Residual Limb Lengthening System
Operative Technique
Residual Limb Lengthening System

The Residual Limb Lengthening System is designed to treat limb lengthening of the femur following an above-the-knee amputation.

This Operative Technique offers guidance but, as with any such technique guide, each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding Instructions For Use.

It is the surgeon’s responsibility to discuss all relevant risks with the patient prior to surgery.
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The Residual Limb Lengthening System

is a cutting-edge solution for patients with short above-the-knee amputations seeking increased mobility. The FREEDOM nail features a proprietary telescoping design that minimizes the overall initial implant length (130 mm) while maximizing distraction capability (100 mm).

- Patented magnetic remote control technology
- Designed for lengthening of short proximal femoral stumps
- Physician's lengthening prescription is entered via the External Remote Controller (ERC)
- The FREEDOM Implant is gradually lengthened via the ERC based on the patient’s requirements
- Intramedullary Fixation will continue to provide stability throughout the consolidation phase even after the desired length is achieved
FREEDOM System Components

The Residual Limb Lengthening System is comprised of the following components:

- Intramedullary Nail
- Proximal and Distal Locking Screws
- End Cap (optional)
- Instrument Tray
- ERC
FREEDOM System Overview

Typical FREEDOM limb lengthening procedures of the femur include:
- War related injuries
- Trauma or motor vehicle accidents
- Amputation due to cancer

Advantages
- Customizable lengthening protocol
- Non-invasive distraction via External Remote Controller
- Novel magnetic technology
- Up to 100 mm of distraction
- Nail may be reversed
Technical Details

Intramedullary Nail
Diameter: 14 mm
Length: 130 mm

Retracted

Distracted

Locking Screws
4.0 mm Locking Screws
Length = 20–60 mm

End Cap
Sizes: Standard

5.0 mm Locking Screws
Length = 20–75 mm
Pre-Operative Planning

Limb Length Discrepancy Calculation

Careful pre-operative evaluation and planning, proper surgical technique and extended post-operative care are essential for the success of limb lengthening procedures.

Prior to performing the operation, it is imperative for the surgeon to assess both the condition and coverage of the soft tissues. If the soft tissues are inadequate for lengthening, preparatory plastic surgery for skin requirements (including infection prevention measures) must be performed.

Pre-operative evaluation is performed to determine:

- Limb Length Discrepancy
- Intramedullary Diameter
- Required Implant Length
- Osteotomy Location of Femur
- Soft Tissue Assessment

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Antegrade Femur: Operative Technique

Implant Selection
The FREEDOM femoral implant is currently available in one size:

Antegrade Straight

Piriformis fossa entry should only be performed on skeletally mature patients due to the risk of femoral head necrosis.

In all cases, it is imperative that adequate distal segment coverage (by the larger proximal portion of the nail) be maintained at the end of lengthening for biomechanical stability.

Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Antegrade Femur: Operative Technique

Patient Positioning

- Place the patient supine on a radiolucent table with a bump under the ipsilateral hemisacrum.
- Confirm with the image intensifier that a true A/P and cross-table lateral view of the hip are possible.
- Prep and drape the patient’s entire limb from the iliac crest to the foot/ankle using standard sterile technique.
- Antibiotic prophylaxis should be given prior to making an incision.

Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Antegrade Femur: Operative Technique

Proximal Osteotomy Calculation

In all cases, it is imperative that adequate proximal nail segment coverage be maintained at the end of lengthening for biomechanical stability.

The FREEDOM antegrade femoral implant is available in a 14 mm diameter. Overreaming the intramedullary femoral canal by 2.0 mm is recommended to aide in implant insertion.

With radiographs that include a magnification marker, measure from the level of the joint line to the location of the distal end of the FREEDOM implant.

Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Antegrade Femur: Operative Technique

**Entry Point**

Locate the piriformis fossa by laying a Steinmann pin on the skin and using fluoroscopy. Use a surgical marking pen to denote this location (8-10 cm proximal to greater trochanter).

Using A/P and Lateral image intensification views, percutaneously insert and center a Steinmann pin into the intramedullary canal.

Next, use a ruler to measure from the entry point on the proximal femur to the distal end of the FREEDOM implant based on pre-operative measurements and calculations. Mark the skin at this level and also at the level of the planned femoral osteotomy.

**Surgical Incision**

Make a 2.5 cm incision longitudinally over the percutaneous Steinmann pin. A skin incision is made beginning at the level of the Greater Trochanter extending proximally and slightly posterior, in line with the Gluteus muscle, exposing the Piriformis Fossa for nail insertion.

Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Venting of the Femoral Intramedullary Canal

Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism. To avoid these potential complications, place multiple venting holes in the femur at the planned osteotomy site prior to reaming.

- Venting reduces pressure on the bone marrow during reaming and implant insertion
- Venting creates egress for bone marrow at the osteotomy site during reaming
- Venting drill holes will facilitate the osteotomy
- Reamings which exit the vent holes will act as prepositioned bone graft at the distraction gap

Make a 1.0 cm longitudinal incision at the lateral thigh near the determined osteotomy site. Dissect bluntly with a straight hemostat down to the lateral femur. Insert a small periosteal elevator and lift the anterior periosteum and the posterior periosteum including the linea aspera. Using a percutaneous technique, drill at least one lateral and three medial holes with the 4.0 x 152 mm Drill Bit (DBB4-152) or 5.0 x 152 mm Drill Bit (DBC5-152). Make one entry hole lateral and three exit holes medially. Additional holes may be used to facilitate the osteotomy.


Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Antegrade Femur: Operative Technique

Intramedullary Reaming

Advance Steinmann pin under biplanar fluoroscopic guidance.

Make a small vertical incision around the pin and spread the soft tissues using hemostats.

After confirming correct pin placement on A/P and Lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0 – 10.0 mm entry reamer.

Insert a ball tip guide wire into the entry hole and down the length of the femur about 4.0 cm to 5.0 cm beyond the planned distal end of the nail.

Ream the canal with flexible reamers beginning with 8.0 mm and increasing by 0.5 mm increments until the femoral canal is over-reamed by 2.0 mm greater than the planned diameter of the FREEDOM implant.

The FREEDOM femoral implant is 14 mm in diameter.

Due to the hip abductors, the location of the femur in a high above-the-knee amputation can be unpredictable. A retrograde approach should be considered for patients with a severely abducted hip.
Antegrade Femur: Operative Technique

**FREEDOM Guide Arm Assembly**

Connect the FREEDOM Guide (FREEDOM RLLI-000) to the Guide Arm (AGBI-000). Attach the FREEDOM implant to the FREEDOM Guide Arm Assembly by inserting the Locking Rod (LRBI-000) through the top of the Guide Arm and aligning the arrows on the implant with those on the Guide Arm. Engage the threads on the proximal end of the implant with the Locking Rod and gently tighten with the Tommy Bar (TBAI-000).

Verify correct alignment of the 5.0 x 355 mm Drill Bit (LSC5-025) through the Guide Tube (GSBI-000), Drill Guide (DBB5-000) and FREEDOM implant.

Once the FREEDOM implant has been properly attached to the FREEDOM Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.
Antegrade Femur: Operative Technique

Osteotomy of the Femur

Insert the FREEDOM implant with the FREEDOM Guide Arm Assembly into the intramedullary canal until the distal tip of the nail is just below the planned osteotomy site where the vent holes were drilled. Verify this location under image intensification.

The use of osteotomes is always recommended as this is a low-energy osteotomy method that helps avoid an exaggerated inflammatory response and the potential for thermal necrosis.

Pins may be inserted for a temporary external fixator if assistance maintaining rotational alignment or deformity correction is required.

Use an osteotome to complete the osteotomy. Use caution to avoid neurovascular injury and soft tissue damage. An irregular or comminuted osteotomy is acceptable. Ensure that the osteotomy created is completed circumferentially. Verify the osteotomy is complete with multiplanar image intensification and evidence of translation at the osteotomy site.

Immediately after confirming the osteotomy, gently tap the Short Impactor (IMAI-000) attached to the FREEDOM Guide Arm Assembly to advance the FREEDOM implant across the gap and into the distal femur. Using biplanar C-Arm views, confirm the reduction.

If the tip of the FREEDOM nail stops around the level of the cut cortex of the distal segment, stop advancing the device, adjust the reduction and try again. Excessive force on the FREEDOM nail may damage the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 mm to 1.0 mm.

Properly position the implant prior to inserting the locking screws.
Antegrade Femur: Operative Technique

Proximal Locking Screw

Confirm FREEDOM Guide Arm Assembly did not loosen during nail insertion prior to proceeding with proximal locking screw. Position the Trocar through the Guide Tube and place through the FREEDOM Guide Arm Assembly. Make a small stab incision where the Trocar contacts the skin. Advance the Trocar through the tissue until the tip is seated against the cortex. Verify with image intensifier that the Guide Tube is positioned on the femoral cortex.

Remove the Trocar and position the Drill Guide through the Guide Tube. Use the 5.0 mm x 355 mm Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

Select the appropriate length screw by reading the calibration on the 5.0 x 355 mm Drill Bit. 5.0 mm Locking Screws are available in 5 mm increments from 20-75 mm lengths.

Insert the Screw Capture Rod (CRC3-000) through the cannulated 3.5 mm Locking Driver (THF3-000). Hand-tighten the Screw Capture Rod to the appropriate length 5.0 mm locking screw. Attach the 3.5 mm Locking Driver with Screw Capture Rod to the Quick Connect T-Handle (THD2-000). Remove the Drill Guide and position the screw into the Guide Tube to direct it through the FREEDOM implant.

Hand-tighten the screw into the lateral cortex. Remove the Quick Connect T-Handle and untighten the Screw Capture Rod to release the screw. Use the 3.5 mm Solid Hex Driver (DRDI-000) attached to the Quick Connect T-Handle to achieve final secure fixation and to fully seat the screw.

After securing the proximal 5.0 mm Locking Screw, untighten the Locking Rod from the FREEDOM implant to remove the FREEDOM Guide Arm Assembly.

Proximal 5.0 mm Locking Screw positioned
Antegrade Femur: Operative Technique

Distal Locking Screw

The free hand technique is used to position the Locking Screw in the M/L hole of the FREEDOM implant.

Align the C-Arm in the Lateral position to view perfect overlapping circles. For the perfect circle technique, first find the drill hole using the finger hole of an instrument. Make a small skin incision here. Use the Soft Tissue Protector (DSD2-035) and appropriate diameter drill to create a pilot hole for the locking screw.

4.0 mm distal Locking Screw. Use the 4.0 x 152 mm Drill Bit (DBB4-152).

Select the length for the distal Locking Screw by reading the measurement off the calibrated drill bit with the Soft Tissue Protector fully seated on the cortex. Attach the appropriate length Locking Screw to the Screw Capture Rod and 3.5 mm Locking Driver. Tighten the Locking Screw by hand. Release the Screw Capture Rod and perform final tightening of the Locking Screw with the 3.5 mm Solid Hex Driver.
Antegrade Femur: Operative Technique

End Cap Placement (Optional)

If desired, an End Cap (CPA1-000) may be used to help prevent bony ingrowth into the proximal thread of the nail. One standard End Cap is available for all nail sizes.

Secure the End Cap to the 3.5 mm Locking Driver and Screw Capture Rod. Attach this assembly to the Quick Connect T-Handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn Quick Connect T-Handle clockwise until the End Cap fully seats inside the proximal portion of the nail. Untighten the Screw Capture Rod to release the End Cap.
Antegrade Femur: Operative Technique

Locating the Center of the Magnet

Evaluate the final implant construct under image intensification. Locate the magnet within the FREEDOM implant (See Reference Image). Be sure the C-Arm is perpendicular to the implant to visualize the correct position of the central magnet.

Use a surgical skin marker to put a transverse line on the patient’s skin directly over the location of the center of the FREEDOM magnet. Provide a surgical marker postoperatively to the patient to refresh the line as it fades.

Caution should be taken as the magnets in the ERC will attract metal objects, including surgical instruments (Refer to the Operator’s Manual for complete Instructions for Use prior to using the ERC).
Antegrade Femur: Operative Technique

Intra-Operative External Remote Controller (ERC) Distraction

Place the ERC in a sterile bag and place it directly over the transverse mark on the skin. Make sure you have properly aligned the ERC on the patient’s femur and the magnets are pointed toward the ground (Refer to the ERC Operator’s Manual).

Use the implant locator window on the ERC to properly position it over the mark on the patient’s skin.

Activate the ERC to distract the FREEDOM implant 1.0-2.0 mm. This verifies correct functioning of the system. It takes seven minutes to achieve 1.0 mm of lengthening. After functioning verification, it is not necessary to retract the FREEDOM implant.

Confirm under image intensification that the lengthening has occurred by comparing the pre-lengthening image to the post-lengthening image. The Lead Screw space should demonstrate distraction.

Correct alignment of the ERC to the patient’s femur. Always point arrows on ERC toward the ground.
Retrograde Femur: Operative Technique

Implant Selection

The FREEDOM femoral implant is currently available in one size:

Retrograde Straight

Patient Positioning

Confirm with the image intensifier that a true A/P and cross-table lateral view of the hip are possible. Prep and drape the patient's entire limb from the iliac crest to the end of the stump using standard sterile technique.

Antibiotic prophylaxis should be given prior to making an incision.
In all cases, it is imperative that adequate distal nail segment coverage be maintained at the end of lengthening for biomechanical stability.

The FREEDOM antegrade femoral implant is available in a 14 mm diameter. Over-reaming the intramedullary femoral canal by 2.0 mm is recommended to aide in implant insertion.

With radiographs that include a magnification marker, measure from the level of the joint line to the location of the distal end of the FREEDOM implant.

**Retrograde Femur: Operative Technique**

**Distal Osteotomy Calculation**

Calculate the following to determine the measurement from the distal end of the implant.

A) 1.0 cm (distal distraction rod length).
B) The desired amount of bone lengthening (up to 10.0 cm).
C) Add an additional 0.0 cm to 2.0 cm.

\[ A + B + C = \text{Measurement from the Distal End of the Implant to Perform Osteotomy} \]

This measurement determines the suggested level of the osteotomy.
Retrograde Femur: Operative Technique

Entry Point

Using A/P and Lateral views, percutaneously insert and center a Steinmann pin into the intramedullary canal. The entry point should be in line with the long axis of the femoral shaft. Use a ruler to measure from the entry point on the distal femur to the distal end of the FREEDOM implant. Mark the skin at this level and also at the level of the planned femoral osteotomy.

Surgical Incision

Make a 2.5 cm incision longitudinally over the percutaneous Steinmann pin.
Retrograde Femur: Operative Technique

Venting of the Femoral Intramedullary Canal

Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism. To avoid these potential complications, place multiple venting holes in the femur at the planned osteotomy site prior to reaming.

- Venting reduces pressure on the bone marrow during reaming and implant insertion
- Venting creates egress for bone marrow at the osteotomy site during reaming
- Venting drill holes will facilitate the osteotomy
- Reamings which exit the vent holes will act as prepositioned bone graft at the distraction gap

Make a 1.0 cm longitudinal incision at the lateral thigh near the determined osteotomy site. Dissect bluntly with a straight hemostat down to the lateral femur. Insert a small periosteal elevator and lift the anterior periosteum and the posterior periosteum including the linea aspera. Using a percutaneous technique, drill at least one lateral and three medial holes with the 4.0 x 152 mm Drill Bit (DBB4-152) or 5.0 x 152 mm Drill Bit (DBC5-152). Make one entry hole lateral and three exit holes medially. Additional holes may be used to facilitate the osteotomy.

Retrograde Femur: Operative Technique

Intramedullary Reaming

Advance Steinmann pin under biplanar fluoroscopic guidance.

Make a small vertical incision around the pin and spread the soft tissues using hemostats.

After confirming correct pin placement on A/P and Lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0–10.0 mm entry reamer.

Insert a ball tip guide wire into the entry hole and down the length of the femur about 4.0 cm to 5.0 cm beyond the planned distal end of the nail.

Ream the canal with flexible reamers beginning with 8.0 mm and increasing by 0.5 mm increments until the femoral canal is over-reamed by 2.0 mm greater than the planned diameter of the FREEDOM implant.

The FREEDOM femoral implant is 14 mm in diameter
Retrograde Femur: Operative Technique

**FREEDOM Guide Arm Assembly**

Connect the FREEDOM Guide (FREEDOM RLL1-000) to the Guide Arm (AGBI-000). Attach the FREEDOM implant to the FREEDOM Guide Arm Assembly by inserting the Locking Rod (LRBI-000) through the top of the Guide Arm and aligning the arrows on the implant with those on the Guide Arm. Engage the threads on the distal end of the implant with the Locking Rod and gently tighten with the Tommy Bar (TBAI-000).

Verify correct alignment of the 5.0 x 355 mm Drill Bit (LSC5-025) through the Guide Tube (GSBI-000), Drill Guide (DBB5-000) and FREEDOM implant.

Once the FREEDOM implant has been properly attached to the FREEDOM Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.
Retrograde Femur: Operative Technique

Osteotomy of the Femur

Insert the FREEDOM implant with the FREEDOM Guide Arm Assembly into the intramedullary canal until the proximal tip of the nail is just below the planned osteotomy site where the vent holes were drilled. Verify this location under image intensification.

The use of osteotomes is always recommended as this is a low-energy osteotomy method that helps avoid an exaggerated inflammatory response and the potential for thermal necrosis.

Pins may be inserted for a temporary external fixator if assistance maintaining rotational alignment or deformity correction is required.

Use an osteotome to complete the osteotomy. Use caution to avoid neurovascular injury and soft tissue damage. An irregular or comminuted osteotomy is acceptable. Ensure that the osteotomy created is completed circumferentially. Verify the osteotomy is complete with multiplanar image intensification and evidence of translation at the osteotomy site.

Immediately after confirming the osteotomy, gently tap the Short Impactor (IMA1-000) attached to the FREEDOM Guide Arm Assembly to advance the FREEDOM implant across the gap and into the proximal femur. Using biplanar C-Arm views, confirm the reduction.

If the tip of the FREEDOM nail stops around the level of the cut cortex of the proximal segment, stop advancing the device, adjust the reduction and try again. Excessive force on the FREEDOM nail may damage the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 mm to 1.0 mm.

Properly position the implant prior to inserting the locking screws.
Retrograde Femur: Operative Technique

Distal Locking Screw

Confirm FREEDOM Guide Arm Assembly did not loosen during nail insertion prior to proceeding with distal locking screw. Position the Trocar through the Guide Tube and place through the FREEDOM Guide Arm Assembly. Make a small stab incision where the Trocar contacts the skin. Advance the Trocar through the tissue until the tip is seated against the cortex. Verify with image intensifier that the Guide Tube is positioned on the femoral cortex.

Remove the Trocar and position the Drill Guide through the Guide Tube. Use the 5.0 mm x 355 mm Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

Select the appropriate length screw by reading the calibration on the 5.0 x 355 mm Drill Bit. 5.0 mm Locking Screws are available in 5 mm increments from 20-75 mm lengths.

Insert the Screw Capture Rod (CRC3-000) through the cannulated 3.5 mm Locking Driver (THF3-000). Hand-tighten the Screw Capture Rod to the appropriate length 5.0 mm locking screw. Attach the 3.5 mm Locking Driver with Screw Capture Rod to the Quick Connect T-Handle (THD2-000). Remove the Drill Guide and position the screw into the Guide Tube to direct it through the FREEDOM implant.

Hand-tighten the screw into the lateral cortex. Remove the Quick Connect T-Handle and untighten the Screw Capture Rod to release the screw. Use the 3.5 mm Solid Hex Driver (DRD1-000) attached to the Quick Connect T-Handle to achieve final secure fixation and to fully seat the screw.
Retrograde Femur: Operative Technique

Proximal Locking Screw

The free hand technique is used to position the Locking Screw in the M/L hole of the FREEDOM implant.

Align the C-Arm in the Lateral position to view perfect overlapping circles. For the perfect circle technique, first find the drill hole using the finger hole of an instrument. Make a small skin incision here. Use the Soft Tissue Protector (DSD2-035) and appropriate diameter drill to create a pilot hole for the locking screw.

4.0 mm proximal Locking Screw. Use the 4.0 x 152 mm Drill Bit (DBB4-152).

Select the length for the proximal Locking Screw by reading the measurement off the calibrated drill bit with the Soft Tissue Protector fully seated on the cortex. Attach the appropriate length Locking Screw to the Screw Capture Rod and 3.5 mm Locking Driver. Tighten the Locking Screw by hand. Release the Screw Capture Rod and perform final tightening of the Locking Screw with the 3.5 mm Solid Hex Driver.

Always confirm positioning with image intensifier
Retrograde Femur: Operative Technique

End Cap Placement (Optional)

If desired, an End Cap (CPA1-000) may be used to help prevent bony ingrowth into the distal thread of the nail. One standard End Cap is available for all nail sizes.

Secure the End Cap to the 3.5 mm Locking Driver and Screw Capture Rod. Attach this assembly to the Quick Connect T-Handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn Quick Connect T-Handle clockwise until the End Cap fully seats inside the distal portion of the nail. Untighten the Screw Capture Rod to release the End Cap.
Retrograde Femur: Operative Technique

Locating the Center of the Magnet

Evaluate the final implant construct under image intensification. Locate the magnet within the FREEDOM implant (See Reference Image). Be sure the C-Arm is perpendicular to the implant to visualize the correct position of the central magnet.

Use a surgical skin marker to put a transverse line on the patient’s skin directly over the location of the center of the FREEDOM magnet. Provide a surgical marker postoperatively to the patient to refresh the line as it fades.

Caution should be taken as the magnets in the ERC will attract metal objects, including surgical instruments (Refer to the Operator’s Manual for complete Instructions for Use prior to using the ERC).
Retrograde Femur: Operative Technique

Intra-Operative External Remote Control (ERC) Distraction

Place the ERC in a sterile bag and place it directly over the transverse mark on the skin. Make sure you have properly aligned the ERC on the patient’s femur and the magnets are pointed toward the ground (Refer to the ERC Operator’s Manual).

Use the implant locator window on the ERC to properly position it over the mark on the patient’s skin.

Activate the ERC to distract the FREEDOM implant 1.0-2.0 mm. This verifies correct functioning of the system. It takes seven minutes to achieve 1.0 mm of lengthening. After functioning verification, it is not necessary to retract the FREEDOM implant.

Confirm under image intensification that the lengthening has occurred by comparing the pre-lengthening image to the post-lengthening image. The Lead Screw space should demonstrate distraction.

Correct alignment of the ERC to the patient’s femur. Always point arrows on ERC toward the ground.
Antegradegrade/Retrograde Femur: Operative Technique

Final Closure

After the 1.0 mm lengthening of the FREEDOM implant, the surgical incisions are irrigated and closed in standard fashion.

Make certain that the skin mark noting the location of the magnet within the FREEDOM implant is prominent and visible. This will ensure proper alignment and positioning of the ERC for future lengthening during the distraction phase.

Post-Operative Management

The 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.

Each surgeon must prescribe a lengthening protocol for their patient. Factors to consider when determining daily lengthening rate include bone quality, location and invasiveness of the osteotomy, patient age and comorbidities.

Daily lengthenings are typically 1.0 mm per day divided into 3 to 4 sessions. Lengthening typically starts 5 to 7 days after initial implantation. Weekly clinical and radiographic evaluations by the surgeon are important to review the patient’s progression. The ERC can be programmed to optimize the patient’s lengthening prescription (Please Refer to ERC Operator’s Manual for complete programming instructions).

Anti-coagulation treatments are an option during this phase.
Residual Limb Lengthening System

External Remote Controller (ERC) Introduction

The ERC uses strong permanent magnets to distract the FREEDOM implant. The following are important considerations and precautions when using the ERC. For complete instructions, contraindications, warnings and cautions please refer to the Operator's Manual.

- Weekly X-Ray imaging to assess actual distraction length is recommended.
- Only use the External Remote Controller in a manner consistent with the Operator's Manual. Any alternative use may result in injury or damage to property.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the External Remote Controller or shielding the location.
- Persons with a pacemaker or a similar medical aid should not handle or be exposed to the External Remote Controller. The strong magnetic fields may affect the operation of such devices.
- The External Remote Controller uses strong permanent magnets. Misuse of this system can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes personal items such as jewelry, watches, keys and cellular phones. Always return the system to its protective case when not in use.
- Only operate the External Remote Controller by holding onto both of the handles provided.
- The External Remote Controller may be pulled away from your hands if brought too close to other magnetic objects. Always maintain a firm grip on the External Remote Controller and be very aware of other objects in your work area. Also, tools or other hazardous objects may leap towards the External Remote Controller if brought too close.
- Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes or other such devices. It can also damage televisions, VCRs, computer monitors and other CRT displays.
- This device has not been tested for compatibility in Magnetic Resonance Imaging (MRI) environments and should not enter an MRI unit.
Lengthening Phase

The FREEDOM implant cannot withstand the stresses of full weight bearing. The patient should utilize external support and/or restrict activities until consolidation occurs. During the lengthening phase, patient compliance to the planned lengthening prescription is important. Adherence to proper use of the ERC in addition to post-operative rehabilitation protocols must be emphasized. It is the physician’s responsibility to carefully monitor the patient’s progress with routine X-Rays and to make any necessary changes to the daily lengthening prescription. The physician may adjust or reverse a prescription to best meet the needs of the patient.

Consolidation Phase

The consolidation phase should occur with the FREEDOM implant in place. Increase partial weight-bearing to full weight-bearing only after careful clinical and radiographic evaluation of the patient.

Full weight bearing is only permitted when there is solid healing of at least three out of four cortices on the A/P and Lateral radiographs as determined by the physician.

If bone healing is delayed, consider using adjunctive measures such as ultrasound bone stimulation or bone grafting. Make sure the patient maintains a healthy diet with adequate Vitamin D and Calcium. Consider measuring Vitamin D levels and using supplements as needed.

Please refer to the Instructions for Use for additional information.
Removal of the FREEDOM implant is recommended at approximately 12-18 months provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the FREEDOM implant based upon their clinical evaluation of the patient.

Exsanguinate the leg and apply a thigh tourniquet. Expose the threaded end of the implant by careful debridement of heterotopic bone and soft tissue.

Using the image intensifier, locate the proximal and distal locking screws. Make small incisions as required and remove the locking screws using the 3.5 mm Solid Hex Driver and Quick Connect T-Handle. It is recommended to leave one of the locking screws in place prior to tightly threading the Tapered Extractor (CTAI-000) into the FREEDOM implant. If present, the End Cap must be removed prior to threading the Tapered Extractor into the FREEDOM implant.

Attach the Removal Rod (RRBI-000) to the Tapered Extractor, remove the final locking screw and proceed with nail removal. The Slap Hammer (RMBI-000) may be used to assist in nail removal as needed.

Perform skin closure with routine techniques.
## Product Reference

### Instrumentation

<table>
<thead>
<tr>
<th>Model #</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>DBB5-000 Drill Guide</td>
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<td>2</td>
<td>GSB1-000 Guide Tube</td>
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<td>3</td>
<td>AGB1-000 Drill Guide Arm</td>
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<td>4</td>
<td>DSD2-035 Soft Tissue Protector</td>
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<td>5</td>
<td>THD2-000 Quick Connect T-Handle</td>
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<td>6</td>
<td>TBAI-000 Tommy Bar</td>
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<td>7</td>
<td>RMBI-000 Slap Hammer</td>
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<td>8</td>
<td>LRBI-000 Locking Rod</td>
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<td>RLLI-000 RLL Guide</td>
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<td>CBBI-000 Tibial Guide</td>
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<td>11</td>
<td>CTAI-000 Tapered Extractor</td>
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<td>12</td>
<td>RRB1-000 Removal Rod</td>
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<td>13</td>
<td>THEI-000 4.0 mm Locking Driver</td>
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<td>14</td>
<td>PRBI-000 Trocar</td>
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<td>LKA1-000 Locking Key</td>
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<td>IMAI-000 Short Impactor</td>
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<td>DRDI-000 3.5 mm Solid Hex Driver</td>
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<td>19</td>
<td>THF3-000 3.5 mm Locking Driver</td>
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<td>20</td>
<td>CRC3-000 Screw Capture Rod</td>
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Product Reference

FREEDOM Nail (Straight 14 mm)

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FREEDOM Targeting Attachment

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# Product Reference

## Locking PT Screws

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<td>CPAI-000</td>
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## Product Reference

### Disposable Drill Bits, AO

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Please Contact Ellipse Technologies Inc., Customer Service

**1-855-4-ELLIPSE** for Further Assistance and Ordering Information.

www.ellipse-tech.com
Important Safety Information

Rx Only

The Ellipse FREEDOM 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 FREEDOM 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. The FREEDOM System is intended for lengthening of the residual limb of the femur. Contraindications include 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, and patients unwilling or incapable of following postoperative care instructions. The implantable device is only to be used by a trained licensed physician. Please refer to the FREEDOM IMLL System instructions for use for complete Important Safety Information. Caution: Federal law restricts this device to sale by or on the order of a physician.

For a complete list of warnings associated with the FREEDOM System and its components, refer to the Instructions for Use and ERC Operator’s Manual.
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

Please refer to the Instructions For Use and External Remote Controller (ERC) Operator’s Manual supplied with the product for specific information on the indications for use, contraindications, warnings, precautions, cautions and sterilization. These documents are also available by contacting Ellipse Technologies, Inc.

This product, and the use thereof, may be covered by one or more of the following U.S. and/or international patents: US 7,981,025, US 8,057,472, US 8,197,490, US 8,343,192, US 8,382,756, US 8,419,734, US 8,449,543, US 8,715,159, US 8,734,488, US 8,808,163, US 8,852,187, US 8,852,236, 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.

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