

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 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 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 Patient Instructions with the patient before treatment.

To Patients: Read the entire booklet before you use the PRECICE ERC. 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.

PRECICE INTRAMEDULLARY LIMB LENGTHENING SYSTEM PATIENT INFORMATION AND PATIENT INSTRUCTIONS.

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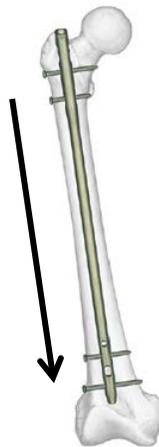
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PRECICE System and External Remote Controller (ERC) Definitions and Glossary.

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

Antegrade: Antegrade refers to a forward or downward direction. In this case, it means the implant is placed downward from the hip toward the knee in the thigh bone (femur) or from the knee toward the ankle in the shinbone (tibia).



Antegrade Rod Implantation in Femur.

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 which 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, which 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: The part of the bone at the ends that grow before you are skeletally mature.

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

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 an indefinite period of time and is not absorbed by the body.

Intramedullary: Intramedullary refers to being inside the bone.

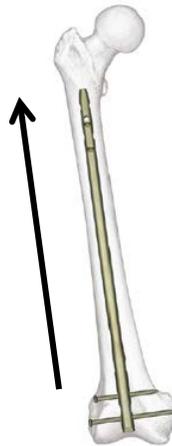
MRI: MRI refers to **Magnetic Resonance Imaging**, which is a medical technique to visualize structures inside the body.

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 from outside your body.

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

Retrograde: Retrograde refers to a backward direction. In this case, it means the implant is placed upward from the knee toward the hip in the thigh bone (femur).



Retrograde Rod Implantation in Femur.

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

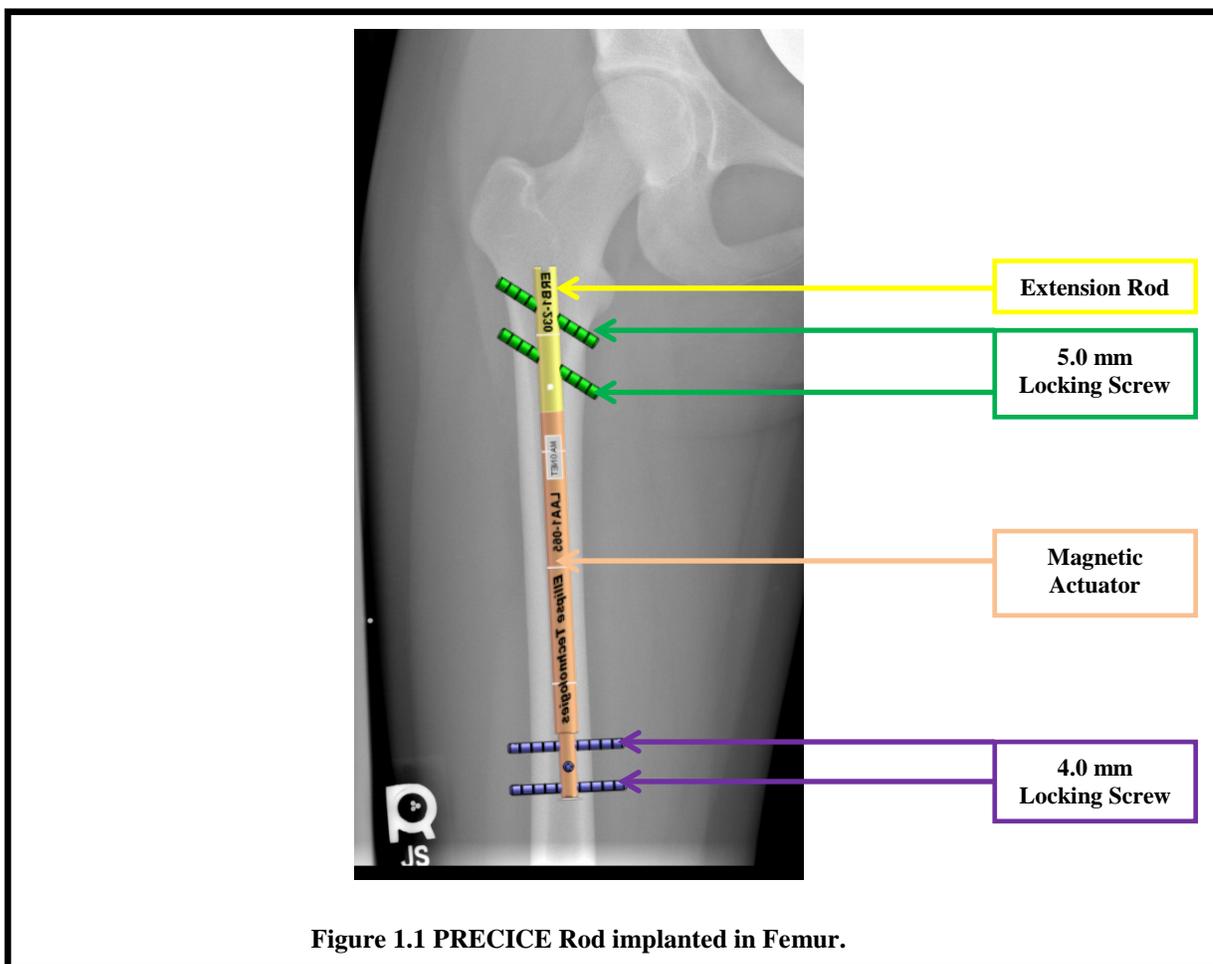
1. WHAT IS PRECICE? (INTRODUCTION)

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).

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. The ERC is a hand held device with two large magnets. The magnet in the actuator turns when the ERC 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.



Inside your ERC Case, you will find the Controller, Hand Piece, Power Supply, and Power Cord.



Figure 1.2 ERC for the PRECICE System.

ERC Parts.

	1	<p>The Case is the outer case that holds and protects the ERC.</p>
	2	<p>The Controller includes software and the keypad. The keypad has buttons you will press to operate the ERC.</p>
	3	<p>The Power Cord connects to the Power Supply and your wall socket to power the ERC.</p>
	4	<p>You will place the Magnetic Hand Piece on your leg to lengthen the implanted PRECICE Rod.</p>
	5	<p>The Cable connects the Controller to the Hand Piece.</p>

2. 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 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 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.

3. 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.

- 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 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:
 - When using the 10.7mm device, that you do not have a distance greater than 51 mm from the surface of the treated limb to the intramedullary canal where the implant will be inserted. The ERC 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.
- That you do not weigh over 114 Kg (250 lb). 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.

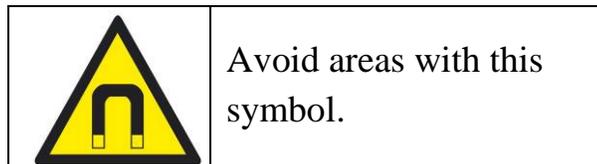
4. WHAT MUST YOU DO TO AVOID SERIOUS HARM? (WARNINGS)

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.



 **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. If you do not follow your prescription, your bone could heal improperly or not at all.

- If you use the ERC 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 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 Hand Piece on the skin directly over the implanted rod and in the right direction. If you place the ERC Hand Piece in the wrong location on your leg, the ERC 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 hand piece on any open sore on your skin. The Hand Piece 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 within two feet 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 and may injure you. Credit cards, cell phones, or electronic devices that are placed closer than two feet of the ERC might be damaged.

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

 **WARNING:** Do not use the ERC within four feet 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, ask people in the same room if they have one of these implants. If they have an implant, do not use the ERC until they have left the room. The magnets in the ERC could damage these implants or cause them to move in ways that could harm the person.

 **WARNING:** Act on all “runaway motor” error messages that appear on the ERC. If you see a “runaway motor” error message, move the ERC off of your leg and disconnect the plug from the wall socket. If you do not move the ERC, 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 Controller or the Hand Piece. The ERC does not have any parts that you can service or adjust. You could damage the ERC or injure yourself. If you fail to follow this warning, you can electrocute or shock yourself.

⚠ WARNING: Point the arrows printed on the ERC Hand Piece toward your feet. Review the illustration on the ERC Hand Piece to make sure you have the ERC in the correct position on your leg. If the ERC Hand Piece is pointing in the wrong direction, the PRECICE Rod will not lengthen properly and may result in the need for another surgery.

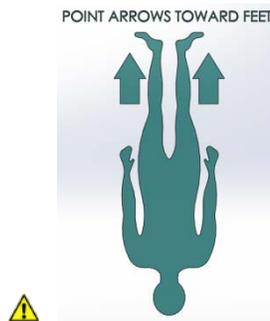


Figure 4.1 shows the right direction to point the ERC.

⚠ WARNING: Before you use the ERC, make sure you receive training from your doctor or nurse. Improper use of the ERC 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 PRECICE ERC unattended around children. The PRECICE ERC 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.

5. WHAT MUST YOU DO TO AVOID OTHER HARM? (PRECAUTIONS)

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

PRECAUTIONS.

 **PRECAUTION:** Only clean the ERC Hand Piece and Controller with a soft cloth damp with water. Common household cleaners (such as Windex[®], bleach, or Clorox[®] wipes) can damage the electrical components of the ERC if they get inside the controller.

 **PRECAUTION:** Do not store the ERC 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 has not been tested to exposure at these temperatures and could be damaged. Refer to the Troubleshooting guide in Section 19 for any problems you have using the ERC.

 **PRECAUTION:** Do not use components that are not part of the ERC System. Only use the Power Cord, Cable, Hand Piece and Controller that came with the ERC. Using other components that do not belong to the ERC System could damage the ERC, the other components, or both.

 **PRECAUTION:** Act on all error messages. See Section 19 (*Troubleshooting*) to learn how to respond to an error message. Failure to take action after an error message could result in the ERC not working properly.

6. 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. These risks include:

- You could have a reaction to the medicines given to you during the surgery.
- You could get an infection during or after 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 the 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.
- Bone deformity may result in limb deformity.
- 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 include:

- Misalignment or improper location of the ERC can result in the implant not distracting which could result in premature bone consolidation.
- Placement of the ERC 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 by the physician. This could result in non-union of your bone.

7. 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 from outside of your body. The PRECICE rod can also be shortened if the bone has been made too long.

8. 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.

9. 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 9.1). 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 9.1 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.

10. TRAINING TO DISCOVER WHETHER YOU CAN USE THE ERC 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 correctly. Your doctor will give you training before you are treated with PRECICE.

11. WHAT HAPPENS BEFORE THE TREATMENT?

The following phases happen before your treatment:

- **Consultation:** This phase is when 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:** This phase is when your doctor shows you how to use the ERC to lengthen your PRECICE rod and discusses your role in the lengthening procedure. Your doctor will make the decision to send the ERC home with you or treat you in the office or clinic with the ERC.

12. 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 to make your leg longer and answer any questions you might have. When you are at home, you will use the ERC 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.

13. 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.

14. HOW TO USE THE PRECICE EXTERNAL REMOTE CONTROLLER.

This section describes how to use the ERC 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 correctly.

14.1 What are the functions of the ERC?

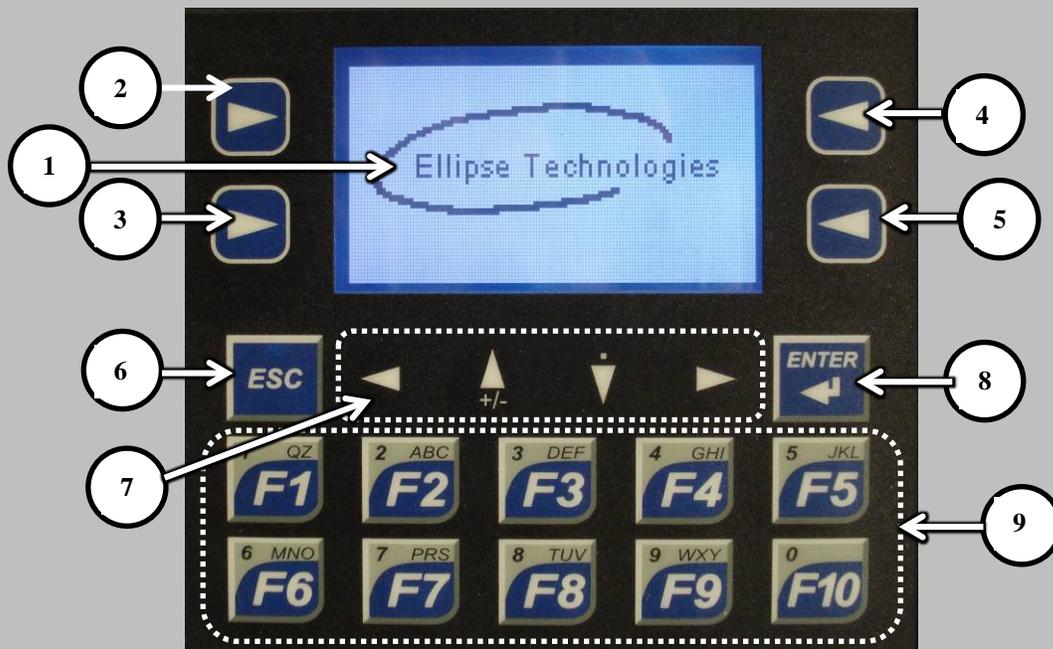
You will use the ERC to lengthen the implanted PRECICE Rod in your leg.

The ERC can also make the implanted PRECICE Rod shorter. Do not use the ERC to make the implanted PRECICE rod shorter unless instructed by your doctor.

14.2 What are the ERC buttons?

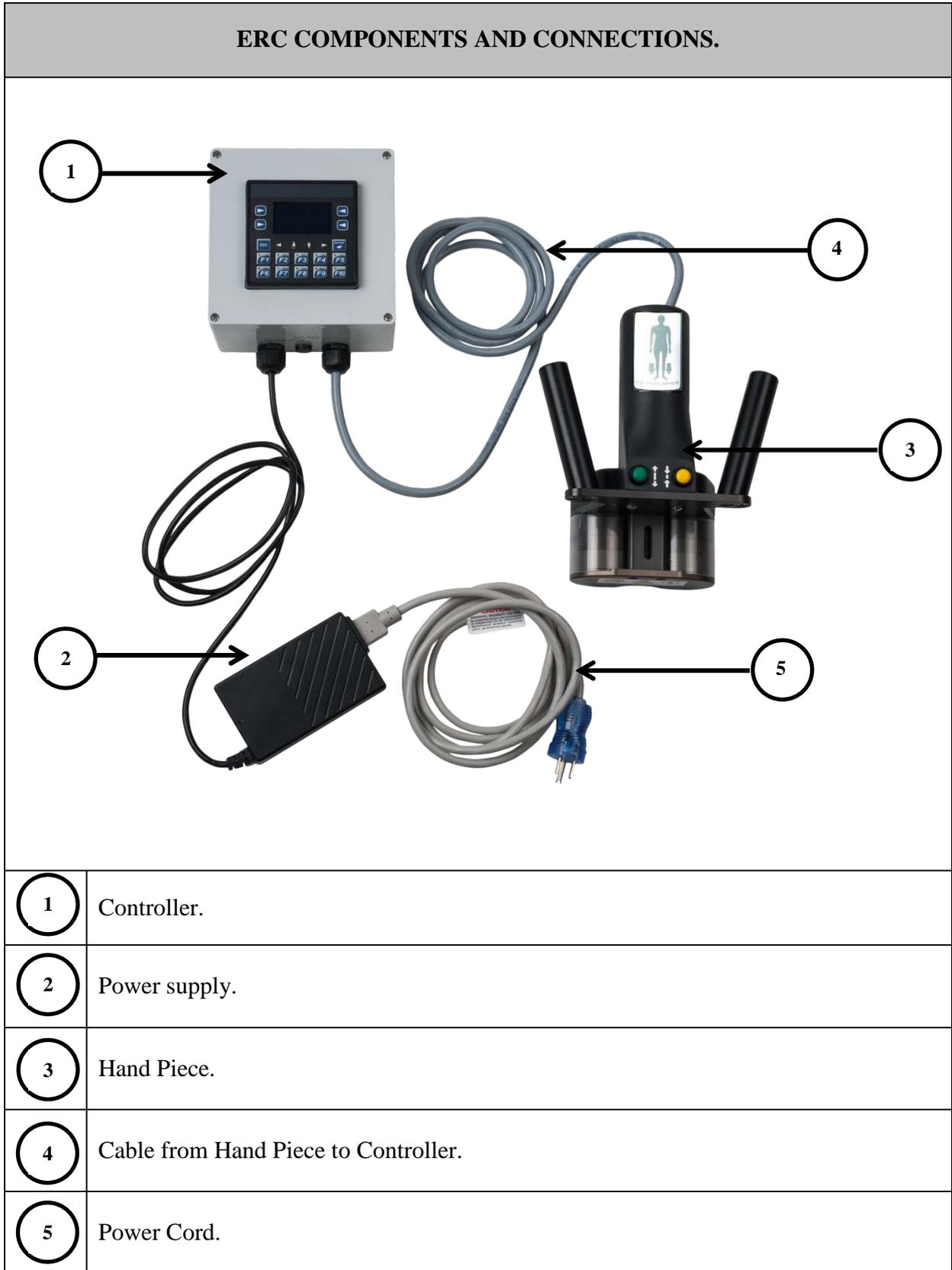
PRECICE ERC HANDPIECE.	
1	Right Handle.
2	Left Handle.
3	GREEN Extend push button with the arrows pointing away from each other (← -- →) may be used to make the implanted PRECICE Rod longer.
4	YELLOW Retract push button with the arrows pointing toward each other (→ -- ←) may be used to make the implanted PRECICE Rod shorter.
5	Locating Window is used to line up the ERC with the implant.

PRECICE ERC CONTROLLER BUTTONS AND DISPLAY.



1	Display Screen.
2	Upper Left Key.
3	Lower Left Key.
4	Upper Right Key.
5	Lower Right Key.
6	Escape Key.
7	Arrow Keys.
8	Enter Key. Shown as [ENT←] on the Display Screen.
9	Function/Number Keys (Functions F1 to F10; Numbers from 1 to 9, 0).

14.3 What are the ERC components and connections?



14.4 How to set up the ERC.

SET UP YOUR TREATMENT AREA.

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



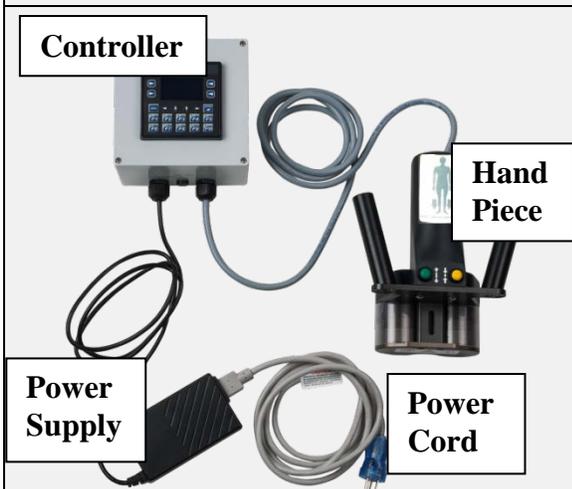
- Check that there is an electrical outlet close to the ERC.
- Make sure that there are no electronic devices within 2 feet that might be damaged by the ERC.
- It will take about 7 minutes for a 1 mm lengthening.

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 within 2 feet of unattached metal objects. Unattached metal objects could be pulled very quickly to the magnets in the ERC and may injure you.

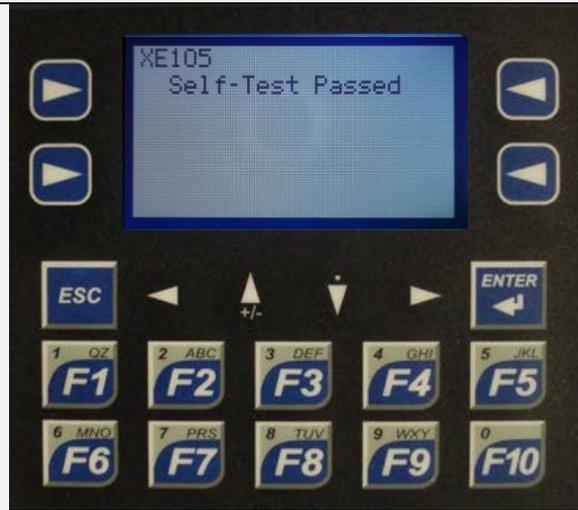
3. Remove the ERC from the case.



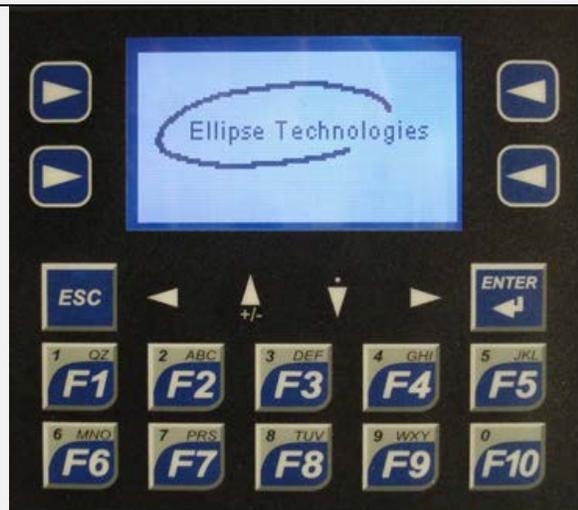
Check that none of the ERC parts have any visible cracks. Check that there are no exposed wires on the cables or cords. If there are cracks or exposed wires, contact your doctor for a replacement ERC.

14.5 How to power the ERC.

Plug in the PRECICE ERC power cord into the electrical outlet.



- When the ERC is connected and plugged in, the display will light up and the controller will perform a self-test.



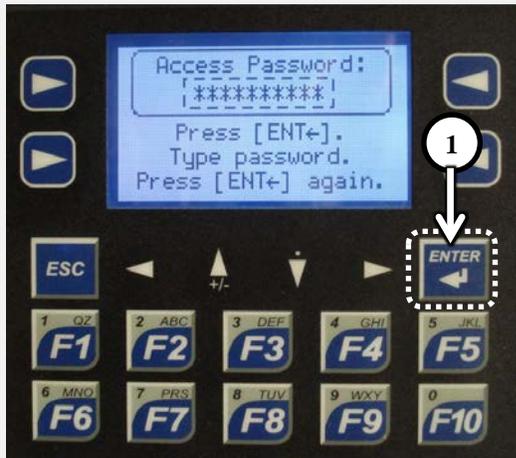
- After the self-test, the Ellipse logo will appear.

14.6 How to use the ERC to treat yourself or another. (Step By Step Instructions)

1. ENTER YOUR PASSWORD.

Your doctor may provide a password for the ERC. Follow the instructions on the screen. If you do not remember your password, contact your doctor.

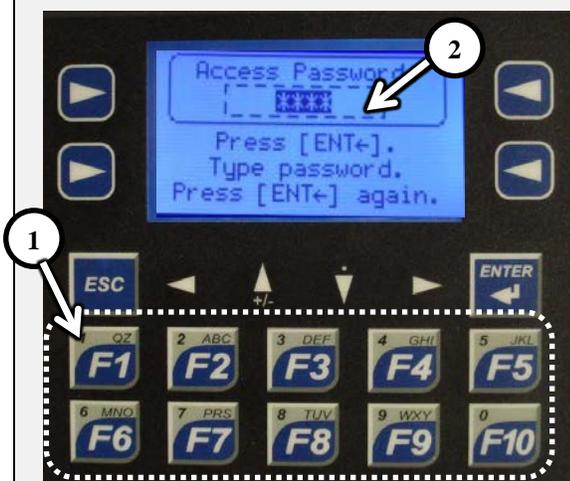
If you did not receive a password, skip to Step 2. “Check Your Prescription.”



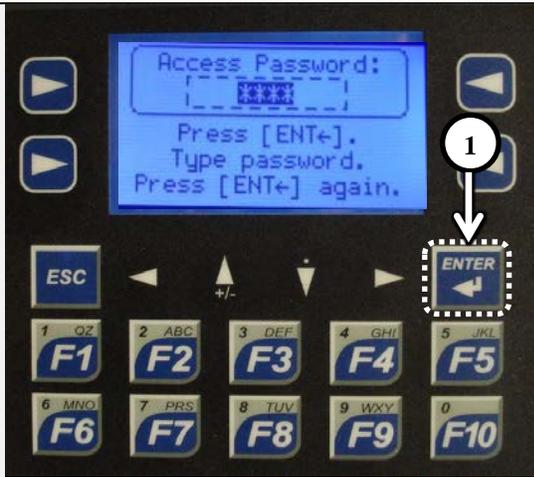
- 1 Firmly press the ENTER Button when prompted to “Press [ENT←]”.



The Access Password field will be highlighted.



- 1 Use the key pad to enter your password.
- 2 Your password will not show on the screen, it will be replaced by a string of ‘*’s.
- If you forget your password, call your doctor.



1 Firmly press the ENTER Button after you enter your password.

2. CHECK YOUR PRESCRIPTION.



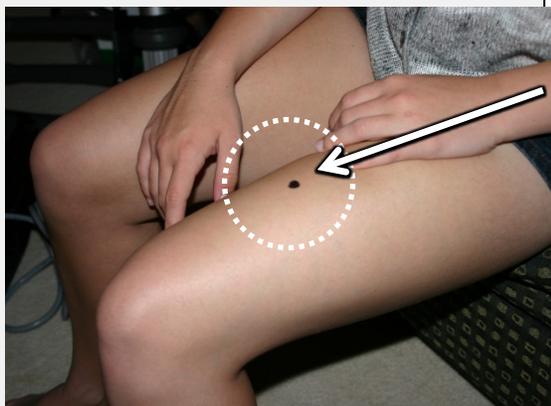
Check the display screen to verify your prescription:

1 Check the Distraction Length to make sure it matches your doctor's prescription.

2 Check the Direction ("Antegrade" or "Retrograde").

If these fields do not match your prescription, contact your doctor.

3. LOCATE YOUR IMPLANT.



- After implanting the rod, your doctor will make a mark on your leg where the magnet in the rod is. Place the ERC here when you lengthen your leg.

- Keep the mark on your skin. After you shower or bathe, be sure to mark the location using permanent ink.

- If the mark is washed or rinsed away, contact your doctor and have your doctor mark the spot again.

4. PLACE THE HAND PIECE ON YOUR LEG OVER THE IMPLANT.



Option 1: Place the Hand Piece over the mark on your leg. You will see the mark in the Locating Window.



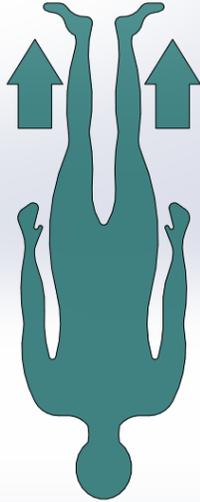
Option 2: Hold the Hand Piece to the side of the mark on your leg and roll it into place over the mark.



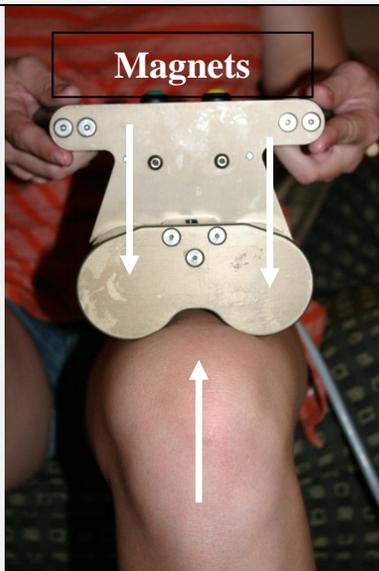
Option 3: Tilt the Hand Piece up so you can see the mark and drop the Hand Piece down over the mark.

5. ALIGN THE HAND PIECE WITH YOUR LEG.

POINT ARROWS TOWARD FEET



Make sure that the Hand Piece is pointing down your leg. The picture of the feet on the Hand Piece should point toward your feet.



When placed on your leg correctly, the magnets in the Hand Piece will rest on your leg bone.

6. LENGTHENING THE ROD.

***Note: If you find yourself on a screen other than what appears in these step-by-step instructions, the ERC will not function properly. In order to use the ERC again, you will need to restart the ERC. To do this, disconnect the power cord from the electrical socket in the wall and reconnect the power cord into the electrical socket. Return to Section 14.6 to treat yourself.**



The Display before you start lengthening.



1 Press the F1 button once to start lengthening.



ERC starts to make your bone longer.



1 On the Controller, the distance will count up.

2 The bar on the display will show the progress.

- It takes about 2 minutes to complete a 0.25 mm lengthening.



This shows the display during lengthening.



The lengthening process stops when the prescription is reached.



After the ERC has stopped, you can confirm that you are done lengthening by:

1 The lengthened amount has reached the prescribed amount.

2 The status bar is completely filled in.

7. HOW TO STOP THE ERC, IN CASE OF EMERGENCY.

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

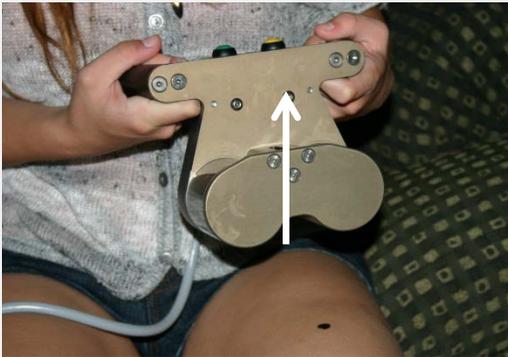


You can stop the ERC in the middle of a lengthening by:

- 1 Pressing any button on the Controller.

You may continue the lengthening by placing the Hand Piece over the implant (Steps 2, 3, and 4) and pressing the F1 Button again (Step 5).

- The ERC will start counting from where you stopped.



At any time during the lengthening process, you can move the Hand Piece off your leg. The motor will still run but it will not lengthen your rod.

8. RESET THE CONTROLLER FOR YOUR NEXT TREATMENT.



1 After you have completed lengthening, the arrow on the display next to the top left key will flash.

2 Press the top left key to reset the lengthening amount to 0 mm to be prepared for your next treatment.



Now you are ready for your next treatment.

9. PUT THE PRECICE ERC AWAY AFTER EACH USE.



- Move the Hand Piece off your leg.
- Disconnect the power cord from the wall socket.
- Put the ERC back into the case.

14.7 Maintenance of the ERC.

- Before each use, check the parts and condition of all the ERC components. If there are exposed wires or visible cracks, call your doctor for replacements.
- The ERC has no user serviceable parts; do not open the Controller or Hand Piece.

14.8 Cleaning.

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

14.9 Storage.

The ERC should be stored in the Case.



- Place the Hand Piece, Controller and Power Cord in their compartments.
- 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 close to a heater, fireplace, or in other areas that may have extreme temperatures. (Do not store the ERC above 140°F/60°C or below 14°F/-10°C).

15. 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 malfunctions, you should call your doctor for a replacement ERC.

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.

16. 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.

17. 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 that will work where you will be.

“Carrying On” ERC.

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

Contacting physicians while in travel status.

Inform your doctor prior to traveling.

18. 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, you 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 move 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, you will be limited and 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.

19. TROUBLESHOOTING.

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

Problem.	Possible Reason.	Possible Solution.
The display Screen is different from the step-by-step instructions.	Navigated to an unintended screen.	Restart the ERC. Disconnect the power cord from the electrical socket in the wall, and re-connect the power cord into the electrical socket. This will bring you back to the password entry or the main screen.
You missed a treatment.	You forgot.	Contact your doctor for guidance.
Display screen does not light up.	The ERC does not have power.	<ol style="list-style-type: none"> 1. Make sure that the ERC Power Cord is plugged in to the outlet. 2. Plug the ERC into a different outlet. 3. Make sure that the Power Cord is connected to the Power Supply.
	The ERC is damaged.	Contact your doctor for a replacement.
The ERC is cracked or damaged.	ERC was accidentally dropped.	Do not use the ERC. Call your doctor for a replacement.
Magnet does not turn or you do not hear the motor running	ERC is damaged.	Contact your doctor for a replacement.
	You are not operating the ERC correctly.	Check the controller for error messages and follow the instructions (see below) for clearing the error. Attempt the lengthening again. If the ERC is still not working properly, contact your doctor.

The following error messages may appear on the display screen if you have reached the maximum distraction limit, or if there is a fault with the machine. If an error message appears, press the exit button (1 Right lower button) as shown in the picture below to clear the message.

If the error message persists, remove the Hand Piece from your leg and disconnect the power cord from the wall socket. Contact your doctor for further assistance.

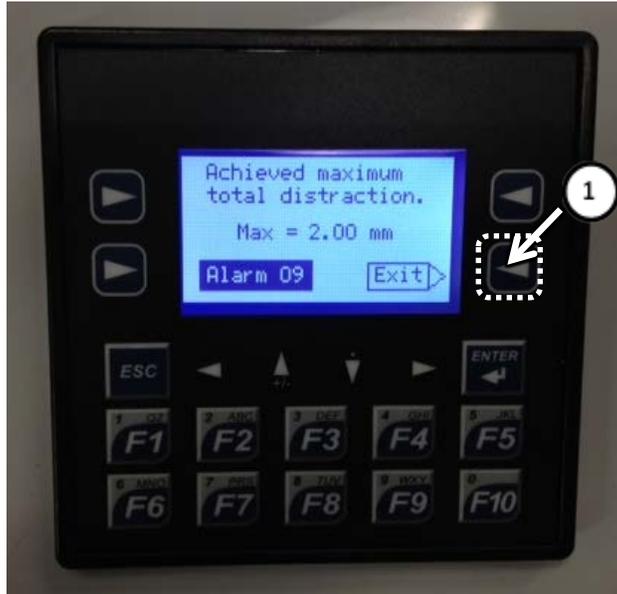
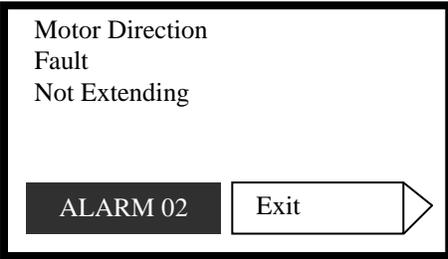
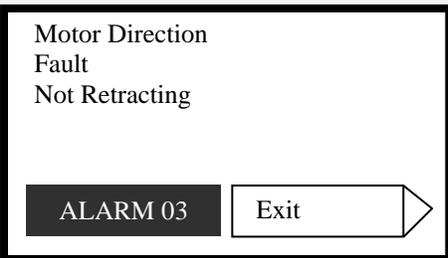
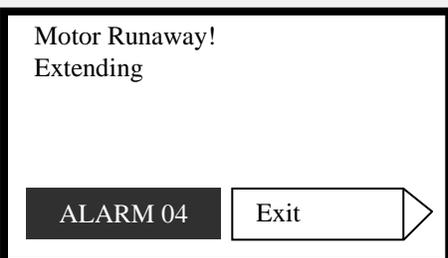
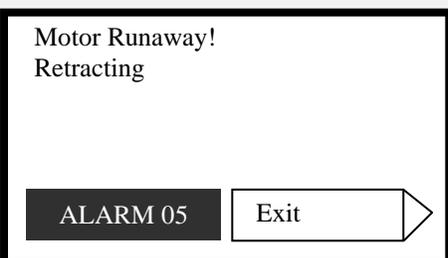
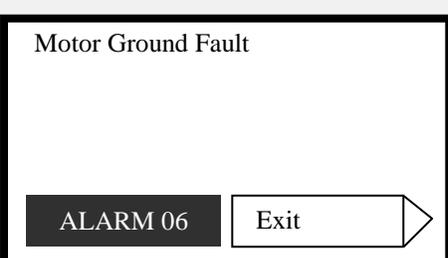
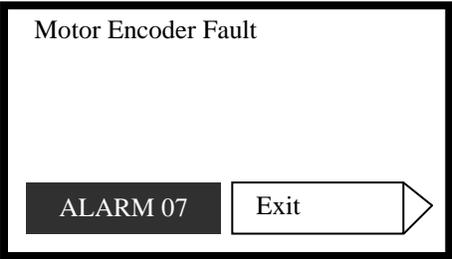
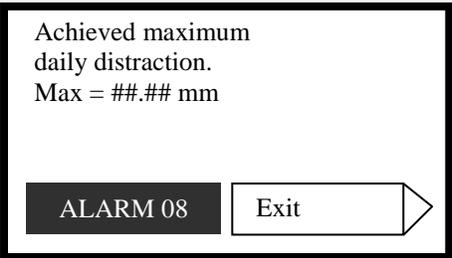
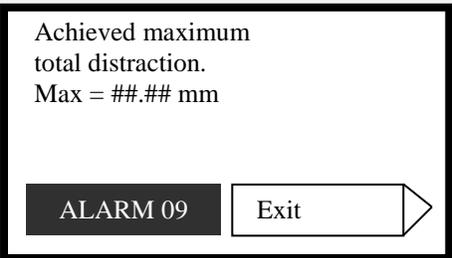


Figure 21.1 Display Screen with Error Message

Display Screen Error Message.	Error Code.	Error Message.
	ALARM00.	Input Fault, I3.
	ALARM01.	Input Fault, I4.

Display Screen Error Message.	Error Code.	Error Message.
	ALARM02.	Motor Direction Fault Not Extending.
	ALARM03.	Motor Direction Fault Not Retracting.
	ALARM04.	Motor Runaway! Extending.
	ALARM05.	Motor Runaway! Retracting.
	ALARM06.	Motor Ground Fault.

Display Screen Error Message.	Error Code.	Error Message.
 <p>A screenshot of a display screen showing the error message "Motor Encoder Fault". At the bottom, there is a dark grey button labeled "ALARM 07" and a white button labeled "Exit" with a right-pointing arrow.</p>	ALARM07.	Motor Encoder Fault.
 <p>A screenshot of a display screen showing the error message "Achieved maximum daily distraction. Max = ##.## mm". At the bottom, there is a dark grey button labeled "ALARM 08" and a white button labeled "Exit" with a right-pointing arrow.</p>	ALARM08.	Exceeded Maximum Daily Distraction.
 <p>A screenshot of a display screen showing the error message "Achieved maximum total distraction. Max = ##.## mm". At the bottom, there is a dark grey button labeled "ALARM 09" and a white button labeled "Exit" with a right-pointing arrow.</p>	ALARM09.	Exceeded Maximum Total Distraction.

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

1-855-4ELLIPSE (1-855-435-5477)



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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. Other U.S. and international patents pending.

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