

#### Biomet OrthoPak

Non-invasive Bone Growth Stimulator



**Frequently Asked Questions** 

#### **ABOUT**

#### Why are bone growth stimulators prescribed?

Physicians may prescribe a bone growth stimulator to aid in the bone healing process. The Biomet® OrthoPak® Non-invasive Bone Growth Stimulator is an FDA approved, clinically proven, nonsurgical treatment device prescribed by physicians for over 35 years to aid in the healing of nonunion fractures.

#### How does the OrthoPak® device work?

The Soft-Touch® electrodes that accompany the OrthoPak® stimulator are placed on each side of the treatment site; 180 degrees apart from one another. The Soft-Touch® electrodes deliver a safe and scientifically proven stimulation technology called capacitive coupling. The area surrounding the electrodes is stimulated thus inducing the body's natural healing mechanisms to safely and effectively promote bone growth at the targeted treatment site.



## How can patients confirm the device is working?

When the device is properly activated, the blinking check mark on the controller's display indicates treatment is in progress. If the system is not properly activated and/or the system's components accidentally disengage, an audible and visual alert will prompt the patient that the device is not functioning properly.

#### USE

#### How long is the OrthoPak® device worn?

The OrthoPak® device is a unique, nonsurgical treatment device that may be utilized continuously each day following surgery to help promote the recovery and healing process. The prescribing physician will determine a customized treatment for the patient including when to discontinue treatment.

## Can the OrthoPak® device be used by pregnant or nursing women?

The effects of the stimulation treatment have not been studied during pregnancy or nursing so the prescribing physician should be consulted prior to use.

## Can the OrthoPak® device be worn with a pacemaker?

The use of the OrthoPak® device and a pacemaker or cardioverter can be assessed on an individual basis. The OrthoPak® device is not contraindicated for patients with pacemakers, however, it is recommended a cardiologist evaluate any potential interaction prior to use.

## How often does the battery need to be replaced?

The battery packs last approximately 24 hours. It is recommended to change the battery pack daily.

## How often should the electrodes be replaced?

The disposable Soft-Touch® electrodes are intended to be replaced at leisure within 1-7 days. With continuous use, the hydrogel on the electrodes may dry out. The electrodes may be renewed by dampening the gel area on the electrode or replacement electrodes may be ordered.

#### CARE

#### How may additional supplies be ordered?

Additional supplies including the Soft-Touch® electrodes and optional cover patches may be ordered free of charge by calling the EBI® Customer Care team at 800-526-2579.

#### Can the OrthoPak® device be worn while traveling?

Yes. The OrthoPak® device is comfortable and discreet and may be worn while traveling to continue therapeutic treatment while on the go. If traveling with the OrthoPak® stimulator on an airplane, it's recommended to remove the device prior to going through security at the airport and to keep the Patient Manual with the device at all times.

## What happens to the device when treatment is complete?

Once the prescribing physician has determined treatment completion, the device may be disposed according to local governing ordinances. The EBI® Customer Care team may also be contacted at 800-526-2579 to support device disposal.

#### How should the OrthoPak® device be stored and cleaned?

When not in use, the OrthoPak® device should be stored in a cool and dry place. A damp cloth may be used to clean the device. Cleaning products or detergents should not be used.

## Who do patients call with additional product questions or concerns?

Patients may call the EBI® Customer Care team at 800-526-2579.

#### COVERAGE

### Is the OrthoPak® device covered by insurance?

Each patient has a different insurance coverage policy. The OrthoPak® device is covered by Medicare, Medicaid, and most commercial healthcare plans along with worker's compensation.

#### Does the OrthoPak® device need to be preauthorized?

If pre-authorization is required, an EBI® representative will verify the patient's eligibility and benefit levels to obtain an advanced preauthorization prior to the patient receiving the device.

# Are there additional support options provided for patients with financial concerns?

Yes. A dedicated EBI® Patient Advocacy Group is available to assist all OrthoPak® patients with financial concerns. The patient may call the EBI® Patient Advocacy Group directly at 888-236-3652.



## LEADING THE INDUSTRY IN BONE GROWTH STIMULATION

As the pioneer of bone growth stimulation, EBI has been leading the industry for almost half a century with the largest portfolio of clinically proven solutions and is dedicated to advancing their mission of helping people heal to restore their daily life.

#### EBI, LLC

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#### Legal Manufacturer

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Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Highridge Medical or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Highridge Medical. The 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. Contraindicated if the individual has synovial pseudarthrosis. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. HM431 REV A 01/25. ©2025 EBI, LLC. All rights reserved.