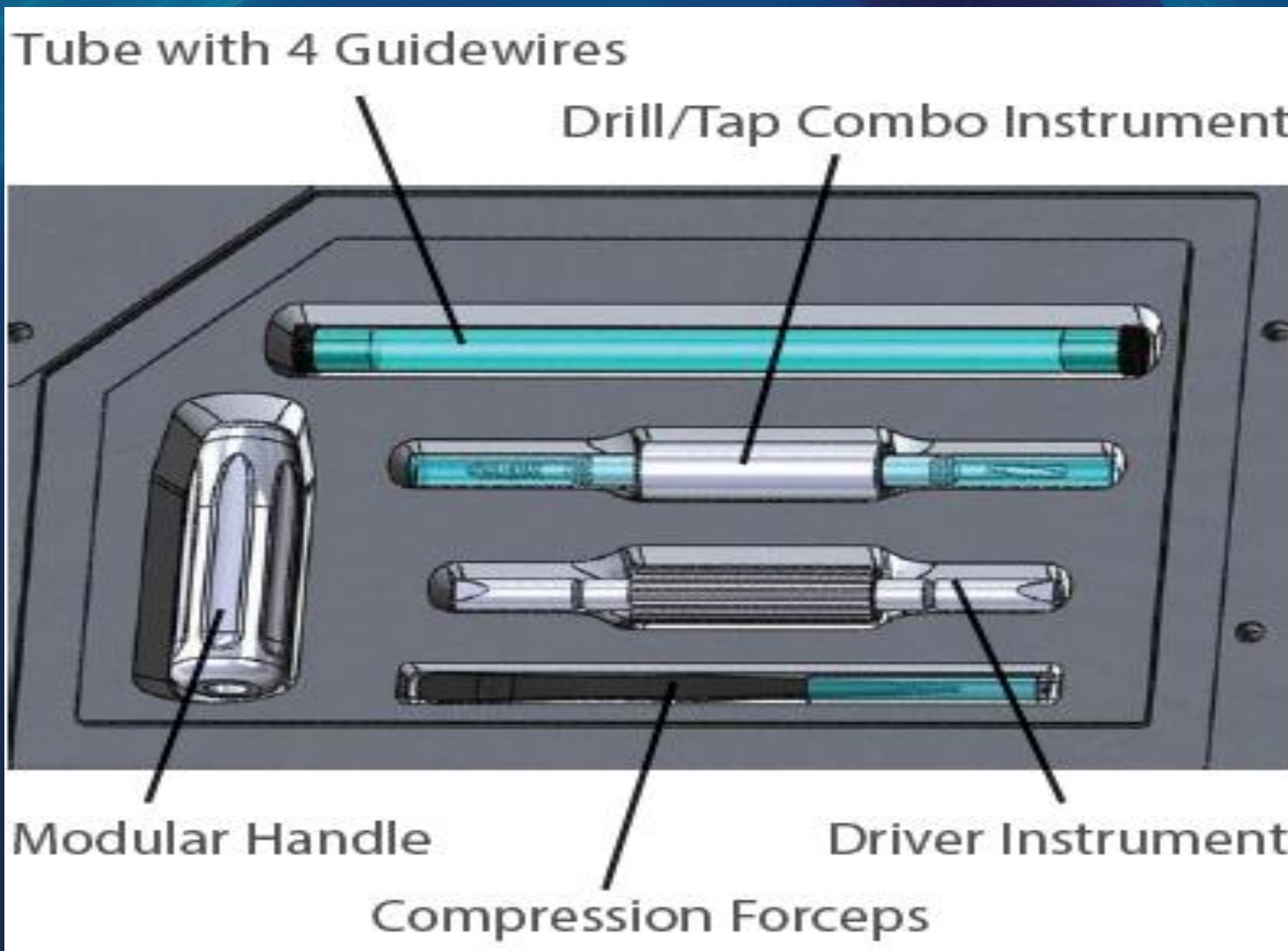
Resect proximal phalanx at a 10° angle



Guidewire and drill (proximal phalanx) perpendicular to the 10° resection



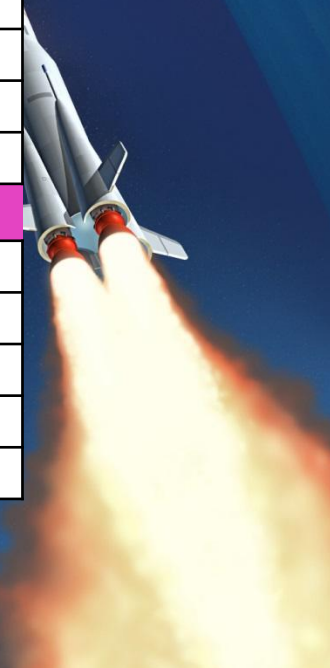
Sterile Packed Implants & Instruments



Sterile Packaging Instruments

One for Each Size Implant

Description	Prototype PN	Production Part Number	Material	Quantity
SMALL KIT COMPONENTS				
1.1 mm k-wire	gS 78.2070	TBD	316 SS	3
Drill Tap Combo - SML	XX-01069	TBD	455 SS	1
Driver Combo - SML	XX-01072	TBD	Radel or 455 SS	1
Modular Handle	XX-01068	TBD	Radel or Equivalent	1
Compression Forceps	gS 18.4640	TBD	316 SS	1
MEDIUM KIT COMPONENTS				
1.4 mm k-wire	gS 78.2080	TBD	316 SS	3
Drill Tap Combo - MED	XX-01070	TBD	455 SS	1
Driver Combo - Med	XX-01073	TBD	Radel or 455 SS	1
Modular Handle	XX-01068	TBD	Radel or Equivalent	1
Compression Forceps	gS 18.4640	TBD	316 SS	1
LARGE KIT COMPONENTS				
1.6 mm k-wire	gS 78.2090	TBD	316 SS	3
Drill Tap Combo - LRG	XX-01071	TBD	455 SS	1
Driver Combo - LRG	XX-01074	TBD	Radel or 455 SS	1
Modular Handle	XX-01068	TBD	Radel or Equivalent	1
Compression Forceps	gS 18.4640	TBD	316 SS	1



Implant Bank

(case w/sterile packed implant & instruments)

- 3 each size implant
- 2 each instrument set
- 2 each sizing template
- Color coded Labels:
 - **Small**
 - **Medium**
 - **Large**
 - **Sizing Template**

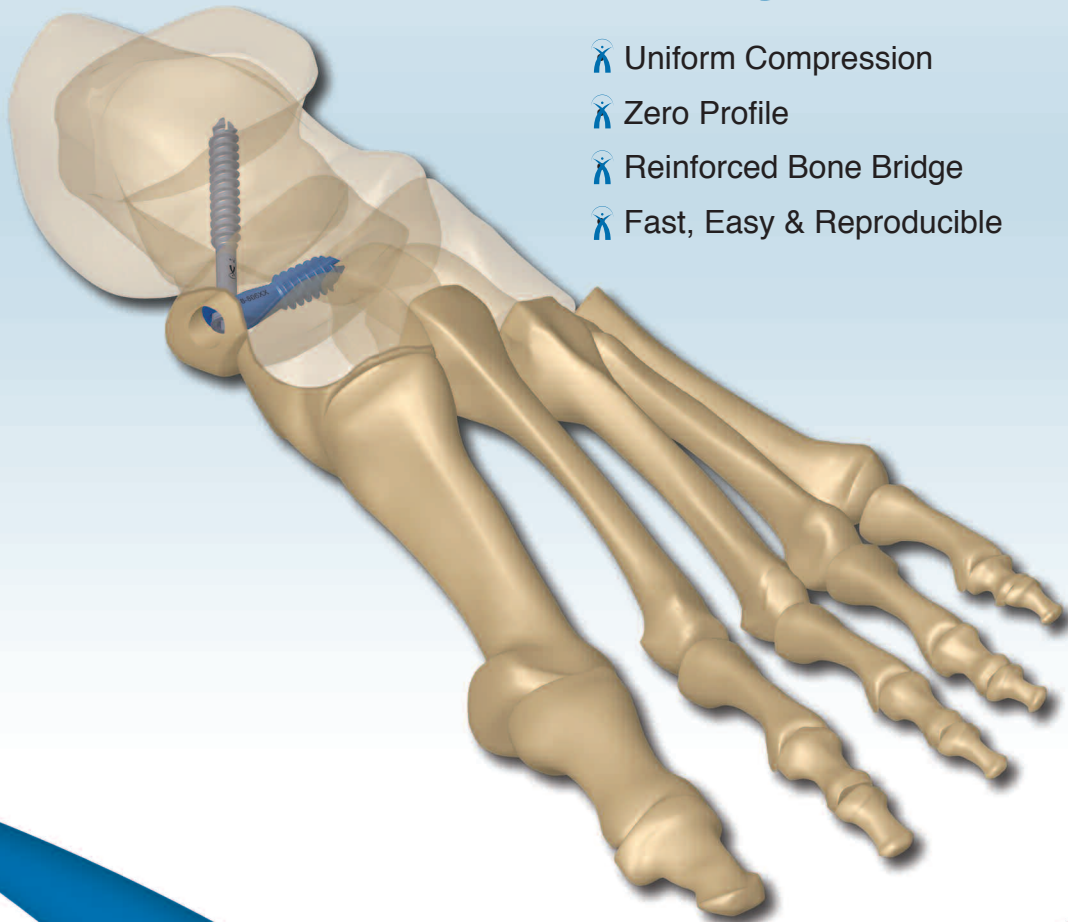




IO FiX™

Fusion Fixation

The IO FiX™ Advantage: *Designed for Fusion*



- Uniform Compression
- Zero Profile
- Reinforced Bone Bridge
- Fast, Easy & Reproducible

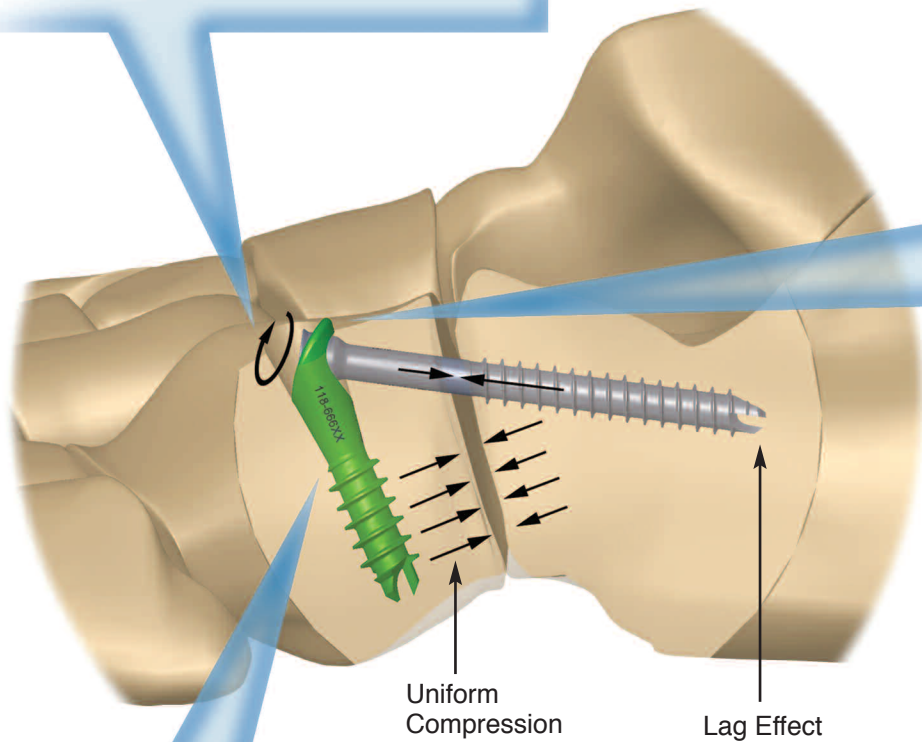
Because Uniform Compression
is **Better** Compression

How IO FiX™ Works

Zero Profile

Implants are placed within the bone

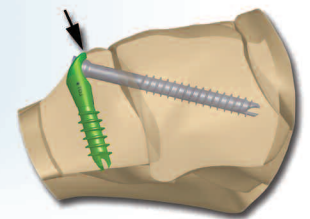
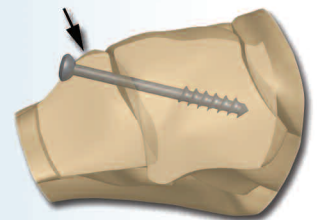
- ⌘ Minimizes soft tissue irritation
- ⌘ Decreases need for hardware removal



Reinforced Bone Bridge

Screw lags against a reinforced metallic bone bridge

- ⌘ Unlike screws, IO FiX™ maintains compression if the cortical bridge is compromised



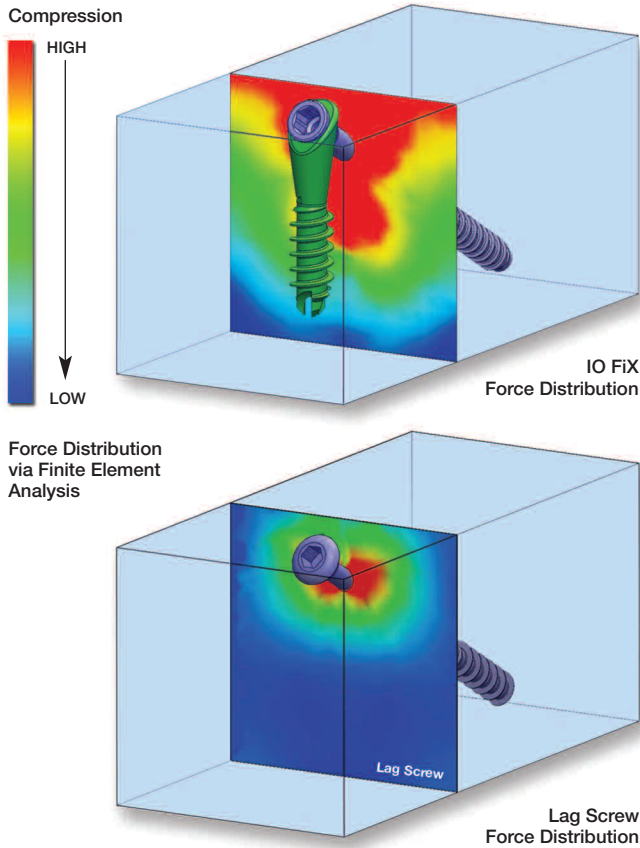
X-Post™

Distributes compressive forces across a greater surface area

- ⌘ Unique Morse Taper Locking System lags and locks simultaneously
- ⌘ More uniform compression*
- ⌘ Higher peak compression*

Designed for Fusion

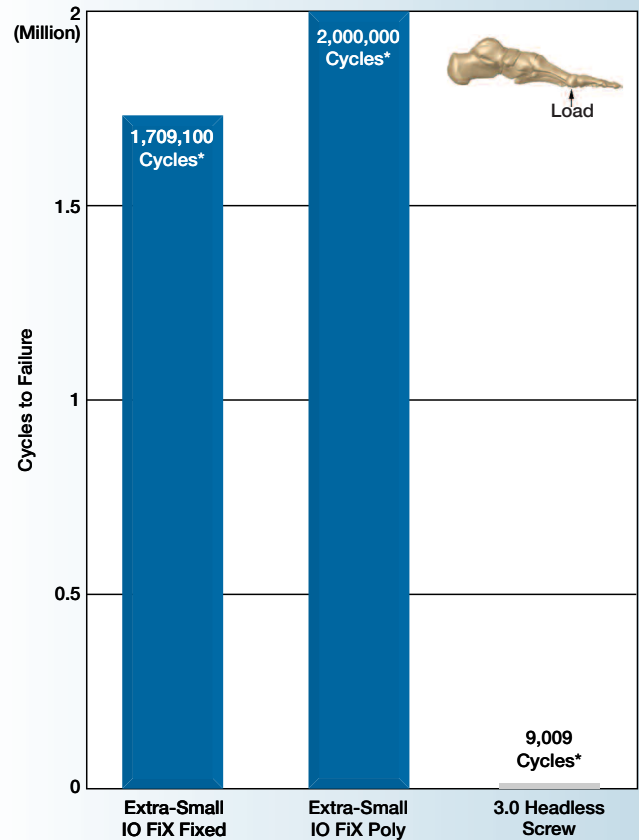
Uniform Compression*



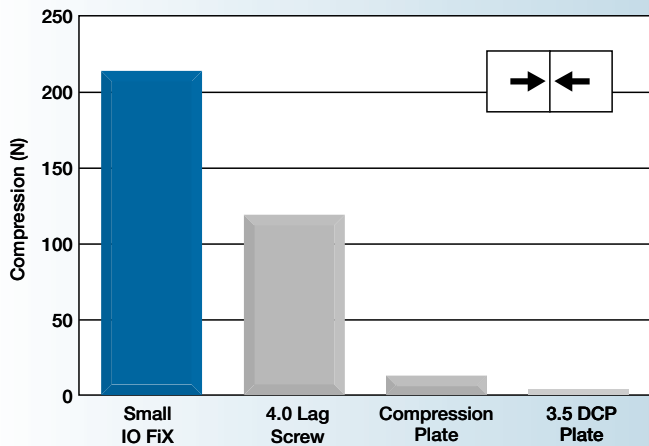
Stability**

Superior fatigue and strength resistance decrease the likelihood of a construct failure

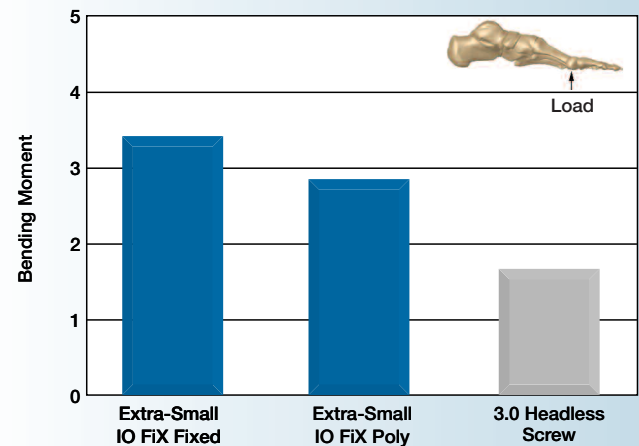
Fatigue Strength*



Peak Compression*



Bending Strength*



* Data on file, Extremity Medical ** Manual of Internal Fixation - AO

Versatility

Various sizes available for many foot and ankle indications



Lapidus



Talonavicular Arthrodesis



Triple Arthrodesis



Ankle Fusion



MTP Fusion



TMT Fusion



Calcaneal Osteotomy

300 Interpace Parkway
Suite 410
Parsippany, NJ 07054
Phone: 973.588.8980
Customer Service: 888.499.0079
Fax: 888.499.0542
www.extremitymedical.com

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Patent Pending
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