

Your progress. Our promise.®

*Biomet® OrthoPak®  
Non-invasive Bone Growth  
Stimulator System*

**Patient Information  
Brochure**



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## *What is the OrthoPak Non-invasive Bone Growth Stimulator System?*

Your doctor has prescribed the OrthoPak Stimulator System to help your fracture nonunion heal. The OrthoPak Stimulator System is a proven, safe and effective device that consists of two dermally applied electrodes and an electronic control unit that sends an electrical therapeutic treatment signal to your fracture nonunion site.

A nonunion is considered to be established when there are no visibly progressive signs of healing.



\*Not an actual patient.

# Biomet® OrthoPak® Non-invasive Bone Growth Stimulator System

## *The Bone Healing Process*

Bone is one of the tissues within the human body capable of healing itself when damaged, in much the same way as skin and other tissues. When you fracture a bone, the body naturally produces low level electric impulses that help to heal the fracture site. Occasionally, the fracture may not heal on its own. This will result in what is called a nonunion. The OrthoPak Stimulator System is a proven, safe, and effective method for promoting the healing of fractures that have progressed to a nonunion.

## *How does the OrthoPak Stimulator System Work?*

The OrthoPak Stimulator System delivers an electrical treatment signal that is intended to help your fracture nonunion heal. Two round lightweight, disposable, hydrogel-based electrodes are applied directly on the skin on either side of the fracture nonunion site approximately 2 to 3 inches apart. The electrodes are easy to apply and are extremely lightweight. The OrthoPak Stimulator System is battery operated with a replaceable rechargeable battery. Upon insertion of a charged battery, the OrthoPak Stimulator System is automatically activated and ready to deliver therapeutic treatment. The OrthoPak Stimulator System is portable and easy to operate. You will be able to treat your fracture nonunion while going about your daily routine, relaxing or while sleeping. Results will vary due to health, weight, activity and other variables. Not all patients are candidates for this medical device. Only a medical professional can determine the treatment appropriate for your specific condition.



## *How do I know the system is working?*

The OrthoPak Stimulator System has been designed so that it's convenient to use, comfortable to wear and safe to operate. You will not feel the OrthoPak Stimulator System therapy as it delivers the therapeutic treatment signal to the fracture nonunion site. When the system is properly activated, you will see battery and check mark symbols displayed on the controller's LCD screen. Please refer to the patient manual for a description of each symbol that may appear on the display screen. If you have any questions, please contact Zimmer Biomet's Customer Care line at 1-800-526-2579 extension 6000.

## *I have a pacemaker. Can I use the System?*

The use of a pacemaker or cardioverter must be assessed on an individual basis. Zimmer Biomet recommends that you consult with your cardiologist, who can monitor your pacemaker with an electrocardiogram while you are wearing the OrthoPak Stimulator System.

## *Is the system safe to use during pregnancy?*

Use of the OrthoPak Stimulator System during pregnancy has not been evaluated; therefore it is not recommended.

## *Is the system MRI safe?*

MRI scans and procedures should not be performed until the OrthoPak Stimulator System has been completely removed.

## *How long will I have to treat with the device?*

The OrthoPak Stimulator System is designed to deliver 270 days of continuous therapeutic treatment. The indicated treatment time is 24 hours per day. Certain factors such as smoking and instrumentation may factor into the duration of your treatment. Your doctor will closely monitor your healing progress to determine how long you should wear the device. It is important that you wear the device as prescribed.



\*Not actual patients.

### *Will my insurance cover the cost of the device?*

Insurance coverage varies depending on your insurance plan. The OrthoPak Stimulator System is generally accepted by Medicare, Medicaid and workers compensation, as well as by private and public health plans. Zimmer Biomet's Patient Advocacy Group is available to assist you and discuss any questions regarding insurance coverage, deductibles and potential out-of-pocket expenses. You may contact our Patient Advocacy Group at 1-888-236-3652

### *What is the process for obtaining a OrthoPak Stimulator System?*

You can only obtain the OrthoPak Stimulator System with a doctor's prescription.

### *Who do I contact if I have questions?*

Zimmer Biomet Customer Care Representatives are ready to answer your questions at 1-800-526-2579 extension 6000.

## Zimmer Biomet - A Name You Can Trust

Zimmer Biomet non-invasive stimulation devices trace their lineage to Electro-Biology, Inc. (EBI), an industry pioneer that introduced the world's first FDA approved electrical non-invasive bone growth stimulation device more than 40 years ago. Zimmer Biomet's extensive sales and customer service support helps both physicians and patients obtain access to appropriate therapeutic treatment technologies and works with each patient to optimize and monitor compliance, track progress and assist with insurance reimbursement.

## View the Patient Video

To learn more about how to properly wear the OrthoPak Stimulator System, please visit:

<https://zimmerbiomet.tv/videos/2226>

**INDICATION:** The Biomet OrthoPak Non-invasive 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 - P850022/S017.

**USAGE:** All OrthoPak Bone Growth Stimulator Systems are designed to deliver 270 days of continuous therapeutic treatment for 24 hours per day. The recommended daily therapeutic treatment is continuous for 24 hours. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only - Prescription Only - Single Use Only - Do Not Reuse.

**CONTRAINDICATIONS:** The use of these device systems is contraindicated if the individual has synovial pseudarthrosis.

For complete prescribing information including contraindications, warnings, and precautions, please refer to the Biomet OrthoPak Non-invasive Bone Growth System Complete Manual and Package Insert PN1067799-00 or call 1-800-526-2579 extension 6000.



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