



# External Remote Controller ERC 2P Operator's Manual



# **PRECICE® INTRAMEDULLARY LIMB LENGTHENING SYSTEM PATIENT INFORMATION AND INSTRUCTIONS.**

**To Doctors & Providers:** Provide a copy of this booklet to each patient. Reference the **PRECICE ERC 2P Operator's Manual** and **PRECICE Instructions for Use** for detailed instructions on clinical set-up and related information for healthcare practitioners. Provide a copy of the **PRECICE ERC 2P Patient Instructions** to the patient, making sure to record the patient's prescription on the next page in this booklet. Make sure to review the ERC 2P Patient Instructions with the patient before treatment.

**To Patients:** Read this entire booklet before you use the PRECICE ERC 2P. Refer to this booklet at any time during your treatment. You can also talk to your doctor about any questions you have.

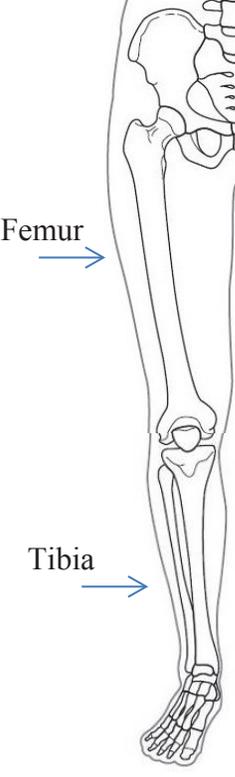
**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

# MY PRESCRIPTION.

Date	Target Distance Per Treatment <i>(example: 0.50mm)</i>	Treatments Per Day <i>(example: 2 times/day)</i>

## Where to place the ERC 2P during each treatment:

*(Circle the general location – there will be a specific mark on your leg)*

	<b>RIGHT LEG</b>	<b>LEFT LEG</b>
<p><b>IMPLANT #1</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Right Leg</li> <li><input type="radio"/> Left Leg</li> <li><input type="radio"/> Tibia</li> <li><input type="radio"/> Femur</li> </ul>		
<p><b>IMPLANT #2</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Only One Implant</li> <li><input type="radio"/> Right Leg</li> <li><input type="radio"/> Left Leg</li> <li><input type="radio"/> Tibia</li> <li><input type="radio"/> Femur</li> </ul>		

Special Notes *(example: always use crutches):* \_\_\_\_\_

Need help? Call:

My Provider: \_\_\_\_\_

Phone: \_\_\_\_\_

My Doctor: \_\_\_\_\_

Phone: \_\_\_\_\_

# PRECICE INTRAMEDULLARY LIMB LENGTHENING SYSTEM PATIENT INFORMATION AND PATIENT INSTRUCTIONS.

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## PRECICE System and External Remote Controller (ERC 2P) Definitions and Glossary.

This section gives terms that are used in the PRECICE ERC 2P Patient Instructions and their definitions.

**Active Medical Device:** The term "active" means any medical device that needs a power supply. Power can be supplied by any means including electricity, battery, or gas. Examples of active devices include ventilators, pacemakers, and patient monitoring devices.

**Actuator:** The part of the implanted metal rod that can change in length when activated.

**Distract:** Distract means to extend or lengthen. The PRECICE system is used to *distract* bones.

**Electronic Device:** This refers to any device that has a power cord, that is plugged in to the wall for electrical power, or is battery operated. Examples of electronic devices include computers and cell phones.

**Epiphyseal growth plate:** These layers are at the ends of long bones (see femur, tibia) for children and adolescents who are still growing.

**ERC 2P:** ERC 2P refers to **External Remote Controller**. The ERC 2P is used to adjust the PRECICE Rod that is in your leg from outside of your body. The ERC 2P system consists of the ERC 2P, and Power Cord.

**Femur:** The femur is the thigh bone in the leg. It is the largest bone of the body.

**Implant:** An implant is a device that is inserted into the body for a period of time and is not absorbed by the body.

**Intramedullary:** Intramedullary refers to being inside the bone.

**MRI:** MRI refers to **Magnetic Resonance Imaging**, which is a medical technique to visualize structures inside the body.

**Osteopenia:** Osteopenia is a condition where the density of your bone is lower than normal.

**PRECICE Rod:** The PRECICE Rod is the adjustable rod that is implanted into your leg bone (tibia or femur) and is lengthened by the ERC 2P from outside your body.

**Regenerate:** Regenerate refers to new growth. In this manual, it refers to new bone tissue growth.

**Tibia:** The tibia (or shinbone) is the large leg bone between the knee and ankle.

## 1. ABOUT PRECICE

### 1.1 What is PRECICE? (Introduction)

The PRECICE System includes:

- an adjustable metal rod that goes into your leg bone,
  - the actuator is the part of the rod that can change length,
- screws that attach the rod to your bone, and
- an External Remote Controller (ERC 2P).

The adjustable metal rod has a part called an “actuator” that can change length, and an extension rod that your doctor will connect to the actuator during your surgery. The actuator has a small magnet that allows the rod to get longer when the magnet is turned by the ERC 2P. The ERC 2P is a hand held device with two large magnets. The magnet in the actuator turns when the ERC 2P is placed on your leg and turned on. When the rod gets longer, your leg bone will also get longer.

In addition to the information you will receive in this booklet, your doctor will provide you instructions about what you need to do during treatment.

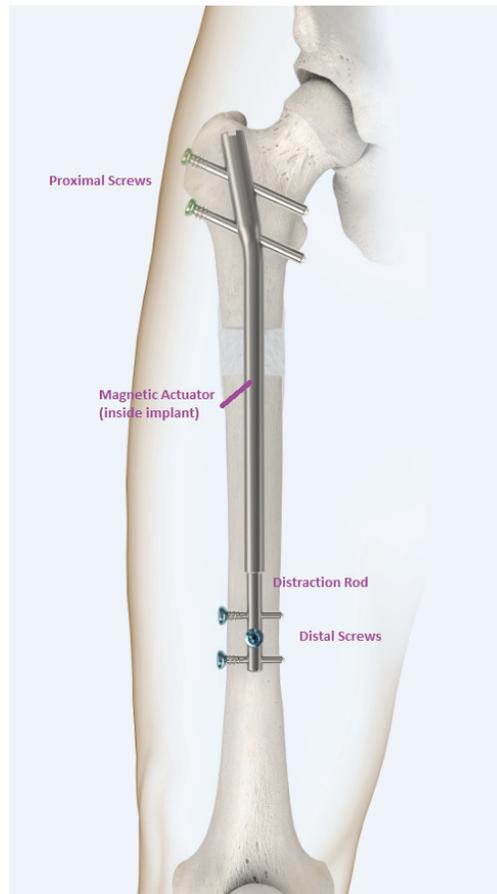


Figure 1.1-1 PRECICE Rod implanted in Femur.

### 1.2 Getting to know your ERC 2P.

Inside your ERC 2P Case, you will find the ERC 2P and Operator's Manual. The critical parts of the ERC 2P are labeled below:

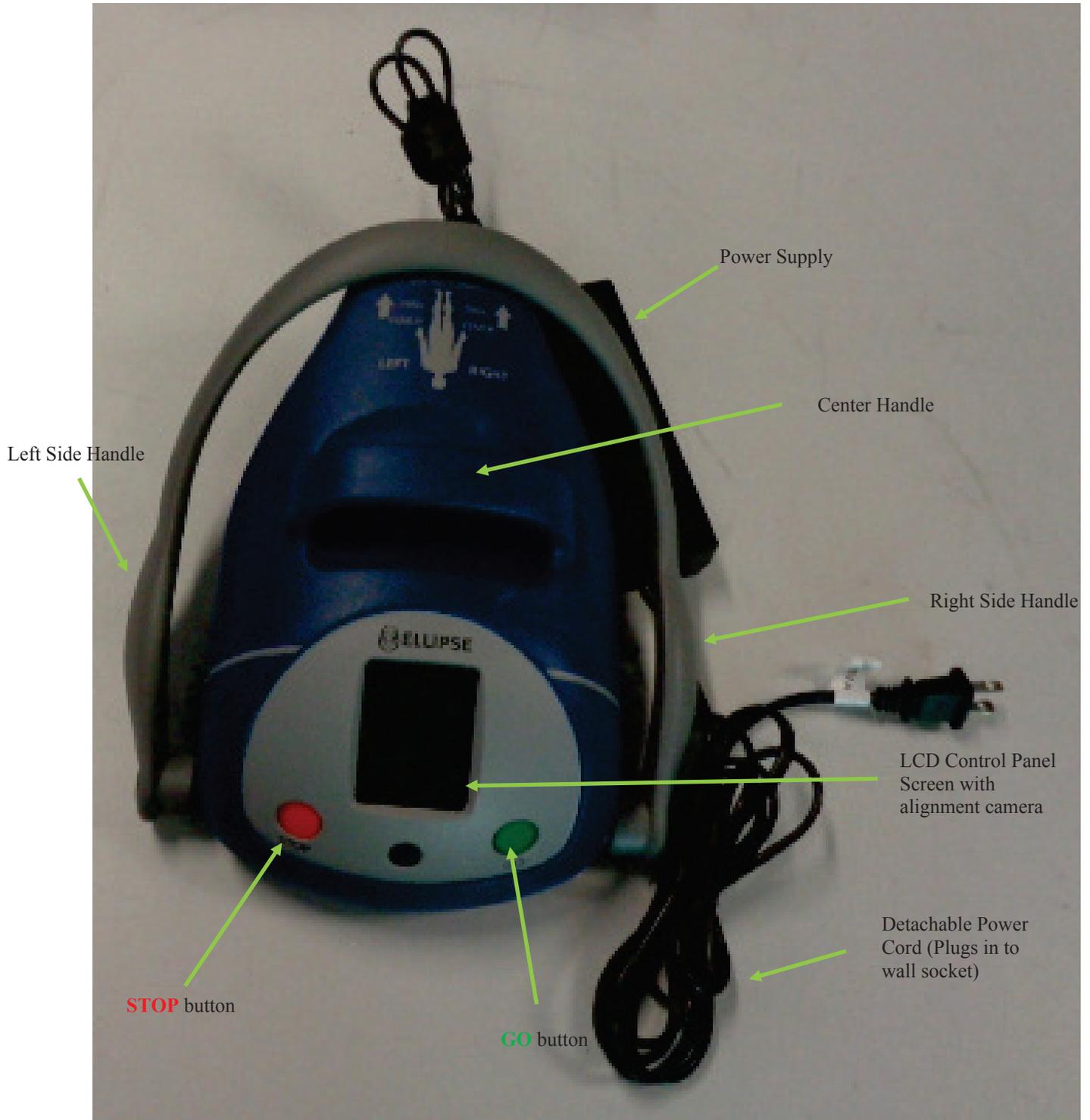


Figure 1.2-1 ERC 2P for the PRECICE System.



Figure 1.2-2 ERC 2P Case.

### 1.3 Why is PRECICE Used? (Indications)

PRECICE is prescribed by your doctor to lengthen your tibia or femur. You may benefit from this treatment if you have a deformity or if your legs are not the same length.

You should discuss your condition with your doctor. Your doctor can give you information to see if PRECICE is the right option for you.

After your doctor implants the rod into your leg, you will use the ERC 2P to make the rod longer. The lengthening phase usually starts about five days after your surgery. You will make the rod a small amount longer each day (usually about 1 millimeter each day). This phase of your treatment could last up to 65 days. Your doctor will tell you how much and how often to adjust the rod. Usually once a week you will visit your doctor to check on your progress. Your doctor may X-Ray your leg during these visits. Your doctor will also tell you to use crutches and avoid putting weight on your leg with the rod. A good result requires your active cooperation and dedication to certain tasks. If you do not follow your doctor's instructions, you could seriously harm yourself.

You will stop using the ERC 2P and let your bone heal after your leg has reached its goal length.

During the consolidation phase, the bone heals. Your bone will change, or regenerate, from a soft material into hard bone over time. This healing process usually takes about 2 months for every inch that your bone has been lengthened. During this healing phase, it is very important that you follow all of your doctor's instructions. You will continue to see your doctor for visits, usually once a month.

### 1.4 Who cannot have this procedure done? (Contraindications)

**Important Safety Information – Read Before Use!**

**Please read and consider the information in this pamphlet before deciding on your treatment.**

This section describes the Contraindications for the PRECICE System. If you have any of these contraindications, you cannot use PRECICE to be treated.

**CONTRAINDICATIONS:**

- DO NOT USE the PRECICE System if you have a pacemaker or other active electronic implant such as an implanted infusion pump or implantable cardiac defibrillator (ICD).

The magnets in the PRECICE System could interact with these implants or cause them to move in ways that could harm you. Discuss your entire medical history with your doctor before you are treated with the PRECICE System.

- DO NOT USE the PRECICE System if you are unwilling or incapable of following postoperative care instructions from your doctor. Failure to follow instructions may result in the need for an additional surgery. Your doctor will discuss what you need to do during the treatment.
- Tell your doctor about any of the following conditions you may have:
  - An infection or pathologic condition of the bone, such as osteopenia.
  - A sensitivity or allergy to metal.
  - A condition that may slow healing, such as an obliterated medullary canal, blood supply limitations, peripheral vascular diseases, or evidence of inadequate vascularity.

If you have any of the conditions mentioned above, your doctor must not prescribe the PRECICE System for you. Your doctor needs a complete medical history to recommend the best way to treat your condition. If you do not tell your doctor about your medical history, he or she may recommend a treatment that can seriously harm you.

- Your doctor will give you a thorough exam to make sure you are a candidate for PRECICE by checking the following:
  - For the 10.7mm device, that the distance should not be greater than 51 mm from the surface of the treated limb to the intramedullary canal where the implant will be inserted. For the 8.5mm device, that the distance should not be greater than 38 mm from the surface of the treated limb to the intramedullary canal where the implant will be inserted. The ERC 2P will not properly activate the PRECICE rod if the distance between the surface of your limb and the inside of your bone is too great.
  - That you do not have an irregular bone diameter. Having an irregular bone diameter may prevent the rod from fitting into the intramedullary canal.

- That the implant will not cross joint spaces or open epiphyseal growth plates at the end of the bones. If a growth plate is crossed, this can cause your bone to stop growing and result in a bone defect.
- For the 10.7mm device, that you do not weigh over 114 Kg (250 lbs). For the 8.5mm device, that you do not weigh over 57 Kg (125 lbs). If you weigh more than this amount, the implant is more likely to break. If the implant breaks, you may need another surgery to replace the implant.

**1.5 What must you do to avoid serious harm? (Warnings)**

This section describes the Warnings associated with the PRECICE System. This will help you to avoid serious harm when using the PRECICE System. Please read all of these warnings before you use PRECICE.

**WARNINGS.**



**WARNING:** Avoid all places labeled as having a strong magnetic field. PRECICE is unsafe in Magnetic Resonance Imaging environments (MR environments).

You may see a written warning or the “magnet” symbol similar to the one below. The implant has not been tested for safety or compatibility in the MR environment. An MR environment may damage your implant.



Avoid areas with this symbol.



**WARNING:** Discuss any pain or discomfort you are having with your doctor. This treatment may cause some pain and discomfort. This could be a normal part of your treatment or a symptom of other issues. Your doctor may want to adjust your prescription during your treatment if you are experiencing pain or discomfort.

 **WARNING:** Always follow the prescription and instructions from your doctor when using the ERC 2P. If you do not follow your prescription, your bone could heal improperly or not at all.

- If you use the ERC 2P less than your doctor prescribes, your bone might harden too early and stop getting longer before it has reached its target length. If this happens, you may need another surgery to make your bone the right length.
- If you use the ERC 2P more than your doctor prescribes you could lengthen the bone too quickly and cause your bone to heal improperly or not at all. If this happens, you may need another surgery to treat the bone that will not heal.

 **WARNING:** Always position the ERC 2P on the skin directly over the implanted rod and in the right direction. If you place the ERC 2P in the wrong location on your leg, the ERC 2P and the rod may not interact. This could result in your bone not lengthening correctly. If your bone does not lengthen properly, it could harden too early and you may need another surgery to make your bone the right length.

 **WARNING:** Do not place the ERC 2P on any open sore on your skin. The ERC 2P may not be clean and you could get an infection. You may need medical intervention or surgery to treat an infection. An open sore is any cut on your skin.

 **WARNING:** Do not use the ERC 2P within two feet (61 centimeters) of unattached metal objects, credit cards, cell phones, or electronic devices. Unattached metal objects could be pulled very quickly to the magnets in the ERC 2P and may injure you. Credit cards, cell phones, or electronic devices that are placed closer than two feet (61 centimeters) of the ERC 2P might be damaged.

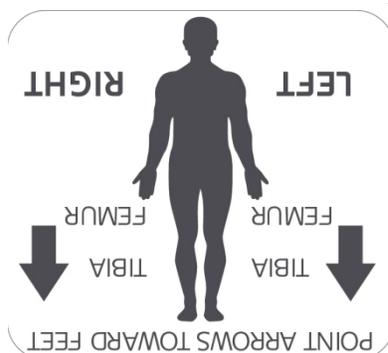
If a metal object becomes attached to the ERC 2P, shut off the ERC 2P and remove the piece of metal that is attached.

 **WARNING:** Do not use the ERC 2P within four feet (1.2 meters) of people who have a pacemaker or other active or electronic implant, such as an implanted infusion pump or implantable cardiac defibrillator (ICD). Before using the ERC 2P, ask people in the same room if they have one of these implants. If they have an implant, do not use the ERC 2P until they have left the room. The magnets in the ERC 2P could damage these implants or cause them to move in ways that could harm the person.

**! WARNING:** If the ERC 2P fails to stop running or the **red STOP** button does not work, move the ERC 2P off of your leg and disconnect the plug from the wall socket. If you do not move the ERC 2P, the motor may continue to run and the implant may get too long. This could result in the need for another surgery.

**! WARNING:** Do not attempt to open or repair the ERC 2P. The ERC 2P does not have any parts that you can service or adjust. You could damage the ERC 2P or injure yourself. If you fail to follow this warning, you can electrocute or shock yourself.

**! WARNING:** Align the ERC 2P toward your feet as in the picture below. The Display screen should be closest to your head. If the ERC 2P is pointing in the wrong direction, the PRECICE Rod will not lengthen properly and may result in the need for another surgery. This figure shows the correct direction to point the ERC 2P.



**! WARNING:** Before you use the ERC 2P, make sure you receive training from your doctor or nurse. Improper use of the ERC 2P could cause your bone to harden too soon or not at all. This could result in the need for another surgery.

**! WARNING:** Follow the instructions your doctor gives to you about how much weight to put on your leg during your treatment. If you put more weight on your leg than your doctor recommends, the rod could be damaged or break. This could result in the need for another surgery.

**! WARNING:** Do not leave the ERC 2P unattended around children. The ERC 2P is not intended to be used by anyone under the age of 18. Use of this device by anyone under the age of 18 may result in improper use, which may result in the need for another surgery.

 **WARNING:** Do not attempt to manipulate or remove the SD card in the ERC 2P. The SD card contains your prescription. Damaging or removing the SD card may cause a delay in treatment, which may result in an additional surgery. If the SD card is accidentally removed, contact your physician.

## 1.6 What must you do to avoid other harm? (Precautions)

This section describes the Precautions associated with the ERC 2P. This will help you to avoid harm when using the ERC 2P.

### PRECAUTIONS.

 **PRECAUTION:** Only clean the ERC 2P with a soft cloth damp with water. Common household cleaners (such as Windex<sup>®</sup>, bleach, or Clorox<sup>®</sup> wipes) can damage the electrical components of the ERC 2P.

 **PRECAUTION:** Do not store the ERC 2P near a heater or fireplace or in other areas that may have extreme temperatures (Above 140°F/60°C or below 14°F/-10°C). The ERC 2P has not been tested to exposure at these temperatures and could be damaged. Refer to the Troubleshooting guide in Section 20 for any problems you have using the ERC 2P.

 **PRECAUTION:** Act on all error messages. See Section 7 (*Troubleshooting*) to learn how to respond to an error message. Failure to take action after an error message could result in the ERC 2P not working properly.

## 1.7 Risks of this procedure.

There are risks of the surgery to implant the rod into your leg. The anesthesia and surgical risks are the same as for any patient who undergoes a surgical procedure. The risks listed could result in the need for additional medical or surgical procedures to correct.

### The risks associated with anesthesia and surgery include:

- You could have a reaction to the medicines given to you during the surgery.
- You could get an infection during or after the surgery.
- You could have an embolism during or after the surgery.

- You could experience some stiffness or soreness from the surgery.
- You could experience some pain from the surgery.
- You could experience some bleeding from the surgery.
- You could have an allergic reaction to the medicines or devices used to treat you during the surgery.
- You could have a stroke from the surgery.
- You could have a heart attack (Myocardial infarction) from the surgery.
- You could get pneumonia from the surgery.
- You could die from the surgery.

**The additional potential risks of the limb lengthening procedure include:**

- You may feel pain from lengthening your bone.
- There may be a delayed union or non-union of the bone (the bone does not heal).
- The screws may pull out or break.
- There may be an infection.
- The implant may malfunction or break.
- The bone can consolidate (harden) before the lengthening is complete.
- You may have contracture or stiffness of the soft tissue in your leg that may cause pain.
- You may experience muscle weakness from not using the implanted limb.
- You may experience nerve injury.

**The additional risks associated with the use of the ERC 2P include:**

- Misalignment or improper location of the ERC 2P can result in the implant not lengthening which could result in premature bone consolidation.
- Placement of the ERC 2P in the improper orientation can result in shortening of the implant rather than lengthening. Note that the implant cannot be shortened less than its initial packaged length.
- Over distraction could occur due to improper programming of the ERC 2P by the physician. This could result in non-union of your bone.

### **1.8 Benefits of this procedure.**

The benefit of this procedure is to make your leg longer. The PRECICE rod can be lengthened by using the ERC 2P from outside of your body. The PRECICE rod can also be shortened if the bone has been made too long.

### **1.9 How to decide about this treatment.**

When considering PRECICE as an option for limb lengthening, it is important to consult with your doctor and ask about all treatment options. Your doctor will help you to decide what treatment will best fit your lifestyle. Read all of the information in this pamphlet to help decide if PRECICE is the right treatment for you.

### 1.10 Alternative treatments.

Some Alternative Therapies to the PRECICE System include:

- **Use shoe lifts.**

Lifts can be inserted inside your shoe to adjust for differences in the length of your legs. This does not require surgery but does not actually make your leg longer.

- **Lengthening with External Fixation Devices.**

Your leg can be made longer using external fixation devices (Figure 1.10-1). These devices have rings that are placed outside of your leg. These rings are connected to your bone by pins or wires that go from outside the leg, through the skin, and into the bone. There is one hoop near the top part of the bone and one hoop near the bottom part of the bone. The rings are connected with bars that can be adjusted. With these devices, you adjust the length of your leg each day by turning screws on the bars. You need a surgery to have an external fixator attached.



Figure 1.10-1 External Fixation Devices.

- **Other Types of Internal Nail Lengthening.**

There are other implants, like PRECICE, that are adjustable rods placed inside your leg bone. Some of these implants have a mechanical ratchet that lengthens by normal body motion or by twisting your leg.

### 1.11 Training to discover whether you can use the ERC 2P yourself.

Your doctor is trained to use the PRECICE System. Your doctor will provide you hands-on training and ask you to demonstrate usage to make sure that you use the ERC 2P correctly. Your doctor will give you training before you are treated with PRECICE.

### 1.12 What happens before the treatment?

The following phases happen before your treatment:

- **Consultation:** During this phase, your doctor will discuss with you the ways to treat your condition. Your doctor will also talk to you about your exact condition and needs. You will review the risks and benefits of the procedure and discuss other possible treatments for your condition. Your doctor will ask you for your complete medical history. It is important to give your doctor a complete and accurate medical history. If you have certain conditions, you must not be treated with the PRECICE System. If you are treated and you have one of these conditions, you could be seriously harmed.
- **Training:** During this phase, your doctor will show you how to use the ERC 2P to lengthen your PRECICE rod and discusses your role in the lengthening procedure. Your doctor will make the decision to send the ERC 2P home with you or treat you in the office or clinic with the ERC 2P.

### 1.13 What happens during and after the treatment?

There are 4 phases to your treatment.

- **Implantation:** This phase is when you have your surgery and your doctor implants the PRECICE rod in your leg.
- **Lengthening:** You will make your leg longer each day in this phase. About 5 days after your surgery, you will visit your doctor to have your first lengthening. Your doctor will watch you while you use the ERC 2P to make your leg longer and answer any questions you might have. When you are at home, you will use the ERC 2P to make your leg a little longer each day (usually about 1 mm per day). Make sure you follow your doctor's instructions. You will visit your doctor about once a week to check on your progress. Your doctor may x-ray your leg when you visit.
- **Consolidation:** After your leg is the right length, you will stop lengthening your leg each day. Now you will let your leg bone heal and get stronger. This is the consolidation phase. Your doctor will see you about once a month during this phase to check on your progress. Your doctor will tell you how much weight you can put on your leg. It is important to follow all of your doctor's instructions.
- **Explantation:** Within a year of your surgery, your doctor will schedule another surgery to remove the PRECICE rod from your leg. After surgery, you will stay in the hospital until you recover enough to go home. After you have fully recovered from your surgery, your doctor will tell you when you can continue your usual lifestyle.

### 1.14 What happens after the surgery?

- **Implantation:** After the surgery to implant the rod in your leg, you will stay in the hospital until you recover enough to go home. You will have regular office visits to monitor your lengthening progress.
- **Post-Explantation:** After the surgery to remove the rod from your leg, you will stay in the hospital until you recover enough to go home.

## 2. ABOUT THE ERC 2P.

This section will help you or the person who is treating you to understand how to use the ERC 2P correctly.

### 2.1 What are the functions of the ERC 2P?

You will use the ERC 2P to lengthen the implanted PRECICE Rod in your leg.

### 2.2 What are the ERC 2P Buttons and Displays?

### ERC 2P Buttons and Displays.



<p>1</p>	<p>The <b>red STOP</b> button will immediately stop the device if necessary.</p>
<p>2</p>	<p>The <b>green GO</b> button is used to start the device and to move through the menu/screens.</p>
<p>3</p>	<p>The <b>Control Panel</b> screens guide the user through correct usage of the ERC 2P.</p>

### 2.3 How to set up your treatment area.

**1. Choose the location where you will be doing the treatment.**



- Check that there is an electrical outlet close to the ERC 2P.
- Make sure that there are no electronic devices within 2 feet (61 centimeters) that might be damaged by the ERC 2P.
- It will take about 7 minutes for a 1 mm lengthening.

**2. Remove all loose metal from your work area.**



- Remove metal items from your clothing and body.
- Remove unattached metal items from the area (jewelry, knives, keys, etc.).
- Do not use the ERC 2P within 2 feet (61 centimeters) of unattached metal objects. Unattached metal objects could be pulled very quickly to the magnets in the ERC 2P and may injure you.

**3. HOW TO USE THE ERC 2P IF YOU HAVE ONE PRECICE IMPLANT.**

This section describes how to use the ERC 2P to make your implanted PRECICE Rod longer. This will help you or the person who is treating you to understand how to use the ERC 2P correctly.

**1. Remove the ERC 2P from the case.**



Check that none of the ERC 2P parts have any visible cracks. Check that there are no exposed wires on the power cord. If there are cracks or exposed wires, contact your doctor for a replacement ERC 2P.



Plug the power cord into the power supply.

**2. Plug the ERC into the wall outlet.**

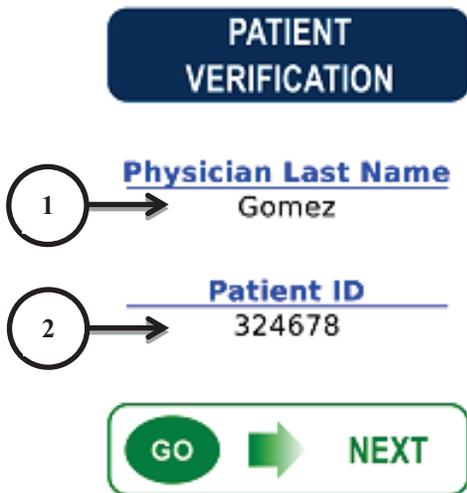


**INITIALIZING SCREEN**

When the ERC 2P is plugged in, the control panel will light up and the software will begin initializing. This screen will display for a few seconds.

**3. Verify your personal information.**

This section explains the screens you will see on the control panel before starting your lengthening session.



**PATIENT VERIFICATION SCREEN**

After initializing, the patient verification screen will be shown. At this time it is important that you:

- 1 Verify that your Doctor's name is correct.
- 2 Verify that patient ID is correct.

If this information is correct, press the **GREEN** button on the ERC 2P to **GO** to the next screen.

If this information is not correct, contact your doctor.

	<h3 style="text-align: center;">PRESCRIPTION INFORMATION SCREEN</h3> <p>This screen shows your prescription information:</p> <ol style="list-style-type: none"> <li>1 <b>IMPLANT NUMBER:</b> The implant that this prescription is for. This will always be 1 if you have only 1 implant.</li> <li>2 <b>SIDE:</b> The leg you will be lengthening – right or left will be shown. In this example screen, “Right” is shown.</li> <li>3 <b>LIMB:</b> The leg bone you are lengthening – femur or tibia will be shown. In this example screen, “Femur” is shown.</li> <li>4 <b>SESSION TOTAL:</b> The lengthening amount for this session.</li> <li>5 <b>DAILY TOTAL:</b> The daily total prescription.</li> </ol> <p>Press the <b>green GO</b> button on the ERC 2P to go to the next screen.</p>
	<h3 style="text-align: center;">IMPLANT LOCATION SCREEN</h3> <p>There are four options for the PRECICE implant location:</p> <ol style="list-style-type: none"> <li>(1) Left Tibia, (2) Right Tibia</li> <li>(3) Left Femur, (4) Right Femur</li> </ol> <ol style="list-style-type: none"> <li>1 Your implant location will be displayed and the limb to be lengthened will be highlighted in red. In this example screen, the “Right Femur” is highlighted.</li> </ol> <p>Press the <b>green GO</b> button on the ERC 2P to align the ERC 2P.</p>

**4. Align the ERC 2P over the implant.**

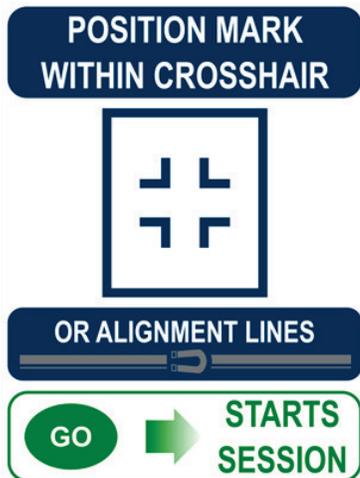
The alignment screen will help you with correct placement of the ERC 2P over the PRECICE implant in your leg.



Place the ERC 2P on your leg, pointing the arrows toward your feet. Position the ERC 2P as shown in the picture.



Verify that the ERC is oriented along the axis of the implant, with the arrows pointing toward your feet.



**CAMERA POSITIONING SCREEN**

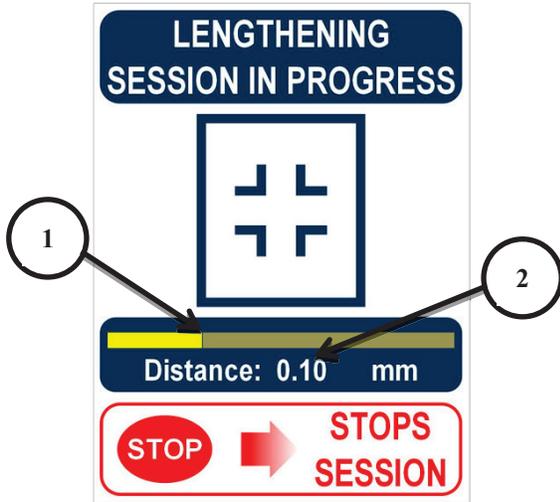
Line up the mark on your leg in the middle of the blinking crosshairs or align with the alignment line.



Once you have positioned the ERC 2P over the implant and the mark is visible on the screen or aligned with the alignment lines, press the **green GO** button to start the session.

**Your session has now started.**

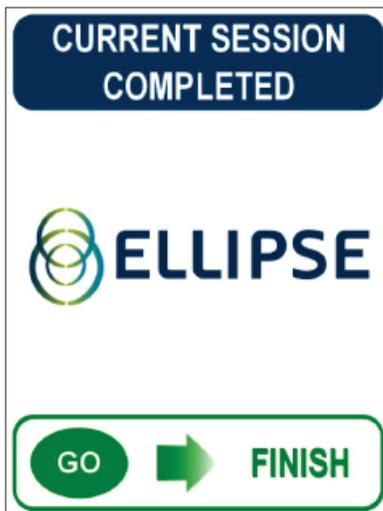
**5. What happens during your lengthening session. (for ONE implant only)**



The ERC 2P is now running and your lengthening session has started.

1 Progress Bar: This will fill as the device lengthens to monitor your progress. When the bar is 100% full, the device has lengthened to the prescribed amount.

2 Distance counter: This number will increase as the device lengthens. It will stop at the prescribed length.



**NO SESSION REQUIRED SCREEN**

After the assigned length for the session has been achieved, the ERC 2P will automatically stop.

You cannot adjust the length of the implant more than the daily prescription.

Press the **green GO** button to finish your session.



SESSION COMPLETED  
UNPLUG DEVICE  
AND STORE IN CASE

**FOLLOW PRESCRIPTION  
FOR NEXT SESSION TIME**

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The **Completion Screen** will appear.

Unplug your ERC 2P.

Place the ERC 2P in the storage case.

**4. HOW TO USE THE ERC 2P IF YOU HAVE TWO PRECICE IMPLANTS.**

This section describes how to use the ERC 2P to make your implanted PRECICE Rod longer if you have **two** implants. This will help you or the person who is treating you to understand how to use the ERC 2P correctly.

<b>1. Remove the ERC 2P from the case.</b>	
	<p>Check that none of the ERC 2P parts have any visible cracks. Check that there are no exposed wires on the power cord. If there are cracks or exposed wires, contact your doctor for a replacement ERC 2P.</p>
	<p>Plug the power cord into the power supply.</p>

**2. Plug the ERC into the wall outlet.**

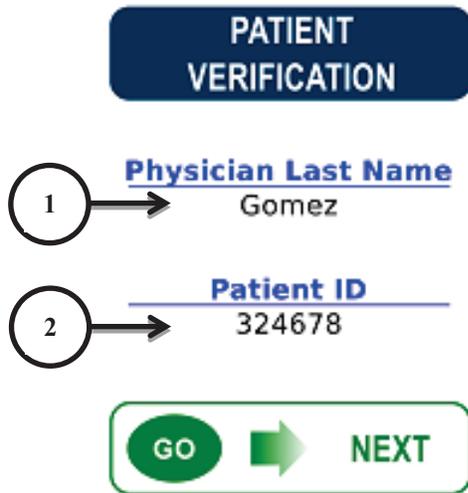


**INITIALIZING SCREEN**

When the ERC 2P is plugged in, the control panel will light up and the software will begin initializing. This screen will display for a few seconds.

**3. Verify your personal information.**

This section explains the screens you will see on the control panel before starting your lengthening session.



**PATIENT VERIFICATION SCREEN**

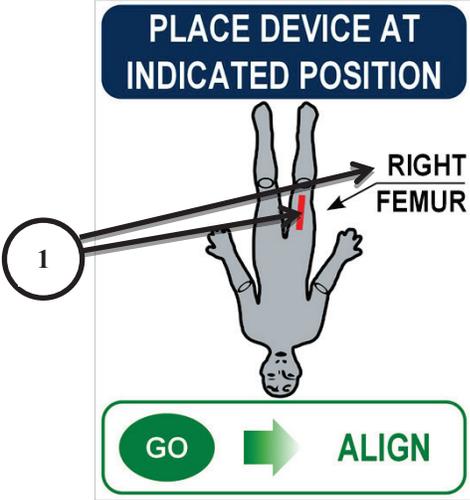
After initializing, the patient verification screen will be shown. At this time it is important that you:

- 1 Verify that your Doctor's name is correct.
- 2 Verify that patient ID is correct.

If this information is correct, press the **GREEN** button on the ERC 2P to **GO** to the next screen.

If this information is not correct, contact your doctor.

	<p style="text-align: center;"><b>IMPLANT #1</b></p> <p><b>PRESCRIPTION INFORMATION SCREEN</b></p> <p>This screen shows your prescription information for your first implant:</p> <ol style="list-style-type: none"> <li>1 <b>IMPLANT NUMBER:</b> The implant that this prescription is for (Implant 1).</li> <li>2 <b>SIDE:</b> The leg you will be lengthening – right or left will be shown. In this example screen, “Right” is shown.</li> <li>3 <b>LIMB:</b> The leg bone you are lengthening – femur or tibia will be shown. In this example screen, “Femur” is shown.</li> <li>4 <b>SESSION TOTAL:</b> The lengthening amount for this session.</li> <li>5 <b>DAILY TOTAL:</b> The daily total prescription.</li> </ol> <p>Press the <b>green GO</b> button on the ERC 2P to go to the next screen.</p>
	<p style="text-align: center;"><b>IMPLANT #2</b></p> <p><b>PRESCRIPTION INFORMATION SCREEN</b></p> <p>The next screen shows your prescription information for your second implant:</p> <ol style="list-style-type: none"> <li>1 <b>IMPLANT NUMBER:</b> The implant that this prescription is for (Implant 2).</li> <li>2 <b>SIDE:</b> The leg you will be lengthening – right or left will be shown. In this example screen, “Left” is shown.</li> <li>3 <b>LIMB:</b> The leg bone you are lengthening – femur or tibia will be shown. In this example screen, “Femur” is shown.</li> <li>4 <b>SESSION TOTAL:</b> The lengthening amount for this session.</li> <li>5 <b>DAILY TOTAL:</b> The daily total prescription.</li> </ol> <p>Press the <b>green GO</b> button on the ERC 2P to go to the next screen.</p>

	<p><b>IMPLANT LOCATION SCREEN</b></p> <p>There are four options for the PRECICE implant location:</p> <ul style="list-style-type: none"><li>(1) Left Tibia, (2) Right Tibia</li><li>(3) Left Femur, (4) Right Femur</li></ul> <p><b>1</b> Your implant location for <b>Implant 1</b> will be displayed and the limb to be lengthened will be highlighted in red. In this example screen, the “Right Femur” is highlighted.</p> <p><b><u>THIS IS THE LEG YOU WILL LENGTHEN FIRST.</u></b></p> <p>Press the <b>green GO</b> button on the ERC 2P to align the ERC 2P.</p>
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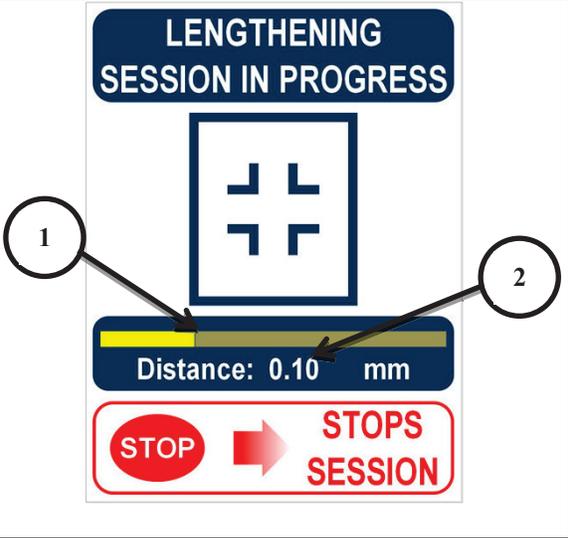
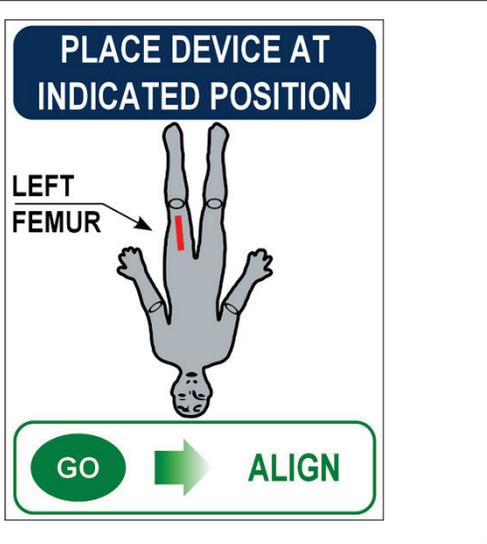
**4. Align the ERC 2P over the implant.**

The alignment screen will help you with correct placement of the ERC 2P over the PRECICE implant in your leg.

	<p>Place the ERC 2P on your leg over <b>Implant 1</b>, pointing the arrows toward your feet. Position the ERC 2P as shown in the picture.</p>
---	---

	<p>Verify that the ERC is oriented along the axis of the implant, with the arrows pointing toward your feet.</p>
	<p><b>CAMERA POSITIONING SCREEN</b></p> <p>Line up the mark on your leg in the middle of the blinking crosshairs or align with the alignment line.</p>
	<p>Once you have positioned the ERC 2P over the implant and the mark is visible on the screen or aligned with the alignment lines, press the <b>green GO</b> button to start the session.</p> <p><b>Your session has now started.</b></p>

5. What happens during your lengthening session. (for TWO implants only)

	<p>The ERC 2P is now running and your lengthening session for <b>Implant 1</b> has started.</p> <p>Progress Bar: This will fill as the device lengthens to monitor your progress. When the bar is 100% full, the device has lengthened to the prescribed amount.</p> <p>1</p> <p>2</p> <p>Distance counter: This number will increase as the device lengthens. It will stop at the prescribed length.</p>
	<p>When the lengthening on <b>Implant 1</b> has been completed, the ERC 2P will stop. You will be prompted to place the device over <b>Implant 2</b>.</p> <p>Press the <b>green GO</b> button on the ERC 2P to Align the ERC 2P. In this example screen, the “Left Femur” is shown.</p>

**6. Align the ERC 2P over Implant 2.**

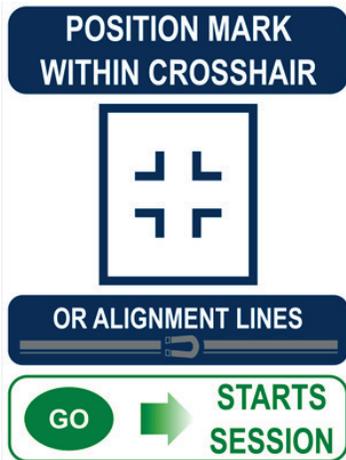
The alignment screen will help you with correct placement of the ERC 2P over the PRECICE implant in your leg.



Place the ERC 2P on your leg over **Implant 2**, pointing the arrows toward your feet. Position the ERC 2P as shown in the picture.



Verify that the ERC is oriented along the axis of the implant, with the arrows pointing toward your feet.



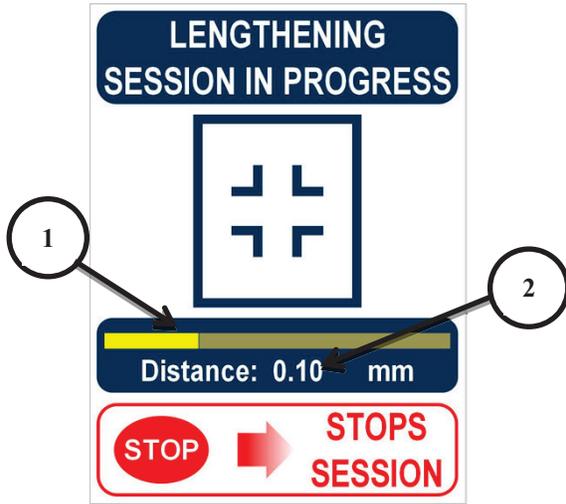
**CAMERA POSITIONING SCREEN**

Line up the mark on your leg in the middle of the blinking crosshairs or align with the alignment line.



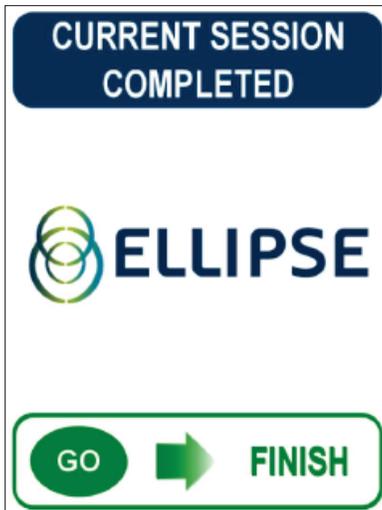
Once you have positioned the ERC 2P over the implant and the mark is visible on the screen or aligned with the alignment lines, press the **green GO** button to start the session.

**Your session has now started.**



The ERC 2P is now running and your lengthening session for **Implant 2** has started.

- 1 Progress Bar: This will fill as the device lengthens to monitor your progress. When the bar is 100% full, the device has lengthened to the prescribed amount.
- 2 Distance counter: This number will increase as the device lengthens. It will stop at the prescribed length.



**SESSION COMPLETED SCREEN**

After the assigned length for the session on both implants has been achieved, the ERC 2P will automatically stop.

You cannot adjust the implant more than the daily prescription.

Press the **green GO** button to finish your session.

 <p>SESSION COMPLETED UNPLUG DEVICE AND STORE IN CASE</p> <p><b>FOLLOW PRESCRIPTION FOR NEXT SESSION TIME</b></p> <p>Version 1.23 03-Jan-2013 03:13:03 PM</p>	<p>The <b>Completion Screen</b> will appear.</p> <p>Unplug your ERC 2P.</p> <p>Place ERC 2P in the storage case.</p>
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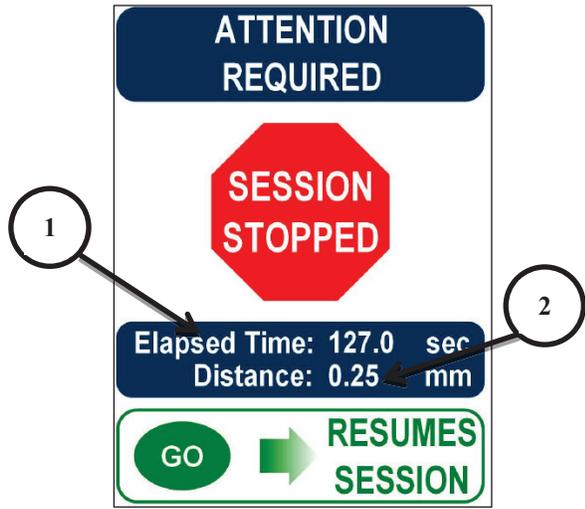
5. ADDITIONAL INFORMATION.

5.1 How to stop the ERC 2P during your lengthening session.

You may stop the ERC 2P at any time during the session. It is not harmful to do this because the ERC 2P remembers your progress. If you do require an emergency stop, follow the instructions below.



1 You may press the **red STOP** button at any time during a lengthening or shortening session. This will cause the ERC 2P to stop immediately.



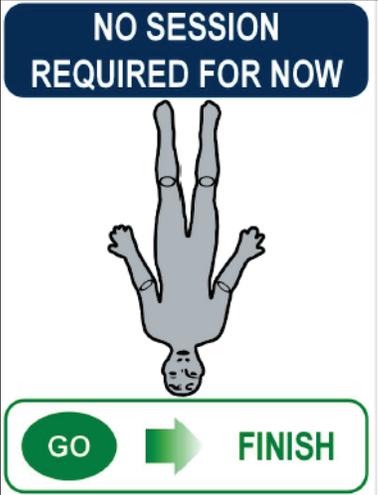
1 **ELAPSED TIME:** The total time in seconds that the ERC 2P was running before the **red STOP** button was pressed will be displayed.

2 **DISTANCE:** The total distance that the ERC 2P was lengthened or shortened before the **red STOP** button was pressed will be displayed.



**5.2 Other Screens you may see while using the ERC 2P.**

You may see any one of the following screens while using the ERC 2P.

	<p><b>NO SESSION REQUIRED SCREEN</b></p> <p>This screen will display if you try to use the ERC 2P more than your daily prescription. (This resets every 24 hours).</p> <p>You cannot lengthen the implant more than the daily prescription.</p>
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	<p><b>ERROR SCREEN</b></p> <p>This screen will appear if there is a malfunction with the ERC 2P. Follow the instructions and contact your physician. In the example screen shown, “Error Code 123” is displayed. The error code on your screen may be different.</p>
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### 5.3 Maintenance of the ERC 2P.

- Before each use, check the parts and condition of all the ERC 2P components. If there are exposed wires or visible cracks, call your doctor for replacements.
- The ERC 2P has no user serviceable parts. Do not attempt to open it.

### 5.4 Cleaning.

- If the ERC 2P becomes dirty, wipe it with a soft cloth damp with water. Be sure that all components are dry before placing the ERC 2P back in the case.
- Do not use household cleaners. Some household cleaners (such as Windex<sup>®</sup>, bleach, or Clorox<sup>®</sup> wipes) can damage the ERC 2P.

### 5.5 Storage.

#### The ERC 2P should be stored in the Case when not in use.



- Place the ERC 2P in the supplied storage Case.
- Make sure that all items are in place and are away from the Case edges.
- Close and latch the Case.
- Store the Case indoors. Do not store the ERC 2P close to a heater, fireplace, or in other areas that may have extreme temperatures. (Do not store the ERC 2P above 140°F/60°C or below 14°F/-10°C).

### 5.6 When and why to visit your doctor to check on progress.

Your doctor will tell you when you need to return for regular visits. Usually, you will return to the doctor's office once a week during lengthening. You will return about once a month during consolidation. If your ERC 2P malfunctions, you should call your doctor for a replacement ERC 2P.

Discuss any pain or discomfort you are having with your doctor. This treatment may cause some pain and discomfort. This could be a normal part of your treatment or a symptom of other issues. Your doctor may want to adjust your prescription during your treatment if you are experiencing pain or discomfort.

### 5.7 Where you can find out more information.

If you need additional information on the PRECICE System or have questions about your treatment, contact your doctor.

## 5.8 Travel.

### *Travel and International Use.*

It is not recommended to travel during your treatment. If travel is necessary, check with your doctor first. If you travel outside of the country during lengthening, ask your doctor about giving you an ERC 2P that will work for where you will be going.

### *“Carrying On” ERC 2P.*

The ERC 2P is not considered “Carry On” luggage. If you travel by airplane, the ERC 2P must be placed with the checked luggage.

### *Contacting physicians while in travel status.*

Inform your doctor prior to traveling.

## 5.9 More about your condition.

### *Life Style Changes.*

As with any broken leg bone, limit your activities and avoid putting weight on your leg during your entire treatment, and as instructed by your doctor. Strenuous activity and putting weight on your leg can cause serious injury to your leg or can cause the implant to break. Your doctor may instruct you to use crutches or a wheelchair to avoid putting excess weight on your leg during your treatment.

For the entire time you have the implant, do not participate in contact or high-impact sports such as weightlifting, tumbling, gymnastics, or rowing until you are cleared by your doctor to do so.

**The life style changes you will experience during the various treatment stages are as follows:**

**Implantation:** You will be admitted to the hospital and may need to stay in the hospital after your surgical procedure. This is typically 5 days. At this time, your activities will be limited and will not be at home.

**Lengthening:** During this phase, your doctor will advise you to keep your weight off of your leg. You may require crutches or a wheelchair to get around. You will have regular (usually once a week) visits with your doctor to check on your progress.

**Consolidation:** During this phase you will still need to keep your weight off of your leg as your doctor advises. You may still need crutches or a wheelchair and have limited mobility. You will also need to have regular (usually once a month) visits to your doctor to check on your progress.

**Explantation:** After your bone has healed, you will require another surgery to remove the rod. During this time, you will be hospitalized during your recovery. At this time, your activities will be limited and you will not be at home.

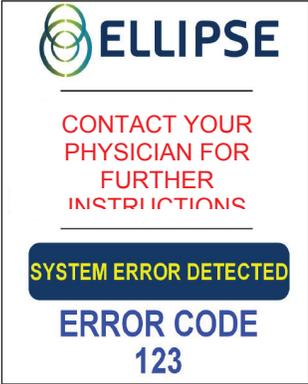
***Need to Adhere to Care Regimen.***

It is important that you follow the treatment schedule and prescription given by your doctor. Reference this pamphlet when necessary. If you do not follow your doctor's instructions the implant may not lengthen properly and additional surgery may be required.

## 6. TROUBLESHOOTING.

This section lists the problems that you may have when running the ERC 2P and what to do. If you cannot fix a problem, call your doctor for help.

<b>Problem.</b>	<b>Possible Reason.</b>	<b>Possible Solution.</b>
<b>You missed a treatment.</b>	You forgot.	Contact your doctor for guidance.
<b>Display screen does not light up.</b>	The ERC 2P does not have power.	<ol style="list-style-type: none"> <li>1. Make sure that the ERC 2P Power Cord is plugged in to the outlet.</li> <li>2. Plug the ERC 2P into a different outlet.</li> </ol>
	The ERC 2P is damaged.	Contact your doctor for a replacement.
<b>The ERC 2P is cracked or damaged.</b>	ERC 2P was accidently dropped.	Do not use the ERC 2P. Call your doctor for a replacement.
<b>Your prescription is incorrect.</b>	Your prescription was programmed incorrectly by your doctor.	Contact your doctor.
<b>Patient ID or physician's name is incorrect.</b>	Your prescription was programmed incorrectly by your doctor.	Contact your doctor.
<b>No session required screen comes on.</b>	You have reached your daily prescription.	Wait until the next day. (The daily maximum has a 24-Hour timer)

<b>ERC 2P ERROR CODES</b>	
	<p style="text-align: center;"><b>ERROR SCREEN</b></p> <p>This screen will appear if there is a malfunction with the ERC 2P.</p> <p>Contact your physician and let them know the Error Code Number. They will give you further instructions and send you a replacement ERC 2P.</p>
<b>POSSIBLE ERROR CODE</b>	<b>REASON</b>
	<p>Firmware Malfunction.</p>
	<p>Magnet Malfunction.</p>

 <p>CONTACT YOUR PHYSICIAN FOR FURTHER INSTRUCTIONS</p> <p><b>SYSTEM ERROR DETECTED</b></p> <p><b>ERROR CODE</b> <b>102</b></p>	<p>Sensor Malfunction.</p>
 <p>CONTACT YOUR PHYSICIAN FOR FURTHER INSTRUCTIONS</p> <p><b>SYSTEM ERROR DETECTED</b></p> <p><b>ERROR CODE</b> <b>103</b></p>	<p>Magnet Malfunction.</p>
 <p>CONTACT YOUR PHYSICIAN FOR FURTHER INSTRUCTIONS</p> <p><b>SYSTEM ERROR DETECTED</b></p> <p><b>ERROR CODE</b> <b>121</b></p>	<p>Motor Malfunction.</p>
 <p>CONTACT YOUR PHYSICIAN FOR FURTHER INSTRUCTIONS</p> <p><b>SYSTEM ERROR DETECTED</b></p> <p><b>ERROR CODE</b> <b>122</b></p>	<p>Motor Malfunction.</p>

If you would like more information on the PRECICE System  
please call:

1-855-435-5477

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, CN 101917918, EP 2,114,258. Other U.S. and international patents pending.



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