Patient's
Instructions
for Use
& Package
Insert

smith&nephew

EXOGEN 4000+◇

Low-intensity Ultrasound Fracture Healing
System for the Treatment of Nonunion
and Fresh Fractures

Caution: This device is intended for use only by the individual for whom it is prescribed.

NOTE: The EXOGEN 4000+® device has been tested and found to comply with the limits for Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against interference with radio or television reception or communication in home use of the device. The EXOGEN 4000+ device uses radio-frequency (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. If abnormal operation of the EXOGEN 4000+ device is observed, certain measures to correct the problem may be necessary, like reorienting or relocating the device.

If the EXOGEN 4000+ device causes interference to radio or television reception, which can be determined by turning the EXOGEN 4000+ device off and on, the patient can attempt to correct the interference by one or more of the following measures:

- Reorient or relocate the radio or television receiver unit or receiving antenna.
- Increase the distance between the device and the radio or television receiver.
- Contact the Patient Services Department of Smith & Nephew, Inc., if the above does not correct the problem.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigencies du Réglement sur le materiel brouilleur du Canada.

Warning: Neither you or your physician can select or change any of the EXOGEN 4000+ ultrasound signal specifications. No attempt should be made to modify or repair the EXOGEN 4000+ device.

DEFINITION OF SYMBOLS

Attention, consult manual.

Refer to Instructions for Use

A blinking addition (+) symbol with an audio tone means you need to add gel to the transducer face.

Pulsing Treating Symbol indicates device is operating properly

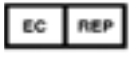
Treatment Stop or Treatment Lockout Symbol

Type B APPLIED PART

CE Mark indicates conformity with European Council Directive of
14 June 1993 concerning Medical Devices (93/42/EEC).

EU: Not for General Waste
The wheelie bin symbol denotes that this device should not be disposed of with ordinary household waste at the end of it's life. For details of how to dispose of this item correctly, please contact your local government waste disposal agency or contact your local Smith & Nephew representative.

Manufacturer



Authorized Representative in the European Community

SN

Serial Number (First four digits of serial number indicate month and year of manufacture)

Caution: 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. The device is only intended for use by the individual for whom it is prescribed.

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A. Introduction

Your physician has prescribed a device, the EXOGEN 4000+◇ Bone Healing System, which may heal your nonunion or accelerate the healing of your fracture. This device utilizes pulsed, low-intensity ultrasound, which has been shown to heal non-unions and to speed up fracture healing. You are an active participant with the physician during this course of therapy.

Questions regarding your fracture should be referred to your physician.

Please call the Patient Service Department of Smith & Nephew, Inc., regarding any problem with the EXOGEN 4000+ device that cannot be resolved after consulting this manual. The Patient Service Department may be reached at:

In the United States, call (800) 836-4080, select option 2;
In Europe, call (+49) 746-22080; and
In Other Countries, call (USA) (+1) 901-396-2121

The EXOGEN 4000+ device is provided to you for the treatment of your fracture upon the prescription of your physician.

PLEASE BE SURE TO READ THE ENTIRE MANUAL BEFORE USING THE EXOGEN 4000+ DEVICE.

B. Indications for Use

The EXOGEN 4000+, or any other EXOGEN Bone Healing System is indicated for the non-invasive treatment of established nonunions† excluding skull and vertebra. In addition, they are indicated for accelerating the time to a healed fracture, for fresh, closed, posteriorly displaced distal radius (Colles') 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 nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

C. Contraindications, General Warnings and Precautions

Contraindications:

There are no known contraindications to the use of this device.

Nonunion Indication:

Warnings:

The safety and effectiveness of the use of this device has not been established in nonunions for the following:

- nonunions of the vertebra and the skull.
- individuals lacking skeletal maturity.

Precautions:

- The safety and effectiveness of the use of this device in pregnant or nursing women has not been established.
- Careful consideration of the use of this device must be decided on an individual basis in the presence of malaligned nonunion since the device will not correct or alter displacement, angulation or other malalignment.
- Cell phones may cause interference and patients should avoid cell phone use during treatments.
- With active, implantable devices, such as cardiac pacemakers, operation may be adversely affected by close exposure to the EXOGEN® device; therefore, evaluation during EXOGEN treatment by the attending cardiologist or physician is recommended.
- Patients in the clinical studies were instructed to apply the device for one treatment period of 20 minutes each day. The safety and effectiveness of the EXOGEN device when used for more than one daily 20-minute treatment period is unknown.
- The age ranges of the patients in the PMA nonunion studies were 17–86. The effect of EXOGEN therapy on patients outside this age range is unknown.

Complications:

No device-related adverse reactions or medical complications related to the use of this device were reported during the clinical studies. Two patients in a post-market registry reported mild skin irritation caused by skin sensitivity to the coupling gel. Both were resolved by a change of coupling medium to mineral oil or glycerin.

Fresh fracture indication:

Warnings:

The safety and effectiveness of the use of this device has not been established for the following:

- Fracture locations other than the distal radius (end of the large bone in the forearm) or tibial diaphysis (middle 80% of the large bone in your lower leg).
- 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).
- Fractures that are open Grade II or III (fractures with large wounds) or that require surgical intervention or with internal or external fixation (screws and/or plates used to hold your broken bone in place) or that are not sufficiently stable for the closed reduction (manipulation of the fracture without surgery) and cast immobilization (cast treatment).
- Individuals lacking skeletal maturity (generally below 18 years of age although one patient in the tibia study was 17 years of age) or who are pregnant/nursing women.
- Pathological fractures due to bone pathology or malignancy (fractures due to disease).
- Individuals with thrombophlebitis (blood clot in a vein), vascular insufficiency (poor blood supply), abnormal skin sensitivity (very sensitive skin), sensory paralysis (lack of sensation), alcoholism and/or nutritional deficiency.
- Individuals receiving steroid, anti-coagulant, prescription non-steroidal anti-inflammatory, 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.

Precautions:

- Animal studies conducted to date do not suggest any long term adverse effects from the use of this device. Clinical studies conducted for the EXOGEN® PMA with long term patient follow up for up to 78 months do not suggest any long term adverse side effects from the use of this device. However, possible longer-term adverse effects in humans are unknown.
- The EXOGEN device will not correct or affect the post-reduction (when your fracture is initially set and placed in a cast) condition of your fracture such as displacement of the bone ends at your fracture or improper alignment of your fractured bone.
- The age ranges of the patients in the fresh fracture PMA study were 17–67 years of age (54% were 31 years of age or older) in the tibia study and 20–78 (74% were 50 years of age or older) in the Colles' study. The effect of EXOGEN therapy on patients outside this age range is unknown.

- Operation of implantable devices, such as cardiac pacemakers, may be adversely affected by close exposure to the EXOGEN® device. This applies to you or any other person in close proximity during treatment. You or the other person should be evaluated by the attending cardiologist or physician before starting treatment with the EXOGEN device.
- Cell phones may cause interference and patients should avoid cell phone use during treatments.
- The clinical studies for the EXOGEN PMA required only one daily treatment period of 20 minutes. Although the EXOGEN device can be used more than once per day, the effects of multiple daily treatments are unknown; therefore, it is important that you use the device as instructed by your physician.

Complications:

No device-related adverse reactions or medical complications related to the use of this device were reported during the tibia or distal radius studies. In the distal radius study, one patient complained of pain during treatment but this resolved by the next follow up visit and one patient, complaining of pain, withdrew from the study.

D. Device Description

1. The EXOGEN 4000+ Bone Healing System

The EXOGEN 4000+ device provides a non-invasive therapy for the healing of nonunion or the acceleration of fresh fracture healing that you administer at home for 20 minutes daily, or as prescribed by your physician, until your physician determines your fracture to be sufficiently healed to discontinue device use. The device transmits a low intensity ultrasound signal to the fracture site through coupling gel. Ultrasound is high frequency sonic pressure waves. The device provides low intensity ultrasound of 30 mW/cm^2, which is comparable to the diagnostic ultrasound intensities used in sonogram (fetal monitoring) procedures, and is 1% to 5% of the intensities used in conventional therapeutic ultrasound. Due to the very low intensity of the ultrasound, you will feel little or no sensation during the treatment. Design features alert you in case of improper application or performance of the device.

2. Technical Specifications of the EXOGEN 4000+◇ Ultrasound Signal

Ultrasound frequency .....1.5 ± 5% megahertz (MHz)
Modulating signal burst width....200±10% microsecond (µs)
Repetition rate .....1.0 ± 10% kilohertz (kHz)
Effective radiating area.....3.88 ± 1% square cm (cm^2)
Temporal average power.....117 ± 30% milliwatts (mW)
Temporal maximum power.....625 ± 30% milliwatts (mW)
Peak power .....1.25 ± 30% watts
Spatial avg.–temporal avg. (SATA) .....30±30% mW/cm^2
Spatial avg.–temporal maximum (SATM)..161±30% mW/cm^2
Beam non-uniformity ratio (BNR).....4.0 maximum

The device uses a non-electrical, plastic locating component, the Retaining and Alignment Fixture (RAF). When incorporated into a strap, the RAF is used for a Non-Cast application or for an On-Cast application. The RAF is also available for incorporation into a cast for In-Cast applications. The RAF Cap Assembly is snapped on the RAF after the insertion of the transducer during treatment periods. In both On-Cast and Non-Cast applications, the RAF/strap is applied to the cast or skin over the fracture site and insures proper positioning during the 20-minute treatment period. During non-treatment periods in both the In-Cast and On-Cast applications, the transducer is removed and replaced with a felt plug to maintain even pressure on the skin. The RAF Cap is replaced on the RAF during non-treatment periods.

Neither you nor your physician can select or change any of the EXOGEN 4000+ ultrasound signal specifications.

3. The EXOGEN 4000+ System Components

The EXOGEN 4000+ device is composed of a Main Operating Unit (MOU) Assembly with a permanently attached transducer, and accessory items, which are shown below in (*Figure 1*).

a. **The Main Operating Unit (MOU):** The Main Operating Unit (MOU) is powered by a non-replaceable and non-rechargeable lithium battery pack with a life of a minimum of 150 treatment periods of 20 minutes each. Since the range of the number of total treatment sessions for some patients may exceed this number, your device may require a battery change (see Section J). The MOU is connected to the transducer by a permanently attached coiled inter-connecting cable.

The MOU:

- monitors and controls system operation during treatment.
- verifies operation of the transducer and the MOU and monitors the MOU battery for a low battery condition.
- controls the duration of the 20-minute treatment period.
- monitors for the presence/absence of coupling gel on the transducer surface. The MOU then alerts you with a visual and an audible beeping sound if gel is not present on the transducer.

Figure 1

- automatically shuts off the device at the end of the 20-minute treatment period, and alerts you with an audio signal that treatment has ended.
- maintains a complete record of your daily use of the device.
- monitors compliance with prescribed treatment usage.

b. **The Transducer:** The transducer is powered by the MOU battery supply and is connected to the MOU by a permanently attached flexible coil cable capable of extending from 1.5 feet (45 cm) to approximately 5 feet (1.5 m). The round, flat, black transducer surface attached to the coil cable transmits the low intensity ultrasound signal to the skin at the fracture site through a layer of ultrasound coupling gel. Coupling gel is necessary, as air will not transmit ultrasound.

c. **Snap-on Cap with Tether:** For In-Cast, On-Cast, and Non-Cast applications, the snap-on cap with a tethering ring is used to hold the transducer in place within the RAF. The snap-on cap has a spring attached to its inner side that keeps a light pressure on the transducer, thereby ensuring contact of the transducer surface with the skin. The tethering ring attached to the cap is placed around the RAF opening and prevents the possible loss of the snap-on cap.

In-Cast Application

d. **Retaining and Alignment Fixture (RAF):** If you are in a cast, the RAF is incorporated into the cast (In-Cast installation—see *Figure 2*). The RAF holds the transducer in the proper position during the daily 20-minute treatment period.

e. **Black Round Foam Disc:** A black round foam disc is available for placement on top of the transducer to ensure contact of the transducer surface with the skin when the cast thickness is excessive. Your installer will advise you if you should use this accessory during treatment periods.

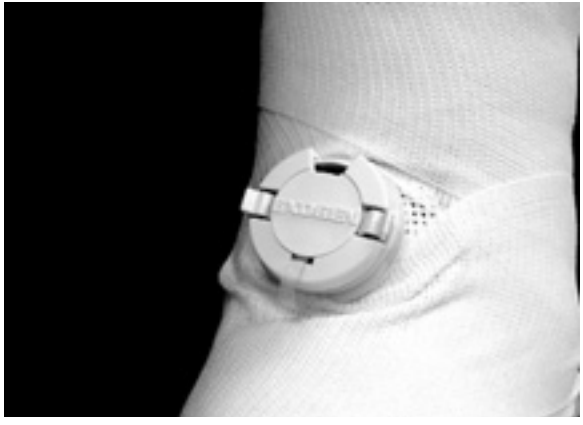

Figure 2

f. **Round Felt Plug/With Tab:** The round felt plug with tab is placed into the center hole of the RAF between treatment periods. The felt plug should be inserted with the tab on top. The tab will assist you in removing the pad. The felt plug maintains even pressure on the skin to prevent "window edema" (swelling). The spring force in the cap assembly will hold the felt plug in place against the skin.

On-Cast or Non-Cast Application

g. **RAF/Snap-on Cap/Strap Assembly:** The strap assembly is used for an On-Cast or Non-Cast application and contains the RAF, with the snap-on cap tethered to the RAF. The snap-on cap has a spring attached to its inner side which keeps a light pressure force on the transducer, thereby ensuring contact of the transducer surface with the skin.

Note: In an On-Cast application, do not loosen the strap after installation, as it should remain securely in place until you are healed. The RAF holds the transducer in the proper position during the daily 20 minute treatment period.

h. **Foam Pad:** A foam pad is supplied with a self-adhesive backing on one surface. The foam pad is used to provide a soft-surface padding under the RAF for contact with the skin in a Non-Cast application.

Other Accessories

i. **Coupling Gel:** Two containers of hypoallergenic ultrasound coupling gel, which is 96% water, are provided with your EXOGEN® device. You must apply coupling gel to the transducer surface at the start of each treatment period in order to permit transmission of the ultrasound signal from the transducer surface to the skin over the fracture site. Each container has 200ml of coupling gel. A single pump (1.4cc) portion is the recommended amount of coupling gel for each treatment session. Each bottle will provide enough gel for approximately 140 treatments. Please replace the clear plastic top on the gel bottle after dispensing gel.

   There are other coupling mediums which can be used if a skin reaction is noted with the standard gel. Please call the Patient Service Department of Smith & Nephew, Inc., if this occurs.

   Note: EXOGEN ultrasound coupling gel supplied is the recommended gel for use with this system. Do not substitute other gels as they may damage the transducer surface or impede signal transmission. Please call the Patient Service Department of Smith & Nephew, Inc., if you need more coupling gel.

   Manuals: This manual describing how to use the EXOGEN 4000+ System is included.

E. Adverse Effects

In laboratory, animal and clinical research, the EXOGEN device intensity (power level) (See Section D — "Device Description") was assessed for its potential for producing significant temperature increases in body tissue, the most common and best understood effect of conventional ultrasound. Conventional therapeutic ultrasound applications utilize ultrasound intensities of approximately 1,000 to 5,000 mW/cm^2, and must be applied in a stroking manner to avoid tissue necrosis caused by excessive temperature increases due to stationary application. The 30 mW/cm^2 output intensity of the device you received is typically only 1% to 5% of the output intensity of conventional therapeutic ultrasound devices and therefore can be used in a stationary application. The ultrasound intensity is comparable to diagnostic ultrasound (1 to 50 mW/cm^2), such as the intensities used in obstetrical sonogram procedures (fetal monitoring). The results of the PMA safety report on the EXOGEN device and EXOGEN PMA research indicate that the EXOGEN device is incapable of producing harmful temperature increases in body tissue and there is also no evidence of non-thermal adverse effects.

F. Device Operating Instructions

1. Starting Your Daily Treatment Period

The instructions shown below are to be followed when using the EXOGEN 4000+◇ device with an ON-cast or IN-cast application. See Section H for instructions on device use when your physician does not use a cast or continues EXOGEN 4000+ treatment after cast removal or uses a removable cast or splint. Your physician or the cast technician will prepare your cast and install the Retaining and Alignment Fixture (RAF) Strap Assembly on your cast or incorporate the separate RAF in the cast at the fracture location (see Section D—"Device Description"). The instructions shown below are to be followed when using the device:

a. Remove the RAF Cap (*Figure 3*) by gently squeezing the tabs on the Cap Assembly with an inward motion and lift it off of the RAF.

b. Remove the round felt plug from the RAF opening. The cap tethered to the strap assembly prevents inadvertent dropping or loss.

c. Prepare the transducer (*Figure 4*) by placing one pump of coupling gel on the round flat black surface of the

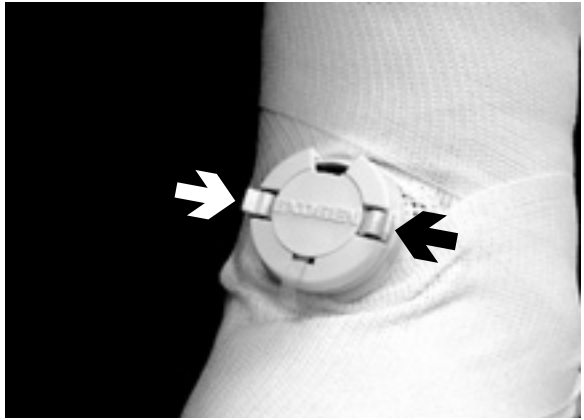

Figure 3

Figure 4

Figure 5a

Figure 5b

transducer. Do not spread the gel over the transducer surface. Replace the plastic top on the gel bottle.

Note: The system is designed so that the gel spreads evenly when the transducer contacts the skin. You should use the recommended amount of gel. The EXOGEN 4000+° device will alert you if insufficient gel is present (see Section J —"Trouble Signals and Corrective Actions").

d. Insert the transducer, with gel applied, into the RAF opening (*Figure 5a*). Align the transducer cable with the cap slot before snapping the cap in place (*Figures 5b, 5c*).

Figure 5c

2. Turning "On" the EXOGEN Model 4000+◇ for a Daily Treatment

Press and release the orange "On/Off" button once on the Main Operating Unit (MOU) (see *Figure 6*) to turn ON the system. When the "On/Off" button is pressed to turn ON the system the following processes occur:

a. The system will emit a 2-tone beep and run its built-in testing circuit that checks the unit operation. This self-test takes approximately 2 seconds during which the display will show all icons.

b. The device will then display the total number of FULL treatments completed.

c. The device will then display the total number of PARTIAL treatments.

d. The device will then start treatment. The Pulsing Treatment Symbol and the countdown clock will be shown on the display (see *Figure 6a*).

The LCD display will provide a warning message if either insufficient gel has been applied or a fault or problem has been detected. After the 20-minute treatment period, the unit will emit a two-tone beep and turn itself off.

The EXOGEN 4000+ device is intended for one 20-minute treatment period per day. It is recommended that there be at least 12 hours between treatments although this spacing may not always be possible to maintain. As an example, if the treatment started at 10:00 PM on Monday, Tuesday's treatment should be performed after 10:00 AM. In any case, you should always follow the treatment schedule as prescribed your physician. Note: Each time the device is turned on and used for at least 3 minutes, a record of the use will be stored in the device.

Figure 6 — Push ON/OFF Button

Pulsing Treating Symbol indicates device is operating properly.

Treatment countdown will continue as long as proper treatment is occurring. Countdown will pause if gel error occurs.

Figure 6a

Figure 7

3. At the End of A Daily Treatment Period:

The device will automatically stop treatment after 20 minutes. A two-tone beeping sound will indicate that treatment has been completed, and the LCD and system will then turn OFF automatically.

a. Remove the transducer from the RAF. The transducer must be removed from the RAF after each treatment session.

b. Using a soft cloth, tissue, paper towel or a cotton swab, gently clean the skin area at the treatment site to remove the coupling gel (*Figure 7*). Clean the inside surface of the RAF and remove any gel that may have accumulated on the transducer to prevent gel hardening on the device.

c. Replace the round felt plug with tab, into the RAF (*Figure 8*).

d. Snap on the RAF cap by positioning it over the RAF hole and pushing down until it snaps securely in place.

G. Interruption of a Treatment Period

It is recommended that each treatment period be a continuous, uninterrupted 20-minute period. During a treatment period, if for any reason you must attend to something for a short

period of time (e.g., to answer a telephone or a doorbell), the device can be carried with you. In this instance, it is not necessary to turn off the device. However, if you do not want to carry the device to attend to the interruption, you will have 30 seconds before the device shuts off, and you will need to begin another complete 20-minute treatment.

Within 30 seconds, complete the following:

1. Open the RAF cap and remove the transducer from the RAF.
2. Attend to the reason for the interruption of treatment.
3. Reapply coupling gel to the transducer, as necessary.

Figure 8

4. Replace the transducer in the RAF.
5. Snap the RAF cap back on.
6. If your total response time for the above steps took less than 30 seconds, the treatment will continue to completion. However, if the total time of response exceeds 30 seconds, the device will turn off. It will be necessary to follow steps 1–5 above before pressing the "On" button to start a complete, new 20-minute treatment period.

H. Special Instructions when No Cast Is Used or when the Cast Is Removed and Treatment Is Continued

1. Without-Cast Treatment:

a. **Starting Your Treatment Period:** Your physician will place a mark over the fracture site or indicate an area on the skin as a landmark to ensure proper placement of the device for each treatment (*Figure 9*).

1. Included with this device is a RAF Strap Assembly (*Figure 1*) used for "on cast" as well as "without cast" treatment.

2. A foam pad is included with the device to provide

a padded surface during “without-cast” treatment. The foam pad has a paper covered adhesive side with a tab for easy removal. The paper backing should be removed and the adhesive side of the foam placed on the underside of the RAF (*Figures 10a, 10b*) to provide a padded surface over the fracture site and to prevent movement of the RAF on the skin surface.

3. For your daily treatment with the EXOGEN 4000+◇ device use the RAF with the attached foam pad and strap to secure the RAF over the fracture site. Ensure the circular opening in the RAF is centered over the treatment area as indicated by your physician (*Figure 11*).

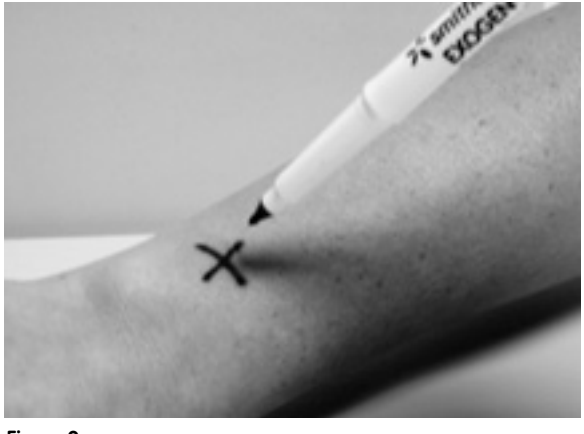

Figure 9

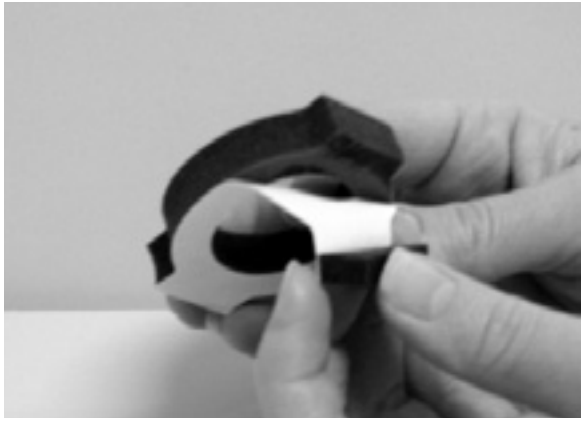

Figure 10a

Figure 10b

Figure 11

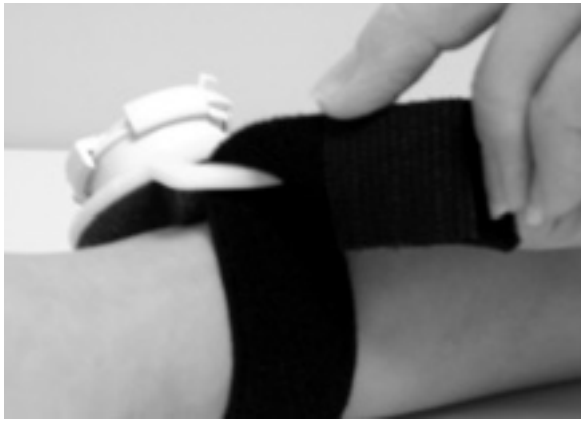

Figure 12

4. The strap should be tightened, utilizing the adjustable fastener to prevent the RAF from sliding out of place. It should not be so tight as to cause discomfort (*Figure 12*).

5. The strap assembly must be secured in place over the treatment site (*Figure 11*) BEFORE the transducer with gel applied is inserted into the RAF. This will ensure that the coupling gel on the transducer is applied directly to the treatment site.

6. Follow directions provided in Section F.1.c. and F.2. for starting a treatment. You should remain in a resting position, as much as possible, during a treatment period to minimize movement of the transducer and RAF Strap/Cap assembly.

b. **At the End of a Without-Cast Treatment Period:**

1. Open the cap and remove the transducer from the RAF Strap Assembly to allow for proper cleaning.

2. Remove the RAF Strap Assembly and gently clean the skin at the treatment site to remove any coupling gel using a soft tissue, paper towel, or cotton swab.

3. Clean any gel residue from the RAF Strap Assembly (*Figure 13*).

4. Clean any coupling gel from the transducer with a soft cloth, tissue or paper towel, to prevent gel

from drying on the transducer surface and interfering with the subsequent treatments. Use a damp cloth or paper towel to remove any dried gel residue.

5. Replace your removable splint or brace if applicable.
6. Place the device in its device container or a safe place until the next treatment period.

Never immerse the EXOGEN 4000+® device in water.

Figure 13

I. Treatment Schedule

You should comply with the recommended daily 20-minute treatment period that has been prescribed by your physician.

Following this treatment schedule with low-intensity ultrasound therapy can provide the clinical benefit of healing your nonunion or accelerating the healing time of your fracture as was shown in the device clinical trials.

Please note that ultrasound therapy is automatically shut off after each treatment period. However, the transducer should be removed from the RAF after each treatment period to allow for proper cleaning and storage.

Use the device for one 20-minute treatment period each day until your physician advises you to discontinue therapy. The EXOGEN 4000+ device contains an internal patient usage timer, which monitors and records the daily use of your device. This record is available to your physician so that he/she can evaluate your adherence with the daily treatment schedule.

J. Trouble Signals and Corrective Actions

Please do not attempt to open the device. There are no user serviceable parts in the EXOGEN device.

At the start of the treatment self-test sequence, the MOU monitors the correct operation of the EXOGEN 4000+

system. During the entire treatment period, the MOU continues to monitor system operation. It detects whether:

- sufficient gel is present on the transducer surface,
- the internal battery has reached a low battery condition,
- the device is operating properly.

If an alarm occurs, do not turn the device off. The MOU display indicates the type of problem by displaying a message on the LCD display along with an audible tone. The following alarm displays may occur during system operation.

1. Add Gel 

A blinking addition (+) symbol with an audio tone means you need to add gel to the transducer face. This display will last for 30 seconds after which the device turns "off."

Correct this condition as follows:

1. Remove the transducer from the RAF Strap Assembly.
2. Add gel to the transducer surface. Avoid overloading with gel.
3. Re-insert the transducer and snap on cap making sure it properly snaps in place.

If the problem has been corrected within 30 seconds of the alarm, the blinking symbol will turn off and the treatment countdown will continue. If the problem is corrected after 30 seconds have passed, the device will turn "Off." It will be necessary to press the "On/Off" button to turn the device back "On" for a new, complete 20-minute treatment period.

2. Error or Problem Messages

Note: The following fault conditions require that you contact the Patient Service Department of Smith & Nephew, Inc. The MOU alerts you of an error or problem condition in the device by displaying the Attention Icon.

Attention: Consult Manual symbol 

An error or problem message is shown on the LCD display as the Attention symbol and is accompanied by an audible alarm—a beeping tone lasting for 30 seconds. This denotes a problem with the operation of the device. The device turns "off" after the 30 seconds.

If the Attention symbol appears, turn the device OFF and wait approximately one minute. Press the "On/Off" button once to turn on. If the device still displays the

Consult Manual icon there is a problem with the device, please call Patient Services at 1-800-836-4080 (select option #2).

Treatment Stop symbol 

This symbol indicates that the current 20-minute treatment period has been completed.

K. Care and Handling of the EXOGEN 4000+◇ System

Do not use cleaning agents or solvents on any of the components of the system. Use a soft cloth, tissue, paper towel, or cotton swab to clean the transducer or the RAF. Use a damp cloth or paper towel to remove any dried gel residue. Never immerse the unit in water. The EXOGEN 4000+ device is intended for home use and, therefore, should be operated within the typical room temperature conditions expected in a home/office environment 60°–100° F (16°–38° C). If the device is stored, moved or transported in temperature conditions other than those described above, the device temperature should be allowed to return to room temperature conditions before treatment is started. The device should not be stored, moved or transported in temperature conditions below 0° F (-18° C) or above 130° F (54° C) range, or damage may result to internal electronic components. The device shall operate in normal use under the following conditions:

- Ambient temperature range : 50° F (10° C) to 104° F (40° C).
- Relative humidity range: 30% to 75%.
- Atmospheric pressure range: 700 hPA to 1060 hPA.

When the EXOGEN 4000+ device is outside its protective packaging, it is important to protect the device from impact, exposure to moisture, liquid spills, sand, dirt, debris, freezing or excessively hot temperatures (such as radiators or heating vents) to avoid possible damage. The device should be handled with the same care as any home electronic device. Please exercise care while handling the transducer as rough handling may adversely affect the device's operation. Please save the packaging materials for device safekeeping and transport.

Periodically inspect the transducer and the transducer cable for cracks or other signs of damage that may allow the entrance of conductive fluids or expose electrical conductors. Contact the Patient Service Department of Smith & Nephew, Inc., if you detect any problems with the device.

To dispose of EXOGEN unit, follow accordance with your

local refuse laws. The EXOGEN® unit is for single patient use only. Dispose of batteries properly to prevent injury. Do not throw into fire.

L. Return Shipping Instructions

For Assistance from the Patient Service Department of Smith & Nephew, Inc.: Assistance is always available from the Patient Service Department of Smith & Nephew, Inc., if you have questions on preparing a return shipment, completing the shipper's air-bill or contacting the freight company. Contact the Patient Services Department at the telephone number listed below for any information you require.

Please follow the instructions below if you have a service problem.

Smith & Nephew, Inc., will pay for all shipping costs. To obtain shipping cost coverage, please contact Customer Service for a return authorization number, 1-800-836-4080, option 2. You must receive a return authorization number from Smith & Nephew, Inc., before shipping costs will be covered.

1. Pack the device in the original packaging. If original packaging is not available, pack the device in a suitable box using packing material to prevent movement of the device during return shipment. Please label the side of the box with permanent marker. Return to: **Smith & Nephew, Inc., 1450 Brooks Rd., Memphis, TN 38116.**
2. Complete the air-bill supplied with your device, and contact the freight company to arrange pick-up.

To reach Patient Services:

In the United States:
Call 1-800-836-4080, option #2.

In the European Community:
Call (+49) 746-22080 for assistance or instructions.

In Other Countries:
Call (+1) 901-396-2121 (USA) for assistance or instructions.

M. General Information

1. **You must notify your physician if your cast or splint becomes loose, if your cast cracks or becomes soft or damaged, or any other reactions/complications occur during treatment.**
2. Your physician or his/her office staff will demonstrate the use of the device. Be sure that you understand the use of the device, how it works, what trouble indicators mean and what you should do if you have any problems during your daily treatments.

3. If your RAF strap is installed on-cast over your treatment site, it is imperative that the unit remains exactly in place as set by the physician or installer. Notify your physician if placement assistance is required.

4. No attempt should be made to modify or repair the EXOGEN 4000+◇ device. There are no user serviceable parts inside the device.

5. You should notify your physician of any reactions, complications or medical problems that occur during treatment.

6. You should notify Smith & Nephew, Inc., of any device problems that cannot be resolved following the instructions in Section J.—"Trouble Signals and Corrective Actions," or the need for additional coupling gel to complete your prescribed number of treatments.

N. Guidance and Manufacturer's Declaration—Electromagnetic Emissions and Immunity Testing

Electromagnetic Environment Guidance: The EXOGEN 4000+ device uses radio-frequency (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.

Interference with proper operation of the EXOGEN 4000+ device may occur in the vicinity of equipment marked with this symbol.

This equipment includes portable and mobile communications units. If abnormal operation of the EXOGEN 4000+ device is observed due to the electromagnetic environment where the device is being used, additional measures may be necessary to correct the problem. These measures include relocating the EXOGEN 4000+ device at a further distance from the interfering equipment or reorienting the EXOGEN 4000+ device in relation to the interfering equipment.

Electromagnetic Compatibility Testing

Summary:

Testing Report for:
Smith & Nephew, Inc.

Equipment Under Test:
EXOGEN 4000+◇

Used for Life Support:
No

Use in shielded enclosure:
No

Test Description	Published Test Level or Class	Pass/Fail, Comments
IEC 60601-1-2:2001		
IEC 61000-4-2 Electrostatic Discharge	±6kV contact discharge ±8kV air discharge	**Pass**
IEC 61000-4-3 RF Electromagnetic Field	1 kHz sine wave (80% AM) 80–2500 MHz , 3 V/m	**Pass**
IEC 61000-4-4 Electrical Fast Transient/Burst	AC or DC power ports, ±2kV	Not Applicable. The EUT is battery operated.
	Signal and I/O ports, ±1kV	Not Applicable. The EUT cable is less than 3 m long.
IEC 61000-4-5 Surge	AC or DC power ports, ±2kV Line to ground and ±1kV line to line	Not Applicable. The EUT is battery operated.
IEC 61000-4-6 Conducted RF Immunity	AC or DC power ports, 0.15–80 MHz, 3 or 10 V	Not Applicable. The EUT is battery operated.
	Signal and I/O ports, 0.15–80 MHz, 3 or 10 V	Not Applicable. The EUT cable is less than 3 m long.
IEC 61000-4-8 Power frequency Magnetic Field	3A(rms)/m, @ 50 Hz and 60 Hz	**Pass**
IEC 61000-4-11 Voltage Dips, Short Interruption	> 95% (10ms), 60% (100ms), 30% (500ms), > 95% (5000ms)	Not Applicable. The EUT is battery operated.
IEC 61000-3-2 Harmonics	Class A, B, C or D	Not Applicable. The EUT is battery operated.
IEC 61000-3-3 Flicker	See standard specifications	Not Applicable. The EUT is battery operated.
CISPR 11 Radiated Emissions	Class B Limits	**Pass**
CISPR 11 Conducted Emissions	Class B Limits	Not Applicable. The EUT is battery operated.

Test Report # 3066582-27-1-0, November 24, 2004. Testing performed by: Intertek, 1950 Evergreen Blvd, Suite 100, Duluth, GA 30096.

Clinical Study Results for the Nonunion Supplement
Completed Cases—Stratification by Categorical Variables

†Two-sided exact p-value, Fisher's exact test, testing homogeneity of strata.

ROW	Categorical Variable Prior to Start of SAFHS° Treatment		Completed Cases Fisher's Exact Probability†				
			Total	Healed	Failed	% Healed	p-value
1	**Gender:**	Female	30	28	2	93%	0.19
		Male	44	36	8	82%	
2	**Age:**	≤17	1	1	0	100%	0.52
		18–29	12	9	3	75%	
		30–49	32	27	5	84%	
		50–64	21	19	2	91%	
		≥ 65	8	8	0	100%	
3	**Weight (kg):**	<65 kg.	12	11	1	92%	0.65
		65–80 kg.	35	31	4	89%	
		>80 kg.	27	22	5	81%	
4	**Fracture age:**	256–365 days	20	19	1	95%	0.001
		366–730 days	27	24	3	89%	
		731–1826 days	17	16	1	94%	
		≥ 1827 days	10	5	5	50%	
5	**Total no. surgical procedures combining initial and all subsequent interventions:**	0	20	15	5	75%	0.16
		1	15	12	3	80%	
		2	24	23	1	96%	
		≥ 3	15	14	1	93%	
6	**Prior days without surgery (days from last surgical procedure to SAFHS start):**	≤82	9	9	0	100%	0.03
		83-365	39	34	5	87%	
		366-730	12	12	0	100%	
		≥ 731	14	9	5	64%	
7	**Bone:**						0.03
	Tibia/Tibia-Fibula/Fibula		28	26	2	93%	
	Femur		13	12	1	92%	
	Radius/Radius-Ulna/Ulna		7	6	1	86%	
	Humerus		6	5	1	83%	
	Metatarsal		4	4	0	100%	
	Other Foot Bones (calcaneus)		1	1	0	100%	
	Ankle††		2	1	1	50%	
	Scaphoid		6	2	4	33%	
	Other Hand Bones (metacarpal)		1	1	0	100%	
	Other (4-clavicle, 1-pelvis, 1-rib)		6	6	0	100%	
	Tibio-talar arthrodesis††						
8	**Long Bone vs. Other Bones:**						0.02
	Long Bones 28 tibia 13 femur 7 radius 6 humerus 4 metatarsal 1 metacarpal		59	54	5	92%	

ROW	Categorical Variable Prior to Start of SAFHS° Treatment		Completed Cases Fisher's Exact Probability† Total	Healed	Failed	% Healed	p-value
	Other Bones	1 calcaneus 4 calvicle 1 pelvis 1 rib 6 scaphoid 2 ankle	15	10	5	67%	
9	**Displaced at the start of SAFHS therapy:**	Missing No Yes	(5) 56 13	(2) 50 12	(3) 6 1	 89% 92%	1.00
10	**Long bone type — Only for long bone cases:**	Missing Metaphyseal Diaphyseal	(5) 8 46	(3) 6 45	(2) 2 1	 75% 98%	0.05
11	**Initial fracture type:**	Missing Closed Open Arthrodesis Osteotomy	(4) 40 22 2 6	(2) 34 21 1 6	(2) 6 1 1 0	 85% 95% 50% 100%	0.16
12	**Fixation present at start of and during SAFHS treatment:**						
	IM rod; only for long bone Cases (N=59)	No Yes	43 16	38 16	5 0	88% 100%	0.31
	Open reduction Internal fixation (ORIF)	No Yes	50 24	43 21	7 3	86% 88%	1.00
	External fixation; only for long bone cases (N=59)	No Yes	50 9	46 8	4 1	92% 89%	0.58

ROW	Categorical Variable Prior to Start of SAFHS Treatment		Completed Cases Fisher's Exact Probability† Total	Healed	Failed	% Healed	p-value
	Conservative (Cast, splint, brace)	No Yes	58 16	51 13	7 3	88% 81%	0.44
	IM rod, or ORIF, or External Fixation, or conservative	No Yes	10 64	7 57	3 7	70% 89%	0.16
13	**Prior failed Lithotripsy therapy:**						
		No Yes	72 2	62 2	10 0	86% 100%	1.00
14	**Smoking status:**						
	Missing Never smoked Stopped smoking prior to SAFHS start Smoker at SAFHS start		(2) 34 10 28	(2) 31 8 23	(0) 3 2 5	 91% 80% 82%	0.47
15	**Nonunion type:**						
	Missing Atrophic Hypertrophic		(22) 41 11	(17) 36 11	(5) 5 0	 88% 100%	0.57

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