

Introducing

exogen[®]

PERFORMANCE GUARANTEE

Performance you can count
on in just 20 minutes a day

Added confidence and high
treatment compliance

- High heal rate for non-union*
fractures - 86%¹
- Incentive for patients to adhere
to EXOGEN treatment



Introducing the EXOGEN Performance Guarantee

Designed to provide you added confidence that EXOGEN will help heal 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, the payment of EXOGEN will be refunded to the buyer.

Adherence to prescribed treatment is essential

EXOGEN has been shown to be effective to treat non-union when used daily for 20-minute treatments^{1,2}. To be eligible for the program, patients must treat their fracture with EXOGEN for 20 minutes a day, for a minimum of 120 days, with a minimum of 90% adherence to the treatment regimen.[‡] The non-union fracture must be stable, non-displaced, with a fracture gap of less than 10 millimeters. Vertebra and skull fractures are excluded.

The treatment period starts from the first treatment with the EXOGEN device and until your assessment is made (minimum 120 days) of first use.

Assessment of Healing Progress

Absence of healing (progression to bony union e.g. callus formation) is measured by your written evaluation of X-Rays taken prior to the patient's fitting of EXOGEN ultrasound and at least 120 days (or beyond) of first use.

Written evaluations must be made by the prescribing physician and reflected in a completed EXOGEN Performance evaluation form – available to you upon request.

Bioventus may request to receive your patient's X-Rays for any further evaluation.

Claims for Refunds

Please contact your Bioventus Representative, or call **0800 05 16 384** (UK) or **1800 552 197** (Ireland) for assistance. All claims must be accompanied by the following:

- Registration Form to the Performance Guarantee Program, sent to Bioventus within the first 30 days of the initial treatment
- Prescribing physician's written assessment, using the EXOGEN Performance Evaluation form
- The prescribed EXOGEN device

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

‡ 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 Guarantee.

Fracture patients are ready to heal – we're ready to support them

EXOGEN Compliance Tools

EXOGEN's Compliance Calendar can help patients use their device consistently and as prescribed.

20-Minute Treatment

With treatments lasting just 20 minutes, EXOGEN fits easily into patients daily routine.

Customer Care

EXOGEN Customer Care is available to answer questions and help maintain continuity of treatment.

References:

1. 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.
2. Gebauer D, Mayr E, Orthner E, Ryaby JP. Low-intensity pulsed ultrasound: effects on nonunions. *Ultrasound Med Biol*. 2005;31(10):1391-1402.

Summary of Indications for Use

EXOGEN is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, non-unions[†], stress fractures and joint fusion. EXOGEN is also indicated for the acceleration of fresh fracture heal time, repair following osteotomy, repair in bone transport procedures and repair in distraction osteogenesis procedures.

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

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.

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