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T2 Alpha®
Femur Retrograde Nailing System

Design Rationale

T2 Alpha® Femur Retrograde Nail

Design Rationale

Contents

Indications, contraindications and intended use 2

T2 Alpha Femur Retrograde Nail Design 4

Short Nail..... 8

T2 Alpha Femur Retrograde Instrumentation 9

T2 Alpha Femur Retrograde Proximal Targeting 10

Stryker is a market leader in intramedullary nailing. For decades, we've been creating solutions that improve treatment and set new standards. Now, with the T2 Alpha Femur Retrograde Nail, you have a new option to treat distal and diaphyseal femoral fractures.

This publication explains the design rationale and features of the T2 Alpha Femur Retrograde Nail. For detailed procedural steps please reference the T2 Alpha Femur Retrograde Nail operative technique.

Indications for use (US and Canada)

The indications for use of these internal fixation devices include:

- Open and closed femoral fractures.
- Pseudoarthrosis and correction osteotomy.
- Pathologic fractures, impending pathologic fractures and tumor resections.
- Supracondylar fractures, including those with intra-articular extension.
- Fractures involving osteopenic and osteoporotic bone.
- Fractures distal to a total hip prosthesis.
- Periprosthetic fractures.
- Nonunions and malunions.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting and increased risk of failure include:

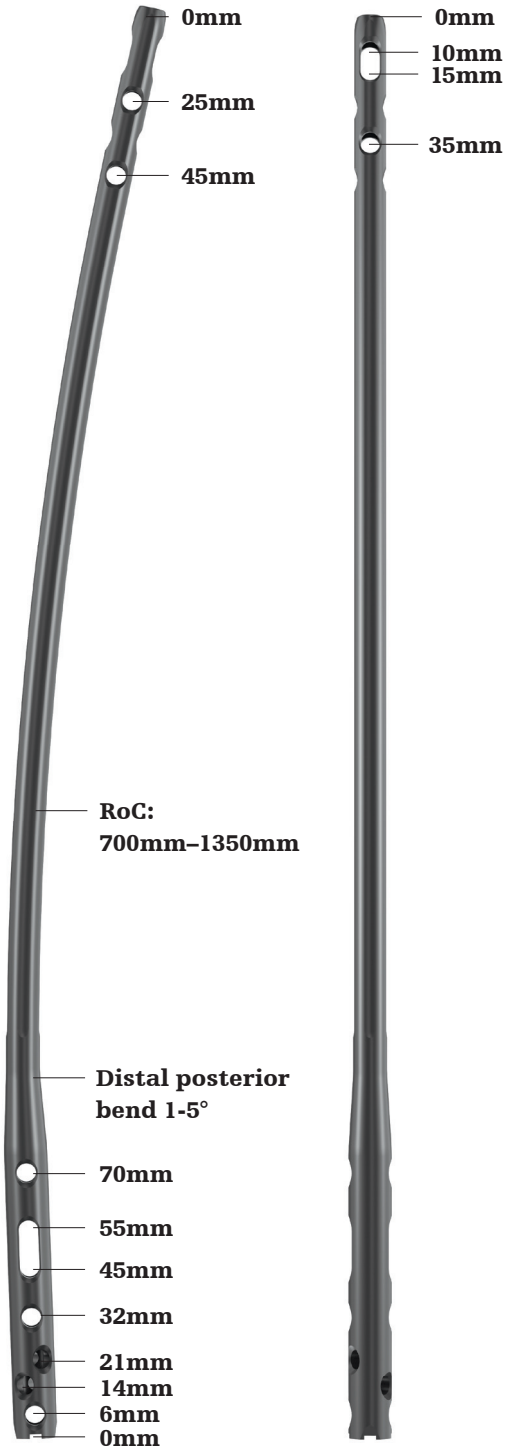
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and /or fixation of the devices.
- Material sensitivity documented or suspected.

T2 Alpha Femur Retrograde Nail Design

The T2 Alpha Femur Retrograde Long Nail features 7 distal locking options, the 4 most distal screw options are placed from 6 – 32mm from the driving end of the nail in three planes of fixation. This is the most distal locking configuration on the market*. This system may allow surgeons to use an IM nail in lieu of plating distal femoral fractures. As a load sharing device, surgeons may prefer intramedullary nails due to early weight bearing potential and their minimally invasive nature[6,7].

The locking configuration was designed for distal and diaphyseal femur fracture fixation[4].

Based on SOMA design we validated that the screw trajectory captures the densest bone. [9,10.]



Examples of locking options for distal diaphyseal and supracondylar fractures

Static locking

Dynamic mode (proximal dynamization)

3 Planes of Fixation

*Compared to Zimmer Natural Nail System Retrograde Femur, DePuy Synthes RFNAdvanced Retrograde Femoral Nailing System and Smith&Nephew Trigen Meta-Nail.[13,14,15]

T2 Alpha Femur Retrograde Nail Design

Mismatch of IM nail geometry and the bow of the femur increases the risk of anterior cortex perforation. The T2 Alpha Femur Retrograde Nail was designed using the Stryker Orthopedics Modeling and Analytics (SOMA) software. The software showed improved anatomic compliance with a length dependent radius of curvature in the long nails[9,10]. The radius of curvature ranges from .70 to 1.35m*.

The distal end of the T2 Alpha Femur Retrograde nail also provides a graduated, length dependent posterior bend which is designed to allow for either a standard retrograde entry point or for a more posterior entry point in periprosthetic fractures[10,12,16].

T2 Alpha Femur Retrograde Nail shows improved anatomic compliance when compared to nails with a radius of curvature of 1.0 and 2.0M.

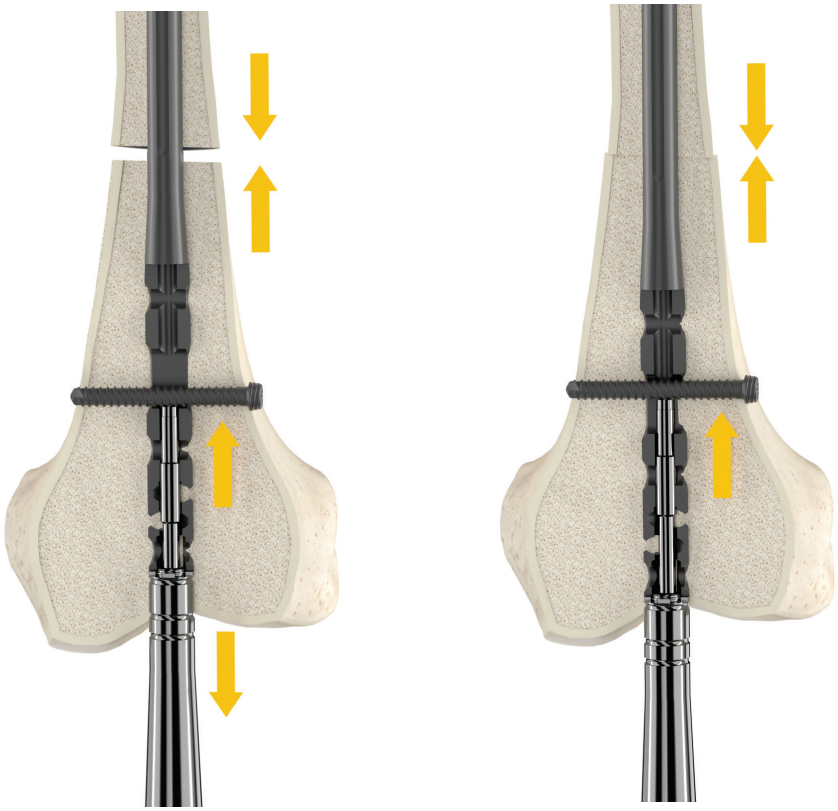
Previous generation Femur Retrograde Nail

T2 Alpha Femur Retrograde Long Nail

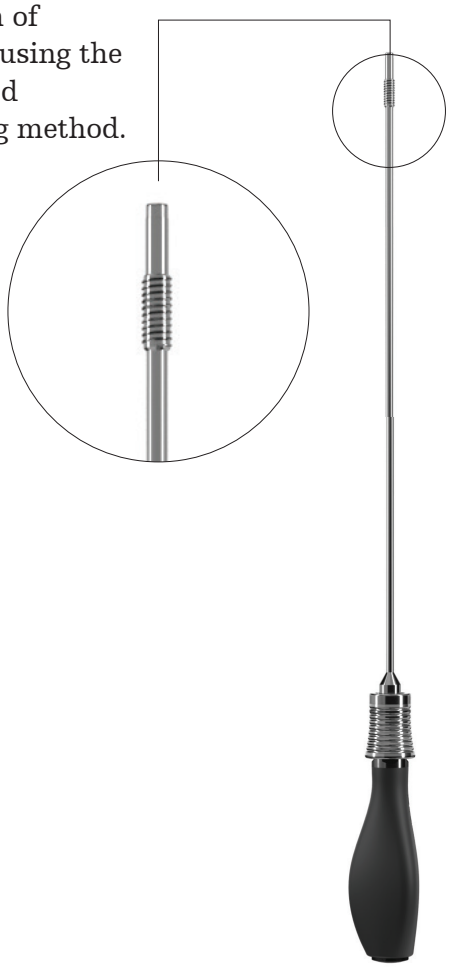
***Long nails only**

T2 Alpha Femur Retrograde Nail Design

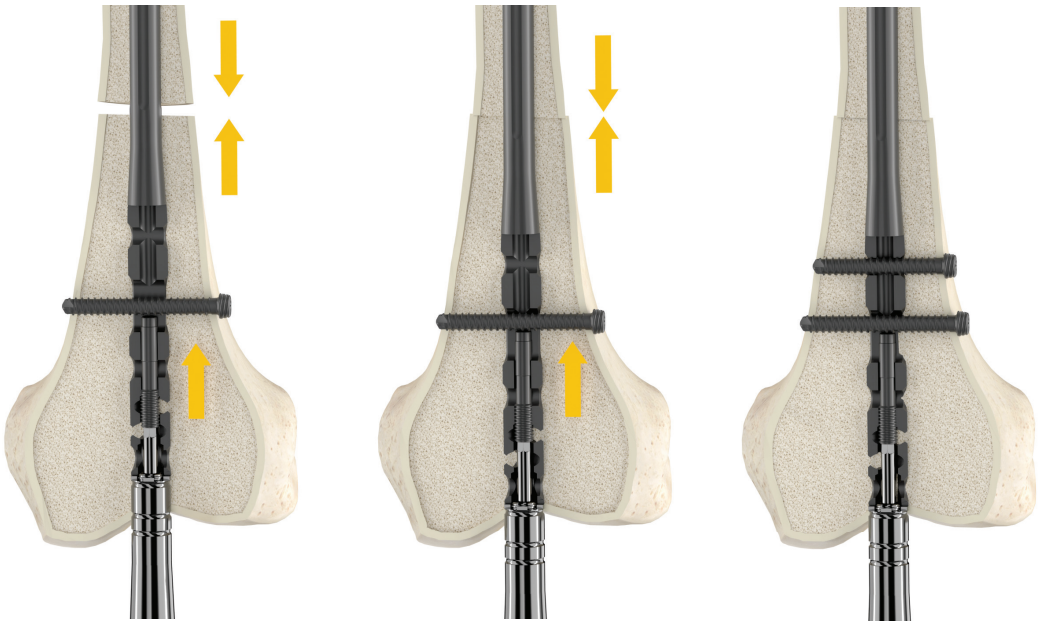
The T2 Alpha Retrograde Femur Nail allows the user to apply up to 10mm of compression through the nail. The user may choose to apply compression using the internal or external compression method. This allows for a more controlled reduction of the fragments when compared to the traditional backslapping method.



External compression*



External compression device*



Internal compression

*** Please note when using external compression device it is required to add a secondary locking screw proximally**

T2 Alpha Femur Retrograde Nail Design

T2 Alpha Femur Retrograde includes three screw options: The IMN Locking Screw, the Advanced Locking Screw and the Condyle Bolts. The Advanced Locking Screw can be used when additional stability is needed.

Advanced Locking Screws*

When treating distal femur fractures, fixed angle constructs may be advantageous in providing stability in short condylar segments and osteoporotic bone[11].

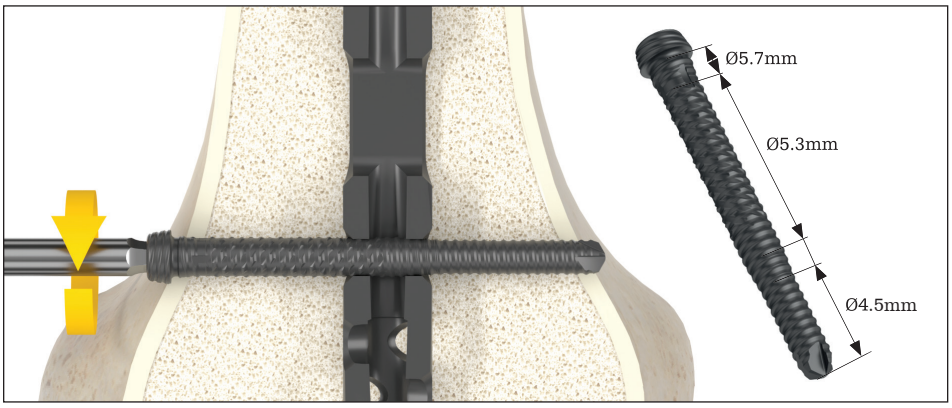
The Advanced Locking Screws are designed with oversized threads which engage with the internal threads of the T2 Alpha Femur Retrograde Nail, thereby limiting relative movement between the nail and the screw[1,3].

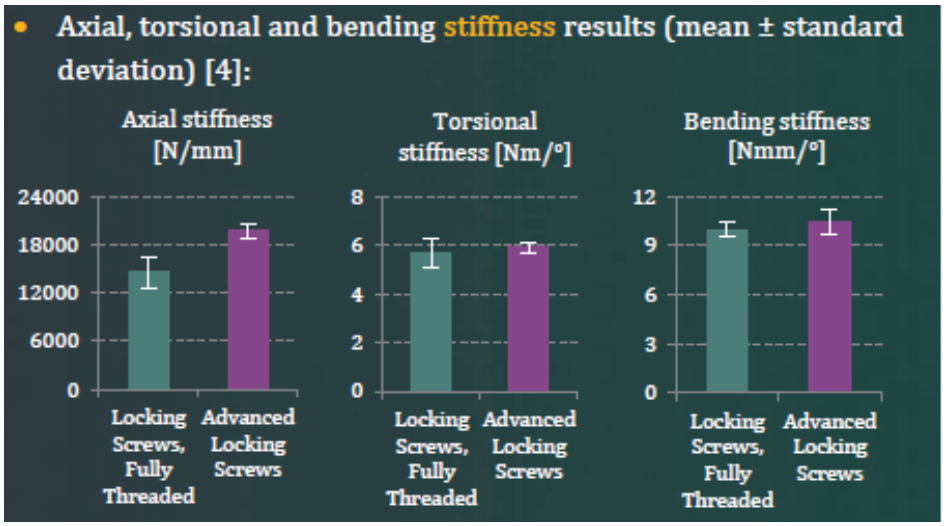
The operative technique requires use of a 5.5mm over-drill, which widens the cortex to allow for insertion of the 5.3mm section of the screw. Closest to the head of the screw, the 5.7mm threads are designed to ensure purchase of the near cortex.

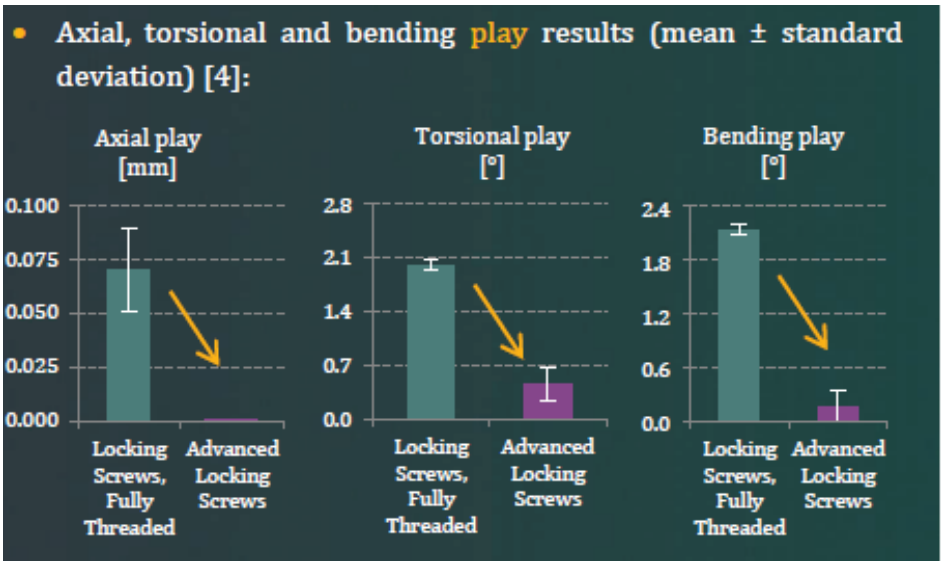
Mechanical Performance[1]

The usage of Stryker's Advanced Locking Screws did not affect torsional and bending stiffness, whereas axial stiffness was increased compared to the fully threaded locking screws. [T2]**.

The usage of Stryker's Advanced Locking Screws resulted in a negligibly low axial play and significantly decreased both torsional and bending play compared to the locking screws, fully threaded [T2]**.







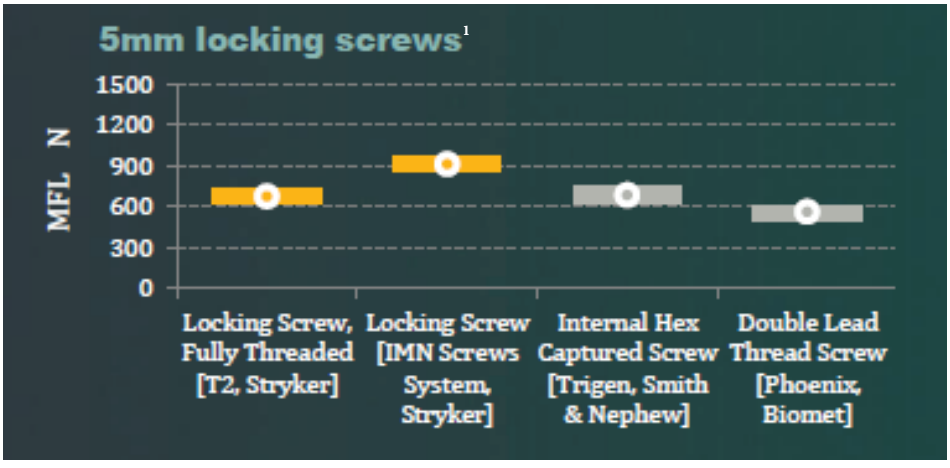
*Advanced Locking Screws can only be used in 5mm round holes
**Locking screws, fully threaded [T2, Stryker]

T2 Alpha Femur Retrograde Nail Design

IMN Locking Screws

The T2 Alpha IMN Locking Screws show an increased fatigue strength of 30% when compared to the legacy T2 Screws[5,12].

Threaded head of both the IMN Locking Screw and Advanced Locking Screw engages with the self retaining screwdriver sleeve



T2 Alpha Femur Retrograde Short Nail

To meet surgeon preference and diverse fracture patterns, the T2 Alpha Femur Retrograde Nailing System offers a 170mm and 200mm short nail option.

The short nail has 4 distal locking options 6 – 32mm from the driving end of the nail in three planes of fixation. Proximally, the nail has two lateral to medial locking options which are inserted using the short proximal targeting arm.

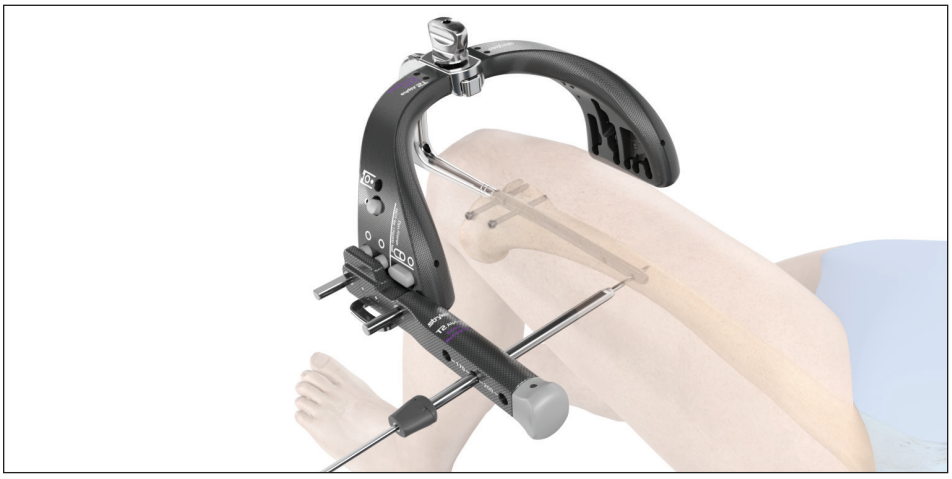
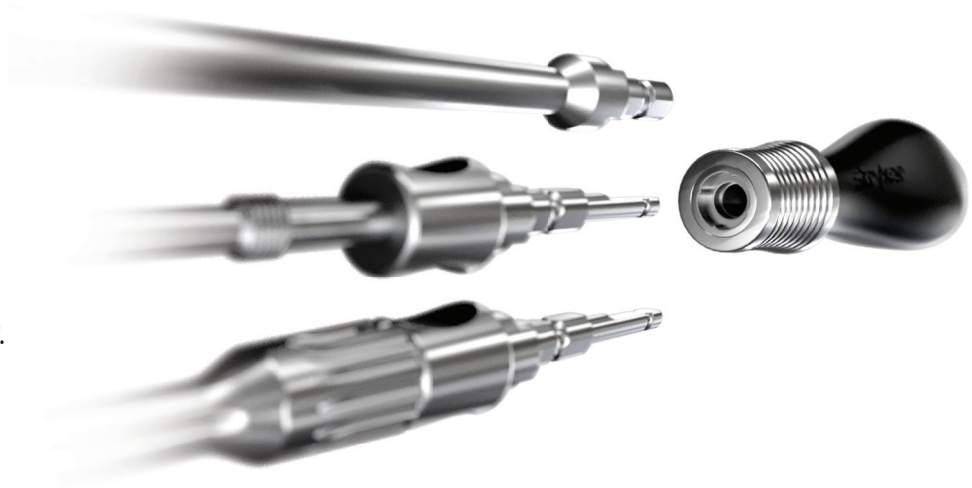


*Plate and nail in the image shown is not a linked construct. The T2 Alpha Femur Retrograde nail is not indicated for linking with plates.

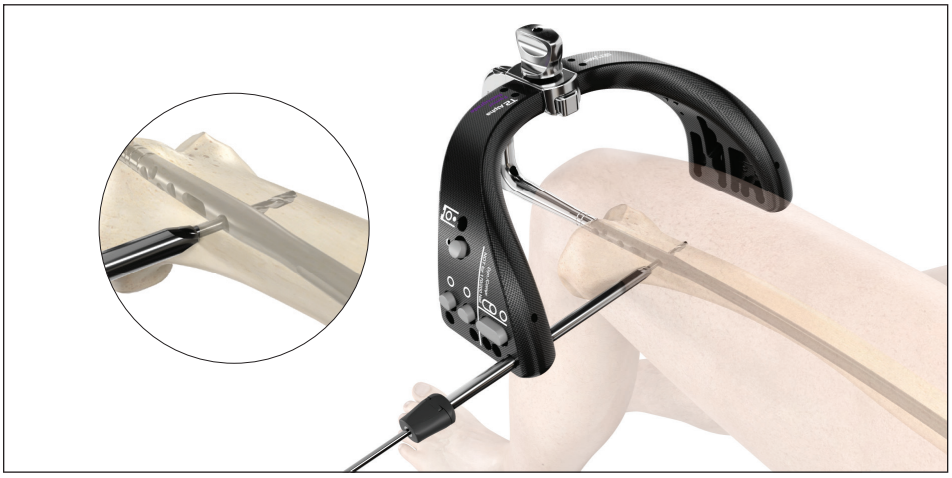
Image of short nail used with a femoral stem and anatomic plate.*

T2 Alpha Femur Retrograde Instrumentation

All T2 Alpha Nailing Systems share a core set of general instruments to ensure consistency across all indications. The T2 Alpha basic instruments and the T2 Alpha Femur Retrograde indication instruments are designed to improve instrument continuity and functionality for a streamlined operative workflow[19].



- Robust self-retaining screwdriver.
- Depth gauges with improved legibility.
- Universal modular interfaces for quick-lock assembly.
- Static distal targeting arm eliminates the need to rotate targeting arm for distal screw insertion.

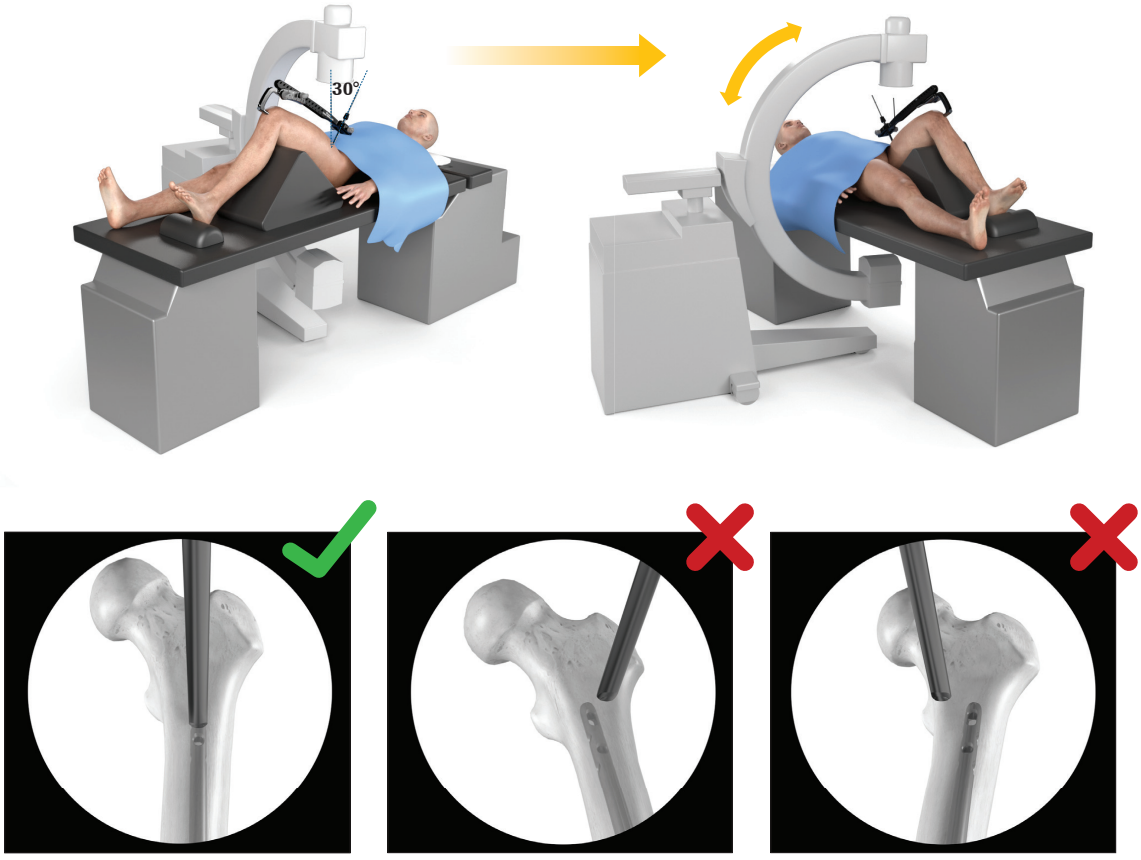


T2 Alpha Femur Retrograde Proximal Targeting

Based on the T2 Alpha GT/PF & Tibia Distal Targeting Technology, The T2 Alpha Proximal Targeting Device provides guided locking for the proximal AP holes of the long T2 Alpha Femur Retrograde nails. The guided proximal targeting device is designed to provide reproducible locking and reduce the total number of x-ray shots compared to freehand locking[12,17,18].

Proximal Targeter Positioning

To perform guided proximal locking, it is essential to place the X-ray beam of a C-arm approximately 30 degree oblique to the axis of the drill sleeve assembly. Please defer to the T2 Alpha Femur Retrograde operative technique for a procedural overview.



Notes

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