

Precice Intramedullary Limb Lengthening (IMLL) System & Precice Short System Patient Information Leaflet

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

Model: NuVasive Specialized Orthopedics Precice Intramedullary Limb Lengthening (IMLL) System and Precice Short System

What is the Precice IMLL System and Precice Short System used for?

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

Indications for Use:

The Precice IMLL 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 IMLL System

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



Post-Operative 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 to four sessions and typically start five to seven days after initial implantation. 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.



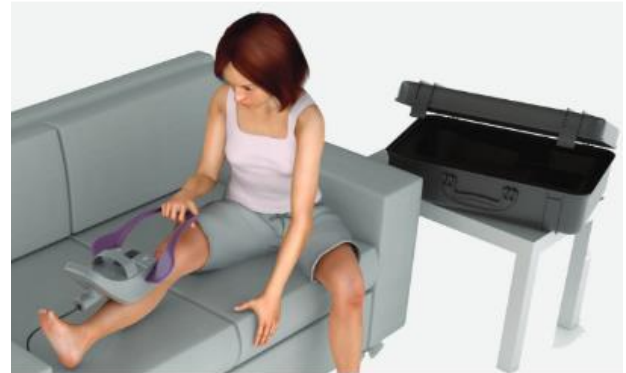
The Precice implant cannot withstand the stresses of full weight bearing. You should utilize external support and/or restrict activities until consolidation occurs.

Consult your surgeon for further information related to weight bearing and your post-operative 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 IMLL 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. Complications can include angular deformity, hip abduction contracture, knee flexion deformity, and soft tissue release reoperations.

- 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). Risks associated with patient exposure to metal ions from wear debris and/or wear debris particles, including all risks associated with development and reproductive toxicity, are known largely based on in vivo scientific work.
- 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. Locking bolt back-out. Injury from excessive weight bearing (>20% of body weight on treated limb) prior to full bone consolidation.

- 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 IMLL System is contraindicated in:

- Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities.
- Patients with an irregular bone diameter that would prevent insertion of the PRECICE Intramedullary Limb Lengthening nail.
- Patients in which the PRECICE Intramedullary Limb Lengthening 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 Intramedullary Limb Lengthening System is MR Unsafe. A patient with the implanted PRECICE Intramedullary Limb Lengthening nail must not come near an MRI scanner and must not undergo an MRI scan.

Name and Address of Manufacturer:

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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.



Therapeutic Goods Administration
136 Narrabundah Lane
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1800 141 144
www.tga.gov.au/medical-devices-ivds