Pro-X1®

Trochanteric Nailing System





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) Indications

The Pro-X1[™] Trochanteric Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis and is also indicated for use in:

- > Intertrochanteric and subtrochanteric fractures.
- > Segmental fractures.
- > Comminuted fractures.
- > Pathological fractures.
- > Fractures with bone loss.
- > Pseudoarthrosis, non-union, mal-union, and delayed union.
- Surgically created defects such as osteotomies.



Contraindications

- Physical conditions that would preclude adequate implant support or retard healing such as blood supply impairment, insufficient bone quality or quantity, infection or gross distortion of the femur.
- Conditions which prevent full expansion of the X-Bolt[®] (osteonecrosis, Paget's disease, osteopetrosis).
- > Mental conditions that preclude cooperation with the rehabilitation regimen.
- > Use in pediatric patients.
- > Known or suspected sensitivity to metal and/or Parylene-C. Although rare, sensitivity reactions and/or allergic reactions to foreign materials may occur. When sensitivity is anticipated, appropriate pre-operative testing should be conducted.
- > Re-expansion of the X-Bolt® following reversal of expansion may lead to product failure. Discard X-Bolt® if full expansion has been reversed.
- > Connection with other metallic materials of different chemical composition, due to the possibility of electrolytic action and posterior corrosion.
- > Medical or surgical issues that would preclude the potential benefit of the surgery. Intertrochanteric and subtrochanteric fractures.



Design Features

Trochanteric Nail, X-Bolt, 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
- > Expandable section 9.0mm original o.d.
- > Up to 20.0mm span when expanded
- > T20 Torx Socket
- > Beveled end for smooth lateral soft tissue interface

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

> Easily reversible

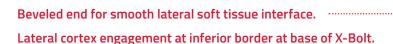
How It Works



Essential Tips and Pearls

- Ream to a precise tip-apex point, under fluoroscopy, noting that blunt-nosed X-Bolt cannot advance any deeper than the reamer.
- 2. Always recheck the tightness of the flexi-chain connector following nail advancement and any impaction, as oscillation may loosen the connector and affect assembly of the Metro-Jig to the nail.
- To select X-Bolt length add 4mm-8mm to the ruler measurement, noting that X-Bolt shortens by up to 3mm on expansion. Subtract any fracture gap present to allow for later fracture compression.
- 4. Deploy bone crusher by pulling the trigger to create a 'punch'. Do 3 'punches' at each orthogonal plane to Metro Jig, so covers 5°-10° at each orthogonal plane, as the width of the bone crusher wings are slightly less than the width of the X-Bolt implant wings. A groove on the X-Bolt faces superiorly when 'perfect semi-circles' are seen on AP fluoroscopy.

- 5. The set screw must be in dynamic mode with the X-Bolt (a quarter turn back) to allow freedom for the elbow apex of wings to drive expansion.
- 6. If the set screw is not properly engaged in a groove, the X-Bolt will only spin rather than expand. The depth of the longitudinal grooves is 0.5mm and thus can accommodate up to a half-turn back of the set screw and still remain in the groove.
- 7. If the X-Bolt does not reach full expansion, check that the set screw is in dynamic mode by advancing the set screw with the flexible screwdriver until the 1Nm torque limit and then performing a quarter turn back.





Ability to ream and place X-Bolt to a precise tip apex-point.



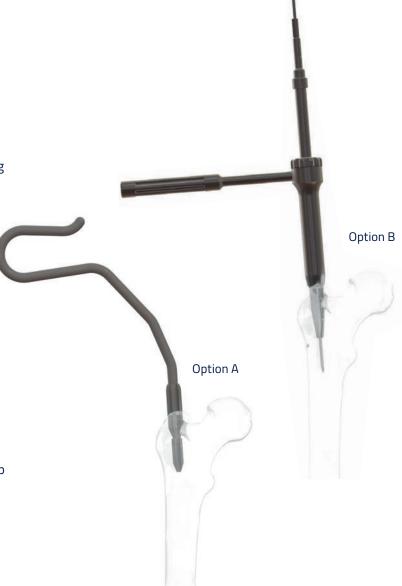
Step 1.

Entry Point and Proximal Reaming

- 1.1 Patient is placed on fracture table with leg on traction. Anatomically reduce fracture. Entry point is just medial to the tip of greater trochanter. This helps prevent lateral drift later when reaming.
- 1.2 Make proximal skin incision in line with expected path. The entry point can be located and progressed in two ways:
- 1.3 Option A: Using the curved awl, initiate and progress the entry point. Pass long guidewire down intramedullary canal into distal fragment.

Option B: Alternatively; using a Ø3.2mm K-wire, proximal sleeves, and a conical reamer, locate the entry point and develop proximal channel.

- 1.4 If distal reaming is needed, use flexible reamers in increments up to 1.5mm to 2.0mm above nail shaft diameter.
- 1.5 In some short nail cases, distal reaming of the subtrochanteric region may not be required, particularly in patients with wide intramedullary canals.



Warning: Reduction should be achieved as anatomically as possible. Insufficient reduction may lead to post-operative complications. If reduction cannot be achieved in a closed approach, open reduction may be considered.



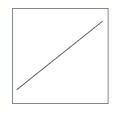
XNI-002 Curved Awl



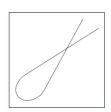
XNI-004 Outer Proximal Reamer Sleeve XNI-005 Inner Proximal Reamer Sleeve



XNI-006 Conical Reamer



XBT032001 Ø3.2mm K-wire

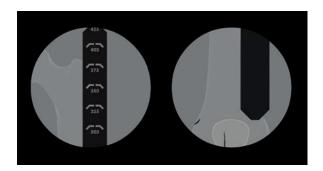


XBT024900 1000mm Long guidewire

Step 2.

Assemble Nail onto Metro™ Jig

- 2.1 A long nail is recommended for 31-A3 and subtrochanteric fracture patterns. A long nail may also be considered for patients with a wide femoral canal (>15mm) or having proximal lateral wall fracture or lateral cortex incompetency.
- 2.2 For long nails, measure from the greater trochanter to the superior aspect of the patella with the long nail ruler under fluoroscopy to gauge nail length.
- 2.3 Mount appropriate nail to Metro Jig using flexi-chain connector. Flexi-chain connector can be tightened using the shaft of any hex screwdriver. Check the alignment of the Metro Jig is correct with drill sleeves.
- 2.4 Attach impaction rod to the threaded impaction piece of Metro Jig.







XNI-028 Long Nail Ruler



XNI-019 Metro™ Jig XNI-026 Impaction Rod



XNI-007 Flexi-Chain Connector



XNI-021 Long Screwdriver Shaft XNI-024 In-Line Screwdriver Handle



XNI-008 Outer Drill Sleeve (for X-Bolt) XNI-015 Outer Sleeve (Green)

Step 3a. Insert Short Nail

- **3a.1** Insert long guidewire through the entry point and down the intramedullary canal.
- **3a.2** Insert short nail over the long guidewire.
- **3a.3** Remove long guidewire when nail is in distal fragment.
- **3a.4** Advance the nail until the expected trajectory into femoral head is correct. AP and lateral images under fluoroscopy should be acquired to establish the expected trajectory.
- **3a.5** Insert inner and outer X-Bolt sleeves through jig. Via skin incision and blunt dissection, advance sleeves onto lateral cortex of femur.
- 3a.6 In the AP view, the projected X-Bolt position should be either in the center or slightly inferior in the femoral head. In the lateral view, the projected X-Bolt position should be centered in the femoral head (optimum tip-apex point).
- **3a.7** Should further impaction be required to advance the nail into position, gentle blows to top of impaction rod should advance the nail.



Warning: Always recheck the tightness of the flexi-chain connector following mallet impaction, as oscillation may loosen the connector and affect assembly of the Metro-Jig to the nail.



XNI-008 Outer Drill Sleeve (for X-Bolt) XNI-009 Inner Drill Sleeve (for X-Bolt)

Step 3b. Insert Long Nail

- **3b.1** Insert long guidewire through the entry point and down the intramedullary canal.
- **3b.2** Insert long nail over the long guidewire.
- **3b.3** Remove long guidewire when nail is in distal fragment.
- **3b.4** Advance the nail until the expected trajectory into femoral head is correct. AP and lateral images under fluoroscopy should be acquired to establish the expected trajectory.
- **3b.5** Insert inner and outer X-Bolt sleeves through jig. Via skin incision and blunt dissection, advance sleeves onto lateral cortex of femur.
- 3b.6 In the AP view, the projected X-Bolt position should be either in the center or slightly inferior in the femoral head. In the lateral view, the projected X-Bolt position should be centered in the femoral head (optimum tip-apex point).
- **3b.7** Should further impaction be required to advance the nail into position, gentle blows to top of impaction rod should advance the nail.

Warning: Always recheck the tightness of the flexi-chain connector following nail advancement and impaction, as oscillation may loosen the connector and affect assembly of the Metro-Jig to the nail.

Instruments Used:



XNI-008 Outer Drill Sleeve (for X-Bolt)
XNI-009 Inner Drill Sleeve (for X-Bolt)



Step 4.

Femoral Head K-Wire

- 4.1 Recheck the tightness of the flexi-chain connector, using the shaft of any rigid screwdriver, prior to insertion and placement of the femoral head K-wire
- 4.2 Through the inner sleeve, advance 3.2mm femoral head K-wire center-center in femoral head within 2mm-3mm of the joint line (optimum tip-apex point). Check position on both AP and lateral views on fluoroscopy.
- 4.3 Measure length using ruler, with the tip of the inner sleeve up against the lateral cortex. To select X-Bolt length, it is recommended to add 4mm-8mm noting that X-Bolt shortens up to 3mm on expansion. Subtract any fracture gap present to allow for later fracture compression.
- 4.4 Final position should ensure that the inferolateral border of the X-Bolt shaft protrudes outside the lateral femoral cortex to ensure full engagement with the lateral cortex as a point of fixation.
- **4.4** Remove impaction rod.

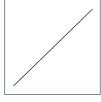
Tip: (Optional) If multiple unsuccessful attempts to get K-wire into optimum position is occurring, widen cortical channel with step reamer to give cortical freedom for K-wire to choose correct path.

Tip: (Optional) Supplemental temporary K-wires can be inserted either side of the jig and nail into femoral head to preserve fracture reduction.





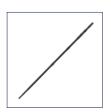
XNI-021 Long Screwdriver Shaft XNI-024 In-Line Screwdriver handle



XBT032001 Ø3.2mm K-wire



XNI-011 Pro-X1 K-Wire Ruler



XNI-012 Step Reamer

Step 5.

Reaming

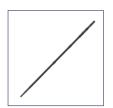
- **5.1** Remove inner X-Bolt sleeve. Ream with step reamer over K-wire to create X-Bolt channel.
- **5.2** Ream to a precise tip-apex point, under fluoroscopy, noting that bluntnosed X-Bolt cannot advance any deeper than the reamer.
- 5.3 Remove step reamer and K-wire leaving a clear bone channel.

Tip: Clean the flutes if high resistance is felt.

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

Warning: There is no stop on the reamer so monitoring the depth under fluoroscopy is mandatory.





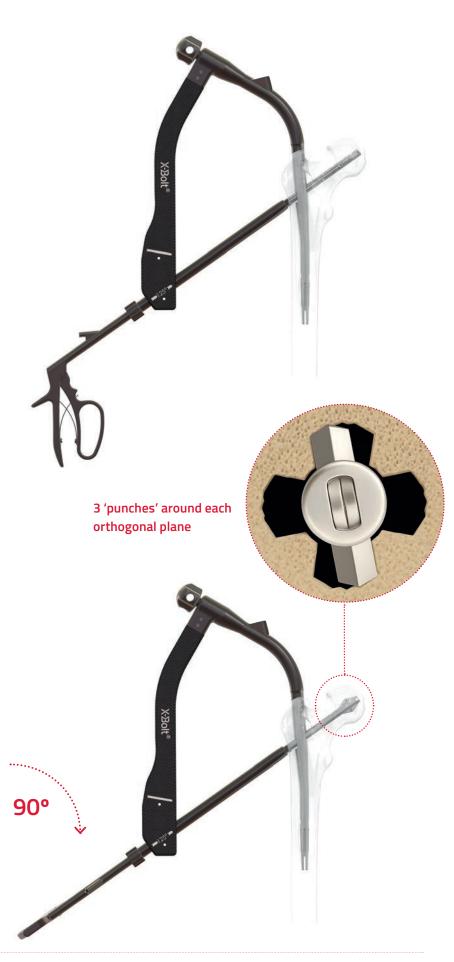
XNI-012 Step Reamer

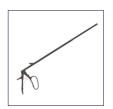
Step 6. Bone Crusher

- **6.1** Fully insert bone crusher to tip-apex point. Do not deploy bone crusher prior to full insertion.
- 6.2 Deploy bone crusher by pulling the trigger to create a 'punch'. Do 3 'punches' at each orthogonal plane to Metro Jig, covering 5°-10° at each orthogonal plane, as the width of the bone crusher wings are slightly less than the width of the X-Bolt wings.

Tip: Bone crusher may be used as a rotational aid to reduction if fracture is rotationally malaligned.

Otherwise, do not rotate the bone crusher when in the deployed position, as may malposition the fracture reduction or damage the instrument.





XNI-014 Bone Crusher

Step 7. Insert X-Bolt

- 7.1 Mount appropriate length X-Bolt onto holding rod, noting the orientation of longitudinal grooves on the X-Bolt.
 Optionally, use T20 Torx screwdriver to insert the X-Bolt.
- 7.2 Insert X-Bolt into prepared channel and advance fully to tip-apex point.

 Rotate the X-Bolt clockwise via the holding rod until one of the four grooves is directly superior, to engage with the set screw.
- 7.3 X-Bolt grooves face superior when 'perfect semi-circles' are seen on AP fluoroscopy.





XNI-017 Holding Rod



XNI-020 T20 Torx Screwdriver (7.5Nm torque limit)

Step 8. Insert Set-Screw

- **8.1** Mount set screw onto the flexible screwdriver.
- 8.2 Insert set screw through the flexichain connector in the Metro Jig and advance into the top of the nail.
- **8.3** Tighten the set screw via flexible screwdriver until the 1.0Nm torque limit is achieved.
- 8.4 Check the set screw is within the groove by gentle clockwise rotation of the holding rod and X-Bolt. If the set screw is fully engaged, resistance to rotation will be felt.
- 8.5 If the set screw was not originally in the groove, an engagement feel will be detected as the X-Bolt rotates to align with the groove. Then, tighten the set screw again via flexible screwdriver until the 1.0Nm torque limit is achieved.
- 8.6 Loosen the set screw back by a quarter-turn, to place set screw in dynamic mode and thus allow freedom for X-Bolt expansion.



Instruments Used:



XNI-023 Flexible Screwdriver Shaft with XNI-027 Mini-axial Screwdriver Handle (1.0Nm torque limit)

Note: The set screw must be in dynamic mode with the X-Bolt (a quarter turn back) to allow freedom for the elbow apex of wings to drive expansion.

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

The depth of the longitudinal grooves is 0.5mm and thus can accommodate up to a half-turn back of the set screw and still remain in the groove.

Step 9.

Expand X-Bolt

- 9.1 Remove holding rod and insert T20 screwdriver. Turn the T20 screwdriver clockwise to expand the X-Bolt until the desired expansion, or until a stop is felt, or to the 7.5Nm screwdriver torque limit. Do not use excessive force.

 The torque to expand the X-Bolt should give excellent tactile feedback on the quality of the bone. Once the X-Bolt is expanded, remove the T20 screwdriver.
- 9.2 If the X-Bolt does not reach full expansion, check that the set screw is in dynamic mode by advancing the set screw with the flexible screwdriver until the 1Nm torque limit and then performing a quarter turn back.
- 9.3 If reversal of the X-Bolt is necessary, rotate the T20 Torx screwdriver counterclockwise.

If the X-Bolt has been damaged or has been fully expanded prior to implantation, then the X-Bolt must be discarded and replaced.





XNI-020 T20 Torx Screwdriver (7.5Nm torque limit)



XNI-023 Flexible Screwdriver Shaft with XNI-027 Mini-axial Screwdriver Handle (1.0Nm torque limit)

Step 10.

Fracture Compression (Optional)

- 10.1 Ensure set screw is in dynamic mode with X-Bolt (a quarter turn back) to allow for dynamic sliding.
- 10.2 Take the leg off traction and observe any fracture compression on fluoroscopy. If further compression is desired, insert the holding rod into back of X-Bolt. Pull back on holding rod using the outer sleeve and Metro Jig as a counter force, to provide further compression following on fluoroscopy.
- 10.3 If a static construct is desired, re-tighten the set screw to the X-Bolt using the flexible screwdriver until the 1Nm toque limit is reached. The design of the components enabling static mode are based on a friction fit, where the user tightens the locking mechanism down into the X-Bolt groove. In some instances, sliding may occur.

Warning: Take care when applying compression (especially in osteoporotic bone), as overcompression may result in X-Bolt pullout, and an increased tip-apex distance.





XNI-017 Holding Rod



XNI-023 Flexible Screwdriver Shaft with XNI-027 Mini-axial Screwdriver Handle (1.0Nm torque limit)

Step 11a.

Distal Locking – Short Nail

11a.1 Metro Jig and distal locking sleeves
direct a distal locking screw placement in
'limited dynamic' mode to allow 1.5mm
of dynamic compression along the
mechanical axis of the femoral shaft.

11a.2 Insert sleeves through distal locking aperture and advance via skin incision and blunt dissection to the lateral femoral cortex.

11a.3 Use Ø4.0mm x 305mm drill bit via inner sleeve, and drill through the lateral and medial cortices.

Measure screw length, rounding up to nearest 5mm, from drill bit markings. Remove inner sleeve.

11a.4 Confirm screw length using depth hook.

11a.5 Insert appropriate length Ø5.0mm distal interlocking screw, using long hex screwdriver.







XNI-015 Outer Distal Locking Sleeve (Green) XNI-016 Inner Distal Locking Sleeve (Gold)



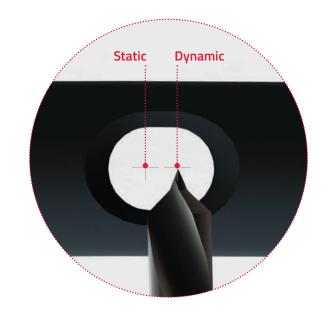
XNI-018 Depth Hook



XNI-021 Long Screwdriver Shaft XNI-024 In-Line Screwdriver Handle

Step 11b. Distal Locking – Long Nail

- **11b.1** Use Ø4.0mm x 150mm drill bit mounted on a power driver, for freehand distal locking.
- 11b.2 Distal screw apertures are oblong, allowing for up to 1.5mm of 'limited dynamic' fracture compression. Set-up the lateral fluoroscopy to see perfect oblong holes.
- **11b.3** Make skin incision and blunt dissection to lateral cortex.
- 11b.4 For 'limited dynamic' of 1.5mm of compression, aim drill bit towards the distal aspect of aperture, furthest from fracture site. For static fracture compression, aim drill bit proximally in the aperture, closest to the fracture site.
- and measure screw length with standard depth gauge.
 Insert appropriate length Ø5.0mm distal interlocking screw with short hex screwdriver, rounding up to nearest 5mm.







XNI-030 Depth Gauge



XNI-022 Short Screwdriver Shaft XNI-024 In-Line Screwdriver Handle

Step 12.

De-Couple Metro[™] Jig

- **12.1** Remove flexi-chain connector using screwdriver shaft through horizontal apertures to gain greater counterclockwise rotation leverage.
- **12.2** Remove Metro Jig.
- **12.3** Wound closure and post-operative management as per surgeon's instructions.





XNI-022 Short Screwdriver Shaft XNI-024 In-Line Screwdriver Handle



Instruments Used:



XNI-020 T20 Torx Screwdriver (7.5Nm torque limit)



XNI-017 Holding Rod

Removal

Reverse Expansion.

Ensure set screw is seated in an X-Bolt groove to provide counter torque.

Retract X-Bolt wings with counterclockwise rotation of T20 screwdriver. The X-Bolt mechanism can crush new cancellous bone formed under the expanded wings. X-Bolt can pass through nail aperture when the wings are collapsed to a 10.6mm diameter.

Remove X-Bolt.

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

Remove Nail.

Insert holding rod before removing distal interlocking screw, so as to prevent the nail from spinning. Then remove interlocking screw before removing 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 insitu. Remove nail and distal interlocking screw as above. The 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-Chain Connector	•
XNI-008	Outer Drill Sleeve (for X-Bolt)	-
XNI-009	Inner Drill Sleeve (for X-Bolt)	—
XNI-011	Pro-X1 K-Wire Ruler	1 - - - - - - - - - - - - -
XNI-012	10.5mm/9.0mm Step Reamer	
XNI-014	Bone Crusher	76
XNI-015	Outer Sleeve (Green)	D-
XNI-016	Inner Sleeve (Gold)	ì—————————————————————————————————————

) Instruments

XNI-017	Holding Rod	-
XNI-018	Depth Hook	
XNI-019	Metro™ Jig	
XNI-020	T20 Torx Screwdriver (7.5Nm 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-026	Impaction Rod	
XNI-027	Mini-axial Screwdriver Handle (1.0Nm torque limit)	
XNI-028	Long Nail Ruler	
XNI-030	Depth Gauge	
XNI-032	Lag Screw Tap	<u> </u>

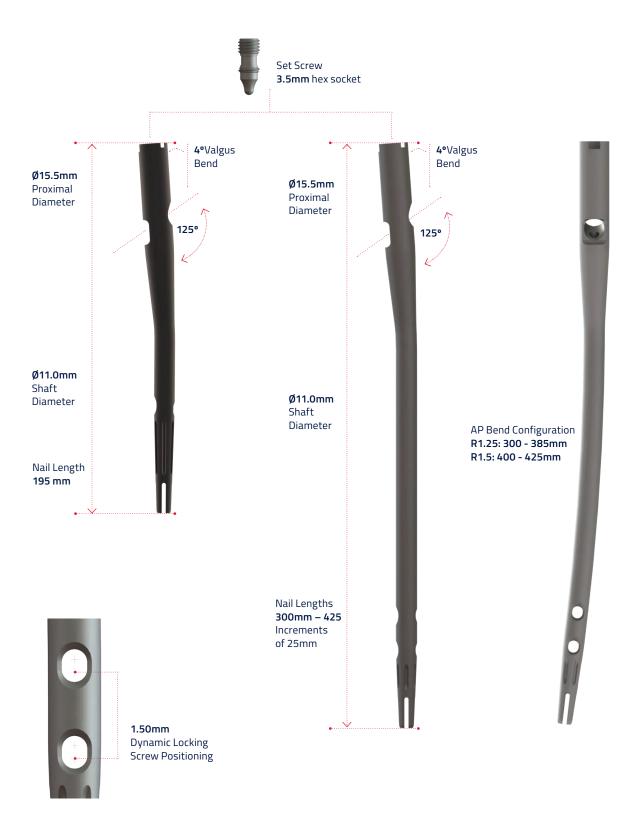
) Implant Dimensions

X-Bolt® (Expanding Bolt)

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



) Implant Dimensions

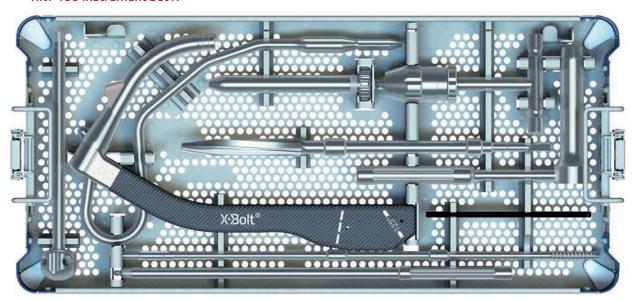


Ordering Information

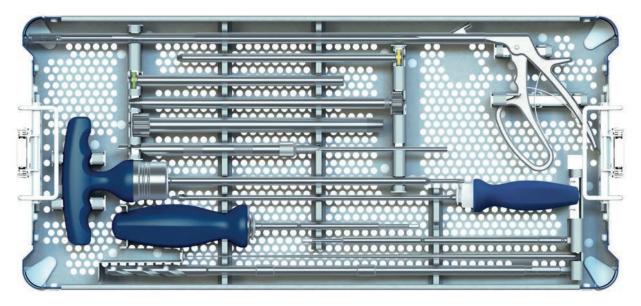
Part Code	Description (implants)
XBT105080	80mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105085	85mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105090	90mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105095	95mm x Ø10.5mm Trochanteric X-Bolt and Set-Screw
XBT105100	100mm x Ø10.5mm Trochanteric 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	195mm x Ø11mm, 125° Short Trochanteric Nail
XBT110300L	300mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110300R	300mm x Ø11mm, 125° Trochanteric Nail, Right
XBT110325L	325mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110325R	325mm x Ø11mm, 125° Trochanteric Nail, Right
XBT110350L	350mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110350R	350mm x Ø11mm, 125° Trochanteric Nail, Right
XBT110375L	375mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110375R	375mm x Ø11mm, 125° Trochanteric Nail, Right
XBT110400L	400mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110400R	400mm x Ø11mm, 125° Trochanteric Nail, Right
XBT110425L	425mm x Ø11mm, 125° Trochanteric Nail, Left
XBT110425R	425mm x Ø11mm, 125° Trochanteric Nail, 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 390mm 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	Ø2.5 x 1000mm Long guidewire (3.8mm ball tip diam.)

Ordering Information

XNI-100 Instrument Set X



XNI-200 Instrument Set Y



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The information presented in this brochure is intended as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific X-Bolt products. Always refer to the package insert, product label and instructions for use before using any X-Bolt product. Surgeons must always rely on their own clinical judgement, training and expertise when deciding which products and techniques to use with their patients.

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European Patents: EP 2175790, EP 3496637, EP 2175790 **US Patents:** US 9724141B2, US 8911446B2, US 11259854B2

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