exogen®
PERFORMANCE PROGRAM

REGISTRATION FORM

EXOGEN Serial Number: _____

Patient Information

Patient Initials	
Date of Birth (DD/MM/YYYY)	
Date of Injury (DD/MM/YYYY)	

☐ I authorise my treating facility and its staff, including my physician, to communicate my personal data (including sensitive health information) to Bioventus. Bioventus is permitted to collect, store and use this information to provide benefits in relation to the EXOGEN Performance Program and review the results of my EXOGEN treatment. Bioventus may store and access my personal data in countries outside of Great Britain and the EU, where laws may be less protective of personal data. Where it does so, Bioventus will ensure that the level of data protection applied meets applicable laws. I agree to be a minimum of 90% compliant with treatment over the course of a minimum of 120 consecutive treatment days, or when advised by my prescribing physician to end treatment.

Patient Signature: _____ Date: _____

Prescribing Physician Information

Name	
Email Address	
Hospital Name	
Defined Fracture Location	
Diagnosis	☐ Acute ☐ Delayed union ☐ Nonunion
Comorbidities	☐ Diabetes ☐ NSAID use / chronic opioid use ☐ Smoking ☐ Vascular insufficiency ☐ Obesity ☐ Nutritional deficiency ☐ Osteoporosis

I confirm that the fracture to be treated is:

☐ Stable and well-aligned
☐ Fracture gap ≤ 10 millimeters
☐ Aligned with all other EXOGEN Performance Program criteria, as described on the back of this form

I understand that if all of the above boxes are not checked, refund is not eligible under the EXOGEN Performance Program if there is failure of progression in healing.

Physician Signature: _____ Date: _____

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The EXOGEN Performance Program is a Bioventus program that refunds the payment for EXOGEN if progression of healing (progression to bony union) is not shown per criteria below. The program is also designed to help reinforce patients' adherence with the prescribed treatment.

Criteria

EXOGEN device must be prescribed by a qualified physician to treat a stable, well-aligned fracture with a fracture gap less than 10mm (excluding vertebra and skull fractures). Patients must treat their fracture with EXOGEN per product instructions, for a minimum of 120 consecutive days and achieve a 90% minimum level of adherence. The EXOGEN Performance Program Registration form must be completed by both patient and physician and submitted to Bioventus within 30 days of the start of patient treatment with EXOGEN.

Exclusions

The EXOGEN Performance Program is not valid when:

- The fracture is one or more of the following: Unstable, malaligned, greater than 10 millimeters fracture gap, vertebral or skull, pathological
- Multiple fractures locations are treated (the guarantee is valid to treat only a defined fracture)
- The device has been modified and/or altered
- Alternative interventions occurred during the 120-day treatment period
- The device was not purchased and received directly from Bioventus
- The customer did not register for the EXOGEN Performance Program within 30 days of the initial treatment
- Patients for whom EXOGEN was not prescribed
- Costs other than the purchaser's payment to Bioventus for the EXOGEN device
- Valid only in the United Kingdom
- Valid for EXOGEN 250 treatment devices or where EXOGEN 150 treatment devices have been purchased privately through self-payment
- Extension SD card has been provided
- Claims must be received by Bioventus within one year of first EXOGEN treatment date

Indications for Use: EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, nonunions,* 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 nonunion 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, including warnings and precautions, can be found in product labeling, or at EXOGEN.com/prescribing-information.

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bioventus®
Innovations For Active Healing