

Indications for Use

The OrthoPak® 2 Bone Growth Stimulator System is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. A nonunion is considered to be established when the fracture site shows no visible progressive signs of healing.

The original approval was based on a PMA Study, which included 69 patients with efficacy of 72.5%. An additional cohort of 21 recalcitrant patients with multiple prior procedures and unsuccessful electrical stimulation with different modality was added and yielded efficacy of 33.3%. Seventy-nine patients out of 90 treated had at least 4 years follow-up after the date of treatment termination for a follow-up rate of 88%. The follow-up results were 45 patients healed; four previously healed patients have died; three patients, who were healing at the end of treatment, were healed with additional treatment. Counting only the 45 unconditionally healed patients, the efficacy at 4 year follow-up was 50%. A subsequent survey of 295 patients conducted from March 1988 to September 1990 by an independent agency, yielded an efficacy of 73.2%.

Device Design Rationale

The OrthoPak 2 Bone Growth Stimulator System provides a noninvasive, transdermally applied electrical treatment of nonunions secondary to trauma. The transdermal application of the treatment current to the patient has been also referred to as "capacitive coupling", to denote the resulting capacitive phase shift between the treatment current and the applied voltage in the OrthoPak 2 Bone Growth Stimulator System. The time varying electrical field developed in the tissue between the electrodes is distributed through a wide volume of tissues, including bone. Thus, some latitude is permitted in the placement of the electrodes. A 20 degree misalignment is allowed in the placement of the electrodes on either side of the nonunion site, and the permissible tolerance in the plane of the long axis of the bone is equal to the diameter of an electrode (i.e., plus or minus 1-3/8 inches). Utilization of this device allows full weight bearing on the casted extremity unless gross motion (greater than 5 degrees in any plane) at the nonunion site is presented. In such cases, weight bearing is not advised.

Contraindications

The use of this device is contraindicated of the individual has synovial pseudoarthrosis.

Warnings

Utilization of this device allows full weight bearing on the casted extremity unless gross motion (greater than 5 degrees in any plane) at the nonunion site is present. In such case, weight bearing is not advised and should not be permitted as this may compromise the effectiveness of the treatment. The safety and effectiveness of the use of the device on individuals lacking skeletal maturity has not been established. In the presence of a maligned nonunion, careful consideration on the use of this device must be undertaken on an individual basis, as treatment with this device is not yet intended to alter or affect the degree of malalignment. Animal safety studies indicate that the OrthoPak 2 Bone Growth Stimulator does not interfere with the normal intrinsic activity of the heart. However, the Stimulator does interfere with the operation of certain pacemakers. The concomitant use of the device and a pacemaker must be assessed on an individual basis, prior to use (such as with an electrocardiogram). The amplitude of the treatment current must be between 5 and 10 milliamperes RMS. Treatment with this device is not recommended on patients whose electrical impedance of the tissue between the electrodes will not allow the device to operate within the prescribed 5 to 10 milliamperes range. The safety and effectiveness of the use of this device on individuals with nonunion secondary to, or in conjunction with, a pathological condition has not been established. Animal studies conducted to date do not suggest any long term adverse effects from use of this device. However, long term effects in humans are unknown. General tissue sensitivity at the skin/electrode site with unknown specific etiology may occur. This tissue sensitivity may be caused by the electrode gel, excess perspiration or a combination of both. Such a reaction generally resolves spontaneously following diagnosis and correction of the underlying cause. Other components and parts may not be compatible, and may damage the device. If any component does not function properly, contact Biomet at (800) 524-0677. No attempt should be made to modify or repair the device.

Precautions

Although laboratory teratological studies performed with this device demonstrate no adverse findings, the safety of this device used during pregnancy and nursing in humans has not been established. Compliance with the treatment schedule, daily battery change and proper maintenance of the device and the change of the electrodes are essential. The device will not perform properly and treatment may be unnecessarily prolonged if you fail to adhere to the care routine. Components in this system are to be used only with Biomet approved parts. No attempt should be made to modify or repair this device.

Adverse Events

NOTE: With the exception of the following, no known adverse effects have resulted from the use of this device:

General tissue sensitivity at the skin/electrode site with unknown specific etiology may occur. This tissue sensitivity may be caused by the electrode gel, excess perspiration or a combination of both. Such a reaction generally resolves spontaneously following diagnosis and correction of the underlying cause.

A Patient's Guide

ORTHOPAK²



A Patient's Guide to
the Treatment of
Nonunion Fractures



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Description of the OrthoPak® 2 Bone Growth Stimulator System

The **OrthoPak 2** Bone Growth Stimulation System is a nonsurgical treatment technique designed to promote the healing of bone fractures that have failed to mend in the normal period of time. This condition is commonly called a nonunion.

The condition of a nonunion is not rare. Approximately 1 in 20 bone fractures become a nonunion. The most common method of treating a nonunion has been bone graft surgery. In this procedure, bone is taken from another location of the patient's body and surgically implanted at the nonunion site. Metal rods or plates and bone screws also may be attached to the broken bone to secure the ends in place while it mends.

An alternative nonsurgical procedure was developed for the treatment of nonunions. This method incorporated the transmission of an electrical signal through the nonunion site to stimulate the healing process.

The use of this device requires the immobilization of the fractured bone and a minimum of three months of use with the device for adequate treatment.

The **OrthoPak 2** Bone Growth Stimulation System has been designed so that it is convenient to use, comfortable to wear and safe to operate. Although this is an electrical stimulation treatment device, you will not feel any sensation of stimulation.

Device Design Rationale

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The time varying electrical field developed in the tissue between the electrodes is distributed through a wide volume of tissues, including bone. Thus, some latitude is permitted in the placement of the electrodes. A 20 degree misalignment is allowed in the placement of the electrodes on either side of the nonunion site and the permissible tolerance in the plane of the long axis of the bone is equal to the diameter of an electrode (i.e., plus or minus 1-3/8 inches). Utilization of this device allows full weight bearing on the casted extremity unless gross motion (greater than 5 degrees in any plane) at the nonunion site is presented. In such cases, weight bearing is not advised.

Your OrthoPak 2 Kit consists of:

- **OrthoPak 2** Bone Growth Stimulator
- Extra Electrodes
- Additional adhesive electrode covers to enhance electrode security (if needed)
- Electrode cables (to connect the electrodes to the **OrthoPak 2** device)
- 2 rechargeable batteries
- Battery charger

Wearing the OrthoPak 2

- **OrthoPak 2** has been designed so that it is convenient to use, comfortable to wear, and safe to operate. You should begin using the **OrthoPak 2** device immediately after you have read the instructions for use.

Directions For Use:

It is important that you familiarize yourself with the directions for use and the routine maintenance procedure for the **OrthoPak 2** Bone Growth Stimulation Device. Please read the following directions carefully and make sure that you understand them thoroughly. Contact your local Biomet representative if you need additional clarification or help. Your full compliance with these directions will contribute greatly to the successful outcome of your treatment.

Electrodes

Electrodes are provided for patient use. Low profile Electrodes (Figure 1) are to be used in all applications of the OrthoPak® 2.

Electrodes are mounted on a release liner and are effective for multi day use. (See instructions on package for proper electrode application.)

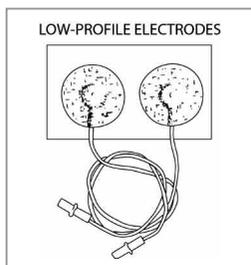


Figure 1

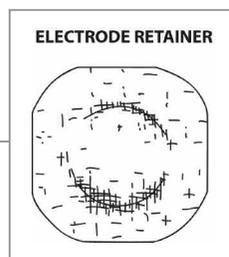


Figure 2

Note: Remove the stimulator before showering.

Insert the electrode cable plug carefully into the jack at the top of the stimulator. The other end of the electrode cable connects to electrode leads. (Figure 3)

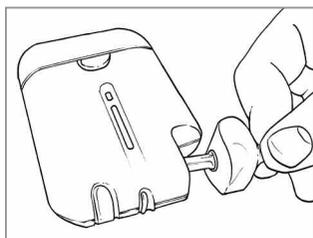


Figure 3

Open the battery compartment by pressing the battery cover release button and sliding the battery cover to open. Insert one of the supplied AA batteries into the battery compartment of the stimulator. (Figure 4)



Figure 4

Replace the cover by sliding back to its closing position. (Figure 5)

The cover will snap into place.

When the electrodes are applied and are making good contact with the skin, there will be a blinking indicator next to the "OK" icon.

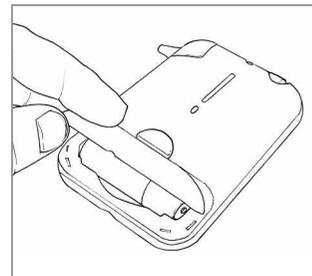


Figure 5

If the audible alarm and the yellow light flashes with the indicator next to the  icon, the battery voltage is too low. Install a fully charged battery.

If the audible alarm is beeping and the yellow light is blinking with the indicator next to the  icon, the continuity of the circuit has been interrupted. First, check that the electrodes are making good contact with the skin. If alarm is still on, detach the electrode and repeat this procedure with one of the other electrode cables supplied in your kit. If the alarm stops, the original cables are defective. If the indicator next to the "ERROR" icon appears, there is a problem with the stimulator. DO NOT ATTEMPT TO FIX IT YOURSELF. Contact Biomet at 1-800-524-0677 or your sales representative.

Connection of Electrodes

If the stimulator is worn on the belt loop attachment, select the 48-inch electrode cable. If the stimulator is to be placed on the cast wrap, select the 12 or 20-inch cable and place the fastener strip on the back of the stimulator as shown on the stimulator's label. Connect electrode pads to the electrode cable as provided in the patient kit (see instructions on electrode package). Gently press electrodes onto the skin.

Depending on your ability to move after your surgery, it may be helpful to ask another person to help you place these electrodes on your skin. See instructions for use on the electrode packet. Consult your doctor or Biomet should you have questions about proper electrode placement.

Make sure you apply the electrodes after your skin has been cleaned and dried. If your skin becomes abnormally red at the electrode sites, the electrodes should be moved either immediately above or below the original sites. If the redness does not go away after 48 hours after moving the electrodes, you should call your doctor first, then call Biomet at 1-800-524-0677.

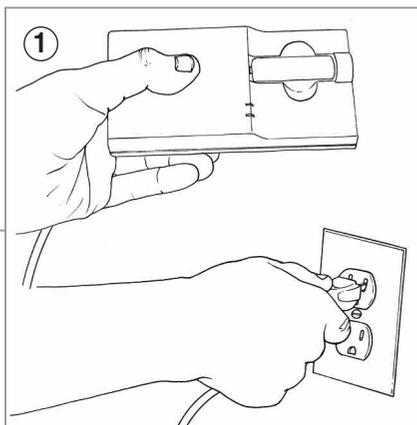
Operating Instructions

Prior to first usage batteries must be fully charged. After 24 hours of use, the **OrthoPak 2** Bone Growth Stimulator battery requires charging. Each **OrthoPak 2** includes two batteries. Always have one battery cell attached to **OrthoPak 2** stimulator and have one battery charging in the battery charger. Additional batteries are available through Biomet customer service at 1-800-524-0677. Each day, preferably at the same time, you should change the battery following these instructions.

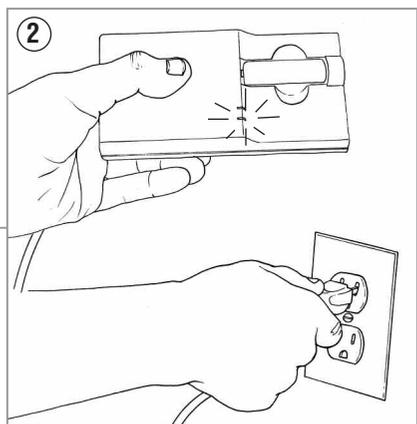
Step 1:

Battery Charging

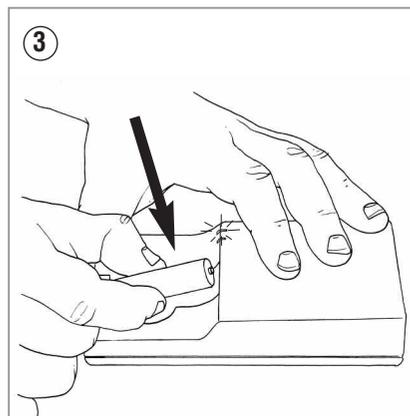
Charging may take approximately two and a half hours.



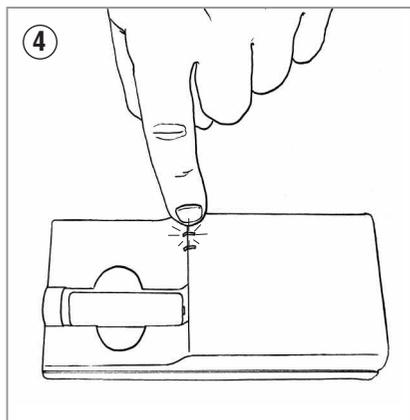
Plug the battery charger unit into a grounded wall outlet.



A green light on the charger will illuminate indicating that the charger is ready and connected to household power.



Place the "AA" battery cell into the battery charger as illustrated. The solid orange light on the charger will illuminate indicating a proper connection.



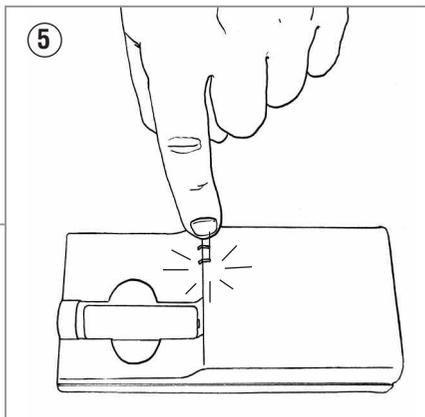
If the orange light continues to flash for longer than two minutes, call Biomet customer service at 1-800-524-0677 and ask for product support.

Note: Make sure the battery in charger is *NOT* a non-rechargeable battery. Make sure the battery in the charger is the one supplied with your kit.

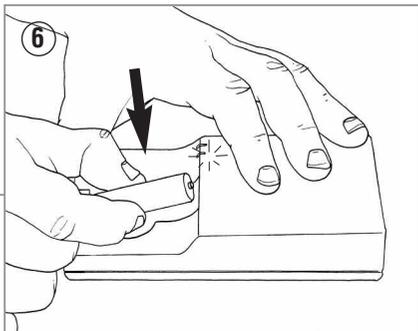
Caution: Do not attempt to charge any other battery. Do not attempt to charge non-rechargeable batteries. Do not use the batteries supplied with this unit in any other device. Use of OrthoPak 2 batteries in any other device may cause damage or malfunction to the batteries and/or devices.

Step 1: (continued)

Battery Charging



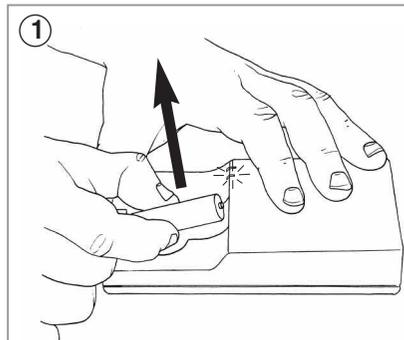
When the battery is fully charged the orange light on the battery charger will be off. The green light should stay on. Otherwise check if the AC plug is appropriately plugged into the AC outlet.



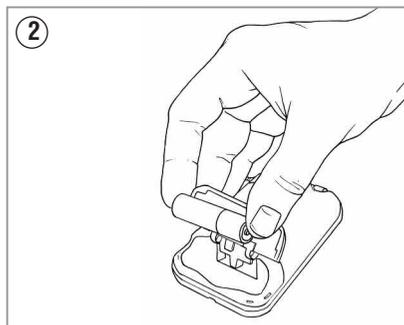
Remove the current battery cell from the **OrthoPak 2** Bone Growth Stimulator and place that battery in the charger for charging.

Step 2:

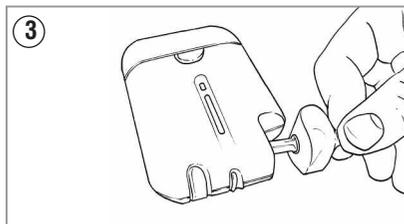
Preparing the System to Begin Treatment



Attach electrodes as per instructions on the package. Remove the fully charged battery cell from the battery charger. The battery is now ready for connection to the **OrthoPak 2** stimulator.



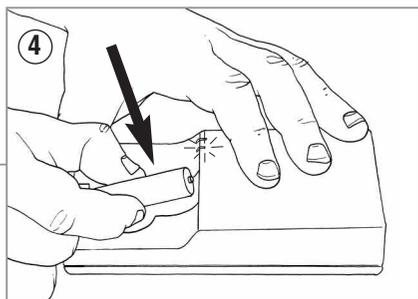
Insert the battery into the **OrthoPak 2** stimulator by pushing it into the battery compartment matching the “+” with “+” on the battery (an LED light will blink and sound a beep, indicating power).



Connect the two electrode wires into the electrode cable. Insert the electrode cable plug into the jack at the top of the stimulator

Step 2: (continued)

Preparing the System to Begin Treatment



Insert the uncharged battery cell into the battery charger cradle.

Step 3:

Recharging the batteries

At room temperature, (24°C [75°F]), charging may take two and a half hours. In warm or cold temperatures, the battery may take longer to charge. Follow Step 1 instructions.

Once daily, patients should do the following:

- Press the release button on the front of the **OrthoPak 2** Bone Growth Stimulator and remove the battery cell.
- Remove the fully charged battery from the battery charger (see preparing the System to Begin Treatment) and place the fully charged battery into the **OrthoPak 2** Bone Growth stimulator.
- Place the depleted battery cell into the battery charger for charging.



Note: The batteries cannot be overcharged. If the battery cell is in the battery charger and the battery is already fully charged, the charger will terminate the recharging process early. This will be indicated by the charger having no orange light when charging is complete. **Do not be concerned if the batteries are kept in the charger for a long period of time.**

When the OrthoPak 2 Bone Growth Stimulator needs a freshly charged battery, the following will occur:

- The **OrthoPak 2** LCD screen will indicate the symbol for the battery. With the audio alarm engaged, beeping will occur.
- Only after inserting a charged battery cell into the **OrthoPak 2** will the message read OK.

 **Warning:** Do not charge an Alkaline battery!

LCD Symbol Description and Instructions

The alarm defaults to audible alarm. Press the button to silence the alarm. The light will continue to flash and the screen will indicate the alarm condition.

Condition	Instruction	Indications
Treating	Normal	OK (Blinking)
Audible alarm engaged	Depress the button briefly to silence the alarm. Depress the button approximately 3 seconds to toggle between engaged and disengaged	
Battery requires charging	Insert a charged battery onto the stimulator	yellow + 
Disconnection of lead wire	Confirm that each electrode is sufficiently contacted on the skin. Reapply the electrodes if necessary. Confirm that the cable is attached completely. Replace the cable if necessary.	yellow + 
System Error	Error in the unit. Do not attempt to fix the stimulator. Please contact Biomet at 1-800-524-0677	yellow + ERROR
End of operation	Please contact Biomet at 1-800-524-0677	yellow + END

Tips

Loose Electrodes — Make sure that both electrodes are in complete contact with your skin. Moisten or replace worn electrodes if necessary.

Incomplete Circuit — Check all connection points, insuring tight fit of cable plug into the **OrthoPak 2** device and full engagement of electrode cable pin into electrode wire receptacle.

Broken Electrode Cable — If you have checked the electrodes and the connections and the alarm continues, a break in the cable may be responsible. Remove the old electrode cable. Attach a new electrode cable into the jack. An extra electrode cable is provided in the kit. If the alarms still continue, please call Biomet at 1-800-524-0677.

Electrodes

- Change your electrodes every five to seven days. Different skin types will provide for a longer or shorter life of the electrodes. If the alarm indicates a disconnection, it is likely that either the cable connection is incomplete or the adhesive (gel) on the electrode is no longer working and the electrodes need changing. Check all cable connection points, to make sure that the electrode cable is tightly plugged into the top of the **OrthoPak 2** Bone Growth Stimulator (Figure 7) and that the cable connectors are completely inserted into both electrode connectors. If all the connections are made and the symbol indicates a disconnection, it is probably time to change the electrodes.

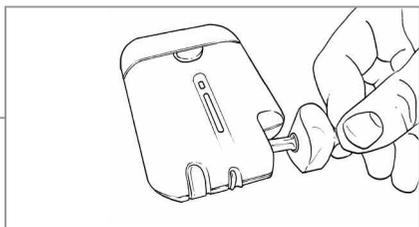


Figure 7

- Remove the old electrodes from your skin.
- Wash your skin gently with soap and water and pat dry.
- Remove two new electrodes from the packaging and store the liner for future use.
- Gently press the electrodes on your skin in the same place as before. Ask another person for help if you cannot reach the site easily. If your skin is very red, place the electrodes slightly above or below the original sites, and call your doctor if the redness does not go away in 48 hours. It is normal to note a slight pinkness of the skin after removal of the previous pair of electrodes. This pinkness will fade within minutes.
- Use **OrthoPak 2** up to 24 hours per day. Your doctor will tell you when to stop using it. After 270 days of use, or after 400 calendar days, **OrthoPak 2** will automatically turn off.

Note: The **OrthoPak 2** Bone Growth Stimulator accurately records the number of days you receive treatment. Your doctor should have a special monitor to read this information. This helps your doctor track your treatment.

Tip

Keep the audible alarm “ON” as much as possible. This alarm will help warn you of any problems with the device. During special occasions when you would like the device not to tell you audibly about stimulator problems, you may press the button for 3 seconds to turn off the audible alarm. It is recommended that you turn the audible alarm back “ON” as soon as possible by pressing the button for 3 seconds again.

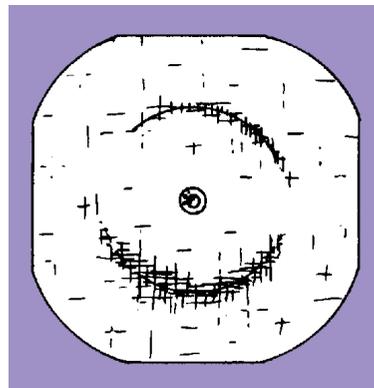


Figure 8

- Remove your **OrthoPak 2** when you bathe, shower or swim. You should also either remove the electrodes or cover them with the additional adhesive covers provided, as shown in Figure 8 if you prefer to leave the electrodes attached to the skin during showering.

Caring for Your OrthoPak® 2 Device

- Do not use cleaning products or detergents on any part of **OrthoPak 2**. You just need a damp cloth with water.
- Do handle **OrthoPak 2** carefully. Dropping or rough handling can cause damage.
- Store **OrthoPak 2** in a cool and dry place when you are not wearing it.
- Contact Biomet at 1-800-524-0677 if you believe that the device has been damaged or is operating improperly.

If You Have Questions

If you have questions about your **OrthoPak 2**, contact BIOMET Customer Service toll-free at 1-800-524-0677, 24 hours a day, seven days a week. A Customer Service Representative is available 8:30am to 5:00pm (Eastern Time Zone excluding holidays), Monday through Friday.

IMPORTANT: All medical questions must be directed to your doctor.

Ordering Information

To order supplies, simply contact Biomet directly at 1-800-524-0677. Outside the United States contact your local Biomet Distributor.

The following information is necessary to expedite any requests:

- Patient name
- Physician name
- Where to send replacement items (patient home, MD office, etc.). Please include your full name, address, city and zip.