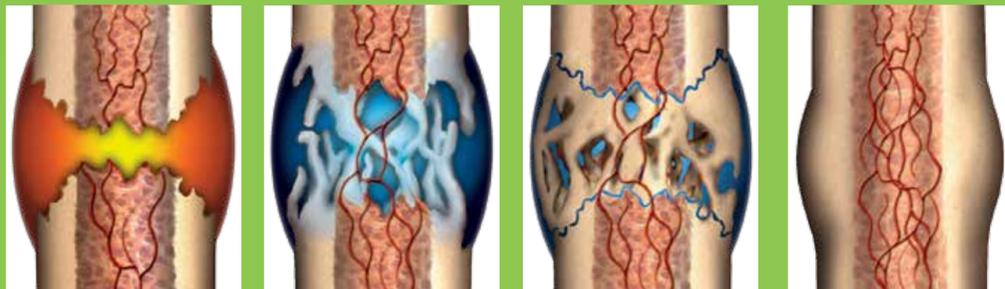


# How EXOGEN Works

Inside the body's natural bone healing process



## Inflammation

When a bone breaks, white blood cells move in to clean up debris created by the break. This creates inflammation, which triggers the growth of new blood cells — the first stage of healing.

## Soft Callus

Blood cells divide and multiply near the break and new blood vessels develop to fuel the repair process. The body also begins to create fibrous tissue to bridge the break in the bone. This material is called the soft callus.

## Hard Callus

The body gradually replaces the soft callus with a hard callus, connecting the bone fragments more solidly. This stronger callus, which creates a bulge at the site of the fracture, can generally be seen in X-rays just a few weeks after the fracture occurs.

## Bone Remodeling

In the final stage of bone fracture healing, the body replaces old bone with new in a process called remodeling. Remodeling makes bones stronger and more compact and blood circulation in the bone improves.

## How EXOGEN ultrasound enhances the healing process

### 1. Stimulation

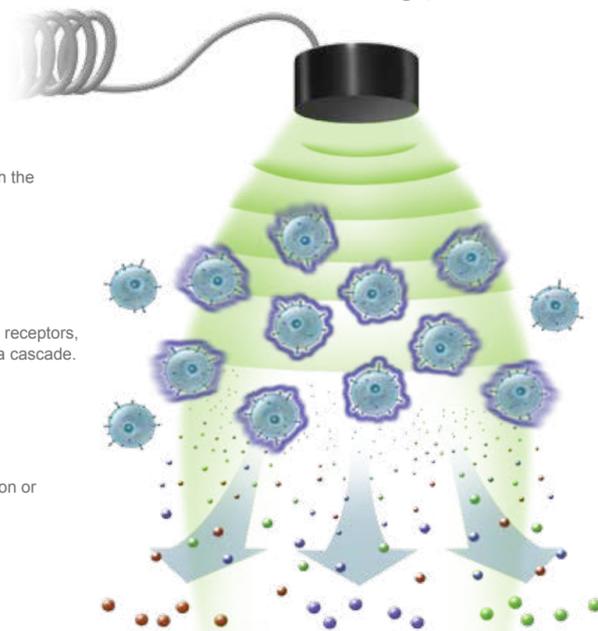
EXOGEN sends ultrasound waves through the skin and soft tissue to reach the fracture.

### 2. Activation

The ultrasound waves activate certain cell receptors, setting off a series of reactions known as a cascade.

### 3. Upregulation

EXOGEN ultrasound increases upregulation or processes critical to bone repair.<sup>6-8</sup>



### \*Summary of Indications for Use:

The EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of established non-unions\* excluding skull and vertebra. In addition, EXOGEN is indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization.

There are no known contraindications for the EXOGEN device. Safety and effectiveness have not been established for individuals lacking skeletal maturity, pregnant or nursing women, patients with cardiac pacemakers, on fractures due to bone cancer, or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel. Full prescribing information can be found in product labeling, at [www.exogen.com](http://www.exogen.com), or by calling customer service at 1-800-836-4080.

\*A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

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#1  
prescribed bone  
healing system<sup>1</sup>

Only FDA-approved bone  
healing device with

38%  
accelerated healing of  
indicated\* fresh fractures<sup>2,3</sup>

86%  
heal rate for fractures not  
healing on their own<sup>4</sup>

20  
minute daily  
treatment

## EXOGEN Patient Resource Guide

The EXOGEN® Ultrasound Bone Healing System is the only FDA-approved bone healing device that uses safe, effective ultrasound waves to stimulate the body's natural healing process.<sup>5</sup>



**exogen**  
ultrasound bone healing system

**bioventus**

# Patient Support Tools

## EXOGEN Performance Program

The EXOGEN Performance Program guarantees that if your non-union† fracture has not shown progression of healing, and you have met the requirements of the program, Bioventus will refund all out-of-pocket costs.



## Treatment Tracking Calendar

EXOGEN's built-in treatment tracking calendar helps you stay consistent with your daily treatments by indicating completed and missed treatments on the monthly calendar.



Missed treatment

Completed treatment

Compliance rate to date

## 20-Minute Treatment

With treatments lasting just 20 minutes, EXOGEN can fit conveniently into your day.

## Customer Support

EXOGEN Customer Support is available to answer questions and help maintain continuity of treatment at 1-800-836-4080.

## Smartphone App with Treatment Reminder

EXOGEN CONNECTS is a free smartphone app that sends automated treatment reminders and provides helpful healing information.



### 1. Download

The EXOGEN CONNECTS app, available on the App Store, is easy to download and activate.



### 2. Receive

Patients receive daily treatment reminders on their smartphone.



### 3. Treat

Automated reminders encourage patients to complete their daily 20-minute treatment.



### 4. Heal

Using EXOGEN as prescribed can help put patients on the road to faster healing.

# The EXOGEN Performance Program

## EXOGEN may help heal your non-union fracture

EXOGEN has a high heal rate for fractures that won't heal on their own, also known as non-union fractures.

The program guarantees that radiographic healing progression will be shown in non-union fractures. If the requirements of the program are met and no healing progression is shown, out-of-pocket costs will be refunded to the patient.

## Adherence to prescribed treatment is essential to your recovery

EXOGEN has been shown to be effective when used daily for 20-minute treatments. To be eligible for the program, you must treat your fracture with EXOGEN for 20 minutes a day, for a minimum of 120 days, with a 90% minimum adherence to the treatment regimen. The EXOGEN device contains an internal patient usage monitor that records the date, time, and duration of each treatment. This monitor will be utilized to confirm that the 90% treatment compliance threshold is met and the device has not been modified or altered. Any devices which have been modified and/or altered will not be eligible to participate in the EXOGEN Performance Program.

If the requirements of the program are met and no healing progression is shown, out-of-pocket costs will be refunded to the patient.

- The treatment period starts from the first treatment with the EXOGEN device and until your prescribing physician's assessment is made (minimum 120 days).
- The EXOGEN Performance Program applies only to non-union fractures (except skull and vertebrae).
- Absence of healing (progression to bony union) is measured by your physician's written evaluation of X-Rays taken prior to your fitting of EXOGEN ultrasound and at least 120 days there after (or beyond) of first use.
- Once we receive and confirm the program criteria are met, you are eligible for a refund of your out-of-pocket costs for the purchase of your EXOGEN device.

# Patient Claim for Refunds

Please contact Customer Service at 1-800-836-4080 for assistance. All claims must be accompanied by the following:

- Prescribing physician's written assessment
- The prescribed EXOGEN device

Claims must be received at Bioventus within one year after the EXOGEN device is applied.

No refund will be made if examination of the returned EXOGEN device reveals that it has been deliberately rendered inoperative or altered in any way.

# FAQ

## About EXOGEN

### Will EXOGEN help heal my fracture?

Clinical studies show that EXOGEN speeds up healing of indicated\* fresh fractures by 38%<sup>2,3</sup> and heals breaks not healing on their own at a high heal rate of up to 86%.<sup>4</sup>

### Is EXOGEN treatment painful?

Most patients don't feel anything at the treatment site, while some patients report experiencing a tingling sensation.

### How will I know if the EXOGEN unit is working?

Your device is working properly when you see the display screen counting down from 20 minutes during treatment. Your physician will update you on your healing status at follow-up appointments.

### How long will I need to use EXOGEN?

Different fractures heal at different rates. Your physician will determine the length of your treatment during follow-up appointments.

### What if I don't place the EXOGEN transducer in exactly the right spot?

Best results are achieved when the EXOGEN transducer is placed at the location marked by your physician.

### Will having two or more treatments per day result in better or faster healing?

Clinical studies have evaluated the effectiveness of EXOGEN with one 20-minute treatment per day. Multiple or longer duration daily treatments have not been studied.

### What if I miss a treatment?

Try to get back on schedule as soon as possible. To stay consistent with your treatments, check the treatment tracking calendar on your device and identify a convenient time to use EXOGEN each day. You can also download EXOGEN CONNECTS, a free smartphone app that sends automated treatment reminders.

### Does insurance cover the cost of EXOGEN?

EXOGEN is covered by the majority of insurance plans, but most require a patient co-pay. Your Bioventus sales representative can help you determine your individual coverage.

### Will I receive a bill?

You will likely receive an Explanation of Benefits (EOB) statement, which is not a bill. If you do receive a bill, contact your Bioventus sales representative for assistance.

### Am I renting the EXOGEN unit?

EXOGEN is for single-patient use only and does not have a rental option. You purchase EXOGEN through insurance and/or patient co-pay.

### What should I do with my EXOGEN unit once I've completed treatment?

You own the unit, so you can keep it or dispose of it per your local waste disposal laws. Please contact Bioventus Customer Service at 1-800-836-4080 if you need guidance on disposal.

### Who do I contact if I have questions about EXOGEN?

Please contact Customer Service at 1-800-836-4080.

## About the EXOGEN Performance Program

### What is the EXOGEN Performance Program?

The EXOGEN Performance Program is designed to encourage your compliance with EXOGEN treatment and provide you added confidence that EXOGEN will help your fracture progress towards healing. Eligible program participants are guaranteed radiographic healing progression will be shown in non-union fractures or your out of pocket costs paid for the EXOGEN device will be refunded to you.

### Who is eligible to participate in the EXOGEN Performance Program?

All EXOGEN patients who have been diagnosed by a health care professional as having a non-union fracture (skull and spine fractures are excluded). A non-union fracture is considered to be established when the fracture site shows no visibly progressive signs of healing.

### What is required to participate in the EXOGEN Performance Program?

You must utilize your EXOGEN device for 20 minutes a day and complete at least 90% of treatments during your treatment period.

### When does the EXOGEN Performance Program start?

The treatment period starts from your first EXOGEN treatment and until your fracture assessment is made by your physician at least 120 days there after (or beyond) of first use. The program is subject to cancellation at any time.

### What if my fracture does not show any improvement?

The absence of fracture healing (progression to bony union) must be measured and confirmed by your physician in writing and sent to Bioventus. In addition, you need to send Bioventus your EXOGEN unit to confirm your actual use of the device. Once we receive and confirm the criteria, a refund will be issued for your direct EXOGEN device purchase.