Pro-X1®

Trochanteric Nailing System

Surgical Technique

X-Bolt
Trauma Orthopedics

Contents

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
- 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

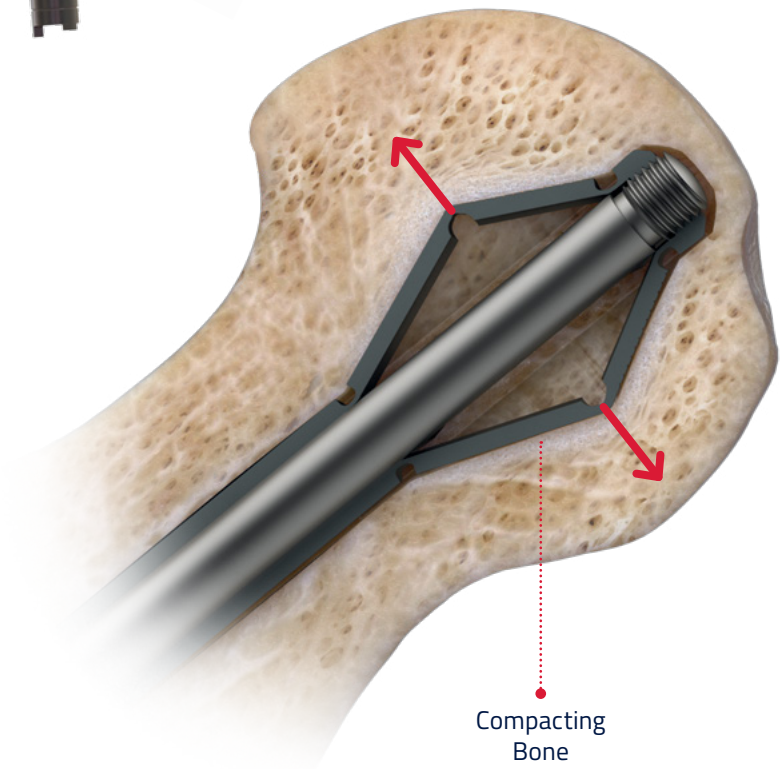
Interlocking Screws

- 5.0mm Diameter, Self-Tapping
- Lengths: 30mm-55mm
- 3.5mm Hex Socket

How It Works

Metro™ Jig

- Curved jig, flexi-drive, and flexible screwdriver
- Facilitates all-outside operation
- Faster surgery and fewer surgical steps
- Easy to uncouple
- Useful in obese/overweight patients
- 10° angled screw path can facilitate shared skin incision



How an X-Bolt® Works

- Inner drive screw with opposing threads
- Actuated with a T20 screwdriver
- Compacts and strengthens surrounding cancellous bone
- Tip-apex point preserved
- No spinning of femoral head
- Tactile feedback on bone quality
- Easily reversible

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 cannulated 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.

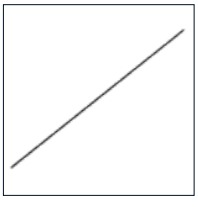
1.4 If distal reaming is needed, use flexible reamers in increments up to 1.5mm to 2.0mm above nail shaft diameter.

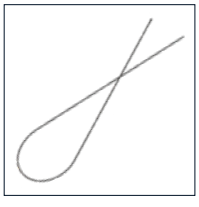
Instruments Used:


Cannulated awl


Proximal sleeves x2


Conical reamer

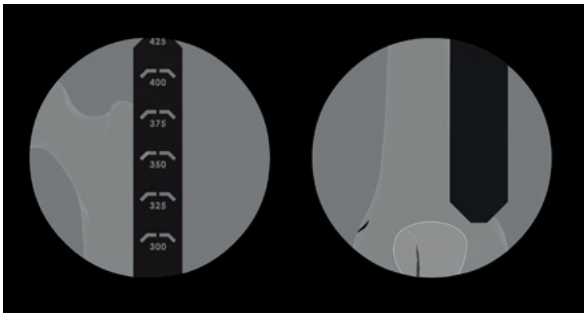

3.2mm K-wire


Long guidewire

Step 2.
Assemble Nail onto Metro™ Jig

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

2.2 Mount appropriate nail to Metro Jig using flexi-drive. Flexi drive can be tightened using shaft of the 3.5mm hex screwdriver. Check alignment of Metro Jig is correct with drill sleeves.



Instruments Used:


Long Nail ruler


Metro™ Jig


Flexi-drive


Screwdriver to tighten


Drill sleeves x4

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. 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).

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. 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).

Step 4.
Femoral Head K-Wire

4.1 Insert inner and outer X-Bolt sleeves through jig. Via skin incision and blunt dissection, advance sleeves onto lateral cortex of femur.

4.2 Through the inner sleeves, 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 A-P and lateral views on fluoroscopy.

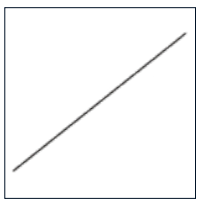
4.3 Measure length using ruler, with the tip of the inner sleeve up against the lateral cortex. To select X-Bolt length, round up to nearest 5mm, noting X-Bolt shortens by 2mm on expansion, and also to allow for later fracture compression.

Tips:

(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.

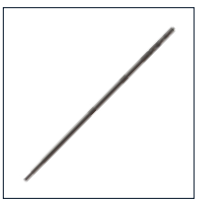
Instruments Used:

Inner & Outer X-Bolt sleeves



Ø3.2mm K-wire

X-Bolt ruler



Step drill-reamer (optional)

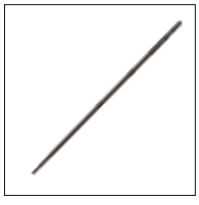
Step 5.
Reaming

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

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

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

Instruments Used:



Step drill-reamer

Step 6.
Bone Crusher

6.1 Fully insert bone crusher to tip-apex point. Do not deploy bone crusher prior to full insertion.

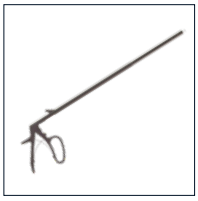
6.2 Deploy bone crusher by pulling the trigger at orthogonal planes to Metro Jig. In strong bone it may be necessary to fan out bone crushing steps 5°-10° in each orthogonal plane.

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

Step 01

Step 02

Instruments Used:


Bone crusher

Step 7.
Insert X-Bolt and Set-Screw

7.1 Mount appropriate length X-Bolt onto T20 screwdriver, noting the orientation of longitudinal grooves with the T-Handle.

7.2 Insert X-Bolt into prepared channel 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.

7.3 Mount set-screw onto the flexible screwdriver.

7.4 Insert set-screw through the flexi-drive using the flexible screwdriver and advance through the nail to engage in the longitudinal groove on superior aspect of X-Bolt. Tighten only to be **two-finger tight** to allow for dynamic sliding. The set-screw prevents rotation while allowing dynamic sliding.

Tips:

If set-screw is not properly engaged in groove, the X-Bolt will spin rather than expand. Gentle rocking back and forth of both screwdrivers will give tactile feedback on set-screw engagement within the groove.

Instruments Used:

T20 Torx screwdriver

Flexible screwdriver

Step 8.
Expand X-Bolt

8.1 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. The torque to expand the X-Bolt gives excellent tactile feedback on the quality of the bone. Once X-Bolt is expanded, remove the T20 screwdriver and outer X-Bolt sleeve.

8.2 If the torque limit is reached during expansion, remove X-Bolt and repeat bone crusher step (6.1 and 6.2)

8.3 If reversal is necessary, rotate the screwdriver counterclockwise. If the X-Bolt has been damaged or fully expanded prior to implantation the X-Bolt must be discarded and replaced.

(Optional) Fracture Compression

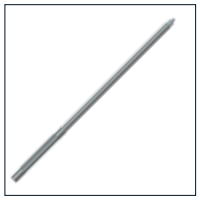
8.4 Ensure set-screw has not been fully tightened down and thus allows dynamic sliding.

8.5 Take the leg off traction and observe any fracture compression on fluoroscopy. If further compression is desired, insert removal rod into back of X-Bolt and pull back to compress fracture, using the Metro Jig as a counter force, following on fluoroscopy.

8.6 To lock final position, tighten the set-screw [four-finger tight] into the X-Bolt groove.

Instruments Used:

T20 Torx screwdriver



(Optional: Removal Rod)

(Optional: Flexible screwdriver)

Step 9a.
Distal Locking – Short Nail

9a.1 Insert sleeves through distal locking aperture and advance via skin incision and blunt dissection to the lateral femoral cortex.

9a.2 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.

9a.3 Confirm screw length using measuring hook.

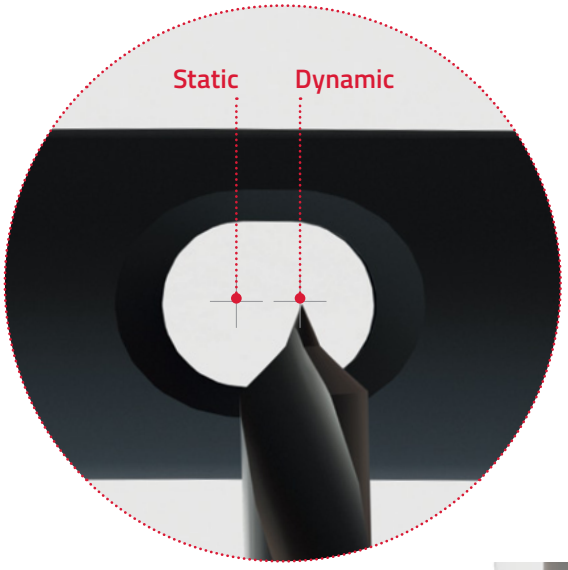
9a.4 Insert appropriate length Ø5.0mm distal interlocking screw, using long hex screwdriver.

Instruments Used:

Inner & Outer distal locking sleeve

Depth hook

Long or short hex screwdriver



Step 9b.
Distal Locking – Long Nail

9b.1 Use Ø4.0mm x 150mm drill bit mounted on a power driver, for freehand distal locking.

9b.2 Distal screw apertures are oblong, allowing for 1.5mm of dynamic fracture compression. Set-up the lateral fluoroscopy to see perfect oblong holes.

9b.3 Make skin incision and blunt dissection to lateral cortex.

9b.4 For dynamic fracture 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.

9b.5 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, rounding up to nearest 5mm.

Instruments Used:

Depth gauge

Short hex screwdriver

Step 10.
De-Couple Metro™ Jig

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

10.2 Remove Metro Jig.

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

Instruments Used:

Long or short hex screwdriver

Removal

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. X-Bolt will pass through nail aperture when the wings are collapsed below 10.50mm diameter

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.

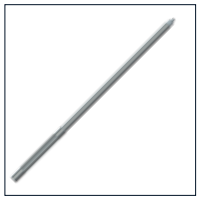
Remove Nail. Insert removal rod before removing distal interlocking screw, so as to prevent the nail from spinning. Remove interlocking screw. Remove nail.

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.

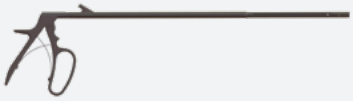
Instruments Used:

T20 Torx screwdriver



Removal rod

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)	

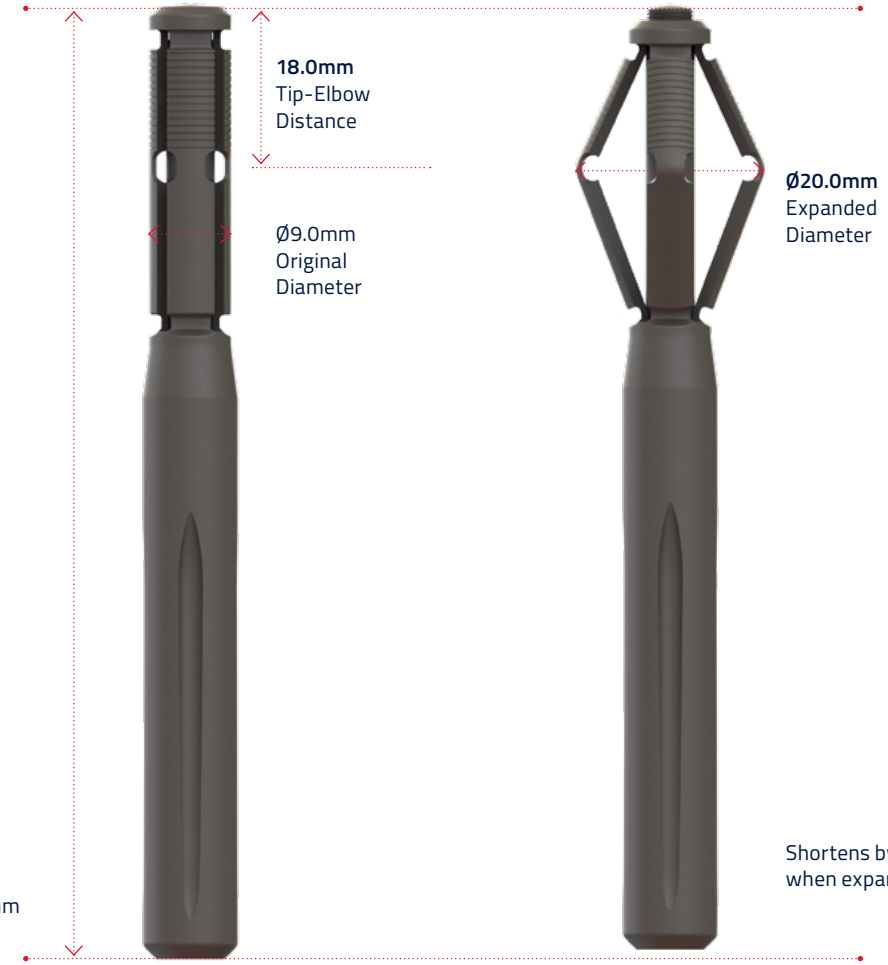
Instruments

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)

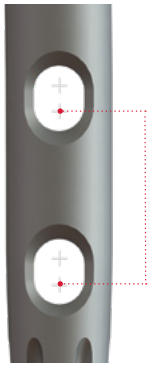
- Tip-apex and tip-elbow distance maintained throughout expansion
- Expand/retract using T20 screwdriver
- Maximal expansion of the four wings visible on orthogonal x-ray views



Implant Dimensions

Set Screw
3.5mm hex socket

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



1.50mm
Dynamic Locking
Screw Positioning

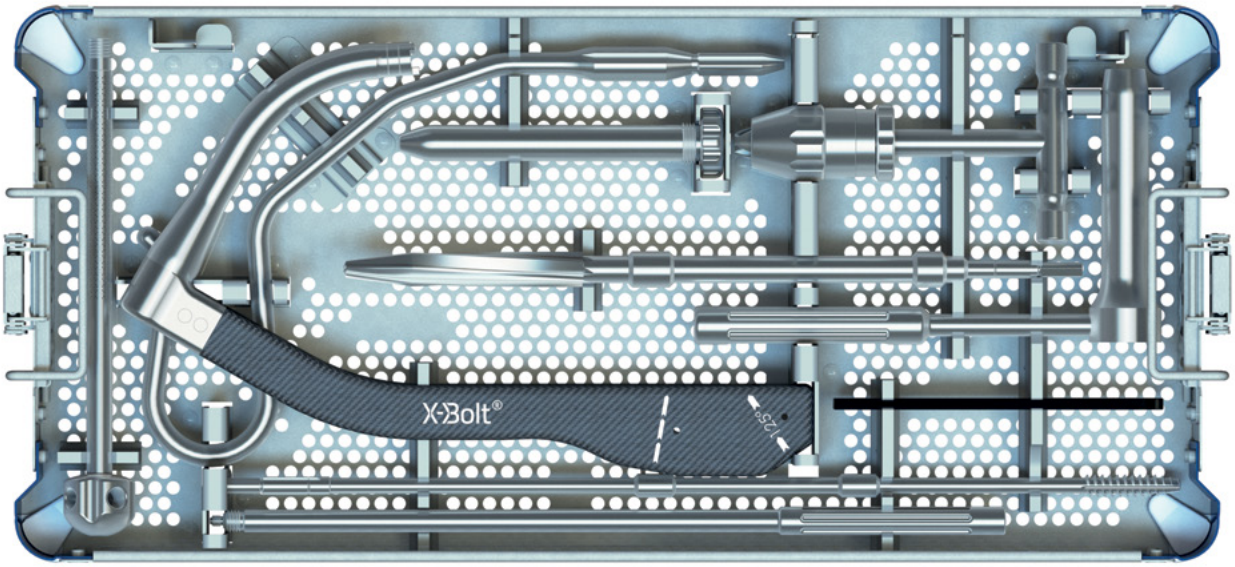
Ordering Information

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
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

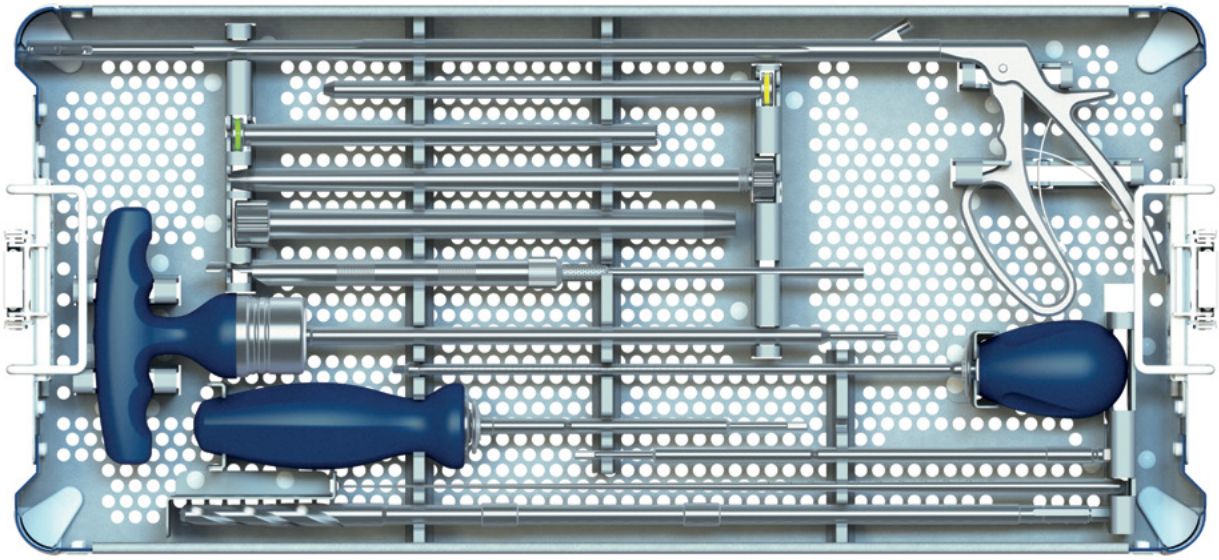
Part Code	Description (single use instruments)
XBT032001	Ø3.2mm x 390mm femoral head K-wire
XBT040305	Ø4.0mm x 305mm drill bit, quick connect (Metro™ Jig)
XBT040150	Ø4.0mm x 150mm drill bit, quick connect (freehand)
XBT024900	Ø2.5 x 1000mm Long guidewire (3.8mm ball tip diam.)

Ordering Information

XNI-100 Instrument Set X



XNI-200 Instrument Set Y



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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