

Precice Unyte System Patient Information Leaflet

Device Name: Intramedullary Limb Lengthening System (Nail, Screws and End Caps).

Model: NuVasive Specialized Orthopedics, Precice Unyte System.

What is the Precice Unyte System used for?

The Precice Unyte System is intended to treat adult patients with complex long bone fractures as well as fractures that are not healing properly (non-union, malunion, pseudoarthrosis, or bone transport). The Precice Unyte System can also be used to treat limb length discrepancies.

Indications for Use:

The Precice Unyte System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones in adults.

What causes limb length discrepancy?

Limb length discrepancy (LLD) can be congenital or acquired. Some causes of congenital LLD include fibular hemimelia, tibial hemimelia, congenital femoral deficiency, hemihypertrophy or other limb hypoplasias. Acquired LLD is usually due to an injury to the growth plate by trauma, infection, radiation, or tumor.

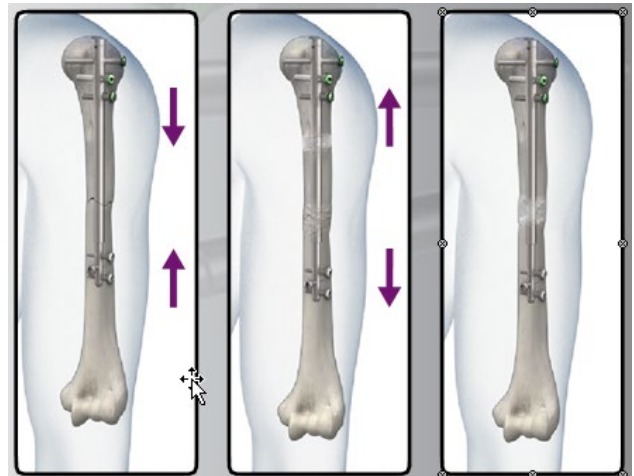
What are treatment options?

There are many options for treatment of a limb length discrepancy (LLD). Below are some of the methods of treatment:

- Shoe lift
- Surgery on the healthy limb
- External fixation devices
- Intramedullary limb lengthening nail

Product Description – The Precice Unyte System

The Precice Unyte System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice Unyte implants are manufactured from titanium. The Precice Unyte nail is a sterile single-use device that is surgically implanted using the instruments and locking screws for compression for the proper fracture reduction and osteoplasty lengthening utilizing distraction osteogenesis. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length.



Postoperative Care

You should be mobilized the first few days after surgery but must avoid full weight-bearing throughout the entire lengthening phase. The surgeon must prescribe a lengthening protocol for you. Daily lengthenings are typically divided into three or four sessions and typically start five to seven days after initial implantation. Weekly or bi-weekly clinical and radiographic evaluations by the surgeon are important to review your progress. The ERC is programmed to optimize the lengthening prescription.

During the lengthening phase, compliance to the planned lengthening prescription is important, in addition to adherence to proper use of the ERC and

to postoperative rehabilitation protocols. It is the physician's responsibility to carefully monitor your progress and to make any necessary changes to the daily lengthening prescription. The physician may adjust or reverse a prescription to best meet your needs.



The Precice Unyte implant cannot withstand the stresses of full weight bearing. You should utilize external support and/or restrict activities until consolidation occurs.

Consult your surgeon for further information related to weight bearing and your postoperative care plan.

Use of the External Remote Controller

The ERC is a portable, handheld unit programmed by the physician/staff with your individual prescription for the treated limb. The ERC precisely lengthens or shortens the implant with the touch of a button. The ERC is designed to be used at the comfort of your home and should be taken to clinic visits. For instructions for how to use the ERC, reference your patient manual within the ERC case.



Consult your surgeon for further information related to your External Remote Controller and post-operative care plan.

Device should be removed after implantation time of no more than one year.

Adverse Events and Residual Risks:

As this is a major surgical procedure, there are known complications associated with orthopedic surgery such as bone fractures, nonunion, delayed union, malunion, premature healing (consolidation), decrease in bone density due to stress shielding, inadequate screw fixation, difficulty with nail or screw removal, early or late infection that may result in the need for additional surgeries, damage to blood vessels or nerves, deep venous thrombosis or pulmonary emboli, acute local inflammatory response, loss of sensory and/or motor function or paralysis, pain, and/or permanent deformity. The following list of failures and adverse events are possible with the Precice Unyte system. Additionally, possible residual risks are also included.

- Soft tissue contractures, loss of joint motion, subluxation and/or dislocation could result in pain or surgical intervention to resolve. Preventative measures should be considered such as but not limited to proactive examinations, change of prescription, bracing, physical therapy, and tissues releases.

- Local tissue discoloration (i.e., metallosis), osteolysis, local acute inflammatory response, pain or other harms associated with exposure to wear debris, metal nanoparticles, and elevated titanium serum ion levels (including neurological issues and the risks associated with reproductive and developmental toxicity).
- Exposure to biohazards or non-biocompatible materials potentially leading to immunological response, pain, skin irritation/rash/sensitization, developmental toxicity related harms and/or infection and which may require medical intervention such as revision surgery.
- Loss of distraction or uncontrolled lengthening which may lead to pain, loss of correction, extension of treatment, progression of deformity, increased limb length discrepancy, over-lengthening, poor regenerate and/or necessitate revision surgery.
- Implant bending, fracture, loosening, disassociation and/or loss of fixation resulting in medical intervention such as revision surgery.
- Failure to lengthen which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), extension of treatment, suboptimal correction, and/or necessitate revision or reoperation.
- Treatment complications from anatomical compatibility issues due to implant configuration selection, implant removals and/or implant sterility which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), inability to complete the procedure and/or cancellation of the procedure, or may result in pain, abnormal sensations and/or suboptimal correction.

Precice Unyte System is contraindicated in:

- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures.
- Patients with pre-existing nerve palsies.
- Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Metal allergies and sensitivities.
- Patients with an irregular bone diameter that would prevent insertion of the PRECICE Unyte Nail.
- Patients in which the PRECICE Unyte 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.

This list above does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

MRI Safety Information:

The PRECICE Unyte is MR Unsafe. A patient with the implanted PRECICE Unyte nail must not come near an MRI scanner and must not undergo an MRI scan.



Consult your surgeon for further information related to magnetic field interference from magnetic resonance imaging devices.

Incident Reporting:

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration.



Precice

Name and Address of Manufacturer:

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