



#1

prescribed bone
healing system¹

20

minute daily
treatment

86%

heal rate for fractures not
healing on their own²

Up to

58

days accelerated
healing of fresh tibial
diaphysis fractures³

exogen[®]

ultrasound bone healing system

EXOGEN 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.

How EXOGEN Works

EXOGEN jump starts bone healing by stimulating your body's natural healing process.

1. Stimulation⁴

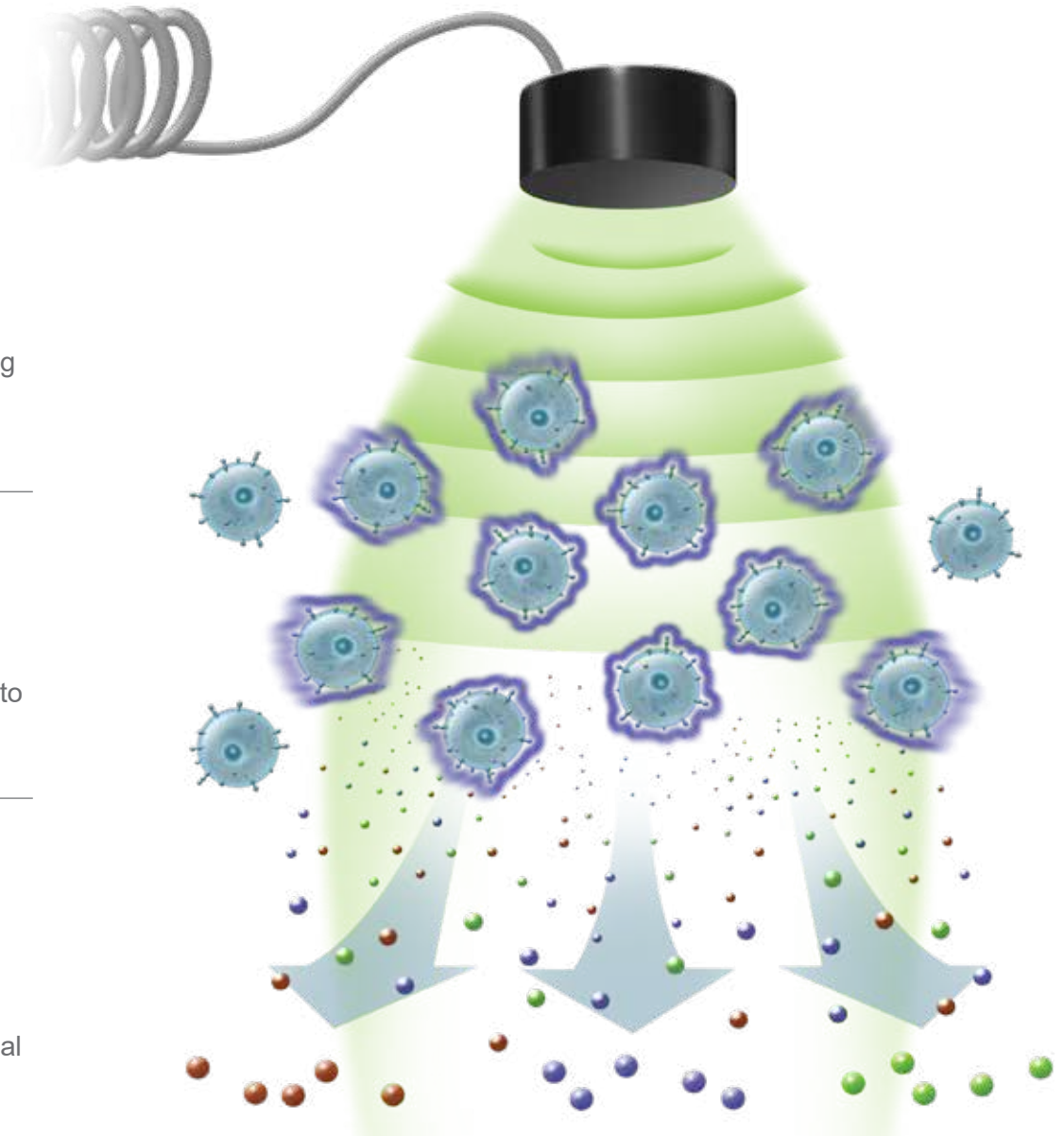
EXOGEN sends ultrasound waves through the skin, creating movement that stimulates your body's cells.

2. Activation⁵

The ultrasound waves activate cells in your body, which leads to gene upregulation.

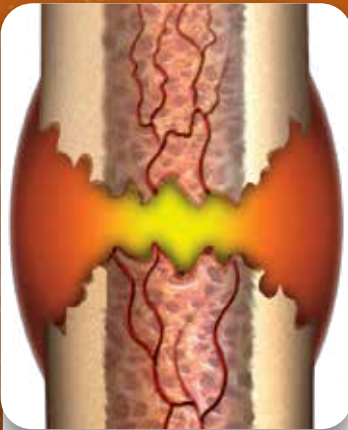
3. Upregulation⁶

Upregulation is increased by EXOGEN ultrasound. This process increases factors that help jump start your body to heal your fracture.



The Stages of Bone Healing:⁷

A look inside the body's natural healing process



1

Inflammation

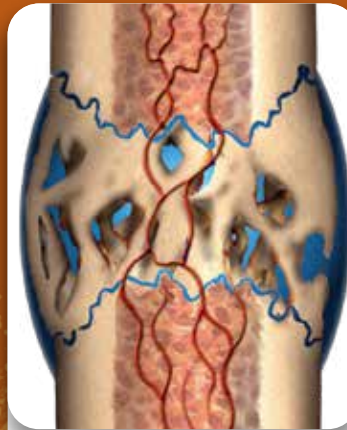
When a bone breaks, white blood cells move in to clean up debris created by the break. This creates inflammation, which triggers the growth of new blood cells — the first stage of healing.



2

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.



3

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.



4

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.

The EXOGEN @Home Experience

The EXOGEN @Home Experience gives you support while using EXOGEN to heal your fracture. Resources are available 24/7 and include videos with topics such as how to use EXOGEN, and how EXOGEN works.



**Scan to learn more about the
EXOGEN @Home Experience**

EXOGEN Connects App

Your journey to healing will be easier with a reliable guide at your side. That's where EXOGEN Connects comes in. Our free app will be with you throughout your healing journey. Features include:

- A Quick Instruction Guide
- The ability to sync treatment reminders with your smart device
- Inspirational user testimonials
- Social links so you can connect with other users and share your EXOGEN story



Download on the
App Store



GET IT ON
Google Play

Download EXOGEN Connects now!

It's Easy to Stay on Track

Treatment Tracking Calendar

EXOGEN's built-in calendar helps you stay consistent with your daily treatments by indicating completed as well as missed treatments.

20-Minute Treatment

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

- Missed treatment
- Completed treatment
- Compliance rate to date



Customer Support

EXOGEN Customer Support is available to answer questions and help maintain continuity of treatment. Call **1-800-836-408**



Follow us on Instagram

Share your story tagging @ExogenBoneHealing

Frequently Asked Questions

Is EXOGEN safe?

EXOGEN is FDA-approved and has been shown to be safe in clinical studies that support its indicated uses.

Is EXOGEN treatment painful?

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

Will EXOGEN help heal my fracture?

Clinical studies show that EXOGEN heals nonunion fractures (breaks not healing on their own) at a high heal rate of 86%² and speeds up healing of indicated fresh fractures (newly broken bones) by 38%.^{3,8}

Does EXOGEN have any contraindications?

There are no known contraindications for the use of the EXOGEN device. The EXOGEN package insert includes a section on Precautions and Warnings that highlights situations in which the safety and effectiveness of EXOGEN has not been established, such as specific patient circumstances involving certain types of medication or medical problems other than fractures.

Can I use EXOGEN if I have a pacemaker?

The operation of active, implantable devices such as cardiac pacemakers may be adversely affected by close exposure to the EXOGEN device. If you have a pacemaker, talk with your doctor or cardiologist to find out if EXOGEN is right for you.

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 each treatment. Your physician will update you on your healing status at follow-up appointments.

What if I run out of coupling gel?

Mineral oil can be used in place of the coupling gel that comes with the EXOGEN device. Petroleum jelly, however, is not an acceptable substitute. You may also request more coupling gel by calling Bioventus Customer Service at 1-800-836-4080.

How long will I need to use EXOGEN?

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

Will EXOGEN work through clothing?

Ultrasound waves cannot travel through air or clothing. The EXOGEN transducer requires direct contact with skin and the use of a coupling gel (included with your device).

Best results are achieved when the EXOGEN transducer is placed at the location marked by your physician. Consult with your physician if you are unsure of where to place the EXOGEN transducer.

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.

What if I can't do my treatment the same time every day?

It is better to do a treatment at some point every day than skip a treatment for the day, and resume the same time every day as your schedule allows.

Does insurance cover the cost of EXOGEN?

EXOGEN is covered by the majority of insurance plans, but most require a patient copay. Your Patient Financial Service representative can help you determine your individual coverage.

Will I receive a bill?

Yes, you may receive a bill from Bioventus for any deductible and coinsurance due, as determined by your insurance carrier.

Am I renting the device?

EXOGEN is for single-patient use only and does not have a rental option. You purchase EXOGEN through insurance and/or patient deductible and coinsurance if applicable, depending on your insurance coverage.

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** or **customerservice@bioventusglobal.com** if you need guidance on disposal.

Whom should I contact if I have questions about EXOGEN?

Please contact Customer Service at **1-800-836-4080** or **customerservice@bioventusglobal.com**.

References:

1. iData Research. Trauma devices market report suite, United States, 2019-2025. Posted 2019. <https://idataresearch.com/product/trauma-devices-market-united-states/> 2. Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH. Low-intensity pulsed ultrasound in the treatment of nonunions. *J Trauma*. 2001;51(4):693-703. doi:10.1097/00005373-200110000-00012 3. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kiloynne RF. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. *J Bone Joint Surg Am*. 1994;76(1):26-34. doi:10.2106/00004623-199401000-00004 4. Greenleaf JF, Kinnick RR, Bronk JT, Bolander ME. Ultrasound induced tissue motion during fracture treatment?, *Ultrasound Med Biol*. 2003;29(5):S157-8. doi:10.1016/S0301-5629(03)00634-3 5. Tang CH, Yang RS, Huang TH, et al. Ultrasound stimulates cyclooxygenase-2 expression and increases bone formation through integrin, focal adhesion kinase, phosphatidylinositol 3-kinase, and Akt pathway in osteoblasts, *Mol Pharmacol*. 2006;69(6):2047-57. doi:10.1124/mol.105.022160 6. Naruse K, Sekiya H, Harada Y, et al. Prolonged endochondral bone healing in senescence is shortened by low-intensity pulsed ultrasound in a manner dependent on COX-2, *Ultrasound Med Biol*. 2010;36(7):1098-108. doi:10.1016/j.ultrasmedbio.2010.04.011 7. Azuma Y, Ito M, Harada Y, Takagi H, Ohta T, Jingushi S. Low-intensity pulsed ultrasound accelerates rat femoral fracture healing by acting on the various cellular reactions in the fracture callus. *J Bone Miner Res*. 2001;16(4):671-80. doi:10.1359/jbmr.2001.16.4.671 8. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. *J Bone Joint Surg Am*. 1997;79(7):961-73. doi:10.2106/00004623-199707000-00002

*Indications for Use:

The EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of established nonunions* excluding skull and vertebra.

The EXOGEN device has also been reported as effective as an adjunctive non-invasive treatment of established nonunions in patients:

- With internal or external fracture fixation hardware present. EXOGEN cannot penetrate metal and therefore should not be applied directly over hardware.
- Undergoing treatment for infection at the fracture site. EXOGEN is not intended to treat the infection.
- Believed to have diminished bone quality. EXOGEN is not intended to treat diminished bone quality.

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.

*A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Full prescribing information can be found in product labeling, at www.exogen.com or by contacting customer service at 1-800-836-4080.



For help with your device, please call customer service at:

1-800-836-4080

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Innovations For Active Healing