EXOGEN® User Guide

Read before using your device

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# EXOGEN Overview

## Indications for Use

EXOGEN is indicated for the treatment of bone fractures in adults and children weighing 30 kg or more. It is intended for single patient use only. This device is not intended for use by the individual for whom it is prescribed.

## EXOGEN Description

EXOGEN is a handheld ultrasound device designed for the treatment of bone fractures. It consists of a Device (EXOGEN), Charger (power supply), Strap, Ultrasound Gel, and Important Things to Know.

## EXOGEN Device (EXOGEN)

- **Catalog Number**: Refer to User Guide.
- **Type BF Applied Part**: The transducer, shown in Figure 2 on page 2 is an applied part.
- **EU: Not for General Waste**: This symbol indicates that EXOGEN should not be disposed of with ordinary household waste at the end of its life. For details on how to dispose of this device correctly, contact your local government waste disposal agency or your local Bioventus representative.
- **Manufacturer**

## Charger (power supply)

- **Serial number (first four digits of the serial number indicate the month and year of manufacture)**
- **WAVEFORM**: Pulsed Signal

## Strap

- **Rx Symbol**: Federal Law (U.S.A.) restricts this device to sale, distribution, or use by or on the order of a physician or properly licensed practitioner. This device is only intended for use by the individual for whom it is prescribed.

## Ultrasound Gel

- **Rx Symbol**: Federal Law (U.S.A.) restricts this device to sale, distribution, or use by or on the order of a physician or properly licensed practitioner. This device is only intended for use by the individual for whom it is prescribed.

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EXOGEN OVERVIEW

EXOGEN Overview

Indications for Use
The EXOGEN Ultrasound Bone Healing System is indicated for:

- The non-invasive treatment of established non-unions excluding skull and vertebra.
- Accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures (fractures of the end of the large bone in your forearm) and fresh, closed or Grade I open tibial diaphysis fractures (fractures in the middle 80% of the large bone in your lower leg) in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization (adult individuals eighteen years of age or older who have fractures, with or without minor skin wounds, that are placed in a cast for treatment).

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

EXOGEN Description
The EXOGEN Ultrasound Bone Healing System provides non-invasive therapy for healing non-unions and accelerating time to healing of fresh fractures. EXOGEN is designed both for use with conservatively-treated fresh fractures and non-unions, or surgically-treated non-unions. EXOGEN transmits a low-intensity ultrasound signal to the fracture site through coupling gel, with little or no sensation felt by the patient during the treatment. Low-intensity pulsed ultrasound has been shown in in-vitro and in-vivo studies to stimulate cells to produce growth factors and proteins that are important to bone healing.

The patient administers treatment at home or at work, once daily, for 20 minutes, or as prescribed by a physician. EXOGEN automatically alerts the patient in case of improper application or performance. The EXOGEN Ultrasound Bone Healing System consists of:

- One EXOGEN device, a charger, a gel bottle and strap.
- The EXOGEN device provides the treatment control circuitry, the battery supply and monitors the operation of the transducer at the fracture site. The signal specifications cannot be changed.
- Everything you need to treat your fracture is included in the EXOGEN Ultrasound Bone Healing System. (See Figure 1). If one of the items in Figure 1 is missing, please contact Customer Service at 1-800-836-4080 to receive a replacement.

EXOGEN Device (EXOGEN)
EXOGEN (Figure 2) features a transducer at the end of a coiled cord, color screen, power button and USB charging port. The cord and transducer are not removable from EXOGEN.

EXOGEN contains the internal electronics and battery. It checks the ultrasound signal to make sure EXOGEN works properly. The transducer sends low-intensity pulsed ultrasound to the fracture site through the gel. EXOGEN can also sense if gel is present on the transducer surface. EXOGEN stores and displays a calendar of daily use. This data is available to you and your physician.

EXOGEN has a mini-USB charging port to allow you to recharge the battery. EXOGEN will not communicate with any other electrical devices.

Charger (power supply)
EXOGEN is powered by a rechargeable battery. A charger (Figure 3) is included with EXOGEN. Only use this supplied charger with EXOGEN. Do not plug other chargers into EXOGEN. Other chargers may cause injury to you or others near EXOGEN as well as damage to the charger.

The USB plug end of the cord plugs into EXOGEN. The other end plugs into a wall outlet. The charger requires a standard US 120 VAC, 60 Hz, household electrical outlet. Read more about how to charge EXOGEN in “Getting Started” on page 5.

Figure 1: EXOGEN Ultrasound Bone Healing System

Figure 2 – EXOGEN Device (Part Number: 71034401)

Figure 3 – EXOGEN Charger (Part Number: 71034460)

Figure 4 – EXOGEN Strap (Part Number: 71034622)

Strap
The strap (Figure 4) is used to position the transducer over your treatment site. The strap has a port in it to hold the transducer in place. The cap holds the transducer down on the treatment site. The strap is adjustable to fit most fracture locations. If your strap does not fit the location of your fracture, please contact Customer Service at 1-800-836-4080 to find out if there is another strap which may fit better.
Important Things to Know

EXOGEN is approved for use by persons that are 18 years or older and skeletally mature. There is no maximum age limit to using EXOGEN. The anticipated education level of an EXOGEN user is to read English at an 8th Grade level or equivalent, and the ability to read and understand Western Arabic numerals. No special previous experience or skills are needed or expected to be able to operate EXOGEN. There may be physical impairments that result from the presence of a fracture, such as reduced range of motion or immobility, EXOGEN is expected to be used with one hand for guiding and holding EXOGEN. Read "Getting Started" (page 5) and "Treatment Your Fracture" (page 10) before you begin using EXOGEN.

EXOGEN Usage

EXOGEN should be used for 20 minutes per day or as prescribed by your doctor. It is important that you use EXOGEN as prescribed by your doctor to get the full benefit of the treatment. Your doctor will decide when your fracture is healed. Every fracture is different and it takes some fractures longer to heal than others. Call your doctor if you have questions or concerns about your fracture.

EXOGEN is for single patient use only. EXOGEN will deliver 300 full 20-minute treatments. If this number is reached and you are still treating your fracture under your doctor's direction, contact Customer Service at 1-800-836-4080 for instructions.

Contraindications

There are no known contraindications to the use of EXOGEN.

Warnings

The safety and effectiveness of the use of EXOGEN has not been established for:

- Fractures with post-reduction displacement of more than 50% (i.e., fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone)
- Pathological fractures due to bone pathology or malignancy (fractures due to disease)
- Pregnant or nursing women
- Individuals receiving steroid, anticoagulant, calcium channel blocker and/or diphosphonate therapy. Individuals using these therapies were excluded from the studies because of the possible effects of these therapies on bone metabolism
- Non-unions of the vertebral and the skull
- Individuals with abnormal bone density
- Fresh fracture locations other than the distal radius (end of the large bone in the forearm) or tibial (end of the large bone in your lower leg)
- Fresh fracture that are open Grade II or III (fractures with large wounds) or that require surgical intervention with internal or external fixation (screws and/or plates used to hold your broken bone in place) or that are not sufficiently stabilized (stabilization of the fracture without surgery) and cast immobilization (cast treatment)

Precautions

- EXOGEN will not correct or alter post-reduction (when your fracture is initially set and placed in a cast) aspects of a fracture such as displacement, angulation or malalignment
- The transducer, strap and gel are not sterile and placement on an open wound is not advised
- The operation of active, implantable devices, such as cardiac pacemakers may be adversely affected by close exposure to EXOGEN. The patient should avoid the patient or other person in close proximity during treatment to be evaluated by the attending cardiologist or physician before starting treatment with EXOGEN
- The cords pose a risk for strangulation. Keep out of reach of children
- Cell phones, televisions, and other devices using radio frequency energy may cause interference. This interference may cause EXOGEN to operate improperly or stop operating completely. While EXOGEN complies with the limits for Class B digital devices pursuant to Part 15 of FCC rules, it has not been studied with all brands and models of phone
- The safety and effectiveness of EXOGEN when used for more than one full 20-minute treatment period has not been studied. Patients in the clinical studies were instructed to apply EXOGEN for one treatment period of twenty-four minutes each day. The age ranges of the patients in the PMA non-union studies were 17-81. The effect of EXOGEN therapy on patients outside this age range has not been studied
- The age ranges of the patients in the PMA non-union studies were 17-81. The effect of EXOGEN therapy on patients outside this age range has not been studied
- The safety and effectiveness of the use of EXOGEN has been demonstrated for patients followed up over a period of 5.5 years (78 months) after treatment.
- When choosing a treatment site ensure that the site selected allows for full contact of the transducer face with the skin. Failure to do so may re- result in the transducer being only partially coupled to the skin. This may reduce the effectiveness of EXOGEN in treating the fracture.

Display Symbols and Descriptions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Charging Symbol</td>
<td>Flashes to show EXOGEN is plugged in and charging.</td>
</tr>
<tr>
<td></td>
<td>Battery Status</td>
<td>Shows how much charge is left in the battery.</td>
</tr>
<tr>
<td></td>
<td>Calendar X-Mark</td>
<td>A 20-minute treatment was not completed on this calendar day.</td>
</tr>
<tr>
<td></td>
<td>Calendar Checkmark</td>
<td>A 20-minute treatment was completed on this calendar day.</td>
</tr>
<tr>
<td></td>
<td>Calendar Double Checkmark*</td>
<td>Two-20 minute treatments were completed on this calendar day.</td>
</tr>
<tr>
<td></td>
<td>Calendar Double Checkmark Plus*</td>
<td>Three or more 20-minute treatments were completed on this calendar day.</td>
</tr>
<tr>
<td></td>
<td>Treatment Symbol</td>
<td>flashes during use to show you are treating your fracture.</td>
</tr>
<tr>
<td></td>
<td>Treatment Complete</td>
<td>Automatically displays when countdown timer reaches zero to show that treatment is complete.</td>
</tr>
</tbody>
</table>

*MEDICAL DEVICE

EXOGEN OVERVIEW

**EXOGEN should be used for only 20 minutes per day, or as prescribed by your doctor.**
EXOGEN has a rechargeable lithium-ion battery. A fully-charged battery delivers approximately five 20-minute treatments. It takes about 5 hours to fully charge a discharged EXOGEN battery.

**WARNING:** To avoid the risk of electric shock, EXOGEN must only be connected to a supply mains with protective earth (a 3-prong electrical outlet). Do not use any adapters or extension cords to charge EXOGEN. Only plug the charger into an UL listed electrical outlet.

**Charge EXOGEN** before you begin a treatment or turn EXOGEN on. Follow the steps below to charge EXOGEN:

1. Find the USB cover on the left side of EXOGEN.
2. Pull the tab down to open the USB cover.
3. Plug the end of the charger into an electrical outlet. Plug the USB plug end of the charger into the USB port.
4. You will see the charging symbol (white lightning bolt) and battery status symbol flashing in the corner of the screen. This lightning bolt charging symbol tells you EXOGEN is charging. Charge EXOGEN until a fully-charged battery is shown by the battery status. (Figure 6)
5. When charging is complete, remove the USB plug from EXOGEN, close the USB cover and unplug the charger from the wall.

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**BATTERY PROBLEM?**
Try fully charging EXOGEN with the charger provided. If your EXOGEN unit still does not work, call Customer Service at 1-800-836-4080. Do not try to fix EXOGEN yourself.

You may charge EXOGEN at any time, whether it is on or off. When the battery level is low, you must charge EXOGEN before your next treatment.

You can charge EXOGEN and treat your fracture at the same time. Use the charger provided in the EXOGEN Ultrasound Bone Healing System. Do not connect EXOGEN to any other electrical equipment. EXOGEN is unable to communicate with any other electrical equipment.

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As you use EXOGEN, the symbol will change to show the reduced battery level. See Figure 6.

- **Full Charge**
- **Partial Charge**
- **Partial Charge**
- **Low Charge**

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You can charge EXOGEN and treat your fracture at the same time. Use the charger provided in the EXOGEN Ultrasound Bone Healing System. Do not connect EXOGEN to any other electrical equipment. EXOGEN is unable to communicate with any other electrical equipment.

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**Recharging EXOGEN**
Check the charge level on EXOGEN following treatment. If the battery is low, charge EXOGEN with the supplied charger. See “Charging EXOGEN” (page 5) for instruction on charging EXOGEN.
Preparing to Treat Your Fracture

To treat your fracture you will need EXOGEN, the gel and strap. If you have a cast around your fracture, you will not need the strap.

Your doctor may have marked your fracture site with an ‘X’, or told you where to treat your fracture. This is the spot to place the transducer to treat your fracture. Contact your doctor if you are not sure where to treat your fracture.

Before you begin, check the cable and the transducer for any cracks or signs of damage. If damaged, do not use EXOGEN and contact Customer Service at 1-800-836-4080.

Precaution: The transducer, strap and gel are not sterile and placement on an open wound is not advised.

If you have a cast, proceed to "If You Have a Cast" (page 8).

Place the Strap

1. Position the strap with the cap facing up.
2. Pull the long end of the strap through the plastic loop, as shown.
3. Use 2 fingers to squeeze the cap tabs together to open the cap.
4. Slide on the strap and place the port over the ‘X’ mark on your skin.
5. Tighten the strap by pulling on the long end. Fasten the strap in place. Do not make the strap too tight!

» Continue to “Add Gel and Place Transducer”

If You Have a Cast

1. Your cast will have a plastic port with cap built into it.
2. Use 2 fingers to squeeze the cap tabs together to open the cap.
3. Pull out the round felt plug inside the opening.

Add Gel and Place Transducer

Note: Some patients have experienced mild skin irritation caused by skin sensitivity to the gel. If you feel your skin is sensitive to the gel, you may change the gel to mineral oil or glycerin.

Add gel on the transducer every time you treat your fracture.

1. Take the cap off the gel bottle.
2. Hold the transducer so the cord is down and the smooth side of the transducer is up.
3. Press down on the gel bottle nozzle to put gel on the smooth side of the transducer. You only need one full pump of gel on the transducer. (Note: The first time you use the gel, you may need to pump a few times to start the gel flowing.)
4. Put the transducer, gel side down, into the port. The gel will be touching the skin over your treatment site.
5. Align the cord coming out of the transducer with the notch in the cap. Snap the cap shut on the strap or the cast.
6. Replace the cap on the gel bottle.

Note: Some patients have experienced mild skin irritation caused by skin sensitivity to the gel.

If you feel your skin is sensitive to the gel, you may change the gel to mineral oil or glycerin.

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4. Put the transducer, gel side down, into the port. The gel will be touching the skin over your treatment site.
5. Align the cord coming out of the transducer with the notch in the cap. Snap the cap shut on the strap or the cast.
6. Replace the cap on the gel bottle.
**EXOGEN Setup**

**First Use**

EXOGEN has a calendar which tracks how often the system is used. The current hour needs to be set to make sure the calendar is accurate. The hour must be set once, the very first time EXOGEN is turned on.

**Hour Setting**

1. Press the button once. The hour and AM/PM show on the screen. This may or may not be your current hour. The clock must be set to your current hour. For example, if your time is anywhere between 2:00 PM and 2:59 PM, set the hour to 2 PM.

2. Press the button once to advance the time one hour. Press the button, one press at a time, until the correct hour and AM/PM is displayed on the screen.

3. Press and hold button until you see the hour confirmation screen. This indicates that the hour has been set on EXOGEN. You do not need to set the minutes. After 5 seconds the device will beep and automatically turn off.

Contact Customer Service at 1-800-836-4080 if you have incorrectly set the hour and would like to reset it. Note: EXOGEN will effectively deliver treatment even if the correct hour is not selected.

**Treating Your Fracture**

**Start Treatment**

Hold EXOGEN in your hand to view the screen, or set EXOGEN down on a nearby flat surface. Perform the following steps to begin treatment:

1. Press the button on EXOGEN. EXOGEN beeps and the start-up screen appears for 2 seconds.
2. A calendar appears on the screen for 5 seconds. It shows the current month and your treatment summary. For more information on the calendar screen, see “Tracking Your Treatment” on page 13.
3. Next, the 20-minute countdown timer appears on the screen. EXOGEN automatically begins the ultrasound treatment. A treatment symbol flashes as the timer counts down. This means you are treating your fracture. (Note: To stop EXOGEN in the middle of the 20-minute treatment, press and hold the button until EXOGEN turns off.) If your EXOGEN has an error during treatment, see “Troubleshooting” on page 20.
4. When the countdown timer reaches zero, EXOGEN beeps and shows the treatment complete checkmark. The treatment complete checkmark displays for 5 seconds. Then, EXOGEN beeps and turns itself off.

**EXOGEN Setup**

**First Use**

EXOGEN has a calendar which tracks how often the system is used. The current hour needs to be set to make sure the calendar is accurate. The hour must be set once, the very first time EXOGEN is turned on.

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Contact Customer Service at 1-800-836-4080 if you have incorrectly set the hour and would like to reset it. Note: EXOGEN will effectively deliver treatment even if the correct hour is not selected.
EXOGEN Cleaning

After treatment is complete, you must clean the transducer after each use.

1. Squeeze tabs to open the cap on the port.
2. Gently remove the transducer from the port. Do not yank the cord! Pulling hard on the cord to remove the transducer may cause the cord to detach from the transducer and require your EXOGEN to be serviced.
3. Wipe off any gel on the transducer with a soft cloth. You do not need any cleaning fluid.
4. Remove the strap and clean any gel from your skin and strap with a soft cloth.
5. Place EXOGEN, the strap and gel back into the carrying case until you are ready to treat again.

EXOGEN SETUP

1. Squeeze tabs to open the cap on the port.
2. Gently remove the transducer from the port. Do not yank the cord! Pulling hard on the cord to remove the transducer may cause the cord to detach from the transducer and require your EXOGEN to be serviced.
3. Wipe off any gel on the transducer with a soft cloth. You do not need any cleaning fluid.
4. Carefully clean any gel from your cast, skin and port with a soft cloth.
5. Insert the felt plug, with the tab up, into the port. This plug helps prevent swelling in the cast when you are not using EXOGEN.
6. Snap the cap shut.
7. Place EXOGEN and the gel back into the carrying case until you are ready to treat again.

If You Have a Cast

Follow steps 1-3 (previous page), and then do the following instead of step 4:

4. Carefully clean any gel from your cast, skin and port with a soft cloth.
5. Insert the felt plug, with the tab up, into the port. This plug helps prevent swelling in the cast when you are not using EXOGEN.
6. Snap the cap shut.
7. Place EXOGEN and the gel back into the carrying case until you are ready to treat again.
Tracking Your Treatment

Track Usage
EXOGEN tracks how often you use it. A calendar shows your usage on the screen. There are two parts to the calendar screen. The top part shows a calendar month and the bottom part shows the treatment summary information. See Figure 7.

Figure 7 – Treatment Calendar

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X-mark</td>
<td>You did not complete a 20 minute treatment on this day.</td>
</tr>
<tr>
<td></td>
<td>Checkmark</td>
<td>You completed a 20 minute treatment on this day.</td>
</tr>
<tr>
<td></td>
<td>Double checkmark</td>
<td>You completed two 20 minute treatments on this day.</td>
</tr>
<tr>
<td></td>
<td>Double checkmark plus</td>
<td>You completed three or more 20 minute treatments on this day.</td>
</tr>
</tbody>
</table>

EXOGEN treatment summary

- treatment days = 60
- total days = 60
- compliance = 100%

REMEmber: Use EXOGEN every day for 20 minutes, or as directed by your doctor.

Treatment Summary Data
The treatment summary shows your overall use of EXOGEN. The summary data always accounts for all your days of treatment, not just the current month.

- Treatment days are the number of days that you have completed a 20-minute treatment. This includes days marked with a checkmark, double checkmark, or double checkmark plus.
- Total days are the number of days passed since your first treatment.
- The large compliance % is the number of treatment days divided by the number of total days.

For example, if you use EXOGEN every day for 60 days, you will have the following numbers:

- Treatment days = 60
- Total days = 60
- Compliance = 100%

If you have EXOGEN for 60 days, but forgot to treat 10 of those days, your numbers will look like:

- Treatment days = 50
- Total days = 60
- Compliance = 83%
Treatment History

After using EXOGEN over time, you may want to view your treatment history month by month. EXOGEN will store up to twelve months of recent treatment history. You can show your treatment history to your doctor. EXOGEN lets you view your treatment history without having to start a treatment. You can start EXOGEN in “Treatment History” mode when EXOGEN is being charged.

To view your treatment history, perform the following steps:

1. EXOGEN must be “OFF” and unplugged from the charger.
2. Press and hold the power button until the Treatment History screen appears.
3. Then, a calendar of the current month of treatment appears for 5 seconds.
4. EXOGEN then shows the previous month of treatment for 5 seconds. EXOGEN will display up to 12 months of previous treatment history. This continues until your most recent twelve months of treatment have been shown. Please note, if you have treated with EXOGEN for fewer than 12 months, the EXOGEN device will only display treatment history for the number of months you have used your device. This could be as few as one or two months. You may exit the Treatment History mode at any time by pressing and holding the button until EXOGEN turns itself off.
5. After the last month displays for 5 seconds, EXOGEN beeps and turns itself off.

Calendar Pause

You can pause the calendar screen to view your treatment history for longer than 5 seconds. Any calendar screen can be paused. To pause the calendar, perform the following steps:

1. When you see a calendar screen, press the button to pause.
2. The calendar will pause, a pause symbol appears, and the word “PAUSED” flashes.
3. Press the button again to un-pause the calendar and continue.
4. The calendar screen will automatically un-pause after 2 minutes and continue.
EXOGEN Care

EXOGEN should be handled with care. Please note the following:

• Use only a clean, soft cloth, paper towel, or cotton swab to clean EXOGEN. Do not use cleaning agents or solvents on any of the components of the system.

• Do not attempt to modify, disassemble or repair the EXOGEN. There are no user-serviceable parts inside EXOGEN.

• Exercise care when handling the transducer as rough handling may scratch the transducer face and cause EXOGEN not to work properly.

• If any parts of EXOGEN or its accessories are damaged, do not use EXOGEN. Please contact Customer Service at 1-800-836-4080 to return your EXOGEN for servicing.

• EXOGEN is classified as an IP-22 device. The IP-22 classification indicates that EXOGEN provides:
  - Protection against the access of fingers or similar objects from the internal components of EXOGEN
  - Protection against the harmful ingress of water into the enclosure of EXOGEN when tilted up to 15° from normal position

• The EXOGEN transducer is classified as an IP-67 component. The IP-67 classification indicates that the transducer is:
  - Dust-tight
  - Water not damaged by water under defined conditions of pressure and time (up to 1 meter underwater)
• Never put EXOGEN in or under water

Operating Conditions
EXOGEN should be operated within:

Ambient temperature range: 5°C to 32°C (41°F to 89°F)

Relative humidity range: 15% to 75% (non-condensing)

Atmospheric pressure range: 700 hPA to 1060 hPA

Interference with proper operation of EXOGEN may occur in the vicinity of equipment such as portable and mobile communication units marked with this symbol £. If abnormal operation of EXOGEN is observed, attempt to relocate or reorient EXOGEN in relation to the interfering equipment until the interference stops.

The charger will function with an input voltage range from 100 VAC to 240 VAC and has an operating frequency range of 50/60 Hz. The charger output is 5 VDC.

EXOGEN and accessories should be stored and transported within:

Ambient temperature range: 0°C to 32°C (32°F to 89°F)

Relative humidity range: 15% to 75%

Atmospheric pressure range: 700 hPA to 1060 hPA

EXOGEN is classified as an IP-67 device. The IP-67 classification indicates that EXOGEN will not be damaged by water under defined conditions of pressure and time (up to 1 meter underwater).

EXOGEN is classified as an IP-22 device. The IP-22 classification indicates that EXOGEN provides:

• Protection against the access of fingers or similar objects from the internal components of EXOGEN
• Protection against the harmful ingress of water into the enclosure of EXOGEN when tilted up to 15° from normal position

EXOGEN Expected Service Life

The expected service life of EXOGEN and its accessories is 343 treatments (8680 minutes).

Once EXOGEN delivers 343 treatments, it will not provide further treatment.

EXOGEN Expected Service Life

Storage

• To prevent damage to EXOGEN and its accessories, store EXOGEN in its carrying case while not in use.

• Do not store EXOGEN near radiators or extreme heat.

• Do not expose EXOGEN to extreme temperatures or the internal electronic components may be damaged.

• As with any home electronic device, protect EXOGEN from impact, exposure to moisture, liquid spills, sand, dirt or debris.

If your fracture has healed or prior to long-term storage of EXOGEN, remove the battery to prevent leakage of the battery.

Battery and Charging Safety

Battery

• Do not attempt to replace the lithium-ion battery.

• Do not attempt to replace the lithium-ion battery with non-approved batteries. Incorrect replacement of the battery could result in damage to EXOGEN. The battery should only be serviced by Bioventus trained personnel.

• Be sure to use only the USB battery charger (Part Number 71034460) provided with the system. Other battery chargers may cause battery overheating and damage the battery, EXOGEN, the battery chargers or the user.

• Do not use an extension cord with the battery charger as this may cause overheating.

• Do not use the battery charger with other devices as this may damage the battery charger and/or the other device.

• If the battery area on EXOGEN or the battery charger becomes excessively warm, discontinue using and contact Customer Service at 1-800-836-4080.

Charging

• Charge the battery to at least 25% capacity (one bar) before attempting to perform a treatment when the battery is used for the first time or after prolonged storage.

• The battery will charge whether EXOGEN is turned off or on.

• If the battery power decreases quickly even after recharging for many hours contact Customer Service at 1-800-836-4080.

Do not recharge the battery in any of the following locations:

• Where the ambient temperature is below 0ºC or above 45ºC
• Clamp or wet location and/or near water
• Outside (use indoors only)
• Within the reach of small children
• With the battery charger cable stretched across a floor or other areas where people walk that would cause a tripping hazard
• On floor or other areas where EXOGEN or the cable may be damaged by people walking on them
EXOGEN Disposal

EXOGEN is designed for single patient use only. For details on how to dispose of EXOGEN correctly, contact your local government waste disposal agency or Customer Service at 1-800-836-4080.

Caution: Dispose of the battery properly to prevent environmental contamination and possible human injury.

Warning: Do not throw any part of EXOGEN into fire.

Removing the Battery for Disposal

Only remove the battery from EXOGEN for disposal. To remove the battery, follow these steps:

1. Make sure EXOGEN is not plugged in to an electrical outlet.

2. Turn EXOGEN screen side down and find the battery door screw.

3. Use a screwdriver to remove the battery door screw.

4. Remove the battery door by lifting up at the tab.

5. Gently lift the battery out of the compartment.

6. Follow the red and black wires to find the battery connector.

7. Push the small tab in and pull up to unlock the battery connector.

8. Remove and properly dispose of the battery according to your local or national refuse laws.

Caution: Dispose of the battery properly to prevent environmental contamination and possible human injury.

Warning: Do not throw any part of EXOGEN into fire.

Troubleshooting

EXOGEN will alert you if something is not working properly. EXOGEN will beep and display an alert screen. See the table below for examples of alerts and what to do if you get an alert.

<table>
<thead>
<tr>
<th>Alerts</th>
<th>What does this mean?</th>
<th>What should I do?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Gel</td>
<td>The countdown timer stops, EXOGEN beeps and displays the yellow “Add Gel” screen.</td>
<td>Add more gel to the transducer. See “Add Gel and Place Transducer” on page 8.</td>
</tr>
<tr>
<td>Low Battery</td>
<td>You are not able to start treatment or view history. EXOGEN beeps and displays the yellow “Low Battery” screen.</td>
<td>Plug EXOGEN into a power source with the provided charger. You may charge EXOGEN and treat at the same time. See “Charging EXOGEN” on page 5.</td>
</tr>
<tr>
<td>Contact Customer Service</td>
<td>EXOGEN beeps and displays the yellow “Contact Customer Service” screen.</td>
<td>Call Customer Service at 1-800-836-4080. Do not try to fix EXOGEN yourself.</td>
</tr>
<tr>
<td>No Remaining Treatments</td>
<td>EXOGEN beeps and displays the yellow “No Remaining Treatments” screen.</td>
<td>If you are still being instructed by your doctor to treat your fracture with EXOGEN, call Customer Service at 1-800-836-4080 for instructions.</td>
</tr>
<tr>
<td>Blank screen, EXOGEN does not turn on.</td>
<td>The battery may be completely discharged or the EXOGEN device has malfunctioned.</td>
<td>Plug in charger to EXOGEN and fully charge your battery. If EXOGEN still does not respond, contact Customer Service at 1-800-836-4080.</td>
</tr>
</tbody>
</table>

Problems

<table>
<thead>
<tr>
<th>Problems</th>
<th>What does this mean?</th>
<th>What should I do?</th>
</tr>
</thead>
</table>

TROUBLESHOOTING
**Treatment of Non-Union Fractures**

**Study design**
Three prospectively designed studies, undertaken in the USA, Germany, and the Netherlands, were submitted to the FDA as the basis for approval of the EXOGEN Ultrasound Bone Healing system to treat established non-unions. The studies had a self-paired control design with each non-union case serving as its own control, and with the prior treatment result of failed orthopaedic care serving as ultrasound as the only new treatment. The primary efficacy outcome was healed due to the minimum time from fracture of nine months. The criteria for the definition of non-union cases was the minimum time from fracture of nine months. The primary efficacy outcome was healed due to ultrasound as the only new treatment.

**Clinical results**
Data analyzing the study from Germany, the completed cases had a healed rate of 86% (64/74) with a mean time to a healed fracture of 183±9.4 days. The median time heal was 142 days with a range of 53 to 73 days. The mean fracture age for the healed cases was 494±3 days with a range of 257-6011 days. The scaphoid non-union rate of 33% (24/72) was attributed to the third scaphoid non-union failure that were all more than 10 years in fracture age and, therefore, were very difficult and challenging cases. Cases with metal surgical fixation present during EXOGEN treatment were submitted to the FDA, the results are summarized in Table 1.

**Accelerating Ultrasound Bone Healing System**

**Study design**
Placebo-controlled, randomized, double-blind multicentre study with the prospectively defined primary end-point of a combination of clinical and radiographic healing had the effect of increasing the healing rate (as judged by the blinded principal investigator). 67 patients with conservatively treated closed or open fractures that were randomized into the EXOGEN treated and control groups (Heckman et al.).

**Patient population and demographics**
The demographics of the trial participants were comparable across treatment and control groups with regard to age, sex, fracture characteristics, the presence or absence of fracture and commencement of, and duration of follow-up.

**Evaluation schedule**
Treatment was started within seven days of the fracture, and patients were scheduled to enter EXOGEN ultrasound for follow-up at 1 week. Evaluation schedule was performed at the time of any cast change (usually at 6 and 10 weeks) and at the follow-up visit when radiographic evaluation indicated that the fracture had healed sufficiently to allow removal of the cast.

**Clinical results**
EXOGEN treatment accelerated healing by 58% (86/149) and 58% (16/28) in the control group (p<0.0001).

The reduction in the fracture healing time was not a contraindication to the use of ultrasound. Migration – Lotosov reported that in vivo studies with potassium chloride used as an ink of ultrasound, shows that the presence of metal was not a contraindication to the use of ultrasound.

**Ultrasound Bone Healing System**

**Clinical Results**
Several studies were conducted to assess the safety of EXOGEN as part of the FDA summary of safety & effectiveness. Results from a placebo controlled in-vivo study on rabbits with bladed microwire cut into pieces of bone and showed no toxic or pathological adverse effects of EXOGEN as evidenced by pathological, hematological, and histological analysis.

**a. DNA Analysis**
Analysis of effects of EXOGEN on chromosomal bone marrow cells from a rabbit mid-shaft radius osteotomy showed no measurable, significant, detrimental effects.

**b. Temperature**
Measured temperatures in normal skin, on bone, and in muscle showed no changes or effects could be detected. The safety of EXOGEN as part of the FDA summary of safety & effectiveness. Results from a placebo controlled in-vivo study on rabbits with bladed microwire cut into pieces of bone and showed no toxic or pathological adverse effects of EXOGEN as evidenced by pathological, hematological, and histological analysis.

**c. EXOGEN ultrasound output is 20 to 100 times less than that of other therapeutic ultrasound devices currently available.**
The low-intensity pulsed ultrasound delivered by the EXOGEN Ultrasound Bone Healing System is a mechanical stimulus. This has been clearly demonstrated by experimental work on cadavers in which tissue around an osteosynthesized bone moved in response to the ultrasound signal at a frequency of 1 kHz, the same frequency as the EXOGEN Ultrasound Bone Healing System. Their analyses suggested the EXOGEN Ultrasound Bone Healing System induced cellular reactions at each phase of fracture healing from inflammation to endochondral ossification. In addition, a number of preclinical studies have shown acceleration of bone healing with the EXOGEN Ultrasound signal and increased mechanical properties at the fracture site. Pilla et al.47 reported on ultrasound fracture treatment in a model of bilateral closed femoral fracture. Ultrasound treated fractures were shown to be significantly stronger and stiffer than the controls, showing that the stimulatory effect of ultrasound on fracture repair was not inhibited by the presence of a metallic internal fixation device.

Azuma et al.48 through histological analysis and micro-computed tomography, were able to determine that accelerated fracture healing in the ultrasound-treated group was typical of normal bone healing. EXOGEN Ultrasound accelerated early, mid and late stages of fracture healing with maximum impact achieved when applied throughout the healing process. Takikawa et al.49 studied the impact of the EXOGEN Ultrasound Bone Healing System in a haptotrophic non-union model demonstrating 50% resolution in the active group versus 0% in the control group at 8 weeks.

c. Modes

Effects on chondrocytes—Chondrocytes have been shown to respond to the EXOGEN signal by an increase in proteoglycan synthesis (mediated by calcium signaling) and the increase in aggregan mRNA.50 Response of marrow cells to the EXOGEN ultrasound signal—The EXOGEN signal accelerated the differentiation of mesenchymal cells when cultured in a system designed to promote chondrocytic differentiation.51 Periosteal cell responses—Human periosteal cell cultures responded to low intensity pulsed ultrasound by increasing expression of alkaline phosphatase, osteocalcin and VEGF. In addition long term treatment (4 weeks of 20-minute daily treatment) increased the level of mineralization in these cells.52 Osteoblast differentiation—MMP13 and alkaline phosphatase are two enzymes key to the process of mineralization. Unsworth et al.13 demonstrated an increase in both these enzymes in MC3T3-E1 cultures after stimulation with EXOGEN ultrasound. Further evidence that ultrasound affects the mineralization process comes from Saio et al.51 who demonstrated accelerated calcium accumulation in MC3T3-E1 cultures. Significant increases (8.6-fold and 3.6-fold higher than untreated controls) were seen at day 25 and day 30 respectively. In addition the findings of these studies demonstrate that in a pre-osteoblastic culture system EXOGEN low intensity pulsed ultrasound accelerates differentiation along the osteoblastic lineage. Animal studies have shown that such effects in a fracture environment can benefit the formation of a mineralized callus, stabilizing the fracture and increasing the strength of the bone.

Clear evidence exists that the EXOGEN Ultrasound Bone Healing System accelerates the healing process at all stages of fracture repair.53–55 In-vitro evidence supports this by demonstrating effects on various cell types, stimulating proteins involved in various biological processes and demonstrating acceleration of some processes in organ culture.

Adverse Events

Unlike conventional (physical therapy) ultrasound devices, EXOGEN is incapable of producing harmful temperature increases in body tissues. The ultrasound output intensity of EXOGEN is 30 mW/cm² and is typically only 1% to 5% of the output intensity of conventional therapeutic ultrasound devices. The ultrasound intensity is comparable to diagnostic ultrasound (1 to 50 mW/cm²), such as the intensities used in obstetrical sonogram procedures (fetal monitoring).

In addition, there is no evidence of non-thermal adverse effects (irradiation).

Complications

No device-related adverse reactions or medical complications related to the use of EXOGEN were reported during the clinical studies. Some patients have experienced mild skin irritation caused by skin sensitivity to the gel. If you feel your skin is sensitive to the gel, you may change the gel to mineral oil or glycerin. In the distal radius study, one patient complained of pain during treatment but they no longer had the pain by the next follow up visit, and one patient, complaining of pain, withdrew from the study.

Apart from Handolin et al.56, the studies reported above used ultrasound intensity levels ranging from 0.5 W/cm² to 2 W/cm² and no untoward effects were noted. These intensities are 10 to 60 times higher than the intensity used in the EXOGEN Ultrasound Bone Healing System. It is reasonable to conclude that metal present in a healing fracture would not affect the safety or effectiveness of the EXOGEN Ultrasound Bone Healing System.
## Table 1 Clinical Study results for the FDA reviewed non-union cases – stratification by category variables

<table>
<thead>
<tr>
<th>Age Class</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65 kg</td>
<td>41</td>
<td>12</td>
<td>21</td>
<td>8</td>
<td>11</td>
</tr>
<tr>
<td>65-80 kg</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>&gt;80 kg</td>
<td>28</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>15</td>
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</table>

<table>
<thead>
<tr>
<th>Fracture Location</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
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<tbody>
<tr>
<td>Long Bone</td>
<td>106</td>
<td>52</td>
<td>41</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Radius/Radial-Ulna/Ulna</td>
<td>24</td>
<td>14</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Metaphyseal</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Radius/Radius-Ulna/Ulna</td>
<td>11</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Metatarsal</td>
<td>40</td>
<td>20</td>
<td>12</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Metatarsal</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Other Foot Bones</td>
<td>106</td>
<td>52</td>
<td>41</td>
<td>12</td>
<td>11</td>
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</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>69</td>
<td>34</td>
<td>21</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Male</td>
<td>37</td>
<td>18</td>
<td>11</td>
<td>4</td>
<td>15</td>
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</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
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<tbody>
<tr>
<td>Open rod</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>IM rod</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>ORIF</td>
<td>28</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complications</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>41</td>
<td>23</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Yes</td>
<td>28</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Patients</th>
<th>30-49</th>
<th>50-64</th>
<th>65-80</th>
<th>&gt;80</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 months</td>
<td>24</td>
<td>14</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3-6 months</td>
<td>28</td>
<td>14</td>
<td>6</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>&gt;6 months</td>
<td>16</td>
<td>2</td>
<td>8</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

## References

EXOGEN Classifications

EXOGEN has the following classifications:

- Internally Powered Equipment
- Type BF Applied Part
  - EXOGEN device: IP-22 protection against ingress of water
  - Transducer: IP-67 protection against ingress of dust
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or with nitrous oxide.
- Mode of operation – Intermittent

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions and Immunity Testing

Electromagnetic Compatibility Testing

Summary: Testing Report for: Bioventus LLC.

Equipment Under Test: EXOGEN®

Used for Life Support: No

Use in shielded enclosure: No

Technical Information

EXOGEN Operating Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound frequency</td>
<td>1.5 +/- 5% MHz</td>
</tr>
<tr>
<td>Modulating signal burst width</td>
<td>200 +/- 10% microseconds</td>
</tr>
<tr>
<td>Repetition Rate</td>
<td>1.0 +/- 10% kilohertz (kHz)</td>
</tr>
<tr>
<td>Duty Factor</td>
<td>20%</td>
</tr>
<tr>
<td>Effective radiating area (ERA)</td>
<td>3.88 +/- 1% square cm (cm²)</td>
</tr>
<tr>
<td>Temporal average power</td>
<td>117 +/- 30% milliwatts (mW)</td>
</tr>
<tr>
<td>Spatial avg.-temporal avg. (SATA)</td>
<td>30 +/- 30% milliwatts (mW)</td>
</tr>
<tr>
<td>Beam non-uniformity ratio (BNR)</td>
<td>4.0 maximum</td>
</tr>
<tr>
<td>Battery</td>
<td>3.7 VDC, 700 mAh</td>
</tr>
<tr>
<td>Battery Type</td>
<td>Lithium-ion</td>
</tr>
<tr>
<td>Input Voltage (USB)</td>
<td>5.0 VDC, 2.6A max.</td>
</tr>
<tr>
<td>Beam type</td>
<td>Collimated</td>
</tr>
</tbody>
</table>

The essential performance of EXOGEN includes the following:

- Free from the display of incorrect numerical values (numbers) associated with the ultrasound therapy
- Free from the production of unwanted ultrasound output
- Free from the production of excessive ultrasound output
- Free from the production of unintended or excessive transducer surface temperature

EXOGEN is intended for use in the electromagnetic environment specified below. The customer or the user of EXOGEN should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>EXOGEN uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Group B</td>
<td>EXOGEN is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supply buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions</td>
<td>Class A</td>
<td></td>
</tr>
</tbody>
</table>

Summary:

- Testing Report for: Bioventus LLC.

Equipment Under Test: EXOGEN®

Used for Life Support: No

Use in shielded enclosure: No

Guidance and manufacturer’s declaration – electromagnetic emissions
Guidance and manufacturer’s declaration – electromagnetic immunity

EXOGEN is intended for use in the electromagnetic environment specified below. The customer or the user of the EXOGEN should assure that it is used in such an environment.

Immunity test

Compliance Level

Electromagnetic environment – guidance

Radiated RF

Conducted RF

Electrostatic discharge

Mains power quality

Field strength

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and EXOGEN

EXOGEN is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of EXOGEN can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and EXOGEN as recommended below, according to the maximum output power of the communications equipment.

Based maximum output power of transmitter – watts (W)

Separation distance according to frequency of transmitter – meter (m)

150 kHz to 80 MHz

80 MHz to 800 MHz

800 MHz to 2.5 GHz

d = 1.2 √P

d = 1.2 √P

d = 2.3 √P

For transmitters rated at a maximum power output not listed above, the recommended separation distance (in meters) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer:

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ‘should be less than the compliance level in each frequency range. Intolerance may occur in the vicinity of equipment marked with the following symbol:

NOTE Uc is the a.c. mains voltage prior to application of the test level.

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Customer Service

Customer Service is available to answer questions regarding EXOGEN and to handle servicing or disposal needs.

To contact the Service Center in the United States:

- Call 1-800-836-4080 (toll free)
- General Information: 1-800-396-4325 (toll free)
- In Other Countries:
  - 00800 02 04 06 08 (toll free)
  - +31 (0) 23-554-8851

Bioventus Customer Service
1900 Charles Bryan Road, Suite 275
Cordova, TN 38016

If your EXOGEN needs service, please follow these instructions:

1. Call Customer Service at 1-800-836-4080 and request a Return Authorization (RA) number.
2. Customer Service will provide you with a shipping package to return EXOGEN.
3. Pack EXOGEN in its original packaging. Otherwise, pack EXOGEN to prevent movement during shipping.
4. Ship the package to:
   Bioventus LLC
   1900 Charles Bryan Road, Suite 275
   Cordova, TN 38016
5. Contact the shipping company to arrange pickup.

Exclusive Limited Warranty

Bioventus LLC (“Seller”) warrants to the original purchaser (“Purchaser”) of its EXOGEN Ultrasound Bone Healing System purchased by Purchaser directly from Seller (“System”) that the System conforms to Seller’s manufacturing specifications. This warranty shall be in effect for a period of one year from the date of purchase. In the event of a material breach of this warranty, upon timely written notice, Seller will, at its sole option, either repair or replace the System or refund the original purchase price. This will constitute Purchaser’s sole remedy. This limited warranty does not extend to any re-sale or other transfer of the System by Purchaser to any other person or entity.

SELLER EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, RELATING TO THE SYSTEM OR ITS PERFORMANCE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY AND ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Authorized European Community (EC) Representative

EMERGO EUROPE
Molenstraat 15
2513 BH The Hague
The Netherlands
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Fax: +31 (0) 70 346-7299