Ellipse Technologies, Inc.  PRECICE® Intramedullary Limb Lengthening System

Instructions for Use

Product Description:

The Ellipse 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 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 to a prescribed length.

Following implantation, the PRECICE System utilizes distraction osteogenesis to lengthen the limb. Traditional intramedullary surgical techniques are used to implant and secure the proximal and distal sections of the PRECICE nail to the target bone. The PRECICE nail includes a small internal magnet and gearing. After positioning the External Remote Controller (ERC) against the skin over the internal magnet, activation of the ERC causes the magnet to rotate and either lengthen or shorten the nail.

Over a period of days, weeks, or months, sequential distractions are used to produce the target limb length. The PRECICE nail remains implanted until bone consolidation has been completed. Once the physician determines that the nail has achieved its intended use and is no longer required, it is removed using standard surgical techniques.

Intended Use:
The PRECICE System is intended for limb lengthening of the femur and tibia.

Contraindications:
- 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 implant.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 38 mm for the 8.5 mm diameter implant.
- Patients with an irregular bone diameter that would prevent insertion of the PRECICE nail.
- Patients in which the PRECICE 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 implant.
- Patients weighing in excess of 57 Kg for the 8.5 mm diameter implant.
Warnings:

- The PRECICE nail cannot withstand the stresses of full weight bearing. Patient should utilize external support and/or restrict activities until consolidation occurs.
- Do not use if the sterile packaging has been damaged or is open.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the PRECICE System is not recommended in patients with pacemakers.
- The PRECICE System may not be appropriate for patients with poly-trauma.
- Use of the PRECICE System in patients with an active infection of the tibia or femur is not recommended.
- Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect of the bone regenerate during the lengthening process.
- The PRECICE nail is supplied sterile and is for single use only. The nail has not been tested to be cleaned or sterilized for multiple uses. If the nail is used more than once, the device may not be sterile and could cause a serious infection.
- Assure that patient with implanted PRECICE nail does not enter MRI unit. Effect of high magnetic field of MRI unit has not been studied with respect to the implanted magnet, and is therefore unknown.
- Unsafe in Magnetic Resonance Imaging environments. The PRECICE System has not been evaluated for safety and compatibility in the MR environment. The PRECICE System has not been tested for heating or migration in the MR environment.

Precautions:

- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC) Operator’s Manual OM0005 for operation of the External Remote Controller.
- During the distraction phase, patient should not participate in contact sports or other high risk activities that cause more than 20% of body weight to be loaded on implanted leg. These activities may resume upon sufficient bone consolidation, but only as determined by the physician.
- Examine all PRECICE System components carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.

Cautions:

- The PRECICE System is for prescription use only by the order of a physician.
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the PRECICE nail, as materials will be attracted to each other.
- Do not bend the PRECICE nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005) to assure proper alignment between the ERC and magnet of the PRECICE nail.
Figure 1: Detail of the PRECICE Nail with Locking Screws (10.7 mm on left, 8.5 mm on right)
PRECICE Model A – Retrograde Femur 10° Bend

PRECICE Model B – Antegrade Femur Piriformis

PRECICE Model C – Antegrade Tibia 10° Bend

PRECICE Model D – Antegrade Femur Trochanteric 10° Bend
Figure 2: Drill guide set up. Verify drill bit alignment to implant prior to use.

Figure 3: Removal Tool Assembly
Procedures

Careful pre-operative diagnosis and planning, meticulous surgical technique, and extended postoperative care by experienced surgeons are essential to procedure success. Prior to use, the surgeon should be specifically trained in the use of the PRECICE System along with the associated instruments to facilitate correct selection, placement and security of the implant.

Implantation Procedure

1. Sterilize screws, instrument tray and accessory tray prior to the procedure. The PRECICE nail is provided separately in sterile packaging.
2. Use standard surgical techniques to provide for adequate venting of the intramedullary canal during surgery.
3. After accessing the insertion site, use an awl or cannulated cutter to open the medullary canal. Use care to keep the straight part of the shaft of the instrument parallel to the long axis of the bone shaft.
4. If using flexible reamers, insert a guide wire into the medullary canal and advance until the tip of the wire reaches the intended location. Imaging in two planes is required while advancing the guide wire.
5. Ream the intramedullary canal 2 mm greater than the diameter of the PRECICE nail. The cortices must be at least 3 mm thick at any location once reamed.
6. Create an osteotomy at the appropriate location in the bone.
   Note: Do not perform the osteotomy in the proximal or distal metaphyseal areas where the larger intramedullary canal diameter may lead to instability of the distracted fragment, and higher bending moments may result in excessive loading of the implant.
7. For tibial cases, also create an osteotomy in the fibula. To ensure that the fibula lengthens with the tibia, consider using screws to secure the osteotomized fibula to the tibia both distally and proximally.
8. After attaching the Ellipse Drill Guide to the PRECICE nail, insert the device into the medullary canal under image intensification. Advance the device until it is properly positioned.
9. Use the Drill Guide to control alignment and then secure the proximal portion of PRECICE nail using two proximal transverse locking screws of appropriate length. The head of the screw should be flush with the bone surface. Do not drill a second hole until securing the first locking screw.
10. Using a free hand technique and fluoroscopic imaging, secure the distal portion of the PRECICE nail using two transverse locking screws of appropriate length. The head of the screw should be flush with the bone surface.
11. Remove the Drill Guide and associated accessories. Attach the End Cap to the proximal end of the PRECICE nail. Carefully irrigate the surgical site to remove any remaining bone fragments.
12. Locate the center of the implanted magnet and mark the patient’s skin with indelible marker at this location.
13. Close and dress the site using standard techniques.
14. Instruct the patient to maintain the indelible marker mark at the same location on their leg.

Post-Operative Procedures

1. Read the External Remote Controller (ERC) Operator’s Manual (OM0005) prior to performing an adjustment of the PRECICE nail.
2. Identify the mark on the leg where the magnet in the PRECICE nail is located. Carefully place the ERC firmly but comfortably over this area in the correct orientation.
3. Distract the implant to the desired amount, as viewed on ERC display screen.
4. Carefully place the ERC back in its storage container and close.
5. The progress and efficacy of lengthening should be checked regularly against follow-up radiographic evidence of the rate of lengthening and the quality of the regenerate. While 1 mm per day is generally recommended, clinical and radiographic examination may show that lengthening should progress at a faster or slower pace. Weekly X-ray imaging to assess actual distraction length is recommended.

**Implant Removal Procedures**

1. At the time deemed appropriate by the physician, remove the PRECICE nail using standard surgical technique.
2. Access the distal end of the PRECICE nail and attach the removal instrumentation.
3. Once all of the locking screws have been removed, the PRECICE nail can be removed by using the removal tool assembly which consists of the locking rod, removal rod and the slap hammer.
5. Return the explanted product to Ellipse Technologies, Inc. following instructions provided by Ellipse. Please call 1-855-4ELLIPSE (1-855-435-5477) to obtain instructions or if you have any questions.

**Accessory and Locking Screw Cleaning and Reстерilization Recommendations**

The recommended instrument cleaning and sterilization instructions are as follows:

**Manual Cleaning Recommendations:**

<table>
<thead>
<tr>
<th>Step</th>
<th>Solution</th>
<th>Time (Minutes)</th>
<th>Temperature</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hospital Grade Enzymatic Detergent</td>
<td>14-15 Minutes</td>
<td>Room Temperature</td>
<td>Immerse and soak for required time</td>
</tr>
<tr>
<td>2</td>
<td>Hospital Grade Enzymatic Detergent</td>
<td>As required per detergent instruction</td>
<td>Room Temperature</td>
<td>Clean thoroughly. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.</td>
</tr>
<tr>
<td>3</td>
<td>Water</td>
<td>2-3</td>
<td>Warm, as delivered from hot water tap</td>
<td>Rinse thoroughly for required time immediately after Step 2.</td>
</tr>
<tr>
<td>4</td>
<td>Air</td>
<td>As required</td>
<td>Ambient</td>
<td>Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe.</td>
</tr>
</tbody>
</table>
Automatic Cleaning Recommendations:

<table>
<thead>
<tr>
<th>Step</th>
<th>Solution</th>
<th>Time (Minutes)</th>
<th>Temperature</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hospital Grade Enzymatic Detergent</td>
<td>As required</td>
<td>Room Temperature</td>
<td>For instruments with complex design features such as cannulations, lumens, holes, threads or a hard to reach area, it is necessary to soak the instruments and manually scrub all external and internal surfaces with a soft bristle brush until all visible soil has been removed prior to automatic reprocessing to improve the removal of adherent soil.</td>
</tr>
<tr>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Load the instruments so that cannulations, lumens or holes can drain. Do not place heavier instruments on top of delicate instruments.</td>
</tr>
<tr>
<td>3</td>
<td>Water</td>
<td>6</td>
<td>Cold</td>
<td>Pre-wash</td>
</tr>
<tr>
<td>4</td>
<td>Hospital Grade Enzymatic Detergent</td>
<td>10</td>
<td>55° C</td>
<td>Wash</td>
</tr>
<tr>
<td>5</td>
<td>Water</td>
<td>30</td>
<td>N/A</td>
<td>Rinse</td>
</tr>
<tr>
<td>6</td>
<td>Water</td>
<td>5</td>
<td>93° C</td>
<td>Final Rinse</td>
</tr>
<tr>
<td>7</td>
<td>N/A</td>
<td>Vary</td>
<td>Room Temperature</td>
<td>Dry</td>
</tr>
</tbody>
</table>

Sterilization Recommendations:

The Instrument and Accessory Trays have been qualified to be sterilized in a double wrapped configuration (Such as CSR Wrap) using the following autoclave sterilization cycle:

<table>
<thead>
<tr>
<th>Sterilization Type</th>
<th>Sterilization Temperature</th>
<th>Sterilization Time (Minutes)</th>
<th>Drying Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum steam sterilization cycle</td>
<td>132° C</td>
<td>4</td>
<td>Minimum 30</td>
</tr>
<tr>
<td>Gravity steam sterilization cycle</td>
<td>121° C</td>
<td>30</td>
<td>Minimum 30</td>
</tr>
</tbody>
</table>

MRI Information:

- The PRECICE System is MR Unsafe. The PRECICE System has not been evaluated for safety and compatibility in the MR environment.
- A patient with the implanted PRECICE nail must not come near an MRI scanner and must not undergo an MRI scan.
- The PRECICE System has not been tested for heating or migration in the MR environment.
- The effects of high magnetic fields produced by MRI scanners on the PRECICE System have not been evaluated and are therefore unknown.

Other Information:

- The PRECICE nail is provided sterilized by Gamma Irradiation Sterilization.
- Please refer to the package label for the expiration date of the PRECICE nail.
- Do not sterilize the ERC.
- Do not attempt to re-sterilize the IMLL Device. Steam or Ethylene Oxide gas will not reach the internal components of the IMLL Device.
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This product, and the use thereof, may be covered by one or more of the following U.S. and/or international patents: US 7,955,357, US 7,981,025, US 8,057,472, US 8,197,490, US 8,382,756, US 8,419,734, US 8,449,543, US 8,715,159, US 8,734,488, US 8,808,163, CN 101917918, EP 2,114,258. Other U.S. and international patents pending. This product is licensed to the customer for single use only. Any resterilization or subsequent re-use is an unlicensed use and therefore constitutes patent infringement.

Rx only