Pro-X1™ Trochanteric Nailing System

X-Bolt Trauma Orthopedics

Surgical Technique

X-Bolt Trauma Orthopedics

Contents

Design Features

TROCHANTERIC NAIL, X-BOLT, LAG SCREW AND INTERLOCKING SCREWS

Manufactured in Grade 23 Titanium alloy (Ti 6Al-4V ELI). Type-2 anodizing provides a toughened surface finish with reduced friction.

- **X-BOLT® (EXPANDING BOLT)**
- 10.5mm shaft diameter
- 10 length options: 80mm-125mm
- 9.0mm diameter expandable section
- 20.0mm maximum expandable span
- T20 Torx socket

SHORT NAIL

- 15.5mm proximal diameter
- 11.0mm shaft diameter
- 125° neck-shaft angle
- 4° valgus bend
- Length: 195mm
- Distal taper and prongs

LONG NAIL

- 15.5mm proximal diameter
- 11.0mm shaft diameter
- 125° neck-shaft angle
- 4° valgus bend
- 6 length options: 300mm-425mm
- Left and right sides
- Radius of curvature: 1.25m-1.50m

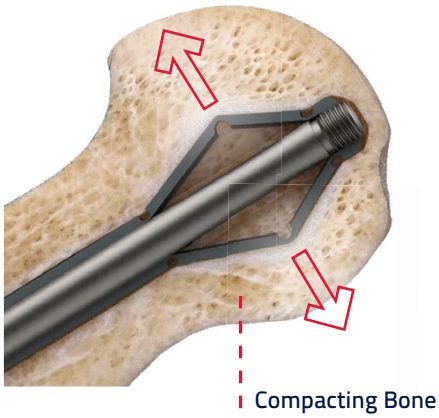
INTERLOCKING SCREWS

- 5.0mm diameter, self-tapping
- Lengths: 30mm-55mm
- 3.5mm hex socket

How It Works

METRO JIG™

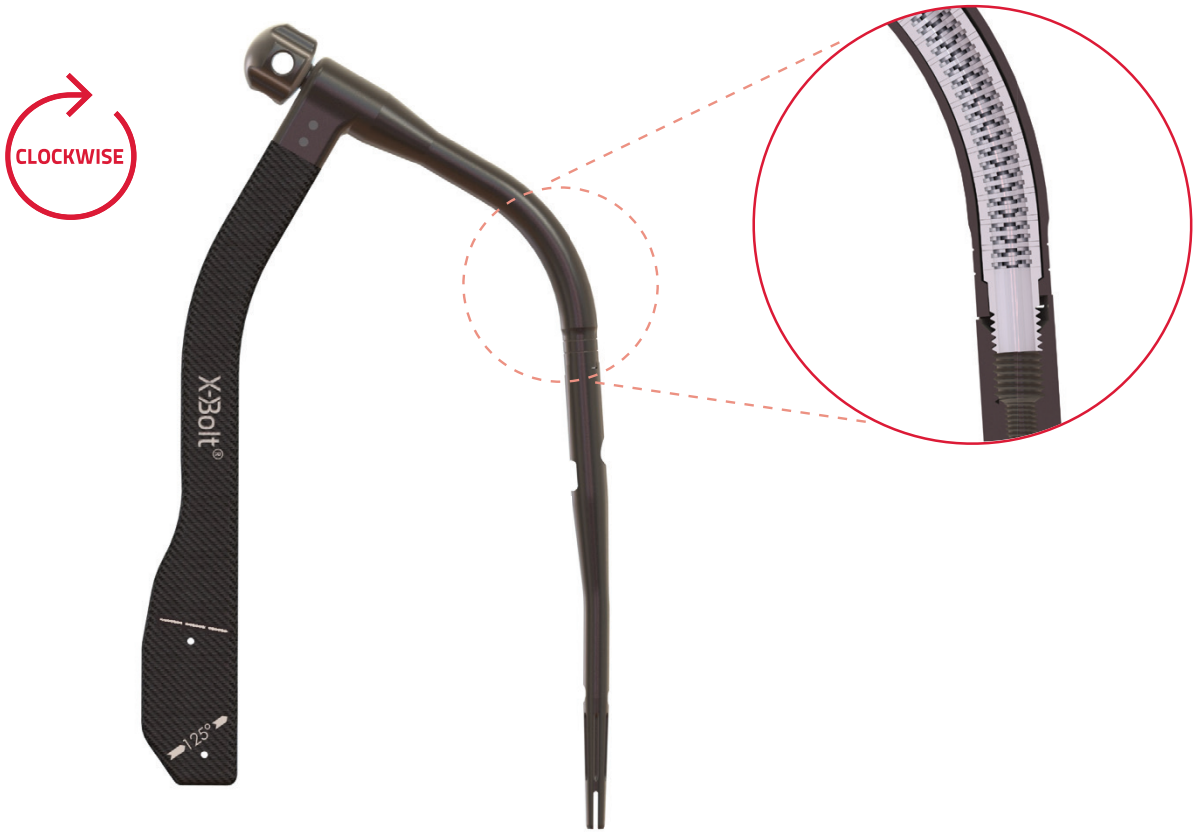
> Curved jig and Flexi-drive
> Flexible screwdriver
> Operable outside of surgical field
> Faster surgery and fewer surgical steps
> Easy to uncouple
> Useful in obese/overweight patients



HOW AN X-BOLT® WORKS

> Drive screw with opposing threads
> Actuated with screwdriver
> Compacts surrounding cancellous bone
> Tip-apex point preserved
> No spinning of femoral head
> Easily reversible

1 Assemble Nail onto Metro Jig™



INSTRUMENTS USED:

- > Long Nail ruler
- > Metro™ Jig
- > Flexi-drive
- > Screwdriver to tighten
- > Drill sleeves x4

ASSEMBLE IMPLANTS

Anatomically reduce fracture.

For long nails, measure from the greater trochanter to the superior aspect of patella with long nail ruler under fluoroscopy to gauge nail length.

Mount appropriate nail to Metro Jig using flexi-drive. Flexi-drive can be tightened using shaft of screwdriver. Check alignment of Metro Jig is correct with drill sleeves.

2 Entry Point and Proximal Reaming

Option (a) Option (b)

1 2 3 4 5 6 7 8 9 10

INSTRUMENTS USED:

- Cannulated awl
- Proximal sleeves x2
- Proximal reamer
- 3.2mm K-wire
- Long guidewire

ENTRY POINT AND PROXIMAL REAMING

Entry point is just medial to the tip of greater trochanter. This helps prevent lateral drift later when reaming.

Make proximal skin incision in line with expected path. The entry point can be located and progressed in two ways:

(a) Using the cannulated awl, initiate and progress the entry point. Pass long guidewire down intramedullary canal into distal fragment

(b) Using a Ø3.2mm K-wire, proximal sleeves and a conical reamer, locate the entry point and develop proximal channel.

After advancing the entry point, if distal reaming is needed, use flexible reamers in increments to Ø13.0mm.

3 Insert Nail

1
2
3
4
5
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7
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9
10

INSERT NAIL

Insert Insert long guidewire through the entry point and down the intramedullary canal.

Insert nail over the long guidewire. Remove long guidewire when nail is in distal fragment.

Advance the nail until the expected trajectory into femoral head is correct.

A-P and lateral images under fluoroscopy should be acquired to establish the expected trajectory. In the A-P view, the projected X-Bolt or lag screw position should be either in the center or slightly inferior in the femoral head. In the lateral view, the projected X-Bolt or lag screw position should be centered in the femoral head (optimum tip-apex point).

4 Femoral Head K-Wire

INSTRUMENTS USED:

- Outer X-Bolt sleeve
- Inner X-Bolt sleeve
- Ø3.2mm K-wire
- X-Bolt ruler
- Step drill-reamer (optional)

FEMORAL HEAD K-WIRE

Insert inner and outer X-Bolt sleeves through jig. Via skin incision and blunt dissection, advance sleeves onto lateral cortex of femur. Through the inner sleeves, place Ø3.2mm femoral head K-wire center-center in femoral head within 2mm-3mm of the joint line (optimum tip-apex point). Check position on both A-P and lateral views on fluoroscopy. Measure length using ruler, with the tip of the inner sleeve up against the lateral cortex.

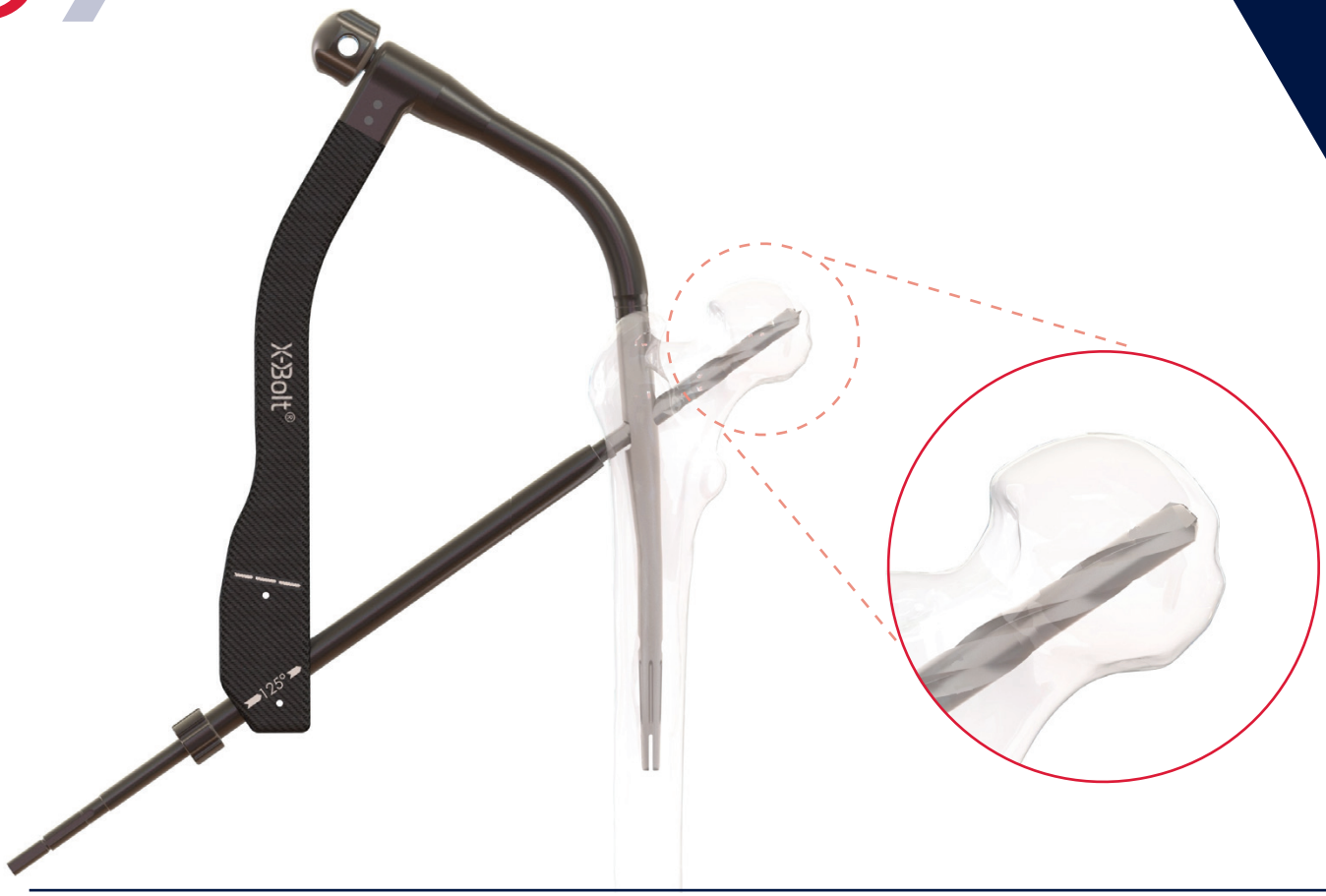
Focus

To select X-Bolt length, add 1mm-5mm to the measurement, as X-Bolt shortens by 2mm from base end on expansion, and also allow for dynamic compression of the fracture that will occur with weight-bearing.

Tips

If multiple unsuccessful attempts to get K-wire into optimum position is occuring, widen cortical channel with step-reamer to give freedom for K-wire to chose correct path.

5 Reaming



INSTRUMENTS USED:

> Step drill-reamer

REAMING

Remove inner X-Bolt sleeve. Ream with step reamer over K-wire to create X-Bolt channel.

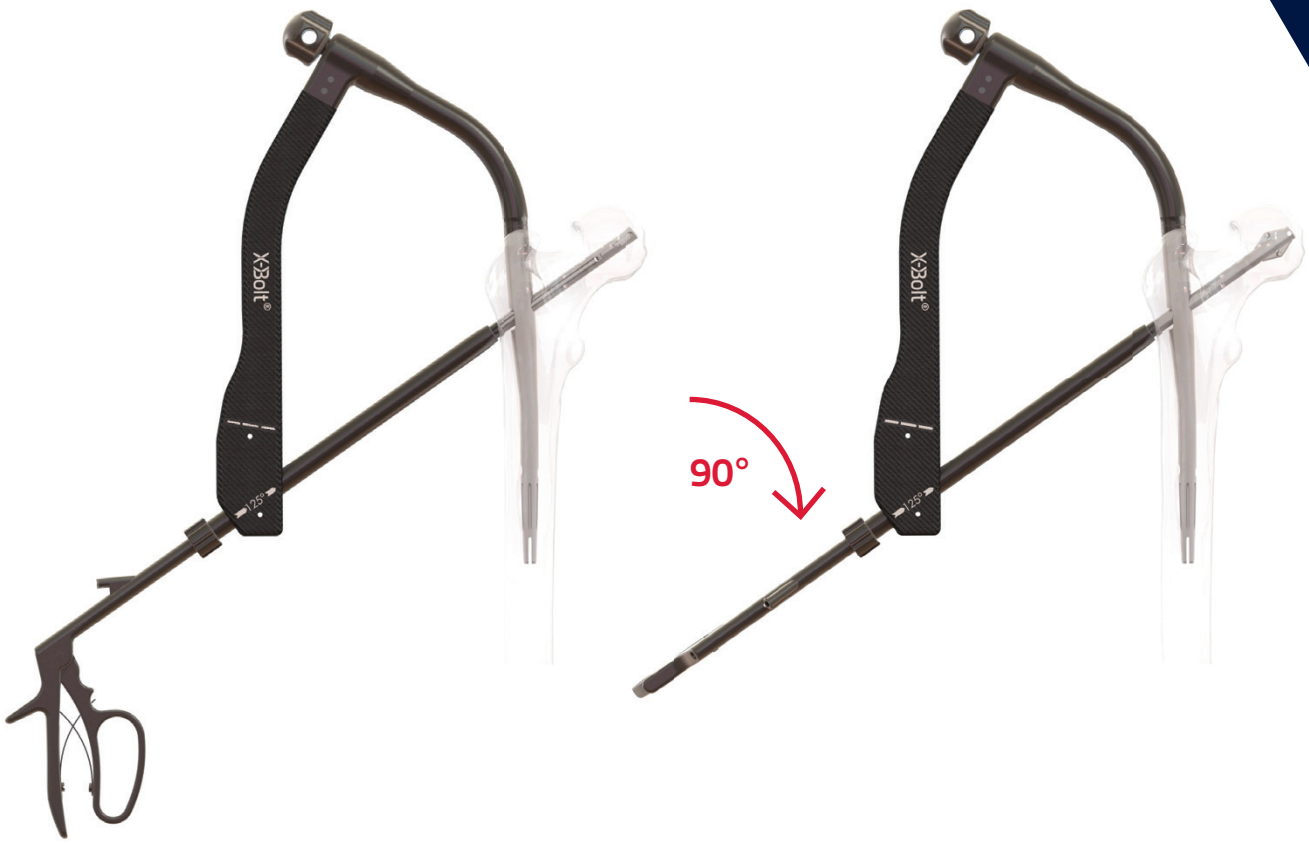
Focus

> **Follow closely on fluoroscopy to ensure K-wire does not advance into pelvis while reaming and to confirm channel created to tip-apex point.**

Remove step reamer and K-wire leaving a clear bone channel.

Ensure reaming fully to tip-apex point, as X-Bolt is blunt nosed and cannot advance deeper than the reamed channel. K-wire usually removes itself with reamer, but should no longer be needed.

6 Bone Crusher



INSTRUMENTS USED:

> Bone crusher

BONE CRUSHER

Insert bone crusher fully deep to tip-apex point. Deploy by pulling the trigger at orthogonal planes to Metro Jig.

Focus

In strong bone it may be necessary to fan out bone crushing steps 5°-10° in each orthogonal plane.

Tips

Bone crusher may be used as a rotational aid to reduction if fracture is rotationally mal-aligned.

7 Insert X-Bolt and Set-Screw

1 2 3 4 5 6 7 8 9 10

INSTRUMENTS USED:

> T20 Torx screwdriver
> Flexible screwdriver

INSERT X-BOLT AND ENGAGE SET-SCREW

Insert X-Bolt, mounted on T20 screwdriver, and advance fully to tip-apex point. Rotate the X-Bolt so that one of the four grooves for the set-screw is directly superior.

Insert set-screw using the flexible screwdriver through the flexi-drive. Advance set-screw to engage in the groove on superior aspect of X-Bolt until two-finger tight to allow for dynamic sliding. The set screw prevents rotation while allowing dynamic sliding.

Tips

Gentle rocking back and forth of both screwdrivers will give tactile feedback on set-screw engagement within the groove.

8 Expand X-Bolt

INSTRUMENTS USED:

> T20 Torx screwdriver

EXPAND X-BOLT

Turn the T20 screwdriver clockwise to expand the X-Bolt until the desired expansion, or until a stop is felt, or to the screwdriver torque limit. Do not use excessive force.

Once X-Bolt is expanded, remove the T20 screwdriver and outer X-Bolt sleeve

Focus

If set-screw is not properly engaged in groove, the X-Bolt will spin rather than expand.

The torque to expand the X-Bolt gives excellent tactile feedback on the quality of the bone. If inadvertent resistance is felt, remove X-Bolt and repeat the bone crusher step. If reversal is necessary, rotate screwdriver counterclockwise. The X-Bolt must be discarded and replaced if full expansion has been reversed, or has been damaged in any way.

9A Distal Locking - Short Nail

1 2 3 4 5 6 7 8 9 10

INSTRUMENTS USED:

- Outer distal locking sleeve
- Inner distal locking sleeve
- Measuring hook
- Long or short hex screwdriver

DISTAL LOCKING

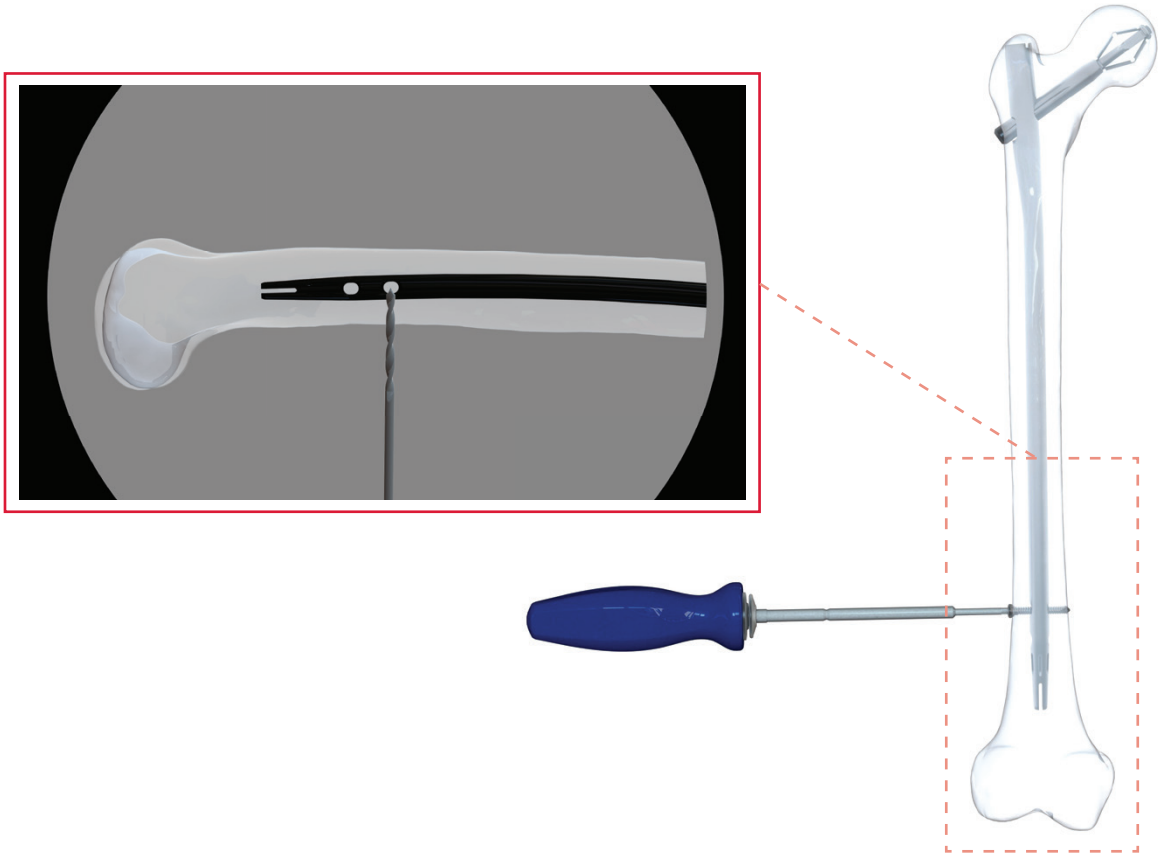
Insert sleeves through distal locking aperture and advance via skin incision and blunt dissection to the lateral femoral cortex.

Use Ø4.0mm x 305mm drill bit via inner sleeve, and drill through the lateral and medial cortices. Measure screw length from drill bit markings. Remove inner sleeve.

Confirm screw length using measuring hook.

Insert appropriate length Ø5.0mm distal interlocking screw, using long hex screwdriver.

9B Distal Locking - Long Nail



INSTRUMENTS USED:

> Depth gauge
> Short hex screwdriver

LONG NAIL

Use Ø4.0mm x 150mm drill bit for freehand distal locking.

Distal screw apertures are oblong, allowing for 1.5mm of dynamic fracture compression. Set-up the lateral fluoroscopy to see perfect oblong holes.

Make skin incision and blunt dissection to lateral cortex.

For dynamic fracture compression, aim drill bit towards distal aspect of aperture, furthest from fracture site.

Drill through lateral and medial cortices, and measure screw length with standard depth gauge. Insert appropriate length Ø5.0mm distal interlocking screw with short hex screwdriver.

10 De-Couple Metro Jig

INSTRUMENTS USED:

> Any screwdriver

DE-COUPLE JIG

Remove flexi-drive using screwdriver shaft through horizontal apertures to gain greater counterclockwise rotation leverage.

Remove Metro Jig.

Wound closure and post-operative management as per surgeon's instructions.

Removal

INSTRUMENTS USED:

> T20 Torx screwdriver
> Hex screwdriver
> Removal rod

REVERSE EXPANSION. Retract X-Bolt with counterclockwise rotation of T20 screwdriver. The X-Bolt mechanism can crush new cancellous bone formed under the expanded wings.

REMOVE X-BOLT. Loosen set screw to enable unimpeded free passage of X-Bolt through nail aperture. Insert removal rod into base of X-Bolt and remove X-Bolt.

REMOVE NAIL. If bony ingrowth at top of nail, use 3.2mm K-wire and rigid proximal reamer under fluorocopy to re-create path. Insert removal rod before removing distal interlocking screw, so as to prevent the nail from spinning. Remove interlocking screw. Remove nail.

BROKEN X-BOLT WINGS. In the rare event of the X-Bolt wings being broken, continue counterclockwise turns to disengage drive screw from deep fragment. Loosen set screw. Remove the X-Bolt shaft and drive screw, leaving the deep fragment in-situ. Remove nail and distal interlocking screw as above.

DEEP FRAGMENT. May be left in-situ or removed with femoral head if converting to arthroplasty. Otherwise, fragment may be retrieved using an arthroscopy grasper or spinal grasper under fluoroscopy.

Instruments

	XNI-002 CURVED AWL
	XNI-003 T-HANDLE QUICK-FIT JACOBS CHUCK
	XNI-004 OUTER PROXIMAL REAMER SLEEVE
	XNI-005 INNER PROXIMAL REAMER SLEEVE
	XNI-006 CONICAL REAMER
	XNI-007 FLEXI-DRIVE
	XNI-008 OUTER DRILL SLEEVE (FOR X-BOLT)
	XNI-009 INNER DRILL SLEEVE (FOR X-BOLT)
	XNI-011 PRO-X1 K-WIRE RULER
	XNI-012 10.5mm/9.0mm STEP REAMER
	XNI-014 BONE CRUSHER
	XNI-015 OUTER SLEEVE (GREEN)
	XNI-016 INNER SLEEVE (GOLD)

Instruments

	XNI-017	REMOVAL ROD
	XNI-018	DEPTH HOOK
	XNI-019	METRO JIG
	XNI-020	T20 TORX SCREWDRIVER (4.5NM TORQUE LIMIT)
	XNI-021	LONG SCREWDRIVER SHAFT (3.5MM HEX)
	XNI-022	SHORT SCREWDRIVER SHAFT (3.5MM HEX)
	XNI-023	FLEXIBLE SCREWDRIVER SHAFT (3.5MM HEX)
	XNI-024	IN-LINE SCREWDRIVER HANDLE
	XNI-025	FLEXIBLE SCREWDRIVER HANDLE
	XNI-028	LONG NAIL RULER
	XNI-030	DEPTH GAUGE
	XNI-032	LAG SCREW TAP

Implant Dimensions

X-BOLT® (EXPANDING BOLT)

> Tip-apex and tip-elbow distance maintained throughout expansion
> Actuated or reversed using T20 screwdriver
> Maximal expansion of the four wings visible on orthogonal x-ray views

TYPICAL LAG SCREW

> 10.5mm outer diameter, self-tapping, cannulated

X-Bolt Lengths
80mm – 125mm
Increments of 5mm

Implant Dimensions

Set Screw
3.5mm hex socket

4° Valgus Bend

Ø15.5mm Proximal Diameter

125°

Ø11.0mm Shaft Diameter

Nail Length
195mm

Distral Taper to **Ø8.0mm** and prongs for distal stress relief

1.50mm Dynamic Locking Screw Positioning

4° Valgus Bend

Ø15.5mm Proximal Diameter

125°

Ø11.0mm Shaft Diameter

Nail Lengths
300mm – 425mm
Increments of 25mm

AP Bend Configuration
R1.25: 300 – 385mm
R1.5: 400 – 425mm

Ordering Information

Part Code	Description (implants)
XBT105080	80mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105085	85mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105090	90mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105095	95mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105100	100mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105105	105mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105110	110mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105115	115mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105120	120mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105125	125mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT110195	Short Trochanteric Nail 125deg (Ø11x195mm)
XBT110300 L	300mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110300 R	300mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT110325 L	325mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110325 R	325mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT110350 L	350mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110350 R	350mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT110375 L	375mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110375 R	375mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT110400 L	400mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110400 R	400mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT110425 L	425mm Left, Trochanteric Nail 125deg, Ø11mm, Left
XBT110425 R	425mm Right, Trochanteric Nail 125deg, Ø11mm, Right
XBT050030	30mm x Ø5.0mm distal interlocking screw, self-tapping
XBT050035	35mm x Ø5.0mm distal interlocking screw, self-tapping
XBT050040	40mm x Ø5.0mm distal interlocking screw, self-tapping
XBT050045	45mm x Ø5.0mm distal interlocking screw, self-tapping
XBT050050	50mm x Ø5.0mm distal interlocking screw, self-tapping
XBT050055	55mm x Ø5.0mm distal interlocking screw, self-tapping

Part Code	Description (single use instruments)
XBT032001	Ø3.2mm x 385mm femoral head K-wire
XBT040305	Ø4.0mm x 305mm drill bit, quick connect (Metro™ jig)
XBT040150	Ø4.0mm x 150mm drill bit, quick connect (freehand)
XBT024900	Ø2.4mm x 900mm long guidewire

Ordering Information

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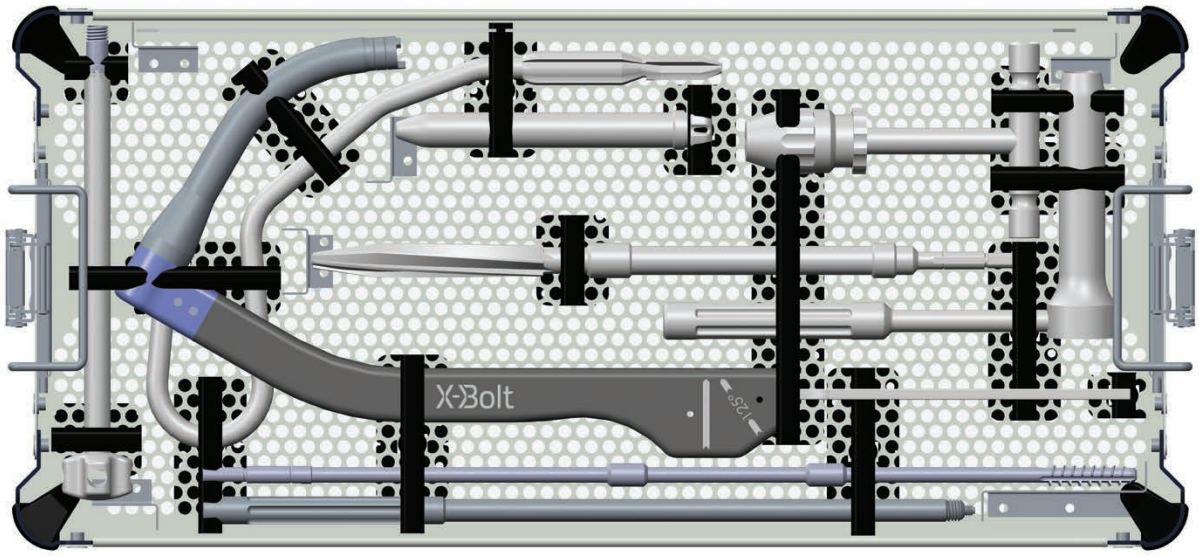

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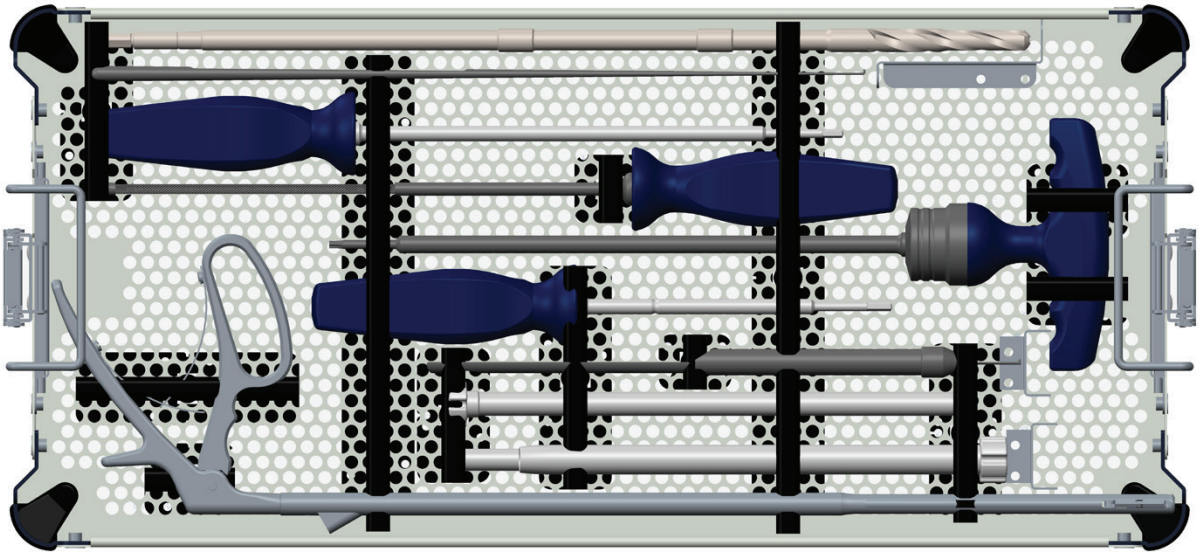

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US Patents: US 9724141B2, US 8911446B2, US 11259854B2

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For further information, or to order, please contact:

X-Bolt Orthopedics
Unit 5, Northwood Court
Santry, Dublin D09AX54
Ireland
IE: +353 1 443 3880
US: +1 813 358 3980
W: www.x-bolt.com

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