

exogen[®]

ultrasound bone healing system



Safe, painless, easy fracture healing

#1 PRESCRIBED BONE HEALING SYSTEM IN THE UNITED STATES

The Healing Advantage

Some fractures can be difficult to heal. EXOGEN uses safe, painless, low-intensity ultrasound waves to amplify the body's natural bone repair processes.*

An FDA-approved device, EXOGEN has been prescribed for over **25 years** to help more than a million patients worldwide.

Easy to use

The user-friendly, single-button device arrives ready to use.

Covered by many insurers

Medicare and the majority of insurance plans cover EXOGEN.

Convenient

Each daily treatment takes just **20 minutes**.

Encouraging

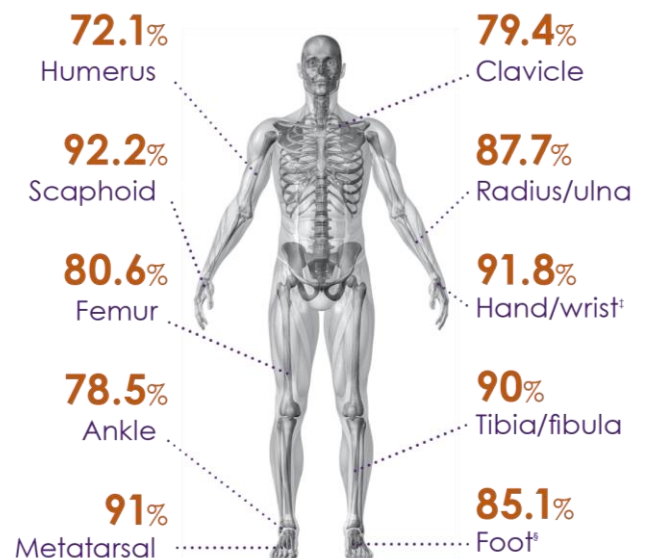
A built-in treatment tracking calendar will help the patient stay motivated to reach treatment goals.

Effective

Clinical studies show that EXOGEN heals up to 86% of nonunion fractures and speeds up healing of indicated fresh fractures by 38%.[†]

Heal rate of common fractures treated with EXOGEN

In many cases, EXOGEN may prevent the need for further surgery.





Heal rates based on fracture age of 91-365 days.

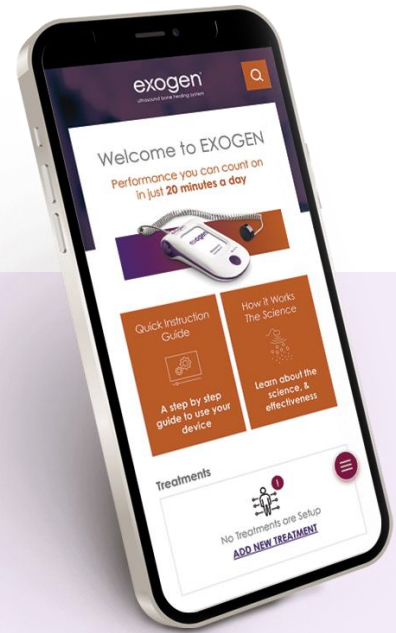
[†]Includes metacarpal, carpal, and hamate.

[§]Includes talus, calcaneus, tarsal navicular, cuboid, and cuneiform.



EXOGEN provides patients:

- Dedicated **EXOGEN** Care Team
- The **EXOGEN CONNECTS** app, with resources for the patient throughout the healing journey
- The **EXOGEN @Home Experience**, with helpful information available to the patient 24/7
- **@ExogenBoneHealing** on  



EXOGEN Ultrasound Bone Healing System

EXOGEN is a fracture-healing device that uses safe, effective, low-intensity pulsed ultrasound to help stimulate the body's natural healing process. Clinical studies show that EXOGEN heals fractures not healing on their own at a high incidence, healing up to 86% of nonunion fractures, and speeds up the healing of indicated fresh fractures by 38%.†



EXOGEN is the first FDA-approved bone-healing device with:

- ✓ 20-minute, noninvasive, daily treatment that fits easily into patient's lifestyle
- ✓ 86% nonunion heal rate
- ✓ Demonstrated 58 days accelerated healing in fresh tibial diaphysis fractures
- ✓ 91% clinically proven adherence rate among patients

The device's easy-to-use design, treatment tracking calendar, and short daily treatment time make EXOGEN an ideal option for patients and promotes treatment adherence.

*The clinical relevance of in vivo findings is unknown.
†Summary of Indications for Use.

Mechanism of Action

EXOGEN jumpstarts bone healing by stimulating biological processes

Stimulation

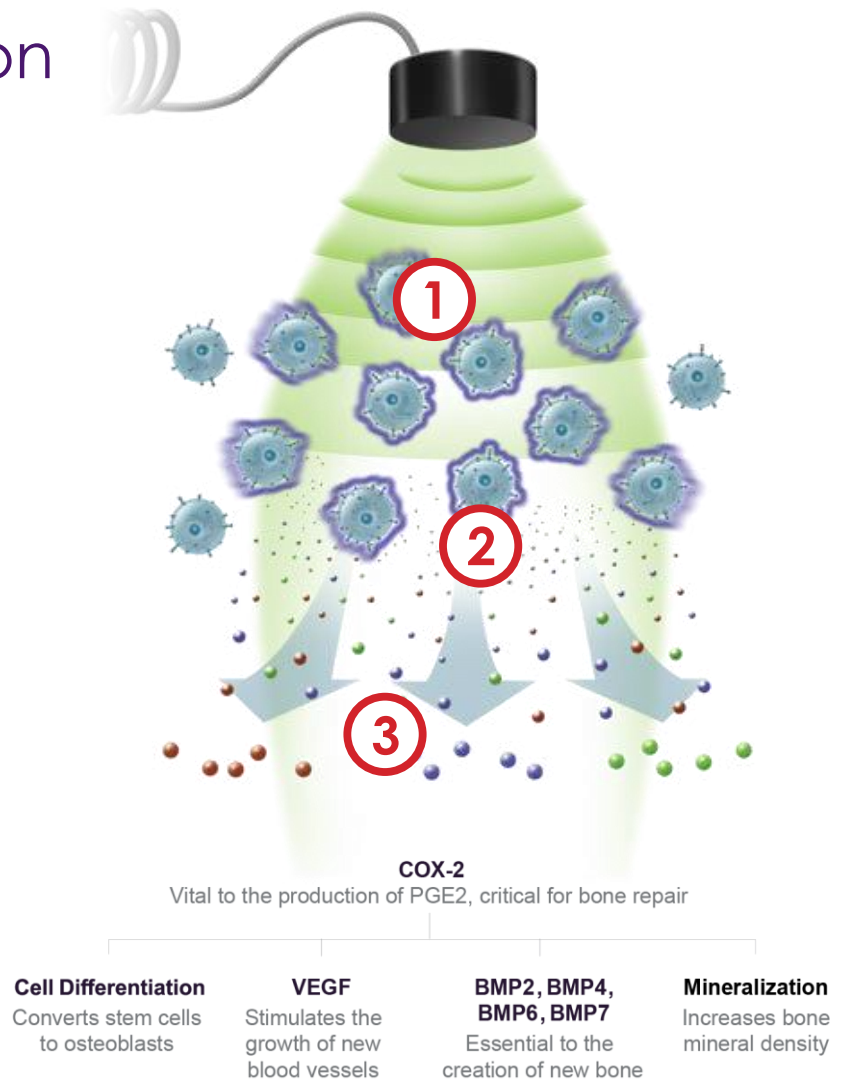
EXOGEN sends ultrasound waves through the skin and soft tissue to the fracture.*

Activation

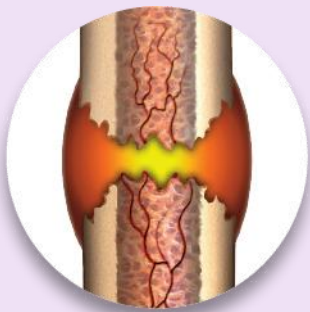
EXOGEN ultrasound activates cell surface mechanoreceptors called integrins, initiating an intracellular cascade that leads to upregulation.*

Upregulation

EXOGEN ultrasound increases expression of genes and proteins critical to bone healing.*



EXOGEN accelerates fracture healing at every stage.*



Inflammation



Soft Callus



Hard Callus

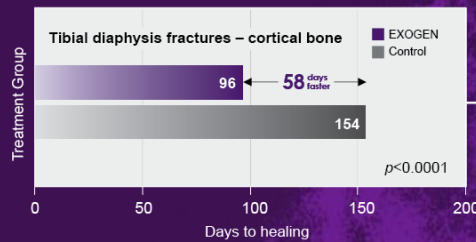


Bone Remodeling

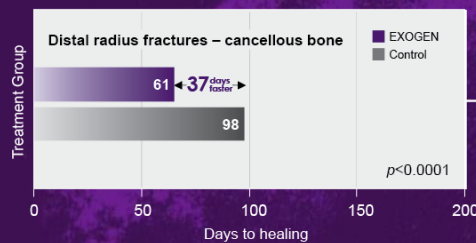
*The clinical relevance of preclinical results is unknown.

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EXOGEN is the first FDA-approved bone healing device that delivers accelerated healing of indicated fresh fractures.*



58
days faster
with EXOGEN



37
days faster
with EXOGEN

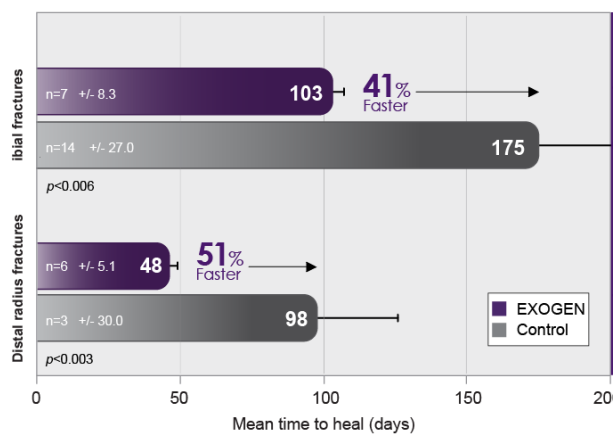
*Summary of Indications for Use.

EXOGEN mitigates the negative impact of certain comorbidities on bone healing.

Smoking and advanced age are just some of the risk factors known to impede fracture healing.

EXOGEN has been shown to accelerate the fracture healing process for patients with certain comorbidities that can delay fracture healing, putting the fractures at risk of nonunion.

One clinical study demonstrated that EXOGEN accelerated distal radius fracture healing by as much as 51% in patients who smoked, versus the incidence of healing in smokers with fractures not treated with EXOGEN.*



72
days faster
with EXOGEN

50
days faster
with EXOGEN

*51% acceleration [EXOGEN (n) = 6; Placebo (n) = 3]

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BONE HEALING **PROVEN.**

#1 Prescribed bone healing system in the United States

20min per day

38% accelerated healing of indicated fresh fractures*

86% resolution of nonunions

91% patient adherence to treatment

Bone stimulator brands and features (listed in order of treatment time)

Product, Manufacturer	Technology	Treatment Time	Indicated Fresh Fractures*	Nonunion	Level 1 ^{†, ‡} Studies	Patient App
EXOGEN Ultrasound Bone Healing System, Bioventus	Low-intensity Pulsed Ultrasound	20 minutes	Yes	Yes	8	Yes
AccelStim™ Bone Healing Therapy, OrthoFix®	Low-intensity Pulsed Ultrasound	20 minutes	Yes	Yes	0	No
CMF OL1000™ Bone Growth Stimulator, Enovis™	Combined Magnetic Field (CMF)	30 minutes	No	Yes	0	No
PhysioStim™ Bone Healing Therapy, OrthoFix	Pulsed Electronic Magnetic Field (PEMF)	3 hours minimum	No	Yes	0	Yes
Biomet® EBI® Bone Healing System, ZimVie	Pulsed Electronic Magnetic Field (PEMF)	10 hours	No	Yes	2	No
Biomet OrthoPak® Non-invasive Bone Growth Stimulator, ZimVie	Capacitive Coupling (CC)	24 hours	No	Yes	2	No
OsteoGen™ Bone Growth Stimulator, Zimmer Biomet	Direct Electrical Current (implanted)	N/A – device is implanted	No	Yes	0	No

*See the Summary of Indications for Use.

[†]These studies include evaluations of applications to bone fractures that are not among the bone fractures indicated in the FDA-approved labeling for EXOGEN (such as distraction osteogenesis, bone transport, acceleration of scaphoid fracture, acute metatarsal fractures, acute complex tibia fractures, high tibial osteotomy, and arthrodesis).

[‡]The *Journal of Bone & Joint Surgery* Level of Evidence 2015 Ratings Table was used to define the level of each clinical study.

This table is reflective of all relevant studies to date as of July 19, 2021. Additional studies may have been published since this time.

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Summary of 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 EXOGEN.com or by contacting customer service at 1-800-836-4080.

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