

PRECICE UNYTE™

ADJUSTABLE SOLUTIONS
FOR NON-UNIONS

PRECICE UNYTE™ Pre-Distracted Nail

The Adjustable Intramedullary Solution for Femur and Tibia Fractures

NuVasive Specialized Orthopedics™, a division of NuVasive®, an innovative company focused on developing implantable technology to treat a broad spectrum of spinal and orthopedic applications, has developed a novel intramedullary nail to treat long bone trauma, non-unions, or mal-unions, often the result of chronic fractures at risk. The PRECICE UNYTE Pre-Distracted Nail is an adjustable, state-of-the-art device that utilizes a remote control to noninvasively compress and distract the femur or tibia to ensure consolidation of open or closed fractures, non-unions or mal-unions.

Indications:

- Open and Closed Fracture Fixation
- Non-unions
- Mal-unions
- Pseudarthrosis

Features:

- Available in 8.5, 10.7, & 12.5 mm Diameters
- Customizable Compression and Distraction Protocol
- Up to 10mm of Compression
- Noninvasive Compression and Distraction via External Remote Controller
- Novel Magnetic Technology



Display Module

External Remote
Controller (ERC)

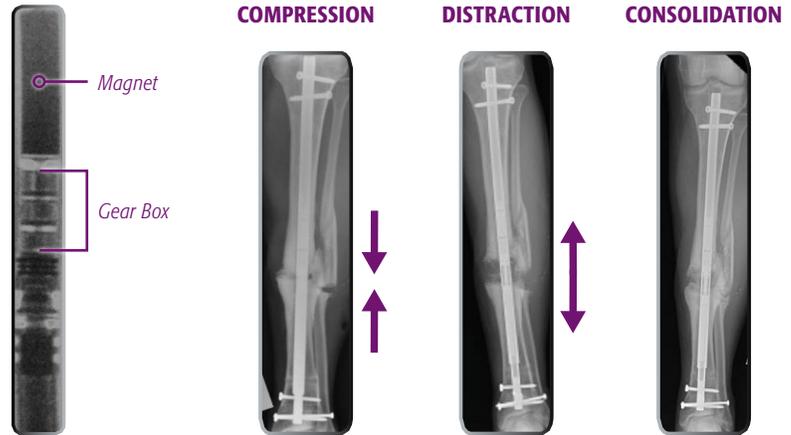
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STATE-OF-THE-ART TECHNOLOGY

The key to the NuVasive Specialized Orthopedics™ platform technology is the magnetic interaction between the PRECICE UNYTE Intramedullary (IM) Nail and external remote control. The proprietary technology includes a complex internal gear system remotely activated and controlled by permanent magnets. This technological advancement allows for a precision-controlled compression and distraction phase with the ability to noninvasively customize treatment.



IMPLANT SIZING

NAIL APPROACH	PRE-DISTRACTION (mm)	INITIAL DISTRACTION AVAILABLE (mm)	TOTAL DISTRACTION LENGTH (mm)	DIAMETER (mm)	OVERALL LENGTH (mm)
ANTEGRADE TIBIA – 10°	10	40	50	8.5, 10.7, 12.5	205, 225, 240
	10	70	80	8.5, 10.7, 12.5	255, 285, 315, 345, 375
ANTEGRADE FEMUR TROCHANTERIC – 10°	10	40	50	8.5, 10.7, 12.5	225, 240
	10	70	80	8.5, 10.7, 12.5	255, 285, 315, 345, 375
ANTEGRADE FEMUR – PIRIFORMIS STRAIGHT	10	40	50	8.5, 10.7, 12.5	225, 240
	10	70	80	8.5, 10.7, 12.5	255, 285, 315, 345, 375
RETROGRADE FEMUR – 10°	10	40	50	8.5, 10.7, 12.5	225, 240
	10	70	80	8.5, 10.7, 12.5	255, 285, 315, 345, 375
RETROGRADE FEMUR – STRAIGHT	10	40	50	8.5, 10.7, 12.5	225, 240
	10	70	80	8.5, 10.7, 12.5	255, 285, 315, 345, 375

EXTERNAL REMOTE CONTROLLER (ERC)

The ERC is a portable, hand-held unit that precisely compresses or distracts the IM nail through the touch of a button. The ERC is fully customizable to each patient, based on their distraction needs. The ERC is designed to be used in a clinic setting to achieve initial compression, or in the comfort of the patient's home if gradual distraction is needed.



For more information about this product, please contact your local sales representative.

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The PRECICE UNYTE™ Intramedullary Nail System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The PRECICE UNYTE nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant. The PRECICE UNYTE Intramedullary Nail System is intended for open and closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones. Contraindications include patients with Gustilo open fracture classification grade IIIB and IIIC fractures, infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the 10.7 mm diameter femoral or tibial implant or greater than 38 mm for the 8.5 mm diameter femoral or tibial implant or greater than 25.4 mm for the 8.5 mm diameter humeral implant that is from 165 mm to 210 mm in pre-distracted length or greater than 51 mm for the 8.5 mm diameter humeral implant that is 225 mm to 300 mm in pre-distracted length, patients with an irregular bone diameter that would prevent insertion of the nail, patients in which the nail would cross joint spaces or open epiphyseal growth plates, patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity, patients unwilling or incapable of following postoperative care instructions, patients weighing in excess of 114 kg for the 10.7 mm diameter tibial or femoral implant or weighing in excess of 57 kg for the 8.5 mm diameter tibial or femoral implant. The implantable device is only to be used by a trained licensed physician. Please refer to the PRECICE UNYTE Intramedullary Nail System instructions for use for complete Important Safety Information.

Caution: US Federal law restricts this device to sale by or on the order of a physician.