Precice Freedom System
Patient Information Leaflet

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

Model: NuVasive Specialized Orthopedics, Precice Freedom System.

What is the Precice Freedom System used for?
The Precice Freedom residual limb lengthening system is designed to lengthen the femur following above-the-knee amputation.

Indications for Use:
The Freedom nail is indicated for lengthening of the residual limb of the femur in adults.

What are common causes for above the knee amputation?
Some of the common causes for above the knee amputations include: cancer/tumor resection, severe infection, traumatic injury, vascular problems resulting in poor blood flow, and complications from diabetes.

What are treatment options?
Treatment options for patients with a residual limb greatly vary based on the functional demand and the starting length of the femur. A residual limb is most commonly treated with a prosthesis but if the residual limb is extremely short, it limits the prosthetic options and/or the patient's ability to control the prosthesis. Other options for short femoral residual limb management include:

- Hip disarticulation prosthesis
- Osteointegration
- External fixation devices
- Intramedullary limb lengthening nail
- Crutches or wheelchair

Product Description – The Precice Freedom System
The Precice Freedom System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice Freedom implants are manufactured from titanium. The Precice Freedom 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.

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 will 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 Freedom is a non-weight bearing device and cannot withstand the stresses of full weight bearing on a prosthetic. Patients should utilize external support or a wheelchair 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.

The 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 Freedom 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.
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Precice Freedom System is contraindicated in:

- 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.
- 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 in which the FREEDOM Nail would cross joint spaces or open epiphyseal growth plates.
- 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 Freedom System is MR Unsafe. A patient with the implanted Precice Freedom 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.

Name and Address of Manufacturer:

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Aliso Viejo, CA 92656
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