Your Biomet® OrthoPak® System consists of:

- Biomet® OrthoPak® Stimulator
- Extra Electrodes (72R and LT-4500)
- A device holster to wear the Biomet® OrthoPak® Stimulator on the patient's waistband or belt
- Additional adhesive electrode covers to enhance electrode security (if needed)
- Two Electrode cables to connect the electrodes to the Biomet® OrthoPak® device
- Two rechargeable battery packs
- Battery charger
- An extremity band that allows the patient to wear the device on their extremity
- Foam Inserts for casted applications

Wearing the Biomet® OrthoPak®

- The Biomet® OrthoPak® Stimulator 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.

Directions For Use:

It is important that you familiarize yourself with the directions for use and the routine maintenance procedure for the Biomet® OrthoPak® Stimulator System. 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.
System Components

Electrodes
Electrodes are provided for patient use. Low profile Electrodes (Figure 1) are to be used in all applications of the Biomet® OrthoPak® Stimulator. Electrodes are mounted on a release liner and are effective for multi day use. (See instructions on package for proper electrode application.)

There are two types of electrodes that are packaged with the Biomet® OrthoPak® Stimulator System assembly: 72R and LT-4500. The 72R electrodes have green writing on their packaging. The LT-4500 electrodes have black writing on their packaging. The 72R electrodes have a hydrogel that is stickier than the LT-4500 electrode hydrogel. The patient can use whichever electrodes best suit their skin type.

Electrode Covers
Covers are to be used for non-casted applications by patients who are experiencing difficulty keeping the electrode pads in good contact with the skin.

When the electrode retainer is properly applied over the electrode pad, you will be able to shower without removing the electrode pad. (Figure 2)

Device Holster
The device holster is designed to securely hold the Biomet® OrthoPak® Stimulator in place. It has a clip on the back which allows the patient to wear the device on their waistband or belt.

Lead Wires
Two different length lead wires are included with the Biomet® OrthoPak® Stimulator system. The patient should choose the lead wire that best accommodates their needs for where they would like to wear the control unit.

Operating Instructions

Each Biomet® OrthoPak® system includes two battery packs. Always have one battery attached to the Biomet® OrthoPak® stimulator and have one battery charging in the battery charger. Both battery packs provided with the Biomet® OrthoPak® Stimulator are charged prior to being packaged. Upon receipt of the Biomet® OrthoPak® device, it is recommended that you take the second battery pack, place it into the charger, and charge fully. In the meantime, you may use the first battery pack to begin your treatment immediately. Note: The first battery pack may not provide a 24-hour treatment initially. Additional batteries are available through Biomet customer Service. Each day, preferably at the same time, you should change the battery following these instructions.

Step 1:

Battery Charging
Charging may take between two to three hours. In warmer or colder temperatures, the battery may take longer to charge.

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.

**Note:** Make sure the battery in the charger is the one supplied with your stimulator.

**Warning:** Do not attempt to charge any other battery. Do not use the battery packs supplied with this unit in any other device. Use of the Biomet® OrthoPak® battery packs in any other device may cause damage or malfunction to the batteries and/or devices. Do not short circuit, overcharge, crush, mutilate, nail penetrate, heat, reverse the + or - terminals or disassemble the battery. Do not allow metal objects to come into contact with the battery terminals. These and any other abuses of the battery may cause serious injury and/or burns. To ensure proper charging and safety, use only the charger supplied with your device. Keep battery dry. This battery pack must be disposed of properly. Disposal information can be obtained by contacting the Rechargeable Battery Recycling Corporation (RBRC) at 1-800-822-8837.

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

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 from the Biomet® OrthoPak® Stimulator and place that battery in the charger for charging. Open the battery compartment by pressing the battery cover release button and sliding the battery cover to open.
Step 2:

Preparing the System to Begin Treatment

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 electrode packet. Consult your local Biomet representative should you have questions about your 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 adjacent to the original sites. If redness does not go away after 48 hours with the electrodes moved, you should contact your prescribing physician.

Place the device in a comfortable and convenient location for you to wear for your prescribed treatment period. If you decide to place the device in the holster, place the holster in a comfortable and convenient location that is close to your fracture site.

Connect the two electrode wires into the electrode cable. Insert the electrode cable plug into the jack at the top of the stimulator. Choose the electrode cable that reaches from the location of the device or device holster to your fracture site (where your electrodes should be placed). The device holster can be worn on a belt, attached to your waistband, or clipped onto the extremity band.

Remove the fully charged battery from the battery charger. The battery is now ready for connection to the Biomet® OrthoPak® Stimulator.

Insert the battery into the Biomet® OrthoPak® Stimulator by placing it into the battery compartment (replace the cover by sliding back to its closing position). 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 “✓” icon (Figure 4).

If the audible alarm and the amber light flashes with the indicator icon blinking, the battery is low. Install a fully charged battery.

If the audible alarm is beeping, the orange light is blinking, and the icon is displayed, 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 with your stimulator. If the alarm stops, the original cables are defective. If the icon appears, there is a problem with the stimulator. DO NOT ATTEMPT TO FIX IT YOURSELF. Contact Biomet or your sales representative.

Helpful 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 Biomet® OrthoPak® 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.
Step 3:

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

Once daily, patients should do the following:
A. Slide down the battery door on the back of the stimulator and remove the depleted battery.
B. Remove the fully charged battery from the battery charger (see preparing the System to Begin Treatment) and place the fully charged battery pack into the Biomet® OrthoPak® Stimulator.
C. Place the depleted battery pack 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 Biomet® OrthoPak® Stimulator needs a freshly charged battery, the following will occur:
1. The Biomet® OrthoPak® Stimulator display will indicate the symbol for low battery. With the audio alarm engaged, beeping will occur.
2. Only after inserting a charged battery pack into the Biomet® OrthoPak® Stimulator will the message read ✓.

Troubleshooting - 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 Biomet® OrthoPak® Bone Growth Stimulator (See figure below) 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.

Troubleshooting-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 Biomet® OrthoPak® Bone Growth Stimulator (See figure below) 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.
**Troubleshooting - Electrodes (cont.)**

- 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. Call your prescribing physician 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.

**Note:** The Biomet® OrthoPak® Stimulator accurately records the number of days you receive treatment. This helps your doctor track your treatment.

**Helpful Tips (cont.)**

- Use the Biomet® OrthoPak® Stimulator up to 24 hours per day. Your doctor will tell you when to stop using it. After 270 continuous treatment days of the Biomet® OrthoPak® Stimulator will automatically turn off.

**Caring for Your Biomet® OrthoPak®**

- Do not use cleaning products or detergents on any part of the Biomet® OrthoPak® System. Please use a damp cloth.
- Do handle the Biomet® OrthoPak® Stimulator carefully. Dropping or rough handling can cause damage.
- Store the Biomet® OrthoPak® Stimulator in a cool and dry place when you are not wearing it.
- Contact Biomet if you believe that the device has been damaged or is operating improperly.

**If You Have Questions**

If you have questions about your Biomet® OrthoPak® Stimulator, contact BIOMET domestically at 1-800-526-2579 or 1-973-299-9300 if calling from outside the United States. Representatives are available from 8:30am to 5:00pm (EST), Monday through Friday. At other times, please leave a clear message for a return call by the next business day.

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

**Ordering Information**

To order supplies, simply contact Biomet directly. The following information is necessary to expedite any requests:

- Patient name
- Physician name
- Address to send replacement items (patient home, MD office, etc.)

_Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician._

**Single Patient Use/Prescription Only**

**Disposal Instructions**

When treatment has concluded as determined by the prescribing physician, Biomet requests that the patient disposes of the Biomet® OrthoPak® Stimulator according to local statutes and regulations.
Indications for Use
The Biomet® OrthoPak® Stimulator 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 Biomet® OrthoPak® Stimulator 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 the Biomet® OrthoPak® Stimulator. 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 present. 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 Biomet® OrthoPak® 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.

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.